autoclart®

User Manual

Product Number GEN-ACT

Instructions for Use

IT IS IMPORTANT TO READ THIS MANUAL BEFORE USING THE INSTRUMENT

Please read this manual carefully before using the autoclart and make it accessible to all users. Failure to comply with the instructions in this manual will void the manufacturer's warranty and may pose a risk to the user. Ensure all users are conversant with the instrument - contact Genomica S.A.U. for any further instrument or training requirements if in any doubt before using the instrument.

Consult User Manual where symbol (left) is seen on the instrument

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Copyright Statement

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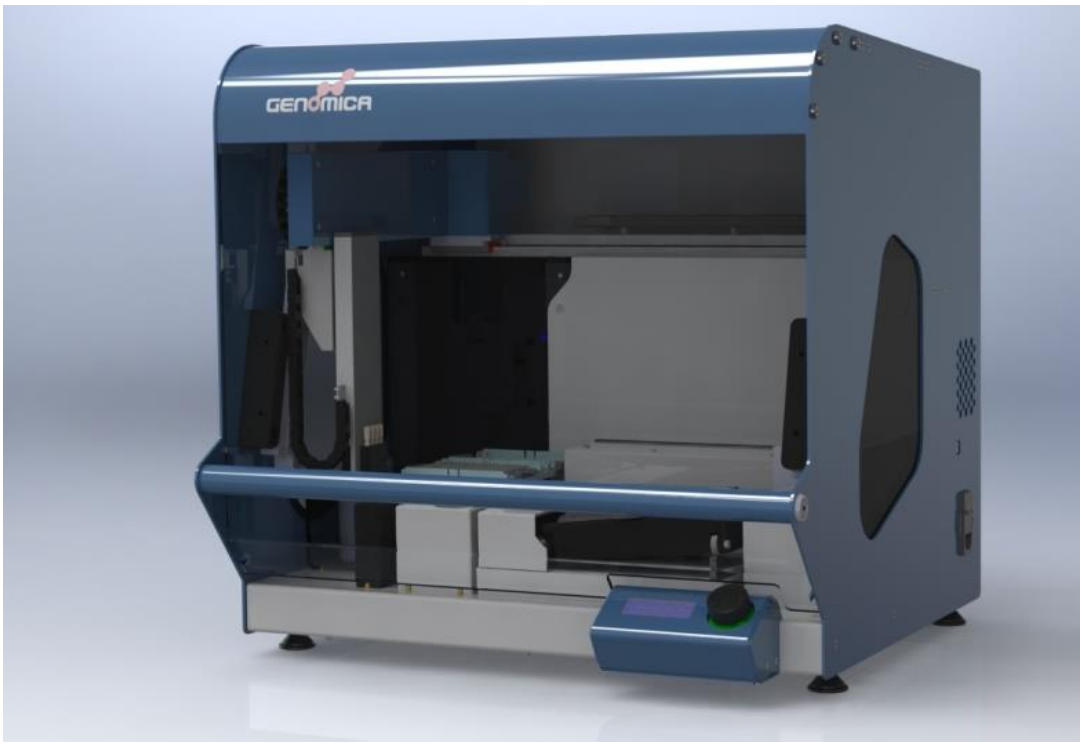
1 Introduction



The autoclart is a bench-top semi-automated system for processing microplate-based assays.

The autoclart is designed for microplate processing and provides reagent addition, liquid handling, heating, cooling, and shaking of the microplate.

The microplate well holder offers:
- heating and cooling under a bespoke peltier controlled system, giving precise temperature control during the assay
- and shaking of the wells during incubation

The autoclart contains an X/Y/Z mechanism for addition and aspiration of reagents, and incorporates a tip picking and ejection system for use with disposable tips. Precise volume control is achieved using a peristaltic pump, driven by micro stepping motors under software control. Incorporated into the tip picking system are 4 aspirating needles, for the removal of waste reagent, which are connected to the peristaltic pump. The minimum number of samples that can be processed during a run is 4 and the maximum is 96.

The autoclart operator interface is via an integral Control Panel containing a control knob and LCD display screen. The Control Panel allows the operator to select the number of samples to be processed and run the appropriate assay. The display screen provides visual feedback outlining the progress of the assay.

The base of the instrument contains positions for:
- a Tip Rack Holder
- Reagent Trough containing 3 vials
- a separate Pre-Heated Hybridisation Trough
- a Waste priming trough
- and Tip Waste Container

All the consumable waste is housed inside the instrument, giving the unit a small footprint in the lab.

2 Technical Specifications

Instrument type:	Stand alone bench top
Processing Capability:	4 to 96 samples per run
Processing Time:	Typically under 3 hours for 96 samples
Temperature Control:	PID under software control (30-65ºC)
Temperature-control speed	Heating rate: 10 min Cooling rate: 4 min
Processing Volumes:	50 µL to 1000 µL
Dispensing Mode & Accuracy:	Peristaltic pumps precision: +0% / -10%
Software:	Embedded software
Voltage & Frequency:	Electrical power source at 100 to 240 VAC 5A 50/60Hz
Fuses	5A UL Approved – Ø5x20mm
Dimensions:	600(H) x 590(D) x 650(W) mm
Weight:	50 kg
Consumption value (energy)	400 W (max)
Acoustic noise level (dB)	~ 60 dB
Electromagnetic emissions	Class A 30 MHz to 1000 MHz
Radiated field immunity	10 V/m 80 MHz to 1000 MHz 3V/m 1.4 GHz to 2 GHz 1V/m 2 GHz to 2.7 GHz

3 Safety & General Information

3.1 Unpacking and installation

CAUTION: HEAVY INSTRUMENT

AT LEAST two people are required to move the carton, to unpack, and to lift the instrument from the carton and position on the bench. The instrument weighs 50 kg and the whole unopened carton may weigh as much as 85 kg.

1. Visually inspect the container for transit damage.

2. Place the carton in an upright position to open.

3. The instrument is packed in a re-usable container, which may be collapsed for storage, or disposed of as required. It is recommended that appropriate gloves be worn for unpacking, as some components of the container may have sharp edges.

4. Remove the outer straps and lift off the main cover. Remove all accessories and keep for if was necessary to forward it.

5. Lift the wooden outer shell upwards and place to one side.

6. Two people are required to lift the instrument off the pallet base, one positioned at the front of the instrument, and one person positioned at the back of the instrument. Lift one side of the instrument and at the same time remove the foam side cheek and gently rest the instrument down; repeat this procedure for the other side of the instrument. Remove any protective bubble wrap, and lift the instrument onto the bench or workspace (refer to section 3.4.1).

7. The outer pallet shell can be collapsed flat and placed onto the base of the pallet, with and the lid replaced over it.

8. Remove accessory box from inside of the instrument, and remove the drive securing tapes from:
   - X Axis
   - Y Axis
   - Reaction Plate Axis

9. Inspect the instrument for any obvious signs of transit damage. Report any damage immediately to your local representative.

