

Automated Nucleic Acids Extraction System ANDiS 350 Instruction For Use

Automated Nucleic Acids Extraction System ANDiS 350

Instruction For Use

3D Biomedicine Science & Technology Co., Ltd.

Table of Contents

Copyright	3
Disclaimer	3
No liability for consequential damages	3
Warranty statement	3
1 Safety Information	4
2 Policy Statement	6
3 Intended Use.....	6
4 General Description.....	7
5 External Appearance	7
6 Installation Procedure.....	7
7 General Operation	9
8 Technical Specifications.....	17
9 Troubleshooting	17
10 Instruction for Replacing Fuse	18
11 Accessories	18
12 Disposal of Instrument	18

Copyright

3D Biomedicine Science & Technology Co., Ltd.. All right reserved. ANDiS is the sole property of 3D Biomedicine Science & Technology Co., Ltd.. Reproduction of the accompanying user documentation in whole or in part is prohibited.

Disclaimer

3D Biomedicine Science & Technology Co., Ltd. reserved the right to change its products and services at any time to incorporate technology developments. This IFU is subject to change without prior notice as part of continuous product development. Although this IFU has been prepared with every precaution to ensure accuracy, 3D Biomedicine Science & Technology Co., Ltd. assumes the liability for any errors and omissions, not for any damages resulting from the application or use of this information.

No liability for consequential damages

3D Biomedicine Science & Technology Co., Ltd. shall not be liable for any indirect or consequential damages whatsoever arising out of the use or inability to use this product.

















Warranty statement

3D Biomedicine Science & Technology Co., Ltd. products are fully guaranteed against defective parts and materials, including defects caused by poor workmanship, for a period of one year from the date of delivery. 3D Biomedicine Science & Technology Co., Ltd. will repair or replace defective parts or materials during the term of warranty at the extra charge of materials and labor provided that the products were used and maintained in accordance with 3D Biomedicine Science & Technology Co., Ltd.'s instrument. The warranty is invalid of products which have been misused or abused. For the warranty to be effective, the product must be purchased directly from 3D Biomedicine Science & Technology Co., Ltd. or from an authorized 3D Biomedicine Science & Technology Co., Ltd. distributor.

The guarantee is not transferable to a third party without prior written approval from 3D Biomedicine Science & Technology Co., Ltd.. This guarantee is subject to the following exclusions:

- Any defects caused by normal wear and tear.
- Defects caused by fire, lightning, flood, earthquake, explosion, sabotage, war, riot, or any other occurrence of the type listed above.

Safety symbols and markings

	Power On	
	Power Off	
	Warning	Hot surface, risk of burns
	Warning	Risk of electric shock.
	Warning	Biohazard risk
	Warning	Risk if injury to the user (s)
		Date of manufacture
		Manufacturer
		Serial number of this instrument
		Catalog number
		Consult Instruction for Use
	WEEE symbol	This product is required to comply with the European Union's Waste Electrical & Electronic Equipment (WEEE) Directive 2012/19/EC.
	Caution	Risk of damage to the instrument, other equipment or loss of performance or function in a specific application.
		No Heavy Load
		Caretechion GmbH Niederrheinstr 71,40474 Duesseldorf,Germany
		CE Mark

1 Safety Information

Before using Automated Nucleic Acids Extraction System ANDiS 350, it is important to read this IFU carefully and pay particular attention to the safety information. The instructions and safety information in this IFU must be followed to ensure safe operations of the instrument and to maintain the instrument in a safe condition.

1.1 Proper use

1.1.1 **WARNING: Risk of personal injury and material damage**

Improper use of Automated Nucleic Acids Extraction System ANDiS 350 may cause personal injuries or damage the instrument.

The Automated Nucleic Acids Extraction System ANDiS 350 must only be used by the trained professionals.

