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ELISA Plate Washer manual was written and produced with the utmost care. However, errors cannot be fully excluded. Gentaur / GDMS Belgium does not take any responsibility and accept no liabilities of any kind that may occur due to errors in this manual.

1. GENERAL INFORMATION

- 1.1. Warranty information
- 1.2. Technical service
- 1.3. Contacts

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.

Gentaur / GDMS

Belgium 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

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

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

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

1.3. Contacts

Gentaur / GDMS BELGIUM Voortstraat 49 BE – 1910 Kampenhout TEL:003222650921 e-mail: account@gentaur.com

2. GENERAL SAFETY WARNINGS

- 2.1. Danger warning symbols
- 2.2. Use of the instrument

2.1. Danger – Warning symbols



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



This symbol represents HIGH ELECTRIC VOLTAGE. It indicates that it is dangerous to touch any part having this label. Only qualified operators can access these components, after unplugging the instrument from the electric Power 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 material. When this label is found, pay attention to the manufacturer's recommendations.



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



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



This symbol indicates a portion, which is particularly important, and must be studied carefully before operating the instrument.



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 performed by qualified personnel.

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 repair the instrument using the original spare parts according to the given instructions. Maintain room temperature and humidity as specified in the manual.

If the instrument is not used as described in the manual, 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.

Contact the MANUFACTURER service or authorized service center in case the instrument need extraordinary maintenance. Specialized technicians who will be able to repair the instrument using original spare parts will carry out the maintenance.

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.



<u>Warning</u>: 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.

3. INTRODUCTION

- 3.1. Description
- 3.2. Special Features
- 3.3. Specifications

3.1. Description

ELISA Plate Washer is a versatile, user friendly & rugged instrument designed by keeping both quality and price in view. The instrument is simple, yet versatile as it uses the state of art hardware for its components.

3.2. Special Features

Built in two plate ELISA incubator

User programmable soak time, wash cycles and dispensing volume

Battery backed up memory for 50 tests.

Waste bottle full indicator with audible alarm.

Built-in stabilizer.

State of art equipment with versatile software.

Real time clock.

Continuous aspiration to prevent overflow.

Loosely held Manifold to prevent scratching of well bottoms.

Uses special software to aspirate "U" shaped, "V" shaped, and wide wells.

3.3. Specifications

Manifold	8 Way Manifold autoclavable	
Dispensing		
Method	Specially designed Peristaltic Pump	
Volume	50 - 1000 μl	
Aspirating	•	
Method	Continuous through diaphragm pump while	
	dispensing hence preventing overflow	
Residual Volume	< 5 µl	
Waste Bottle	One (Capacity 2 liters) with audible alarm when	
	bottle is completely filled in with waste solution	
Wash Bottle	One (Capacity 2 liters)	
Rinse Bottle	One (Capacity 2 liters)	
Display	16 digit alphanumeric fluorescent	
Liquid contact materials	Silicon, stainless steel, derline	
Memory	8 KB Non volatile RAM Battery backup,	
	supporting 35 Open channels	
Washing Program	Plate Wash	
	Strip Wash	
	Bottom Wash	
	Overflow Wash / Top Wash	
	Rinsing	
	Priming	
	Disinfection	
Shaking time	1 to 59 Seconds	
Speed	8 Steps 2 plates at 37°C	
Incubator	2 plates at 37°C	
Timer	Individually Programmable	
Power	70 W	
Wattage	50 Watts	
Voltage	115-240 Volts ± 10%, 50 /60 Hz	
Operating Position	On horizontal, rigid, flat and vibration free surface	
Operating Conditions		
Temperature	+18°C -35°C	
Humidity	Up to 85 %	
Ideal Storage Conditions		
Temperature	10°C-40°C	
Humidity	Up to 85 %	
Enclosure	ABS Fire retardant	
Size (cm)	35 X 35 X 13 (l X b X h)	
Weight	6 Kg. (Approx)	

4. PACKAGING, TRANSPORT & STORAGE

- 4.1. Packaging
- 4.2. Instrument Transportation
- 4.3. Storage of the Instrument

4.1. Packaging

Instrument has to be decontaminated before packing for transportation. Packaging is needed whenever the instrument is to be transported or shipped by courier or other purposes.