10. Check that the serial number on the instrument and the delivery note are the same.

11. Unpack accessory box and check that all accessories are present. Contents should be as follows:

1 x Tip Rack Holder	1 x 250ml Square Spare Bottle
1 x Reagent Trough	1 x Spare fuses 5A (pack of 2)
1 x SH Trough	1 x USB Cable
1 x Priming Trough & Lid	1 x Mains Lead
1 x Waste Tip Basket	1 x User Manual (CD)
1 x D.I. Water Bottle Holder	1 x Set of spare packaging tape
1 x 250ml Square D.I. Water Bottle & Lid	

12. Store all packing materials until completely satisfied that the instrument was delivered safely and that it is performing to specification.

3.2 Instrument labeling

Please observe and respect all caution labels shown on instrument & consumables:

3.3 Detailed Personal Safety Information

The Heater unit underneath the microplate, and the overhead heater above the microplate incubation station can both reach temperatures of 65°C during a run. Take care not to touch the heater plate if run is paused.

Avoid touching the autoclart with wet hands, and DO NOT attempt to disassemble the autoclart. In either case electrical shock may result, and in both cases the warranty will be invalidated.

The autoclart will automatically stop when the Cover is opened. Never attempt to manipulate or run the instrument with the Cover opened.

It is recommended to wear a laboratory coat and protective gloves when operating the instrument and handling reagents. If contact of any reagent occurs with skin or eyes, wash thoroughly with water.

3.4 Environmental Conditions

3.4.1 Bench Space

Always place the autoclart on a solid flat surface.

The **minimum** bench space required is 800 mm width and 700 mm depth – the depth should be 700 mm if there is to be no overhang of the front of the instrument.

Place the instrument a maximum of 1 metre from an appropriate power source.

The cover lid swings upwards, so that when at its maximum opening the height from the instrument base to the extreme of the lid is 1000mm.

3.4.2 Disconnection guidelines

In an emergency immediately turn the power off and unplug from power source.

The mains switch and mains lead connection is located on the right hand side panel of the instrument. Do not place the instrument too close to any object that might impair disconnection in an emergency, particularly any object to the right side panel of the instrument.

3.4.3 Ventilation

Do not place the instrument in line with a direct draft such as an air vent. Otherwise there are no specific ventilation requirements for the instrument. Allow a space of 100 mm between the instrument and any wall or other instruments.

3.4.4 General

Keep free of dust, harsh solvents and acidic vapours. Vibration and harsh sunlight must be avoided to ensure correct results. The autoclart should always be placed on a flat stable surface. The autoclart is intended for **indoor use only** and must not be subjected to unduly large variations in temperature and humidity. This instrument was designed for use in a typical laboratory environment, i.e.:

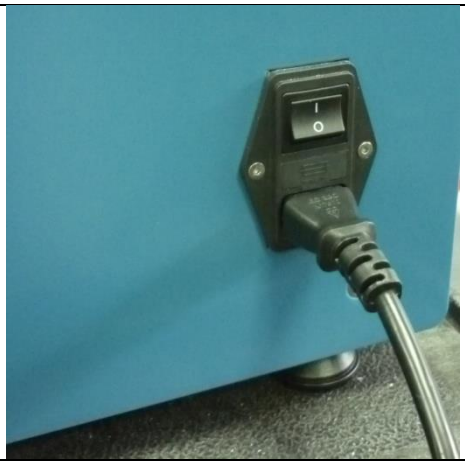
Altitude:	**Up to 2000 m**
Temperature:	**Ambient temperature range: Between 18-25°C**
Humidity:	**Maximum relative humidity 80 % for temperatures up to 31 °C decreasing linearly to 50 % relative humidity at 40 °C**
Mains voltage:	**100 to 240 VAC – 5A 50/60Hz & fluctuations of up to ± 10 % in supply**
Storage conditions:	**from 5°C to 50°C**

Leave to stand for 1 hour before applying power to avoid problems that might arise from condensation.

3.5 Initial Setup

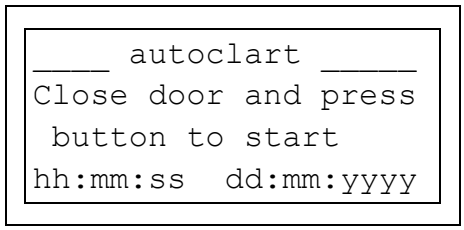
After unpacking according to section 3.1, place instrument on a bench according to section 3.4.1. Check that the instrument deck is level on the bench.

3.5.1 Powering the Instrument

	Attach the mains leads to the power inlet socket on the right hand side of the instrument.

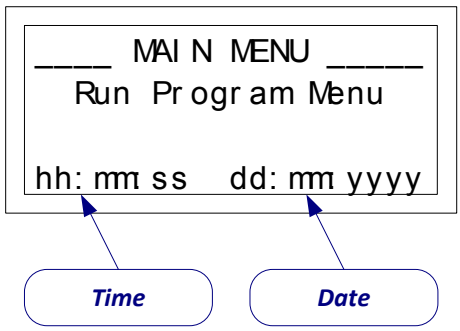
3.5.2 System Start Up & Initial Check

Close the main door. Switch on the instrument power inlet socket. The following will appear on the Control Panel Display:



Observe the instruction to close the door, and press the main button, upon which a number of initialization routines will automatically start on the instrument:
- The 'Z' axis will move upwards to its HOME position
- The 'Y' axis will move to its HOME position
- The 'X' axis will move to its HOME position
- The Heater/Cooler Block will move to its HOME position
- The XY arm will move to be above the tip waste trough, the Z will eject, and XYZ will then return to its HOME position.

The following screen will appear on the Display:

