

# **AP 720S™**

# **Instruction Manual**

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**OPTIGEN®**  
Semi-Automated Instrument

# **HITACHI**

 **Hitachi Chemical Diagnostics, Inc.**

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Document Number: 0780 – ENG Revision: 04  
Date: April 2010

## – Table of Contents –

	Page
1 User Safety.....	3
2 System Overview	
2-1 Specifications.....	4
2-2 Overview.....	5
2-3 Accessories.....	6
3 Identification of Parts	
3-1 Front of Instrument.....	7
3-2 Back of Instrument (Power Panel).....	8
3-3 Back of Instrument (Aspirate-Drain Panel).....	8
4 Installation Instructions	
4-1 General Instructions.....	9
4-2 Tube Connections.....	10
5 Preparation Prior to Operation	
5-1 Power Cord.....	11
5-2 Power ON.....	11
5-3 Pette Rack.....	11
5-4 Sample/Reagent Rack.....	14
5-5 Loading the Racks/Reservoir onto the Instrument.....	16
5-6 Preparation of Wash Buffer.....	17
6 Operation	
6-1 Procedures for Operation.....	18
6-2 Completion of Operation.....	22
6-3 Interruption During Operation.....	23
7 Maintenance	
7-1 Maintenance Menu.....	24
7-2 Cleaning of Instrument.....	24
7-3 Maintenance of Nozzle Head.....	25
7-4 Maintenance of Water Pump MT-11.....	25
8 Troubleshooting.....	26

## 1 User Safety



### **Warning Risk of Danger**

This symbol is used to indicate that noncompliance with the instructions or procedures may lead to physical injury, death, or could cause damage to the instrument.

**This section includes important information for the safety of the user. Read carefully before continuing. When using instruments, a number of fundamental safety rules must be observed, including the following:**

- Read all of the instructions prior to use.
- Do not immerse the instrument in liquid. See the instructions for maintenance.
- Place the instrument on a flat, stable surface that can hold 50kg or more.
- Before installation, ensure instrument is at least 20 cm from wall or any object on the counter/table.
- Avoid dust, magnetic fields, excessive humidity and direct sunlight since they may cause operational errors.
- Operate the instrument at room temperature.
- Unplug the instrument from the power outlet when not in use or prior to cleaning.
- Never operate the instrument with the cable or the plug damaged, if any malfunctions have occurred or if the instrument has been damaged in any way.
- Use maximum care when moving the instrument.
- Do not use the instrument for purposes other than those it has been designed for.
- Do not disassemble or modify this instrument in any way.
- Do not put foreign objects inside the instrument or open the door during the automated operation.
- Electrical Connection:
  - This instrument must be properly grounded. In the event of a short circuit, the ground connection reduces the risk of electric shock, allowing the electrical current to be dispersed.
  - The plug must be connected to a power outlet that has been correctly installed and grounded. Improper use of ground wire may lead to risk of electric shock.
  - If you are unsure if the power outlet is grounded, contact a qualified electrician.
  - Do not use multiple extension cords to power the instrument.
  - Ensure that the power switch is OFF before you insert the power cord.
  - Do not use a wall socket with multiple outlets.
  - Handle the power cable with care; avoid pulling and twisting the cable.
  - The attached power cord is for use in USA/Canada only. For other regions, use an appropriate regional power cord. Failure to do so will result in severe damage to the instrument.
  - This unit is not equipped with an emergency stop button. For an emergency stop, turn the instrument off using the Power Switch button.

## 2 System Overview

The AP 720S Semi-Automated Instrument is a processor for use with the OPTIGEN platform. The OPTIGEN assay is an in vitro test, which provides semiquantitative measurement of circulating allergen specific IgE antibodies in human serum. The OPTIGEN assay is intended to assist in the clinical diagnosis of IgE-mediated allergic disorders.

The AP 720S is a processor that automates the manual OPTIGEN assay. The instrument aspirates samples and reagents, washes, removes residual fluid from the internal channel of the device and washes the nozzle and Pette tips to avoid contamination.

### 2-1 Specifications

Type.....	AP 720S Instrument
Appearance.....	See page 7
Case.....	Body: Firing-painted iron plate
Outer Dimension.....	Body: 380mm(W)×390mm(D)× 505mm(H)
Weight.....	Body: Approximately 30kg
Power Voltage.....	AC100V ~ AC240V (50/60Hz)
Fuse.....	AC250V 4A TYPE: F (φ 5×20)
Consumption Electric Power.....	100W
Control.....	16 bits CPU control
External Communication.....	RS-232C (9P-Dsub)
Pollution.....	Degree II

## 2-2 Overview

### Instrument Components



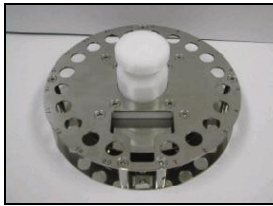








Item	Description
1. Pette Rack	Maximum of twenty (20) Pettes can be loaded.
2. Sample/Reagent Rack	Serum Cups (20) + Reagent Reservoirs (2) will be loaded manually. Two reagent reservoirs are available: Antibody = identified by a blue fill line Photoreagents = identified by a red fill line
3. Nozzle Head	Nozzle Head will connect to the top opening of the Pettes during the Pette washing, sample and reagent aspiration.
4. Sample/Reagent Aspiration	Pettes will move into their specified positions for sample and reagent aspiration.
5. Pette Washing	The Pette Tip and the Pette Body will be washed. Waste liquid will be drained through the vacuum pump.
6. Nozzle Head Washing	Nozzle Head will be washed with Wash Buffer and Deionized Water. Waste liquid will be drained through the vacuum pump.
7. LCD Display	A touch screen will operate the LCD display.