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

- 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)
- o Mark the packaging with address, instrument identification and warning labels

4.2. Instrument Transportation

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

4.3. Storage of the Instrument

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

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

5. INSTRUMENT DESCRIPTION

- 5.1. Rear panel view
- 5.2. Tubing diagram
- 5.3. Keyboard
- 5.4. Priming Area
- 5.5. Micro-plate carriage
- 5.6. Priming and rinsing area
- 5.7. Manifold

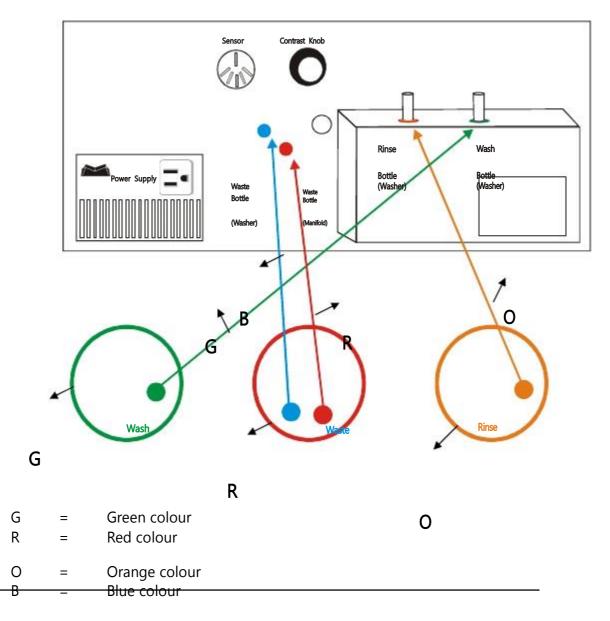
5.1. Rear Panel View

Ensure that the main power switch is in **OFF** position before connecting. Plug the instrument to the **A C** mains. Confirm proper grounding for trouble free operation.

The ELISIA Plate Washer is provided with an inbuilt voltage stabilizer to take care of voltage fluctuations.

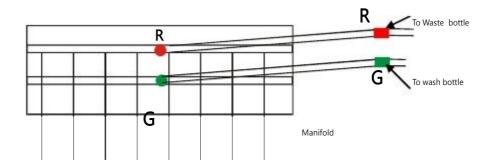
5.2. Tubing Diagram

REAR PANEL TUBING CONNECTIONS



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MANIFOLD TUBING CONNECTIONS



Note: Load ELISA plate carefully in the slot provided for correct washing

5.3. Keyboard

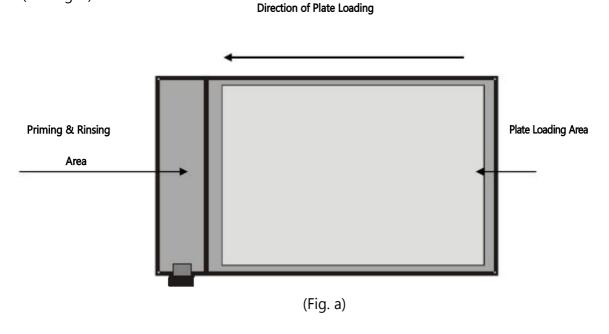


5.4. Priming Area

Carriage plate has a built-in priming area. Priming is essential immediately after starting the instrument, and before shutting down the instrument. It helps smooth flow of buffer and prevents crystallization.

5.5. Micro-plate Carriage

Movement of plate is precisely controlled by stepper motor and timing belt to position the plate exactly below the manifold for washing. (Ref. Fig. a)



5.6. Priming and Rinsing Area

Carriage plate has built-in priming and rinsing area, priming and rinsing is essential immediately after starting the instrument, and before shutting down the instrument. It helps smooth flow of buffer solution and prevents crystallization. (Ref. Fig. a)

5.7. Manifold

Instrument has a specially designed 8-way manifold.

The manifold has a provision to clean the liquid path conveniently hence avoiding common clogging problem because of crystallization, etc.

Manifold is moved vertically up and down by well-controlled stepper motor for proper placement. Manifold needles are laboratory grade steel smooth ends to prevent scratching of the well bottom.