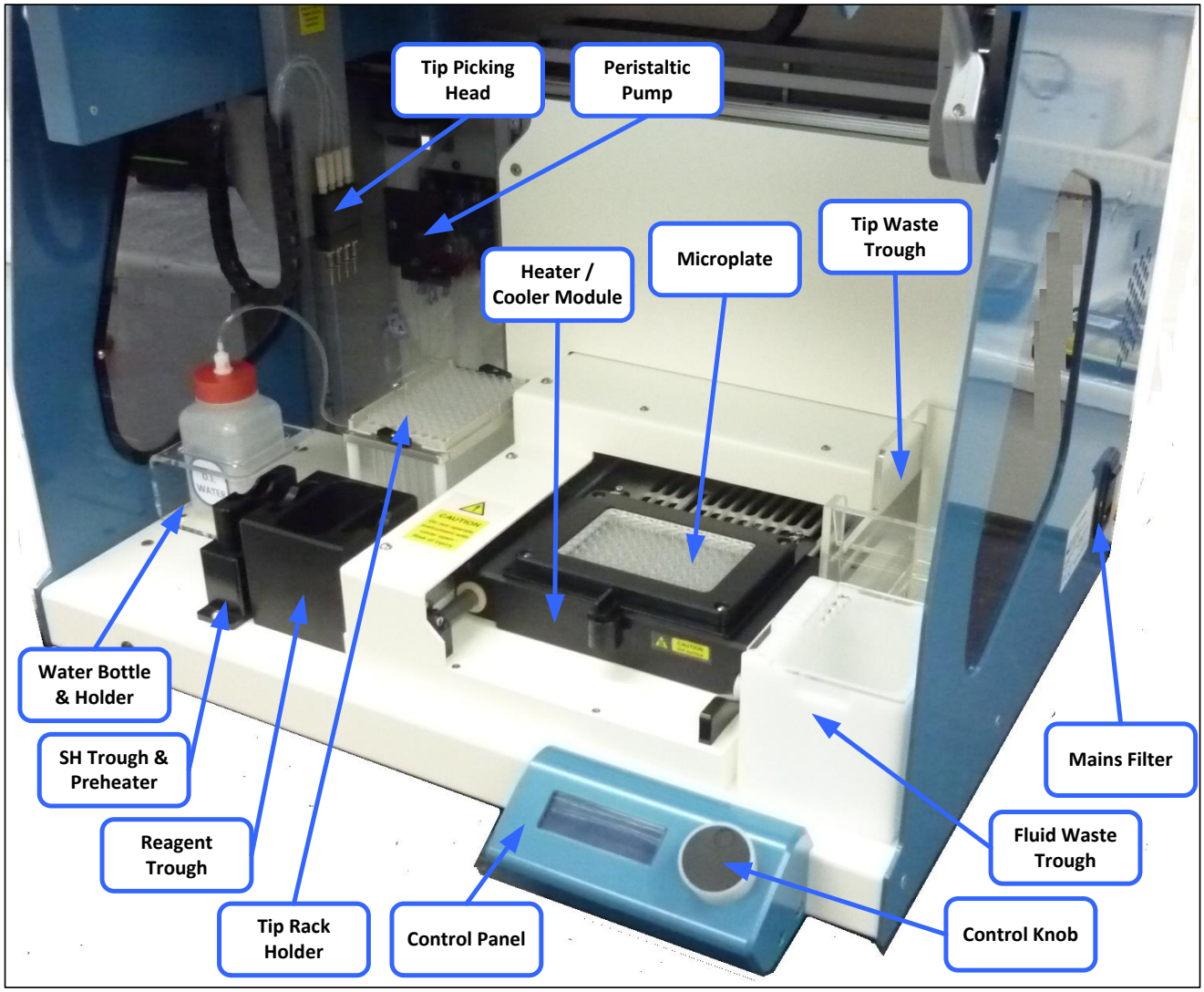


Initialization of the instrument and onboard software is complete.

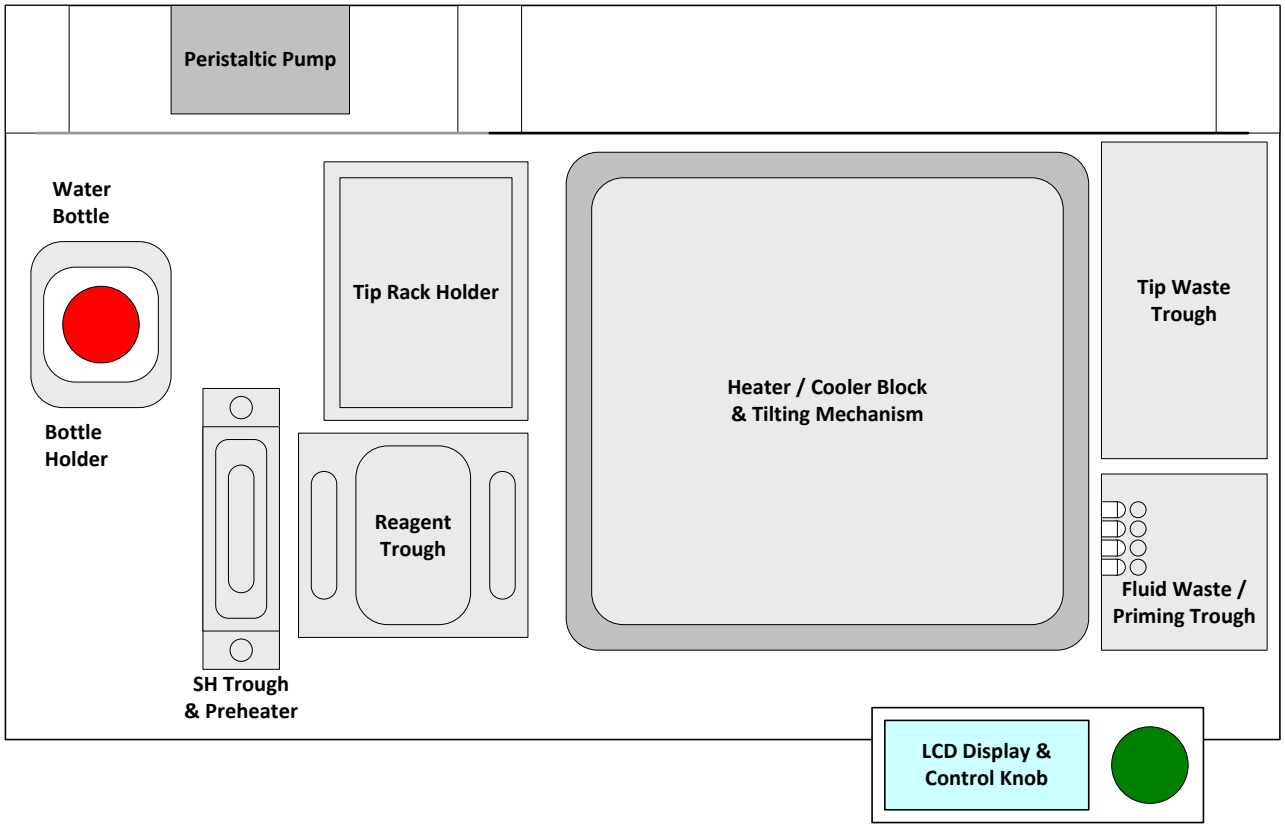
4 System Overview

4.1 autoclart Component Guide

Shown with lid open:



4.2 Instrument Deck Layout



4.3 Installation of Accessories on Instrument Deck

Refer to drawing in section 4.2 above and follow instructions below to assemble accessories correctly. Most accessories are mounted on dimples and can only be positioned one way, in one position only:

DI Water Bottle Holder	Position reagent bottle holder on the dimples at the far left hand side of the deck - it will only fit one way.
DI Water Bottle & Lid	Place bottle into holder, and assemble red cap onto bottle. Connect to tubing from peristaltic pump.
Tip Rack Holder	Position tip rack holder on the dimples towards the back of the deck, to the immediate left of the heater / cooler mechanism (fits one way)
SH Trough	Place SH trough in the Preheater module, to the front right of the wash bottle.
Reagent Trough	Place Reagent Trough on the dimples to the immediate right of the Preheater module.
Tip Waste Trough	Position the tip waste trough on the dimples the far right of the deck, towards the back, to the immediate right of the heater/cooler
Fluid Waste / Priming Trough	Position priming trough on the dimples in front of the tip waste trough.