### Assay Components

No.	OPTIGEN Kit Components	Quantity
1	Pettes	20
2	Photoreagent AB	1
3	Photoreagent CD	1
4	IgE Antibody	1
5	Wash Buffer Concentrate	1
6	White Plugs	22
7	Black Plugs	22

No.	Consumables	Quantity
1	Pette Tips (per bag)	62
2	Sample Cups (per bag)	1000

## 2-3 Accessories

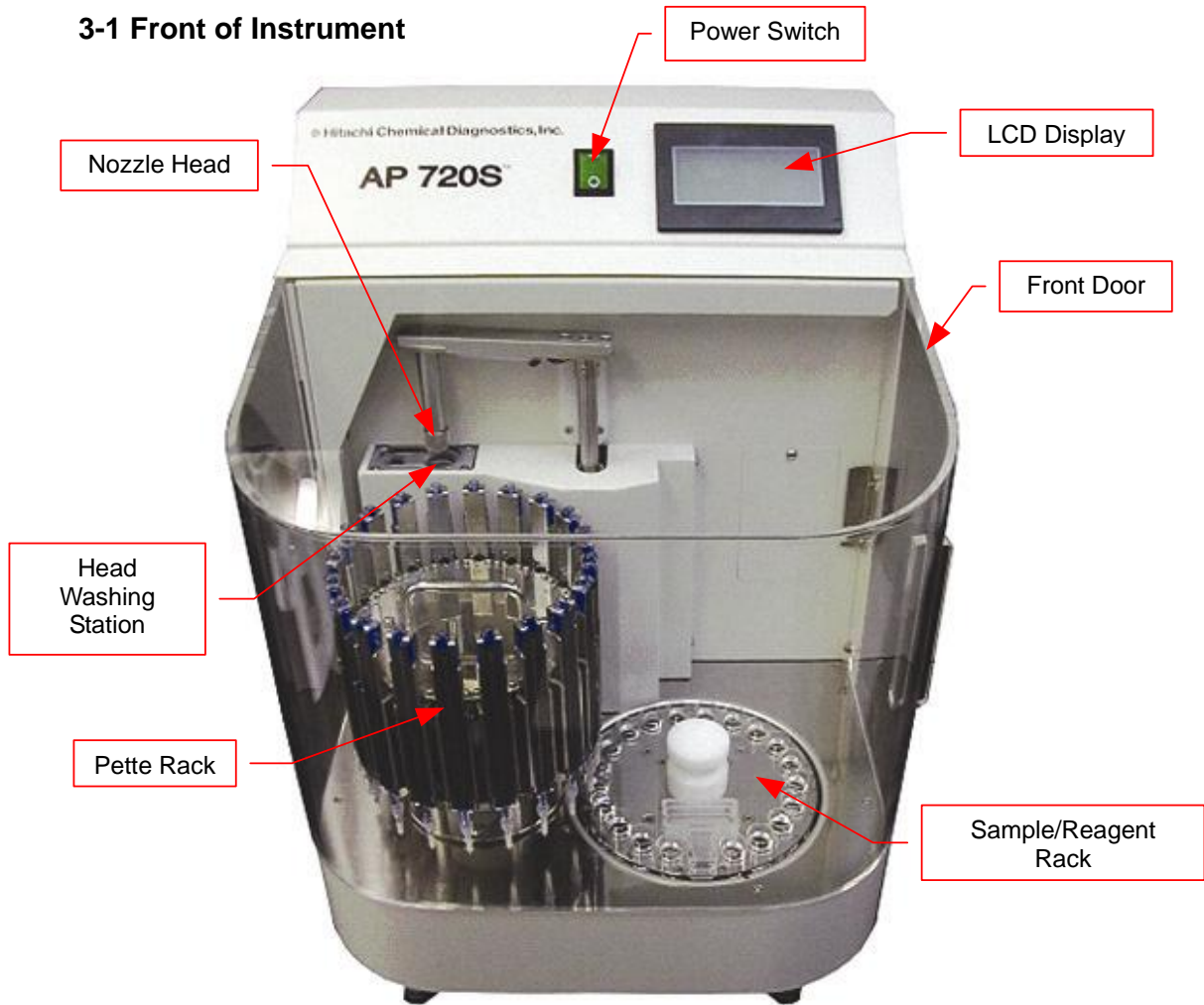
1	2,3	4	5
			
6	7,8	9	10
		 	
11	12,13		
			

No.	Instrument Parts	Quantity
1	Power Cord*	1
2	Pette Rack	1
3	Pette Stand	1
4	Sample/Reagent Rack	1
5	Antibody Reagent Reservoir (blue)	1
5	Photoreagent Reservoir (red)	1
6	Water and Wash Buffer Tubes ( $\Phi 3 \times \Phi 5$ silicon 1.5m)	2
7	Vacuum Tube (orange) ( $\Phi 3 \times \Phi 5$ toaron 1.5m)	1
8	Drain Tube (black) ( $\Phi 3 \times \Phi 5$ toaron 1.5m)	1
9	Water Bottle and Wash Buffer Bottle (1L)	2
10	Waste Bottle (2L)	1
11	Over Flow Tray	1
12	Gasket	1
13	O-Ring	1
14	AP 720S Instruction Manual	1
15	AP 720S LCD Panel Guide	1
16	AP 720S Quick Start	1

\* NOTE: The attached power cord is for use in USA/Canada only. For other regions, use an appropriate regional power cord. Failure to do so will result in severe damage to the instrument. The Auto-Run time (Priming and Processes) for a maximum of twenty pettes is approximately 4 hours and 45 minutes.

### 3 Identification of Parts

#### 3-1 Front of Instrument



Name	Description
Power Switch	Main power switch ON(I)/OFF(O). The power switch will be lit green when the power is ON.
LCD Display	Operation will be controlled by touch screen.
Front Door	The door must be fully closed when the instrument is in operation, to activate safety switch.
Pette Rack	The Pette Rack will be loaded with Pettes and Tips (manual load).
Nozzle Head	Pettes will be positioned for pette wash and aspiration.
Head Washing Station	The Nozzle Head will be washed.
Sample/Reagent Rack	Sample Cups and Reagent Reservoir will be loaded manually.