6. INSTALLATION AND START-UP INSTRUCTIONS

- 6.1. Placing the instrument
- 6.2. Power Supply
- 6.3. Protective grounding
- 6.4. Start-up instructions
- 6.5. Setting time
- 6.6. Waste Bottle connections
- 6.7. Rinsing Strip

While installing and setting up the instrument, the safety warnings and general precautions described in section 7 must be observed.

6.1. Placing the instrument

The instrument has to be placed on a level bench A min. distance of 1m should be maintained from the rear panel to avoid damage to power cord and instrument Room temperature has to be between 18°C and 35°C with a relative humidity below 85%. Protect the instrument from direct sunshine.

6.2. Power supply

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.

Voltage -115 - 240 Volts ± 10%, 50- 60 Hz

6.3. Protective Grounding

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

6.4. Start up Instructions

Instrument Starting Procedure

1. Switch on the instrument. The instrument will display ELISA Plate Washer.

2. The instrument carries out Self Test to check all the internal parameters.

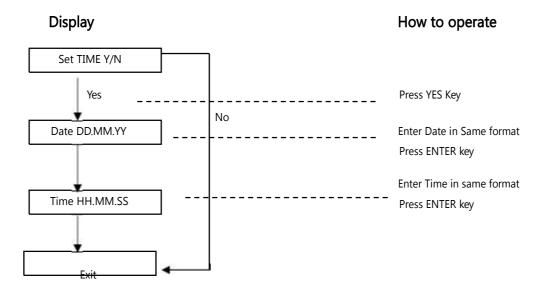
3. It displays **ELISA Plate Washer** and the time indicating that initialization is complete.

4. If the date and time are not correctly displayed, switch off the instrument and switch it on once again.

The instrument is now ready for use.

6.5. Setting date and time

Setting of date and time can be done with the help of FUNC key

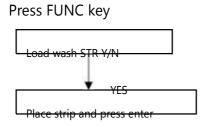


6.6. Waste Bottle connections

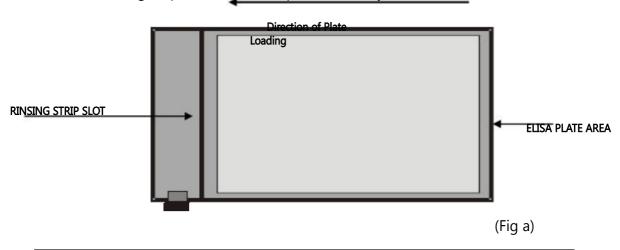
Please refer point No. 5.3, Tubing Diagram.

6.7. Rinsing Strip

Load rinsing strip in the rinsing slot of plate holder.



Place the rinsing strip on the slot and press enter key.



7. PRECAUTIONS

7.1. Precautions

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

Do not attempt to open the instrument and make repair without proper technical training. Do not allow unauthorized persons to operate or repair the instrument.

Place the ELISA Plate carefully on the tray

Ensure that the main power switch is in OFF position before connecting.

Prime the manifold before and after use.

Always Prime immediately after switching ON the instrument.

Always rinse before switching OFF.

Keep wash, waste and rinse bottles clean.

Disconnect the tubing before opening wash, waste and rinse bottle caps.

8. GENERAL KEY OPERATIONS

8.1. FUNC Key

- 8.1.1. Deleting the test
- 8.1.2. Setting Date and Time
- 8.1.3. Storing the test
- 8.1.4. Disinfection

8.2. Menu Key

- 8.2.1. Recalling the saved test
- 8.3. PRIME Key
- 8.4. RINSE Key
- 8.5. TIMER Key

Check whether all the tubings are properly connected. Switch on the instrument.