Note: *Do not place items on top of instrument hood.*

1.1.2 **CAUTION: Damage to the instrument**

Do not spill water or chemicals onto the ANDiS 350 Automated Nucleic Acids Extraction System. The warranty will not be applied for the damage caused by water or chemical spillage.

1.2 Electrical safety

Electric hazard

Any interruption of the protective conductor (earth/ground lead) inside or outside the instrument or disconnection if the protective conductor terminal is likely to make the instrument dangerous.

Intentional interrupt is prohibited.

The voltages inside the instrument is lethal.

When working with Automated Nucleic Acids Extraction System ANDiS 350, please following the instructions below:

- The line power cord must be connected to a line power outlet that has a protective conductor (earth/ground).
- Disconnect the power before fixing the holder of magnetic rods with screws or before moving the instrument
- Do not operate the instrument with any covers or part removed.
- The instrument should install the way that the power code is accessible.

The instrument may become electrically unsafe when:

- Automated Nucleic Acids Extraction System ANDiS 350 or the power code appears to be damaged.
- Automated Nucleic Acids Extraction System ANDiS 350 has been installed under unfavorable conditions for a prolonged period.
- Automated Nucleic Acids Extraction System ANDiS 350 has been experienced to severe transport stress.
- Liquids have come to contact with electric components of Automated Nucleic Acids Extraction System ANDiS 350.
- The power code of Automated Nucleic Acids Extraction System ANDiS 350 has been replaced with a non-official power code.

1.3 Biological safety



Some samples used with this instrument may contain infectious agents. Use safe laboratory procedures as outlined in publications such as *Biosafety in Microbiological and Biomedical Laboratories*, HHS (www.cdc.gov/biosafety.htm).

Always wear safety glasses, gloves, and a lab coat.

Venting for fumes and disposal of wastes must be in accordance with all national, state and local health and safety regulations and laws.

1.4 Waste disposal

Used consumables such as 96-well deep well plate and 8-rod covers may contain hazard chemical or infectious agent from purifications. Such wastes should be collected and disposed of properly according to local safety regulations.

1.5 Environment

- 1.5.1 Automated Nucleic Acids Extraction System ANDiS 350 is not designed for use in an explosive atmosphere.
- 1.5.2 To ensure the proper ventilation, maintain a proper clearance at the rear of the Automated Nucleic Acids Extraction System ANDiS 350.

1.6 Chemical safety

- 1.6.1 Hazardous chemicals used with Automated Nucleic Acids Extraction System ANDiS 350

may be hazardous or may become hazardous after completion of the purification protocol. The precaution must be taken to ensure the surrounding workplace is safe and operators are not exposed to hazardous levels of toxic substances as defined in the applicable Safe Data Sheet (SDS) document.

- 1.6.2 Venting for the fumes and disposal wastes must be accordance with all national, state and local health and safety regulation and laws.
- 1.6.3 Do not use bleach to clean or disinfect Automated Nucleic Acids Extraction System ANDiS 350 and used labware. Bleach in contact with salts from the buffer may produce toxic fumes.

1.7 Mechanical hazard

Automated Nucleic Acids Extraction System ANDiS 350 must be operated with the door closed in order to avoid the contact with moving part during the run.

1.8 Magnetic hazard

- 1.8.1 Automated Nucleic Acids Extraction System ANDiS 350 uses magnetic rods for processing the magnetic beads. These magnetic rods generate a strong magnetic field.
- 1.8.2 Do not place Automated Nucleic Acids Extraction System ANDiS 350 near magnetic storage system such as computer discs.
- 1.8.3 Do not use mental tools when handling the magnetic rods.
- 1.8.4 Do not allow the magnetic rod to contact with other magnets.

1.9 Heat hazard

The elution station of Automated Nucleic Acids Extraction System ANDiS 350 can reach temperature up to 60°C (140 °F). Avoid touching it during, and immediately after operation.