### 3-2 Back of Instrument (Power Panel)



Name	Description
AC	The power cord attachment will be inserted here
FUSE	Two AC 250V 4A TYPE: F (φ 5×20)
RS-232C	Connector for external communication (9P-Dsub)

### 3-3 Back of Instrument (Aspirate-Drain Panel)



Name	Description
AIR ASPIRATE	Vacuum tube connection onto the Waste Bottle
DRAIN	Waste tube connection
WASH BUFFER	Wash Buffer tube connection
WATER	Deionized Water tube connection

## 4 Installation Instructions

The AP 720S should be installed according to the instructions in the Service Manual, by a qualified Service Engineer.

### 4-1 General Instructions:

- Check that the instrument has not suffered any damage due to transportation.
- Place the instrument on a flat, stable surface that can hold 50kg or more.
- Before installation, ensure instrument is at least 20 cm from wall or any object on the counter/table.
- Do not place any object less than 20 cm from the instrument.
- Avoid dust, magnetic fields, excessive humidity and direct sunlight since they may cause operational errors.
- Operate the instrument at room temperature.
- Ensure that the power switch is OFF before you insert the power cord.
- Do not use multiple extension cords to power the instrument.
- Do not use a wall socket with multiple outlets.
- The attached power cord is for use in USA/Canada only. For other regions, use an appropriate regional power cord. Failure to do so will result in severe damage to the instrument.
- If you must transfer the instrument:
  - Apply [Drain] function to remove all liquid completely from the instrument.
  - Remove the Pette Rack, Sample/Reagent Rack, Over Flow Tray and all tubes from the instrument.
  - Secure all moving parts such as the Nozzle Head and door.

## 4-2 Tube Connections

- Connect each tube to a specific color coded tube connector located at the back of the instrument.
  - Lock the tube connector by turning clockwise, until tightened.
  - Ensure all tubes are secure and connected to the correct bottle(s). See figure below for details.
1. Waste Bottle: Black tube into the “DRAIN” connection, Orange tube into the “AIR ASPIRATE” connection.
  2. Wash Buffer Bottle: Yellow tube into the “WASH BUFFER” connection.
  3. Deionized Water Bottle: White tube into “WATER” connection.



1

2

3

## 5 Preparation Prior to Operation

### 5-1 Power Cord

- Ensure the power switch is OFF(O) before inserting the power cord into the outlet.
- Connect the power cord into AC on the back side of the instrument.
- The attached power cord is for use in USA/Canada only. For other regions, use an appropriate regional power cord. Failure to do so will result in severe damage to the instrument.

### 5-2 Power ON

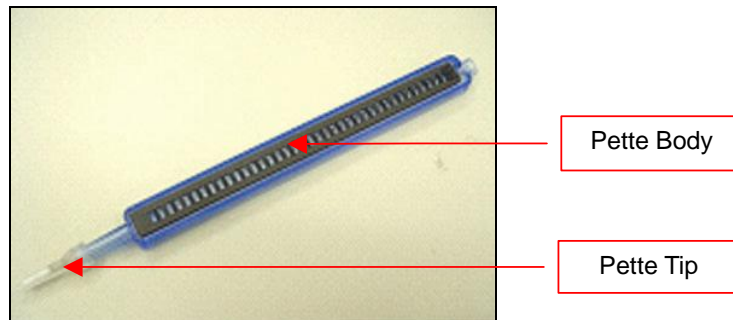
- Switch the Power ON(I).
- The instrument will automatically initialize after about ten seconds from powering ON.

Main Menu screen will appear . Continue with Preparation Instructions .

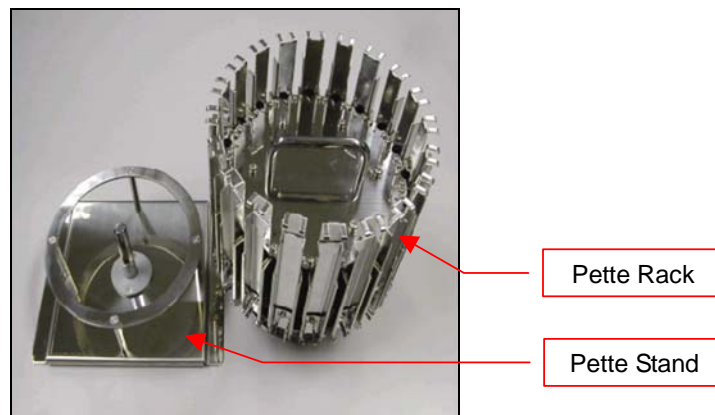
Do not touch the Power Switch with wet hands, as it may cause electric shock.

### 5-3 Pette Rack

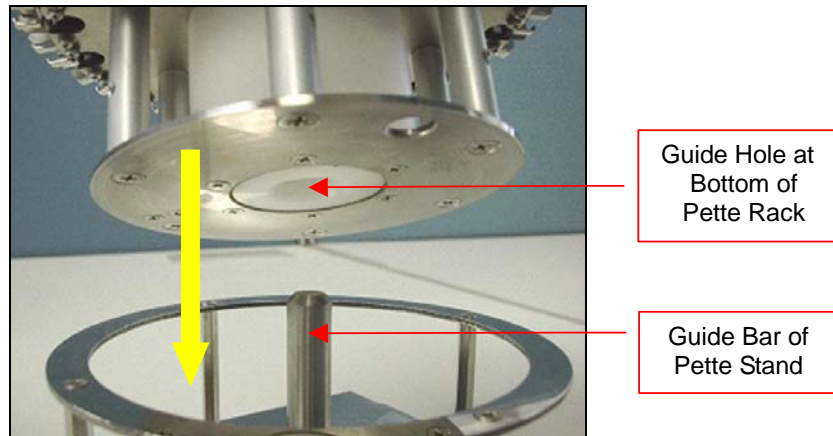
- Attach one Pette Tip onto each Pette Body.



- Collect the Pette Rack and Pette Stand. Always use the Pette Stand when loading or removing the pettes.



- Place the Pette Rack onto the Pette Stand. Use the guide bar on the Pette Stand to match the guide hole at the bottom of the Pette Rack.