4.4 Consumables used on autoclart

Apart from the diagnostic kit used on the instrument:

Disposable Tips:

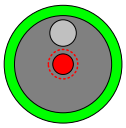
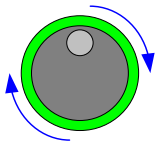
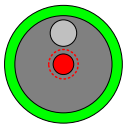
The autoclart has been designed for use with specific disposable tips. Please contact your local representative for further information.
Do NOT attempt to use any other tips. This could result in the failure of the instrument to perform correctly and will validate the warranty.

5 System Operation - Running Programs

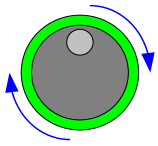
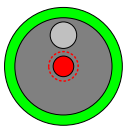
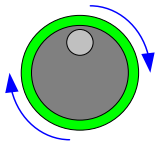
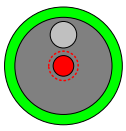
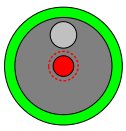
5.1 Starting a Program

1. Switch on the instrument as per section 3.5.

2. After the system has passed the initialization checks, proceed to the main menu page:

____ MAIN MENU _____ Run Program Menu hh:mm:ss dd:mm:yyyy	 Press control knob to proceed...	
_ RUN PROGRAM MENU _ Selected Program: 1 CLART HPV2 Version: V.x.x	The screen will show the: - program number - program name ('CLART HPV2' shown as example) - program version There are 16 different program slots on the autoclart.	
_ RUN PROGRAM MENU _ Selected Program: 1 CLART HPV2 Version: V.x.x	 Rotate control knob to select program (from 1 to 16)...	 ...then press control knob to run selected program

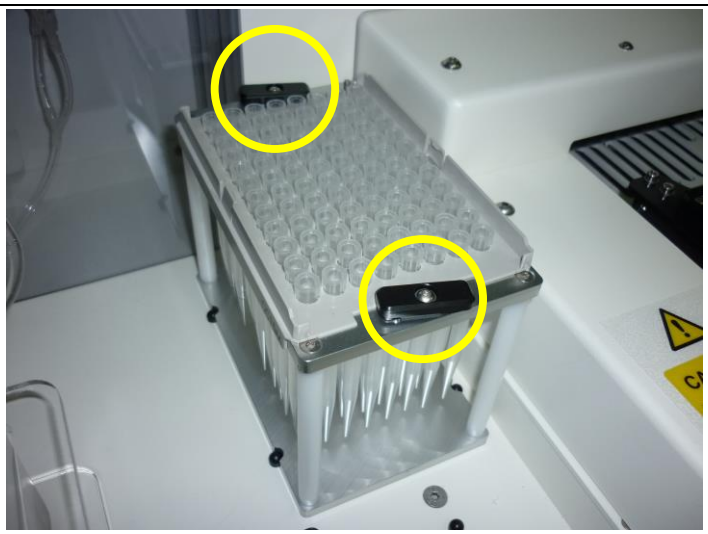
3. The run can be started from either position A1 or E1 on the first strip in the microplate. The E1 option is used if half a strip is to be reused after a previous run - A1 is the default.

_ RUN PROGRAM MENU _ Starting well: A1	 Rotate to select A1 or E1...	 ...press control knob...
_ RUN PROGRAM MENU _ Number samples: x	 Rotate to select no. of samples to be run, from 4 to 96...	 ...press control knob...
	The check-screen states the program to be run, number of samples and starting well. Rotating the knob toggles Confirm to 'No', which if press-	

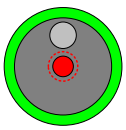
_ RUN PROGRAM MENU _ CLART HPV2 4 samples, from A1 Confirm: Yes?	ed returns to the Main Menu.	Select Yes & press control knob

4. The screen now shows:

_ RUN PROGRAM MENU _ Load tip rack (full) Load microplate	If not already open, open the instrument cover.

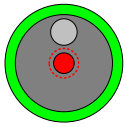
<u>Loading tip rack:</u> Load tip rack on the deck. Ensure that the tip rack is full, is orientated on the only correct position and is flat on the surface on the deck. **Note that tip consumption is the same regardless of number of samples run.** Ensure that both clamps (circled yellow) are fastened.	

<u>Loading microplate:</u> Open the microplate catch (circled yellow, near right), lift the microplate lid and place the microplate in the holder. Ensure that microplate position A1 is at the top-left corner Note: there is a pocket to which the microplate must drop into - ensure that the plate is securely located in the pocket and firmly pressed down (far right). Close the microplate lid and ensure that the catch is fastened in order to clamp the plate down.		

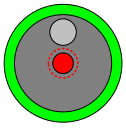
	

_ RUN PROGRAM MENU _ Load tip rack (full) Load microplate	Once tip rack & microplate are loaded, press control knob...

5. The screen now shows:

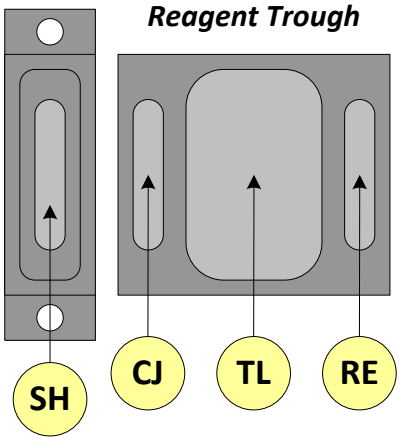
_ RUN PROGRAM MENU _ Check tip basket Check waste trough	Check that the: - tip basket is empty - fluid waste trough is empty If not, empty both parts and reassemble on the deck.	 ...then press control knob...
_ RUN PROGRAM MENU _ Load DI water bottle (250ml DI Water)	Instruction onscreen to load DI Water bottle - see below	

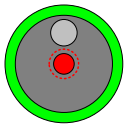
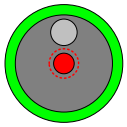
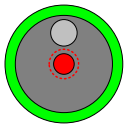
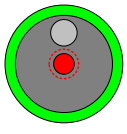
<u>Loading DI Water:</u> Fill the DI Water bottle with 250ml of DI Water. **Note that water consumption is not related to the number of samples run, so the bottle must be filled prior to each run.** Assemble the red cap on the bottle, insert bottle into bottle holder and connect to the pump connector as shown (right).	

_ RUN PROGRAM MENU _ Load DI water bottle (250ml DI Water)	 Once DI Water bottle is loaded, press control knob...

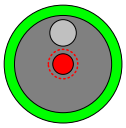
6. The screen now shows:

_ RUN PROGRAM MENU _ Load reagent: TL reagent Volume= xx.x ml	The instrument automatically calculates the required volume of reagent according to the number of samples run, and displays this volume onscreen.

	Schematic diagram of SH and Reagent Troughs shown (left).

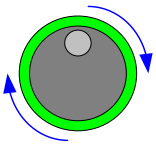
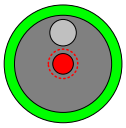
_ RUN PROGRAM MENU _ Load reagent: TL reagent Volume= xx.x ml	Dispense required volume of TL reagent into TL trough...	 ...then press control knob...
_ RUN PROGRAM MENU _ Load reagent: SH reagent Volume= xx.x ml	Dispense required volume of SH reagent into SH trough...	 ...then press control knob...
_ RUN PROGRAM MENU _ Load reagent: CJ reagent Volume= xx.x ml	Dispense required volume of diluted CJ solution into CJ trough...	 ...then press control knob...
_ RUN PROGRAM MENU _ Load reagent: RE reagent Volume= xx.x ml	Dispense required volume of RE reagent into RE trough...	 ...then press control knob...