1.10 Maintenance safety

- 1.10.1 Only performance maintenance as described in this Instruction for Use.
- 1.10.2 Do not use bleach, solvents or reagents containing acids, alkalis, or abrasives to clean Automated Nucleic Acids Extraction System ANDiS 350.
- 1.10.3 Do not use spray bottle containing alcohol or disinfectant to clean the surface of Automated Nucleic Acids Extraction System ANDiS 350.
- 1.10.4 After wiping the metal surface inside of Automated Nucleic Acids Extraction System ANDiS 350, make sure that no bits of paper towel remain. The piece of paper towel remaining on the mental surface could lead to surface collision.
- 1.10.5 Only clean Automated Nucleic Acids Extraction System ANDiS 350 with alcohol-based disinfectant when worktable components have cooled down.

2 Policy Statement

It is a policy of 3D Biomedicine Science & Technology Co., Ltd. to improve products as new techniques and components become available. 3D Biomedicine Science & Technology Co., Ltd. reserves the right to change specifications at any time.

3 Intended Use

The Automated Nucleic Acids Extraction System ANDiS 350 is designed to perform automated purification of nucleic acids.

The Automated Nucleic Acids Extraction System ANDiS 350 is intended for use by professional users trained in molecular biological techniques and the operation of Automated Nucleic Acids

Extraction System ANDiS 350.

4 General Description

4.1 Automated Nucleic Acids Extraction System ANDiS 350

Automated Nucleic Acids Extraction System ANDiS 350 performs fully purification of nucleic acids using magnetic-particle technology. Samples can be process in batches of up to 32 samples.

Automated Nucleic Acids Extraction System ANDiS 350 contains two sets of 8-magnetic rods that protected by rod cover. These rods can pick up or release magnetic particles in the wells of 96-well sample prep plate.

4.2 Automated Nucleic Acids Extraction System ANDiS 350 principle

- Samples are lysed in the wells containing required lysis reagents.
- Nucleic acids bind to the surface of magnetic beads and washed to remove contaminants.
- **Purified nucleic acid is eluted in the well containing elution buffer.**

5 External Appearance



Figure 1: Automated Nucleic Acids Extraction System ANDiS 350

6 Installation Procedure

6.1 Unpacking

Move the packed instrument to its site of operation. Unpack Automated Nucleic Acids Extraction System ANDiS 350 and accessories carefully with the arrows on the transport package pointing upwards. Remove the instrument from the package and place it on a level surface.



Warning Automated Nucleic Acids Extraction System ANDiS 350 is approximately 35Kg without the transport package and should be lifted with care. It is recommended that two persons lift the instrument together, taking proper precautions to avoid injury.

6.2 Check delivery

Check the enclosed packing list against the order. In case of any deviation, contact 3DMed or the distributor(s).

Visual inspect the transport package, the instrument and the accessories for any possible transport damage.

If the package had been damaged in transit, it is particularly important that you retain it for inspection by the carrier in case there has also been damaged to the instrument.

Neither the manufacturer nor its agents can be held responsible for any damage incurred in transit, but the manufacturer will make every effort to help obtain restitution from the carrier. Upon receipt of the carrier's inspection report, arrangements will be made for repair or replacement.

If any parts are damaged, contact 3DMed or the distributor(s).

6.3 Requirements

Site

Automated Nucleic Acids Extraction System ANDiS 350 must be located out of direct sunlight, away from heat surface, and away from sources of vibration and electrical interference. The site of installation should be free of excessive drafts, excessive moisture, excessive dust, and not subject to large temperature fluctuation.

If you choose to position the Automated Nucleic Acids Extraction System ANDiS 350 on an alternative workbench, ensure that it is large enough and strong enough to accommodate the system. Refer to the technical data for the weight and dimensions of Automated Nucleic Acids Extraction System ANDiS 350. Ensure that the alternative workbench is dry, clean, vibration proof, and has additional space for accessories.

Note: *it is extremely important that Automated Nucleic Acids Extraction System ANDiS 350 is placed on a stable surface.*

WARNING Explosive atmosphere



Automated Nucleic Acids Extraction System ANDiS 350 is not designed for use in an explosive atmosphere.