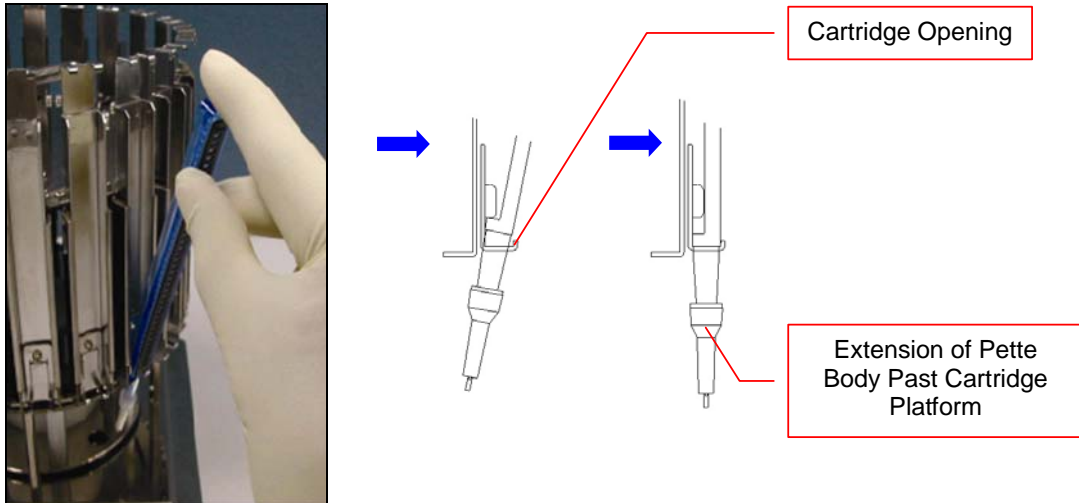


Proper fit of the Pette Rack and Stand is shown below:



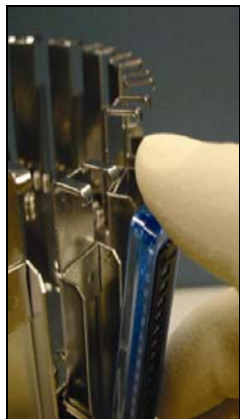
- Load the Pettes with attached Pette Tips, one by one, into the cartridges on the Pette Rack. **Always start at position #1 and do not leave any positions empty when loading.**

1. The black side of the Pette Body should face the Operator.
2. Slide the bottom portion of the Pette Body through the bottom cartridge opening so that the Pette Body extends past the bottom of the cartridge platform.



3. Slide the top of the Pette Body under the upper portion of the cartridge, while pushing down on the Pette Body. Check that the Pette Body is correctly positioned and securely attached to the Pette Rack.

Pette Body sliding into top of cartridge



Top of Pette Body in Pette Rack cartridge

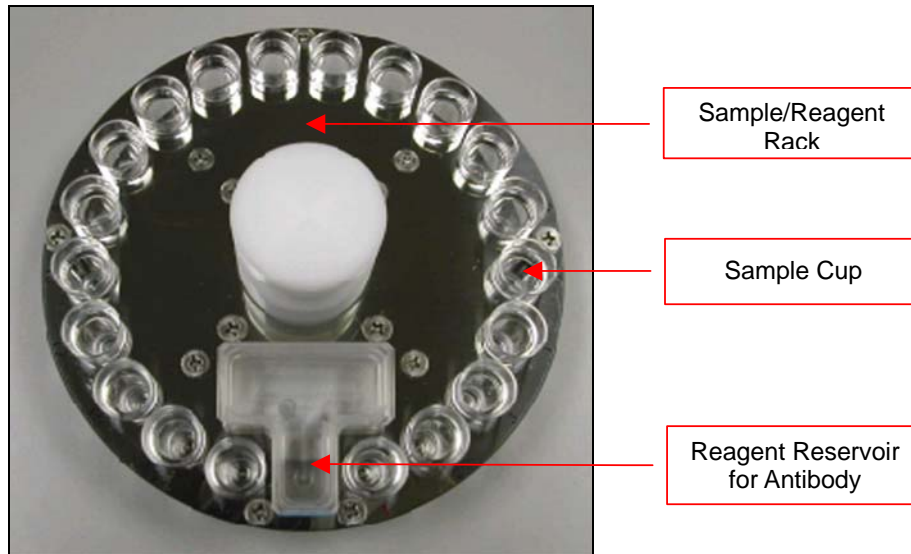


Pette Body in position in Pette Rack



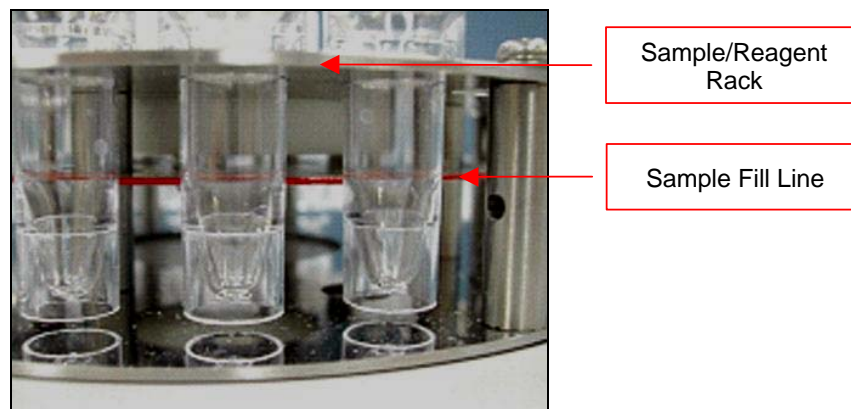
## 5-4 Sample/Reagent Rack

- Gather the Serum Cups, Antibody Reagent Reservoir (BLUE line), and the Sample/Reagent Rack.