7. The screen now shows:

_ RUN PROGRAM MENU _ Close door and press button to start	 Press control knob to start program.

The instrument will begin the program.

Optionally at the above screen...

_ RUN PROGRAM MENU _ Close door and press button to start	 If user needs to return to Main Menu: Rotate control knob...
_ RUN PROGRAM MENU _ Return to Main Menu	 Press control knob to return to Main Menu and restart the program select process.

5.2 Program Steps Guide

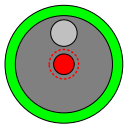
1. Below is a typical screenshot after starting any program:

CLART HPV2 Status: (status) (step name) Next stop in: h:mm	**- The first line displays the name of the program run** **- The second line displays what status the instrument is in** **- The third line displays the step name in the protocol** **- The fourth line displays time left until next user intervention, in hours and minutes**

2. The instrument will initialize; prime and clean the tubing lines in the waste trough; then process the pre-sample addition liquid handling process

3. All programs will have a manual sample addition phase soon after the start of the instrument.
The last line on the display - 'Next stop in: x:xx' - states the time left until this phase, so the user will know when to come back to the instrument.

4. When the ready for manual sample addition, the instrument will emit a consistent periodic beep and display the following screen:

CLART HPV2 Status: Paused Add samples then press button	The instrument will carry on beeping until the door is opened. Open the door, then add samples to the microplate as per the worklist plan. Close door, then...	 ...Press control knob to resume.
CLART HPV2 Status: Running (step name) Next stop in: h:mm	The instrument will re-initialize, and carry on the procedure. The remaining time **for the complete program** is displayed in the last line on the display, in hours and minutes.	

5. The next stage is usually sample incubation, at which stage the microplate is moved to the incubation temperature for incubation at the set temperature, which can be between 30 and 65°C, depending on the protocol. The plate is then cooled down to ambient temperature using the dedicated cooler, before proceeding with the rest of the liquid handling process & protocol.

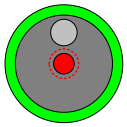
6. At the end of the assay, the instrument will emit a consistent periodic beep and will display the following:

CLART HPV2 Status: Completed open door	The program is now complete - opening the instrument door will return to the Main Menu.

7. A repeat assay may be performed; alternatively shut the instrument down as described in **section 7**.

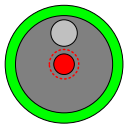
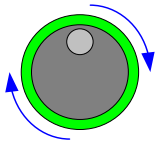
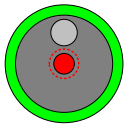
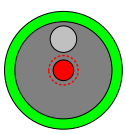
5.3 In-program Features

1. Emergency stop / pause:
   If lid is opened during a run, the instrument will instantly stop the robotic movement for safety reasons. The following screen will be displayed:

CLART HPV2 Status: Stopped Close door and press button to resume	If door is kept open then the instrument cannot resume. Close door and...	 Press control knob to resume.

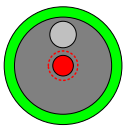
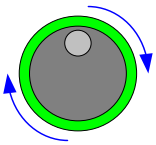
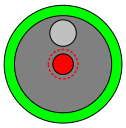
   The instrument will resume the program from the point in which it stopped.

2. **Pausing Program:**
   The user can use the control knob during the program to Pause the program:

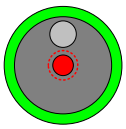
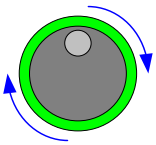
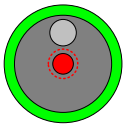
CLART HPV2 Status: (status) (step name) Next stop in: h:mm	 Press and hold control knob down for 3 seconds	
CLART HPV2 Status: Running Return to run screen	 Rotate control knob clockwise (or press to return to program)	
CLART HPV2 Status: Running Pause Program?	 Press control knob...	
CLART HPV2 Status: Paused Close door and press button to resume	The instrument will pause after the particular step it is on has been completed - so note that there may be a delay before pausing.	 Press control knob to resume.

   The instrument will resume the program from the point in which it stopped.

3. **Skipping Incubation:** ***IMPORTANT NOTE: This must not be done when running real samples.***

CLART HPV2 Status: (status) (step name) Next stop in: h:mm	 Press and hold control knob down for 3 seconds
CLART HPV2 Status: Running Return to run screen	 Rotate control knob clockwise thrice (or press to return to program)
CLART HPV2 Status: Running Skip timer?	 Press control knob - the instrument will skip to the next step.

4. **Aborting Program:** The run can be aborted during the program by the user, via the control knob:

CLART HPV2 Status: (status) (step name) Next stop in: h:mm	 Press and hold control knob down for 3 seconds
CLART HPV2 Status: Running Return to run screen	 Rotate control knob clockwise twice (or press to return to program)
CLART HPV2 Status: Running Abort Program?	 Press control knob...
	The instrument will abort the program, with the screen (left) displayed. Press control knob to return to Main Menu.

CLART HPV2 Status: Aborted Press button	

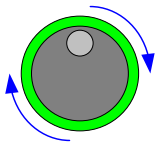
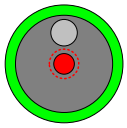
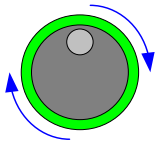
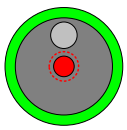
6 System Operation - Other Menu Functions

6.1 Cleaning Menu

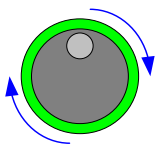
Refer to **section 9.2**.

6.2 Services Menu Functions

To access the service menu:

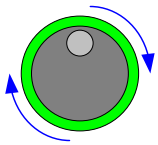
____ MAIN MENU _____ Run Program Menu hh:mm:ss dd:mm:yyyy	 Rotate control knob clockwise (twice)...	
____ MAIN MENU _____ Services Menu hh:mm:ss dd:mm:yyyy	 Press control knob to proceed to Services Menu	
__ SERVICES MENU ___ Return to Main Menu	 Rotate control knob to access Service Menu functions;	 or Press control knob on screen shown to return to Main Menu

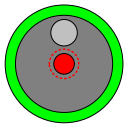
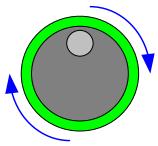
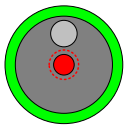
6.2.1 About Instrument

__ SERVICES MENU ___ Return to Main Menu	 Rotate control knob clockwise
	Displays information about the autoclart. - The second line displays the instrument serial number

_ ABOUT INSTRUMENT _ Serial No.: ACT-xxx Controller: V x.xx Init script: V x.xx	- The third line displays the instrument Master Firmware version - The fourth line displays the instrument Init Check Script version