8.1. FUNC KEY



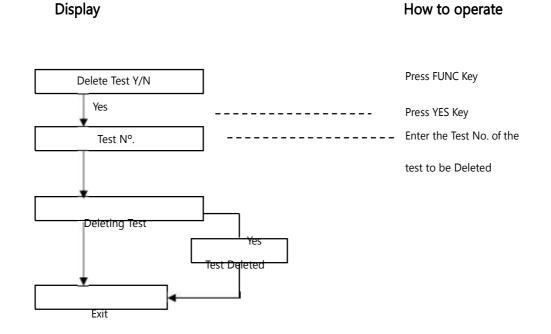
Programming Mode Idle Mode YES Washer will flush the NO Disinfection Y/N manifold effectively Save Test Y/N disinfecting the same NO YES (Ref.8.1.3) /ES Load wash Strip Y/N Place Strip & press Enter Save Option NO (Dof 0 1 1) YES **Delete Option** Delete Test Y/N NO YES Set Time Y/N (Ref.8.1.2) Modify Time Option NO

Exit Y/N

NO

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8.1.1. Deleting the test

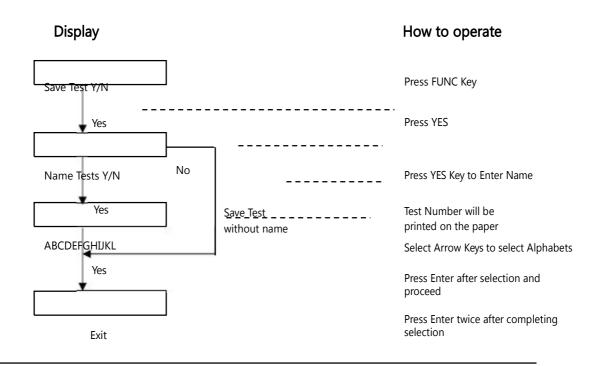


8.1.2. Setting Date and Time

(Refer to point Nº. 6.5)

8.1.3. Storing the test

To save the programmed test under any programming Mode



8.2. MENU KEY



This key is used to recall the test number to be performed.

8.2.1. Recalling the saved test



8.3. PRIME KEY



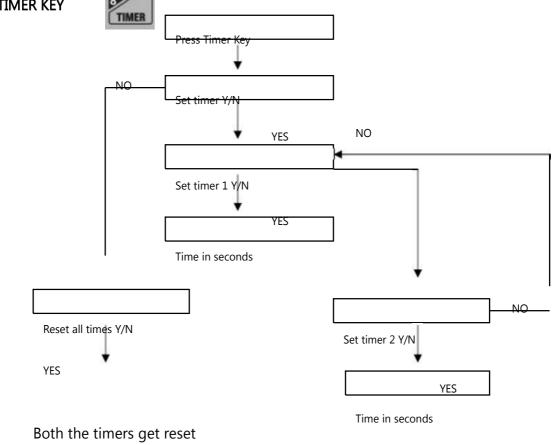
Pressing the 'Prime key', Peristaltic pump#1 operates continuously for few seconds. Wash buffer from wash bottle primes the tubing and manifold needles.

8.4. RINSE KEY



Pressing Rinse key peristaltic pump#2 operates continuously for few seconds. Distilled water from rinse bottle, rinses the tubing and manifold needles.

8.5. TIMER KEY

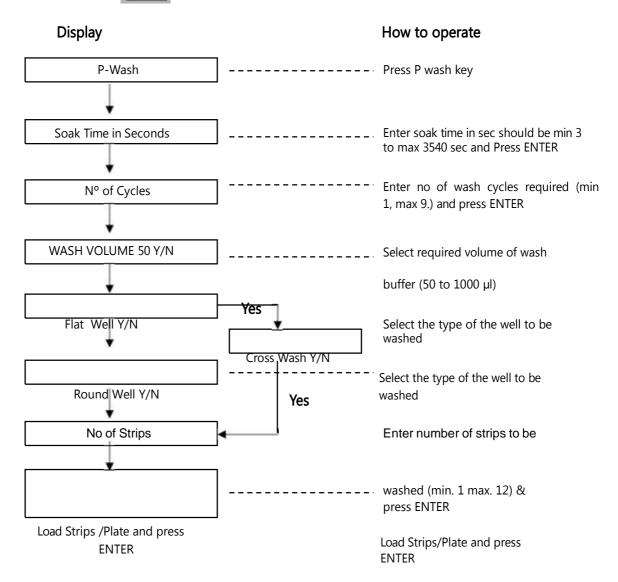


9. PROGRAMMING

- 9.1. Plate Wash
- 9.2. Strip Wash
- 9.3. Incubation
- 9.4. Bottom Wash
- 9.5. Overflow Wash / Top Wash
- 9.6. Priming
- 9.7. Rinsing
- 9.8. Shaking
- 9.9. Disinfection