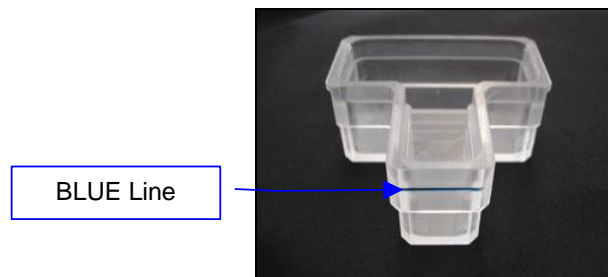
- Load the sample cups starting at position #1. **Always start at position #1 and do not leave any empty positions when loading.**
- Ensure the quantity of Sample Cups matches the quantity of Pette Bodies.
- Use only HCD approved Sample Cups. Other cups may cause the instrument to malfunction and test results may be lost.
- Fill the correct amount of centrifuged serum into the Sample Cups:
  - 600  $\mu$ l serum for a 36-allergen pette
  - 490  $\mu$ l serum for a 20-allergen pette

NOTE: There is a red Sample Fill Line on the Sample/Reagent Rack. This line can be used as a guide to check that there is a fill volume of approximately 600  $\mu$ l in the Sample Cups.



- Fill the Antibody Reservoir with the correct amount of Antibody. Refer to the table below. Gently invert Antibody Reagent Bottle prior to use to mix.

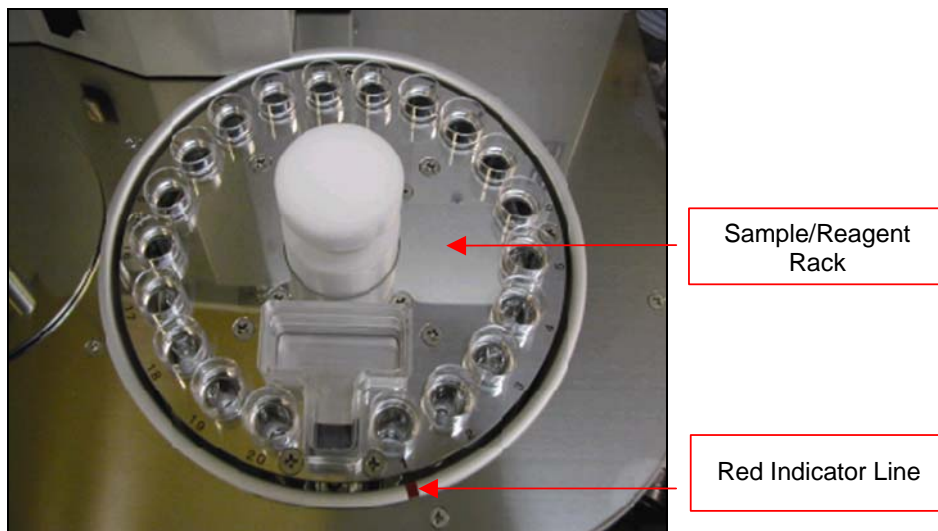
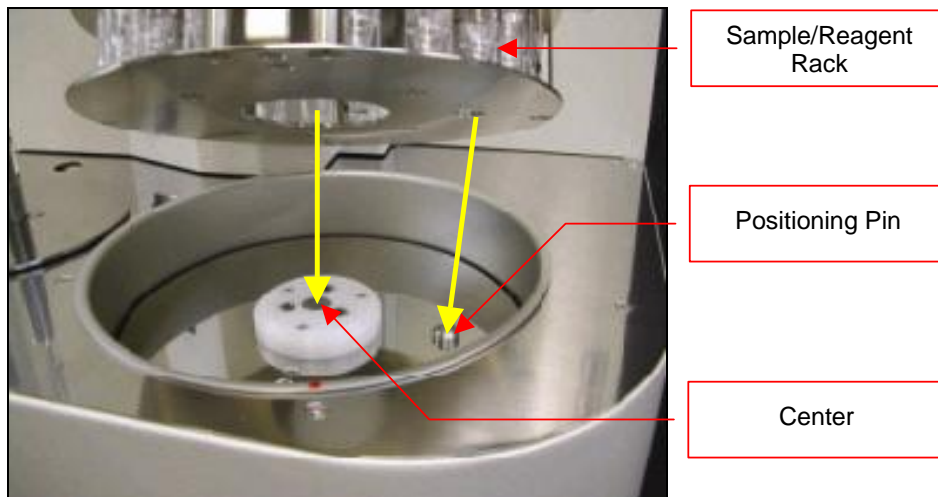
Pette No.	Antibody (mL)	Pette No.	Antibody (mL)
1	1.6	11	7.6
2	2.2	12	8.2
3	2.8	13	8.8
4	3.4	14	9.4
5	4.0	15	10.0
6	4.6	16	10.6
7	5.2	17	11.2
8	5.8	18	11.8
9	6.4	19	12.4
10	7.0	20	13.0



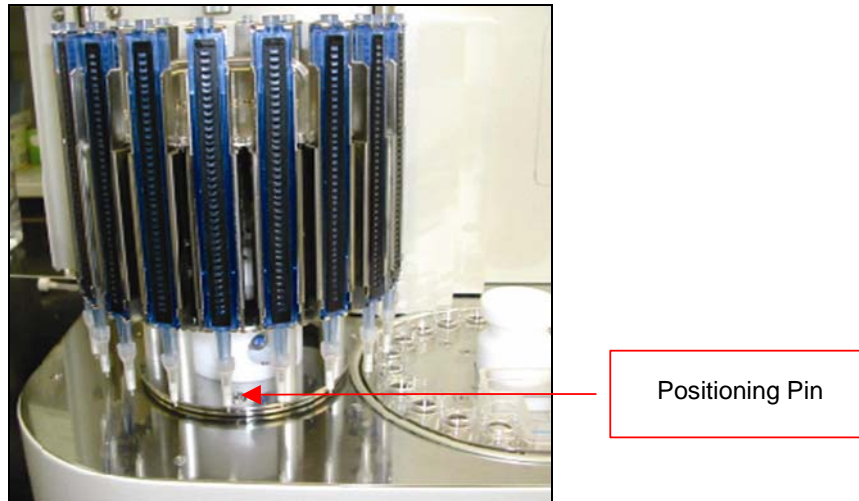
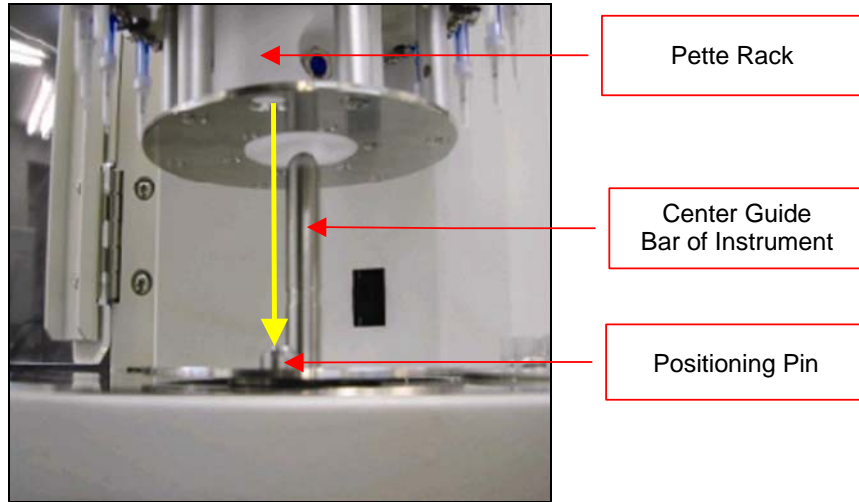