6.2.2 Setting Time and Date

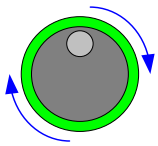
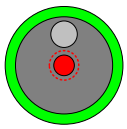
<table>
<tr><td>__ SERVICES MENU ___
Return to Main Menu</td><td colspan="2"> 
Rotate control knob clockwise (twice)</td></tr>
<tr><td>__ SERVICES MENU ___
Set Time/Date

hh:mm:ss dd:mm:yyyy</td><td colspan="2"> 
Press control knob</td></tr>
<tr><td>__ SERVICES MENU ___
Set Time/Date
Set days:
hh:mm:ss dd:mm:yyyy</td><td> 
Rotate control knob to set 'day'</td><td> 
Press control knob...</td></tr>
<tr><td>__ SERVICES MENU ___
Set Time/Date
Set months:
hh:mm:ss dd:mm:yyyy</td><td colspan="2">The user can rotate control knob to set month; press to accept, and repeat for:
Year
Hour
Minute
... after minute is set, the instrument returns to the Main Menu.</td></tr>
</table>

In case of setting a wrong date or time it can be overwritten.

6.2.3 Running the Demo Script

The Demo script is a cut-down version of the normal program script, with the incubation times greatly reduced. It is intended for exhibition use only and must not be used with real samples.

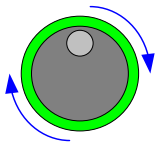
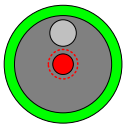
__ SERVICES MENU ___ Return to Main Menu	 Rotate control knob clockwise (x 3)
__ SERVICES MENU ___ Run Demo Program Demo Script: V.x.xx	 Press control knob

The subsequent process is identical to running a standard program - refer to **section 5.1**, point 3 onwards.

6.2.4 Running the Operational Qualification (OQ) Script

1. The Operational Qualification (OQ) script can be performed in order to check all aspects of instrument performance, and especially to check that all XYZ positions are correct.

   It is recommended to run the OQ script after the installation of the autoclart, to ensure that no part has been affected during the transportation, and after any modification of the device (annual maintenance, software updated…)

__ SERVICES MENU ___ Return to Main Menu	 Rotate control knob clockwise (x 3)
__ SERVICES MENU ___ Run Demo Program Demo Script: V.x.xx	 Press control knob

2. The subsequent process is identical to running a standard program - refer to **section 5.1**, point 3 onwards. The only difference is that D.I. Water is used in TL and SH troughs only.

3. The autoclart will commence the OQ Script. The full assay / checklist details can be found in Appendix II (section 14.2) - briefly, the instrument will dispense to all wells, aspirate from all wells, heat, cool, then check for all other positions used in an assay. Note that to use a full rack of tips is absolutely necessary, as all 4 corner co-ordinates of the tip bank will be checked during the program.

4. When the pause command is triggered at sample addition, open the lid, close lid then carry on running the assay. The heating incubation can be skipped if so wished by pressing and holding the control knob for 3 seconds at the incubation phase, which will trigger the Pause / Abort / Skip screen (refer to section 5.3). Rotate to the skip timer feature and Press control knob in order to skip timer.

5. Check that all aspects detailed in ANNEX 3 checklist are performed correctly.

7 Instrument Shutdown

1. If not already removed, remove the microplate from the instrument.
2. Unclip and remove the DI Water Bottle from its holder.
3. Remove the Waste Trough and dispose of waste in accordance with country, federal, state and local regulations.
4. Remove the Tip Waste Trough and empty contents into general hazardous waste.
5. Remove the Tip Rack from the deck.
6. Remove Reagent Trough. If any unused reagent is to be discarded then discard in accordance with country, federal, state and local regulations.
7. Remove SH Trough. If any unused reagent is to be discarded then discard in accordance with country, federal, state and local regulations.
8. Clean the deck with microsol or alcohol wipes (refer to section 9) and replace accessories back on the system.
9. Close instrument door, then switch the mains power inlet off.

8 Troubleshooting and Accessing Logs

If you encounter difficulties with the instrument the simple guidelines below may help you resolve them. The information you gain from these observations will also help qualified service engineers return the instrument to full working order as quickly as possible.

8.1 Simple Troubleshooting

8.1.1 Visual Inspection

A good visual inspection of the instrument prior to switching it on can sometimes reveal problems or potential problems. Performing the following simple checks will help determine the condition of the instrument.

Check for any signs of obvious damage. With the instrument switched OFF, open the lid, and inspect the base of the instrument for any spillages or obstructions that will prevent the accessories from resting flat on the instruments base. Remove all the accessories from the base and clean with a lint free cloth.

8.1.2 Mechanics

Ensuring that the tip picking/ejection system is in the HOME position, move the X and Y-axis by hand to ensure that there are no obstructions. If obstructions are encountered, look for mechanical obstructions, such as loose screws.

Ensure that the probe needles are clean and in good condition. Gently clean each tip with an alcohol wipe. The needles should be straight, if for some reason they have been bent, then a qualified engineer should replace them.

Ensure that there is nothing blocking the path of the reaction plate..

8.1.3 Fluidics

Check for any damage to the tubing, and ensure that there are no kinks visible along the 'Y' and 'X' axis, which could affect the sample processing. Pay particular attention to the connections at the tip picking/ejection mechanism.

If no problems are encountered during visual inspection, the instrument can be switched on. If problems are encountered during visual inspection, these must be rectified prior to switching the instrument on; otherwise further damage may be done to the instrument.

8.1.4 Initialization

During instrument initialization, specific functions of the instrument are checked. In case of any reported errors, refer to **Section 8.2.**
The Initialisation sequence is a separate initialization script named 'Init Check'.
Below are details of the Initialisation sequence script:

Step	Action	Comment	Potential problem	Consequence	Solution	Pass
1	Master controller loads tables, checks modules and FW compatibility	Immediate if performed correctly	Data corrupted Wrong Firmware Module not present	Error generated	Check ribbon cable Check module Contact service provider	
2	Initialization of Z drive		Home not detected	Error generated	Contact service provider	
3	Initialization of X, Y, and RP drives		Home not detected	Error generated	Contact service provider	
5	Tip Ejection					
7	Park XY, and move RP towards the user					
8	End of initialization (3 audible short beeps)					

8.2 Error Codes

The instrument contains an error handling mechanism, with instrument parameters monitored in real time. If an error is detected the instrument stops immediately, the internal buzzer is switched on constantly, and an error code is displayed on the Control Panel. Error codes are stored in a log inside the master controller board. Errors can broadly be :

Physical (mechanical) / Electrical and electronic (wiring etc.) / Corrupted and spurious data / Software related

IN ALL CASES, ERROR CODE(S) MUST BE REPORTED IMMEDIATELY TO THE SERVICE PROVIDER FOR ANALYSIS.

The errors at present can only be fully decoded by the autoclart manufacturer (Bee Robotics), at which point Bee Robotics will advise on a course of action to remedy the potential cause of the error.