9.1. Plate Wash

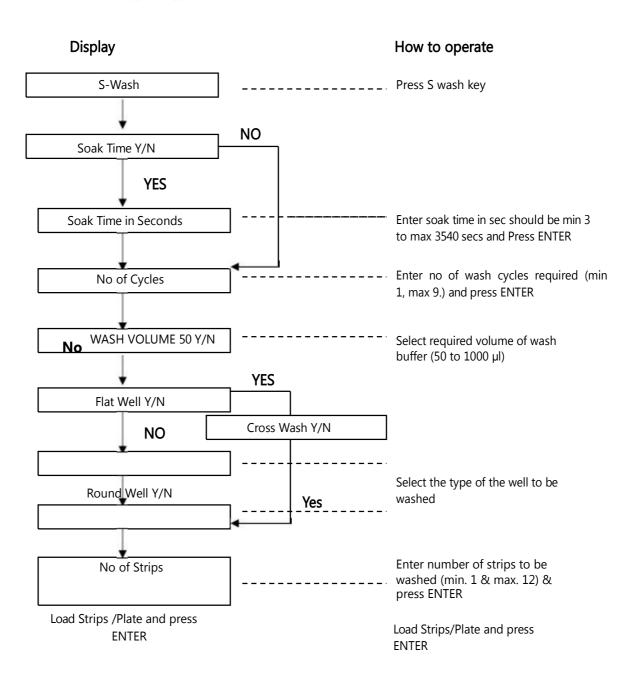




Instrument aspirates the waste solution from the well. Dispenses the programmed volume in to the micro-strip well. Aspiration is continuously kept **'ON'** to prevent the over flow. After completing dispensing cycle, depending on soak time it starts aspirating the solution. After this the instrument transports the micro-plate back to home position.

9.2. Strip Wash





Instrument aspirates the waste solution from the well. Dispenses the programmed volume in to the micro-strip well. Aspiration is continuously kept on to prevent the over flow. After completing dispensing cycle, depending on soak time it starts aspirating the solution. After this the instrument transports the micro-plate back to home position.

9.3. Incubation

Gentaur / GDMS ELISA Washer consists of a two-plate incubator that can be programmed individually. After the set time elapses, the instrument gives an audible alarm as well as notification on display indicating the elapse of time. Both the timers can be programmed separately.

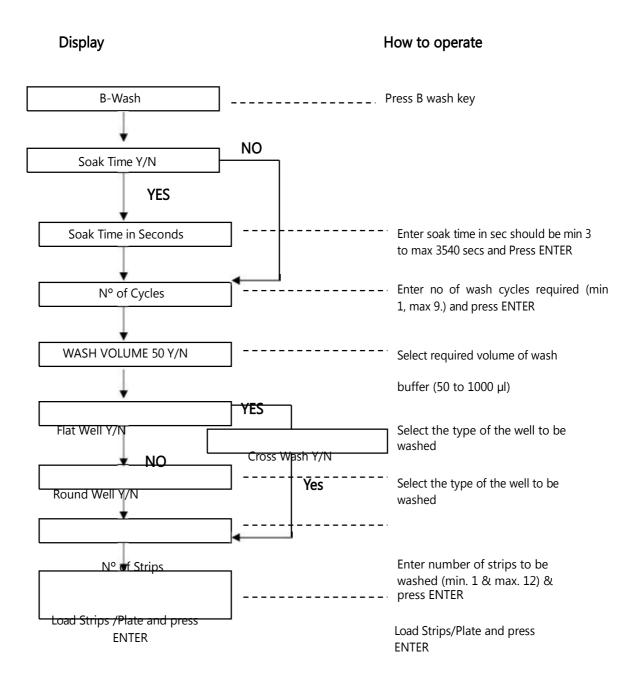
Incubator is activated when the instrument is in power on condition. It takes 10-15 minutes to reach 37°C Temperature. (This temperature is factory set).