## 5-5 Loading the Racks/Reservoir onto the Instrument:

- Setting of the Sample/Reagent Rack
  1. Install the Sample/Reagent Rack first, then insert the Pette Rack into the instrument.
  2. Hold the Sample/Reagent Rack so that the position #1 aligns with the red indicator line (see photo below).
  3. Lower the Sample/Reagent Rack slowly so that the center and the Positioning Pin are aligned into the appropriate hole at the bottom of the rack.
  4. Ensure that the Sample/Reagent Rack is secure and horizontal.
  5. Ensure the Antibody Reservoir has sufficient Antibody and load onto the Sample/Reagent Rack.



- Setting of the Pette Rack
  - Remove Pette Rack from the Pette Stand.
  - Hold the Pette Rack so that number #1 cartridge position is front and center.
  - Lower the Pette Rack, insert the center guide bar and the Positioning Pin into the appropriate holes at bottom of the Pette Rack.



- Ensure Positioning Pin is completely set in the hole at bottom of Pette Rack.
- Close the door.

#### 5-6 Preparation of Wash Buffer

- Prepare Wash Buffer according to the instructions in the OPTIGEN Package Insert.
- Follow the table below to fill Wash Buffer Bottle.

Pette Quantity	Minimum Volume of Wash Buffer (mL)
5	340
10	500
15	670
20	840

## 6 Operation

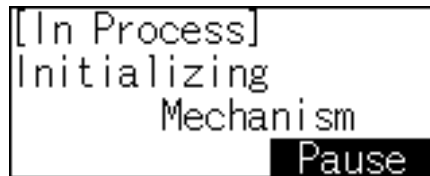
**6-1 Procedures for Operation: Refer to “AP 720S LCD Panel Guide” for details.**

- When racks are in position, close the door.
- Switch the Power ON(I).



AP 720S 09/11/18  
10: 8:30  
PANEL 09,04,17 V1.30  
AP720 09,04,24 V1.40

- The instrument will automatically initialize after about ten seconds from powering ON.



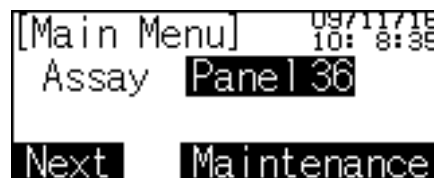
[In Process]  
Initializing  
Mechanism  
Pause

**Do not touch Power Switch with wet hands, as it may cause electric shock.**

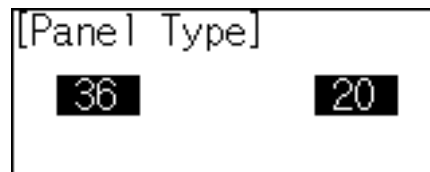
NOTE: Do not touch the instrument or any moving parts when the instrument is in operation.

NOTE: This instrument has an inter-lock safety system. If the door opens during the operation, the system is activated and the instrument can not be started/will not run.

- Select the type of panel (Panel 20 or Panel 36) from the [Main Menu] screen.



[Main Menu] 09/11/18  
10: 8:35  
Assay Panel 36  
Next Maintenance



[Panel Type]  
36 20

- Press “Next” and move to the [Check] screen.



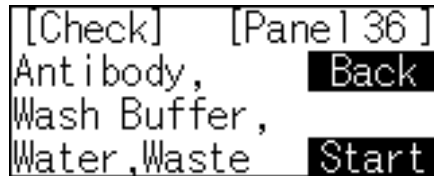
- Check reagents/water:
  1. Make sure sufficient Antibody is in the Reagent Reservoir.
  2. Ensure there is sufficient Wash Buffer in the Wash Buffer Bottle.
  3. Ensure there is sufficient (1L) Deionized Water in the Deionized Water Bottle and fill if needed.
  4. Ensure the color of the cap matches with the color coded bottle label.
    - a. Wash Buffer = Yellow
    - b. Deionized Water = White
  5. Ensure the weighted ends of the Wash Buffer and Deionized Water tubes sit securely at the bottom of their respective bottles.
  6. Empty the Waste Bottle by pressing the quick release connectors to detach the tubes, unscrew the cap, and then empty the waste liquid.

NOTE: The collected waste is a biohazard and should be disposed of according to your local requirements.

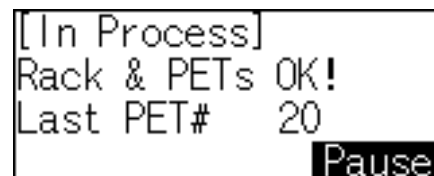
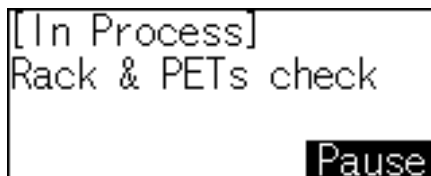
7. Re-Connect the Waste Bottle. Screw the cap back on and tighten. Attach the quick release connectors to the cap, and match the color-coded labels.