8.3 Viewing Run and Error Logs

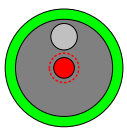
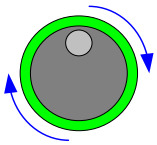
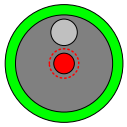
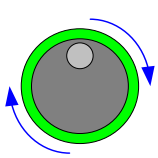
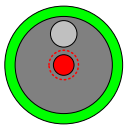
Should there have been an error on the instrument: if the instrument can subsequently initialize, then Error Logs and Run Logs can be viewed on the Control panel, with any error logs to be reported to the Service Provider.

8.3.1 Viewing Run Logs

1. Switch the autoclart on and follow the initialization procedure.

2. Navigate to the Services Menu, then:

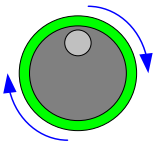
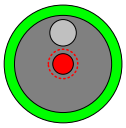
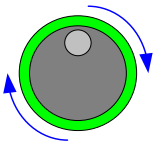
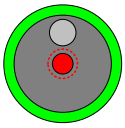
<table>
<tr><td>____ MAIN MENU _____
Services Menu

hh:mm:ss dd:mm:yyyy</td><td>  
Press control knob, then rotate until...</td></tr>
<tr><td>__ SERVICES MENU ___
Display Run Log</td><td> 
Press control knob...</td></tr>
<tr><td>Run log rank: 000
(last run name)
hh:mm dd/mm/yyyy
hh:mm xx samples/A1</td><td>The run log displays the following information:
Name of run (second line)
Start time of run (third line, left)
End time of run (fourth line, left)
Date of run (third line, right)
No of samples and if start well is A1 or E1 (fourth line, right)</td></tr>
<tr><td>Run log rank: -001
(last run name)
hh:mm dd/mm/yyyy</td><td>  Rotating the control knob toggles through previous runs (000 being the last run, -001 being the second last run etc.)
 
Press to return to</td></tr>
</table>

hh:mm xx samples/A1			Services Menu

8.3.2 Viewing Error Logs

1. Still at the Services Menu...

____ MAIN MENU _____ Services Menu hh:mm:ss dd:mm:yyyy	 Rotate control knob until...		
__ SERVICES MENU ___ Display Error Log	 Press control knob...		
Error rank: 0002 - M 012-345-678-910 000-000-000-000 000-000-000-000	The error log displays the following information: Error Rank (i.e. latest error) If Master (M) or other (S) board generated error (first line, right) Error Code The code can then be reported to the service provider / manufacturer for analysis		
Error rank: 0001 - M 109-876-543-210 000-000-000-000 000-000-000-000		Rotating the control knob toggles through any previous errors	 Press to return to Services Menu

9 Cleaning the Instrument

9.1 General Cleaning

Cleaning of the autoclart should be performed regularly using microsol, alcoholic wipes or proprietary decontaminants* followed by water and appropriate detergents*. Only the deck and outside of the instrument should be cleaned, together with running the appropriate cleaning program to keep the tubing clean. Do not attempt to remove any panels in order to clean inside the instrument, as there is a risk of injury and risk of damage to the instrument.

- ALWAYS wear protective gloves prior to cleaning.
- Use an appropriate detergent to clean surrounding surfaces.
- Use a cloth, dampened in detergent and wipe all areas in and around the base and the reagent area. Use the same technique to wash all parts that may come in contact with any accidental spillage.
- Clean all the reagent troughs at the end of each run, ensure that the Waste Trough is emptied and the Tip-Waste Trough also emptied and cleaned.
- The tubing lines are cleaned with water during the assay; further cleaning may be performed as specified below

It is the responsibility of the user not to use decontamination or cleaning agents that could cause hazard as a result of the reaction with parts of the equipment or with material contained in it.

If in any doubt about the compatibility of decontamination or cleaning agents, please contact your local agent, or:

GENOMICA, S.A.U.
Alcarria, 7, Pol. Industrial de Coslada, Coslada
Madrid 28823, Spain

Tel.: +34 91 674 89 90
Fax: +34 91 674 89 91
e-mail: info.genomica@genomica.com

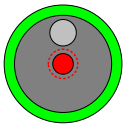
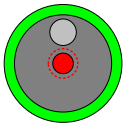
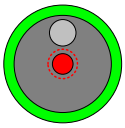
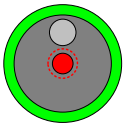
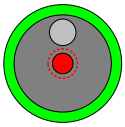
9.2 Using the Cleaning Program

The instrument has a dedicated program to clean the transit lines of the instrument if required.

1. If instrument is not already on, then switch instrument on and initialize according to section 3.5.

2. Generate the cleaning solution. The recommended solution is:
   Bleach diluted to a ratio of 1:25 (4%) with DI Water.
   It is recommended to run the cleaning program every 30 days of use of the autoclart.

3. On the main menu screen, navigate to the Cleaning Menu...

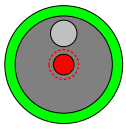
____ MAIN MENU _____ Cleaning Menu hh:mm:ss dd:mm:yyyy	 Press control knob...	
CLEANING PROCEDURE Cleaning Script Version: V.x.x Confirm: Yes?	 Press control knob (or rotate to select 'No' and return to Menu)	
CLEANING PROCEDURE Check waste trough	Check that the waste trough is empty. If not, then empty the waste trough and replace on deck.	 Press control knob...
CLEANING PROCEDURE Load wash bottle (100ml 4% bleach)	Place 100ml of the cleaning solution in the supplied spare 250ml bottle. Place bottle on the deck, assemble the lid and connect bottle to tubing connector.	 Press control knob...
CLEANING PROCEDURE Close door and press button to start	(Rotating the control knob allows the user to return to the main menu if required.) Close door and...	 Press to start

4. The instrument will begin the cleaning procedure, filling the tube lines and washing the probes with the cleaning solution. A screen similar to below will be displayed:

```
Cleaning script
Status: Running
Soaking (wash)
Next stop in:   x:xx
```

The instrument will soak the lines for 10 minutes, with the countdown timer at the bottom right of the screen reflecting this.

5. At the end of the 10 minutes, the instrument will flush more of the cleaning solution into the waste trough and will then pause and audibly alarm for operation intervention:

`Cleaning script`
`Status: Paused`
`Load DI water bottle`
`then press button`
	Open lid. Remove cleaning bottle from deck and remove cap.
	Place 100ml of DI Water in DI Water bottle and replace on deck, replacing cap and connecting to pump tubing.
	Close instrument door.
		
		Press control knob...

6. The instrument will now rinse the lines out and soak with DI Water, following a similar procedure to the cleaning method used with the cleaning solution. The soak will take approximately 7 minutes. At the end of the process, a screen similar to the below will come up, along with an audible alarm signalling the end of the script:

```
Cleaning script
Status: Complete
Open door
```

7. Open door and:
   - remove and empty the Waste Trough
   - remove and empty the DI Water bottle

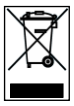
   The cleaning procedure is now complete.

10 Disposal

DISPOSAL:

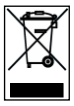
Dispose of any unused reagents and waste in accordance with country, federal, state and local regulations.