Procedure to program incubator time is as follows:

(Please refer to point N° 8.5)

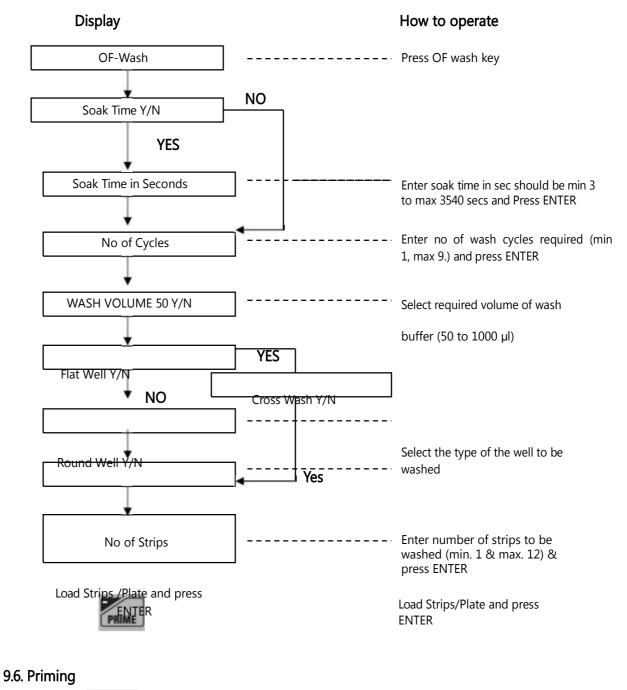
9.4. Bottom Wash





9.5. Overflow Wash / Top Wash







9.7. Rinsing

(Please refer point Nº 8.4)

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9.8. Shaking SHAKE Display How to operate Shake Press 9 Key to check shake mode Shake Plate Y/N YES Select required Speed Set Speed SP 1 Y/N (SP 1 to SP 8) YES Enter Time in secs. 1 to 59 sec & Time in Sec Press ENTER Key FUNC 9.9. Desinfection Display How to operate Press **FUNC** Key Desinfection YES \geq Washer will flush the manifold Desinfection Y/N effectively disinfecting the same NO Ref. 8.1

10. TROUBLESHOOTING

10. Troubleshooting

PROBLEM	SOLUTION	
The Manifold does not dispense	 Clean the path of the steel tubes using needle cleaner. Check Wash bottle tubing connections. Check valve direction. 	
The Manifold does not aspirate	 Clean the path of the steel tubes using needle cleaner. Check the Waste bottle cap and tighten them properly. Check waste bottle tubing connections. 	
The Instrument beeps continuously	 Check the Sensor cable connection. Check whether waste bottle is full. Check the waste bottle cap and clean the cap. 	
Movement Jam	Reset the instrument by pressing the CLEAR key twice or Switch OFF and Switch ON the instrument. Insert the Plate properly and return.	
Memory Full	If Number of saved tests exceeds 50 tests then delete the unwanted test and save the test.	

11. DECONTAMINATION

- 11.1. Decontamination
- 11.2. Purpose of Decontamination
- 11.3. General Considerations
- 11.4. Decontamination procedure

11.1. Decontamination

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

11.2. Purpose of Decontamination

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

11.3. General Considerations

Any laboratory instrument that has been used for clinical analysis is considered a biohazard and should be decontaminated prior to handling. Intact skin is generally considered as an effective barrier against infectious organisms. However, small abbreviations and cuts may not be always visible. Prophylactic gloves must be worn when handling instruments that have not been decontaminated. Gloved hands should be considered contaminated and must be kept away from eyes mouth and nose at all times.

Mucous membranes are considered as the prime entry routes for infectious agents. Wear eye protection and a surgical mask when there is a possibility of aerosols.

Eating and/or drinking while decontaminating instruments are not advisable.

11.4. Decontamination procedure

A solution of 0.5% 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.

12. SAFETY CLEARANCE CERTIFICATE

return. Thank you for your co-operation.	
Customer	Contact
Address	Position
	Dept
	Tel:
Country	Fax:
Post Code	_
Model Nº	Serial Nº
Accessories Returned	
Date of Purchase (if known)	
Complaint	
Has the equipment been exposed to any of the fo	llowing: (*delete as applicable)
a) Blood, body fluids, pathological specimens f YES, please specif <u>y</u>	*YES/NO
o) Other Biohazard f YES, Please specify	*YES/NO