NOTE: The cap must be tightened completely so that the waste liquid can drain properly.

- Press “Start” to start automated operation.



- “Priming” and “Rack & PETs check” will be done automatically, before starting “PROCESS”.



- There are eight (8) processes in all, to complete the Auto-Run.

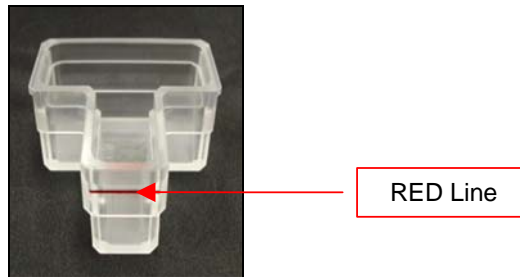
No.	Process
1	Rehydration
2	Sample Aspiration
3	Sample Incubation
4	Wash
5	Antibody Aspiration
6	Antibody Incubation
7	Wash
	Manually Load Photoreagent Mixture
8	Photoreagent Aspiration

- At the end of Process # 7, AP 720S will pause and an alarm will sound. [Change Photo Rgt] will appear on the screen. Press "Alarm Off".

```
[In Process]
Process# 7
Pette# 1
0:12:00 Pause
```

```
[Change Photo Rgt]
Elapsed Time 0: 0:15
Alarm Off Continue
```

- Prepare Photoreagent Mixture by thoroughly mixing an equal amount of Photoreagent AB and CD. Fill the Photoreagent Reservoir (RED line) with the correct amount of Photoreagent Mixture.



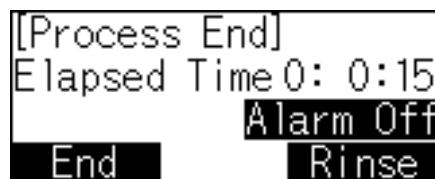
NOTE: Allow Photoreagent AB and CD to come to room temperature prior to use. Once mixed, the Photoreagent mixture should be used immediately for best results.

Pette No.	Photoreagent Mixture (mL)	Photoreagent AB and CD Required (mL)
1	1.6	0.8 each
2	2.2	1.1 each
3	2.8	1.4 each
4	3.4	1.7 each
5	4.0	2.0 each
6	4.6	2.3 each
7	5.2	2.6 each
8	5.8	2.9 each
9	6.4	3.2 each
10	7.0	3.5 each
11	7.6	3.8 each
12	8.2	4.1 each
13	8.8	4.4 each
14	9.4	4.7 each
15	10.0	5.0 each
16	10.6	5.3 each
17	11.2	5.6 each
18	11.8	5.9 each
19	12.4	6.2 each
20	13.0	6.5 each

- Open the door. Remove the Antibody Reservoir and load the Photoreagent Reservoir in the Sample/Reagent Rack. Close the door.
- Press “Continue” on [Change Photo Rgt] screen.
- Press “Yes” on [Check] screen to start Process #8.



- As soon as the first pette is filled with the Photoreagent Mixture, set a timer for 10 minutes.
- At the end of Process #8, an alarm will sound.
- Press “Alarm Off” on [Process End] screen.

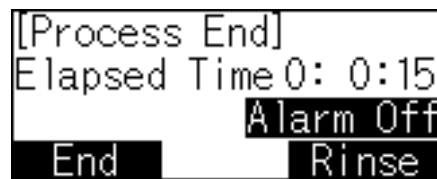


- Open the door. Remove the Pette Rack from the instrument by lifting straight up until it is completely off the Center Guide Bar. Set the Pette Rack in the Pette Stand on a table.

- Insert the black top plug into each pette.
- Unload the pettes, one by one, starting from position #1.
- Remove the pette tip from each pette body with a gentle twist.
- Insert the white bottom plug into each pette.
- Load the pettes in order into the Pette Cassette Tray.
- At the 10 minutes end of the timer, load the tray in CLA-1 Luminometer to read test results. Refer to the CLA-1 Luminometer Operator Manual for details (Document No. 0277).

## 6-2 Completion of Operation

- Remove the Pette Rack from the instrument. Place the Pette Rack onto the Pette Stand.
- Remove the Sample/Reagent Rack and close the door.
- There are two options:



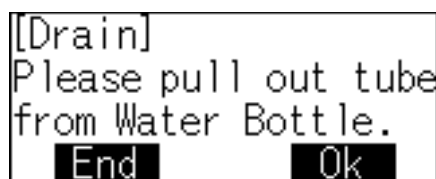
End – to run a second set of Pettes immediately following the first set. You will be taken to the [Main Menu], page 18, and can follow the Auto-Run procedure.

Rinse – to clean the instrument at the end of Auto-Run and prepare for shut down. Continue with the instructions as listed below:

Press “Rinse” on [Process End] screen.  
[Rinse] screen will appear.



- Unscrew bottle caps of both Wash Buffer and Deionized Water. Pull out the tube from Wash Buffer and place into the Deionized Water Bottle along with the Deionized Water tube, which will still be inside the bottle.
- Press “Ok”.
- After rinse is finished, [Drain] screen will appear.



- Remove the Wash Buffer and Deionized Water tubes from the Deionized Water Bottle.
- Place Wash Buffer tube and Deionized Water tube on a clean surface during Drain function. Press “Ok” to start Drain function.
- After the Drain function is finished, [Main Menu] will appear. It is now safe to turn power “OFF”.
- Rinse Reagent Reservoirs well with Deionized Water.
- Clean the instrument as needed. See “Maintenance” for details.

### 6-3 Interruption During Operation

- When the Auto-Run is interrupted by pressing the “Pause” key or by opening the door, a [Run Status] alarm screen will appear (Refer to AP 720S LCD Panel Guide, section 2-8).



- Press “Alarm Off” key to stop the alarm. There are two options:

Option #1: “Continue” option:

If no parts inside the door have been touched or moved, press [Continue] to resume the operation.