Instrument Disposal:



As part of the WEEE EU directives, this instrument should be returned to the manufacturer for dismantling at the end of its life

Packaging Disposal:



Please dispose of all packaging in accordance with local recycling regulations.

11 Technical Support

For all technical support and assistance, contact:

GENOMICA, S.A.U.
Alcarria, 7
Pol. Industrial de Coslada, Coslada
Madrid 28823
Spain

Tel.: +34 91 674 89 90
Fax: +34 91 674 89 91
e-mail: info.genomica@genomica.com

Only by Genomica S.A.U. or associated trained service personnel may authorised repairs and servicing be carried out.

For further details of instrument or to arrange for training to be given on the instrument, contact Genomica S.A.U. at above address.

12 Declaration of Conformity (Copy)

DECLARATION OF CONFORMITY

Legal Identity:	Bee Robotics Ltd 32-33 Cibyn Industrial Estate Caernarfon, Gwynedd LL55 2BD N.Wales UK
Equipment Identification	autoclart
Type of Equipment:	Automated Laboratory Instrument

We, Bee Robotics Ltd hereby declare that the device mentioned above comply with the following European directives:

- Standard: EN 61326-1:2006 and EN 61326-2-6:2006
- EMC Directive 2004/108/EEC
- Machinery Safety Directive: 2006/42/EC
- Standards: EN ISO 121100
- Standards: EN 61010-1:2010
- Standards: EN 61010-1:2001

Classification:	General Laboratory Equipment
Conformity Assessment Procedure:	Machinery Safety Directive 2006/42/EC EMC Directive 2004/108/EC
Date of Validity:	October 2013
Signed on behalf of Bee Robotics:	
Position:	Product Manager
Signing Location	Bee Robotics Ltd, Unit 32/33 Cibyn Industrial Estate Caernarfon, Gwynedd, LL55 2BD N.Wales UK

13 Limited Warranty

Please note the serial number of the autoclart (found on the back of the instrument) below for future reference:

SERIAL No. …….

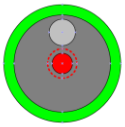
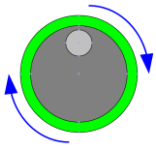
Warranty Statement

Bee Robotics warrants that each product described herein will be free from defects in materials and workmanship for a period of one year from the date of delivery to Genomica S.A.U. and GENOMICA warrants for a one year from the date of delivery to distributor as its sole responsibility under this limited warranty, and upon prompt notice of the defect, to repair or replace any product found to be defective within the warranty period.

The limited warranty is not applicable to: (1) abnormal wear and tear (2) abuse, unreasonable use, improper installation, mistreatment, or neglect (3) damage caused by equipment or system with which the product is used (4) damage caused by modification or repair not made or authorised by Genomica S.A.U., or (5) theft, vandalism, fire, water or other peril. Product may not be returned without proper authorisation from Genomica S.A.U. cost of transportation, removal, or reinstallation of the equipment will be paid by the purchaser. This warranty and the remedies set forth herein are exclusive and in lieu of all other express or implied (including any implied warranties or merchantability or fitness for a general purpose), and no other representations or claims shall be binding on or obligate Genomica S.A.U. in any way. In no event will Genomica S.A.U. be liable for any special, incidental, or consequential damages resulting from use or malfunction of this product or the equipment or system with which it is used, loss of revenue, or cost of replacement of goods.

14 Appendix

14.1 Appendix I: Synopsis of Symbols used in manual & on instrument

Symbol	Colour	Publication	Description	Placement
	Outline: Green Boss: Grey Instruction: Red	N/A	Push / Press Control Knob	In User Manual only
	Outline: Green Boss: Grey Instruction: Blue	N/A	Rotate Control Knob	In User Manual only
	Symbol & Outline: Black	IEC 60417 – 5032	Alternating Current	Instrument Serial Label
	Symbol & Outline: White	IEC 60417 – 5007	On (Supply)	Inlet Filter
	Symbol & Outline: White	IEC 60417 – 5008	Off (Supply)	Inlet Filter
	Background: Yellow Symbol & Outline: Black	IEC 60417 – 5032	Caution, Hot Surface	On Heater / Cooler
	Background: Yellow Symbol & Outline: Black	IEC 60417 – 5007	Caution, Risk of Danger	On Caution Labels

14.2 Appendix II - OQ Script Checklist

autoclart Serial Number:	
Action	*Tick to confirm*
6.2.4 Running OQ Script - action checklist	
Priming performed correctly	
Tip Bank A1-4 position correct	
XYZ position at TL trough correct	
Dispense position to 96 wells correct	
Fluid dispensed to 96 wells	
Aspiration position correct for 96 wells	
XYZ position at SH Trough correct	
Pause correct	
Resume correct	

Skip timer working	
Cooling fan working	
XYZ position at CJ trough correct	
XYZ position at RE trough correct	
All tips picked up / ejected correctly	
Tip Bank A9-12 position correct	
Tip Bank H9-12 position correct	
Notes:	
OPERATOR:	DATE:

14.3 Appendix III - autoclart - INSTALLATION CHECKLIST

INSTRUMENT SERIAL NUMBER:

CUSTOMER NAME:	
ADDRESS:	
TELEPHONE NUMBER:	
FAX NUMBER:	
E-MAIL ADDRESS:	

Did the instrument arrive in good condition? Yes No

If no, provide details:

Were the following accessories present?:

1 x Tip Rack Holder	
1 x Reagent Trough	
1 x SH Trough	
1 x Priming Trough & Lid	
1 x Tip Waste Trough	
1 x 250ml Square D.I. Water Bottle & Lid	
1 x 250ml Square Spare Bottle	
1 x Spare fuses 5A (pack of 2)	
1 x USB Cable	
1 x Mains Lead	
1 x User Manual (CD)	
1 x Set of spare packaging tape	

Did the autoclart initialise correctly? (refer to 3.5.2 in User Manual) Yes ☐ No ☐

If no, provide details:

Any other comments:

Representative Name:	
Representative Address:	

Representative Signature:		Date:	
Customer Signature:		Date:	
Customer Print Name:		Position:	

Customer to retain original copy.

Distributor must send copy to:

GENOMICA, S.A.U.
Alcarria, 7
Pol. Industrial de Coslada, Coslada
Madrid 28823
Spain

e-mail: info.genomica@genomica.com

14.4 Appendix IV - autoclart- DECONTAMINATION CERTIFICATE

Name _____

Make of Instrument _____

Model Number _____

Tick:

☐ This equipment has not been used in an invasive procedure or been in contact with blood, other body fluids or pathological samples. It has been cleaned in preparation for inspection, service or repair.

or

☐ This equipment has been cleaned and decontaminated.
The decontamination method is outlined below:

_____
_____
_____
_____

or

☐ This equipment could not be decontaminated. The nature of risks and safety precautions to be adopted are as follows:

_____
_____
_____
_____

Signed: _____ Date: _____

Position Held: _____

Full Official Address: _____
_____
_____
_____
_____

Telephone number: _____