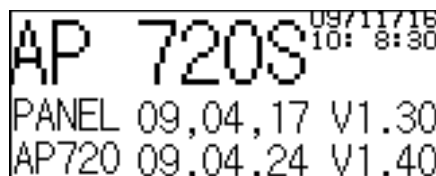
Option #2: “Cancel” option:

If any parts inside the door have been touched or moved, follow the steps below to ensure that the parts return to the correct alignment at initialization, before the operation is resumed.

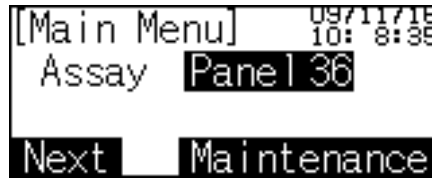
- Press “Cancel” key. [Check] screen will be displayed.



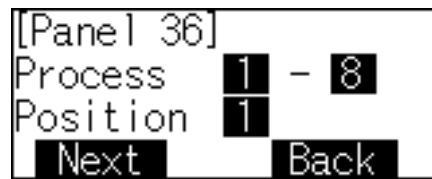
- Press “Yes” key. The panel opening screen will be displayed and followed automatically by the initialization screen and the [Main Menu] screen.







- c. Press the “Next” key on the [Main Menu] screen. The “Start/End Process and Position Setup” screen will appear (Refer to AP 720S LCD Panel Guide, section 2-9).



Confirm the following, as this information is crucial to the run set up:

- The Start Process NUMBER is correct on the screen
- The End Process NUMBER is correct on the screen
- The Pette Position NUMBER is correct on the screen

Re-enter the number information as necessary.

- d. Press “Next” to resume Auto-Run.

## 7 Maintenance

### 7-1 Maintenance Menu

The [Maintenance] menu provides Prime, Rinse, Clock and Language functions.

- [Prime] will begin the Priming operation.
- [Rinse] will begin the Rinse operation.
- [Clock] allows setup of the date and time.
- [Language] allows language selection for the screen display.
- [Back] will take you to the [Main Menu] screen.

### 7-2 Cleaning of Instrument

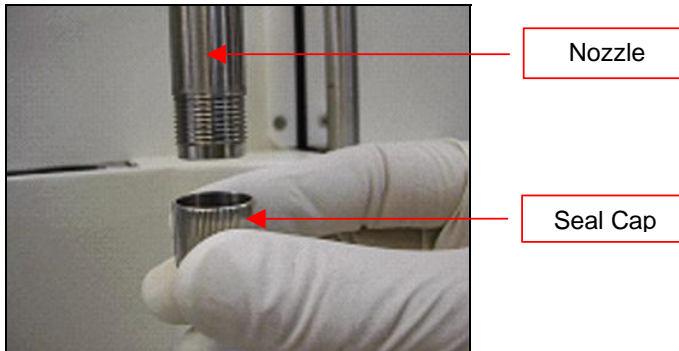
Daily maintenance is necessary in order to maintain the performance of the instrument and to prevent problems during operation.

- Wipe the instrument with a soft lint-free cloth. Do not use any solvents as they may deteriorate the instrument surfaces.
- Ensure all surfaces are clean and that no liquids have been spilt.

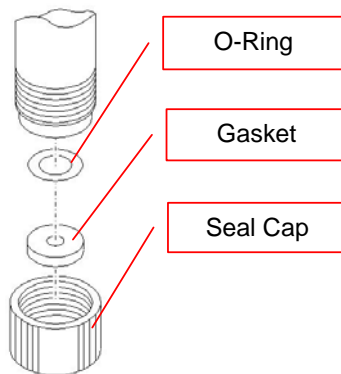
### 7-3 Maintenance of Nozzle Head

Replacement of the O-Ring and Gasket should be done once a year.

- Turn the main power "OFF"
- Turn the Seal Cap clockwise to remove.



- When the Seal-Cap is removed, you will find the O-Ring and the Gasket inside the Seal Cap.
- Remove the O-Ring and Gasket using a pair of tweezers. Be careful if the seal gum is adhered inside of the Gasket.



- To reseal, attach Seal Cap to the nozzle with the replacement O-Ring and Gasket inside as shown.
- It is important that the replacement O-Ring and Gasket are correctly aligned within the Seal Cap.
- Wipe the Nozzle Head with a soft, lint-free cloth. Do not use any solvents.

### 7-4 Maintenance of Water Pump MT-11

The water pump MT-11 can dry when the instrument is left unused for two months or longer. In case of this occurrence contact your distributor for maintenance support.

## 8 Troubleshooting

If you experience problems with the instrument, consult the troubleshooting guide below. If repair is needed, contact your Distributor for service.

Trouble	Cause	Measure
The LCD panel is not displayed when the power is turned ON.	Power cord is not connected.	Reinsert the power cord.
	Blown-out fuse(s).	Replace with new fuse(s).
	The power switch is broken.	Repair as needed.
	A problem has occurred in the electrical system.	Repair as needed.
Warning or Alarm is displayed after the operation has been started.	The door is open.	Securely close the door.
	The rack(s) have not been set properly.	Make sure that the rack(s) have been set correctly. Reinstall the rack(s).
	A Pette Tip is missing.	Reattach a Pette Tip.
	Other Problems	Read the Pause/Alarm section in the LCD Panel Guide.  If it is due to the electrical system or mechanical function, repair may be needed.
The machine does not work at START of operation. (The "SENSOR ERROR" is displayed.)	There is a problem in the electrical system (damage sensor, motor, or PC board, etc.); or mechanical problem (excessive load on the machinery, broken motor/belt, loosened screws, etc.).	Repair as needed.
Liquid(s) cannot be aspirated.	Lack of reagent(s).	Check the fill volume table.
	Cracks or breaks in Pette(s).	Replace with new Pette(s).
	Leakage from Pette Tip(s).	Replace with new Pette Tip(s).
	Pette(s) are not attached properly on Pette Rack.	Reattach the Pette(s) on the Pette Rack.
	Pette Tip(s) are missing.	Attach the Pette Tip(s).
	Gasket and O-Ring damaged/missing	Replace with new O-Ring and/or new Gasket.
The pettes cannot be washed.	Lack of Wash Buffer.	Replenish with Wash Buffer for PRIMING again.
	A problem in the fluidics.	Repair as needed.