WARNING risk of overheat



Proper ventilation and maintain minimum clearance at the rear of the Automated Nucleic Acids Extraction System ANDiS 350 are required.

6.4 AC power connection

6.4.1 Power requirements

The Automated Nucleic Acids Extraction System ANDiS 350 operates at:

- AC100-120V, 60 Hz or AC200-240V, 50/60 Hz
- 450W

Ensure that the voltage rating of the system is compatible with the AC voltage available at the installation site.

6.4.2 Ground requirements

To protect the operator, Automated Nucleic Acids Extraction System ANDiS 350 must be correctly grounded (earthed). Automated Nucleic Acids Extraction System ANDiS 350 is supplied with a 3-conductor AC power cord. To preserve this protection feature,

do not operate the system from an AC power outlet that has no ground (earth) connection.

6.4.3 Installation of AC power cord

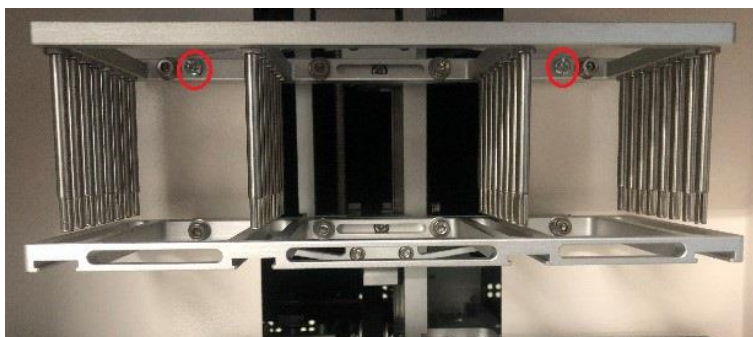
Connect one end of AC power cord to the socket at Automated Nucleic Acids Extraction System ANDiS 350, and the other end to the AC power outlet.

7 General Operation

7.1 Before turn on the Automated Nucleic Acids Extraction System ANDiS 350 for the first time after the installation, remove two Philip screws fixed on the holder of magnetic rods as following:

7.1.1 Prior to plug in the instrument to the power outlet after the installation, open the instrument door, loose the screws on the holder of magnetic rods as showed below.

Figure 2: Philip screws fixed on the holder



7.1.2 Remove the screws, and then close the instrument door.

7.1.3 Plug in the instrument and it is ready for use.

7.2 Switch on the Automated Nucleic Acids Extraction System ANDiS 350

7.2.1 Make sure the door of the system is closed.

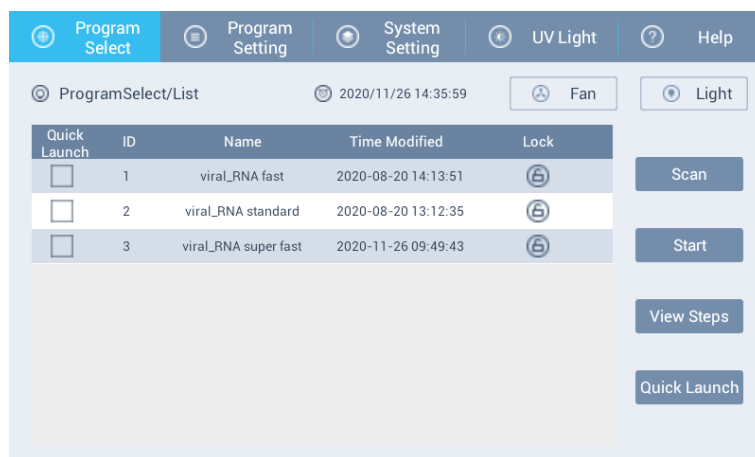
7.2.2 Press the power switch located at back-right side of the instrument

7.2.3 The startup touchscreen appears. The screen displays the progress of instrument startup.

7.2.4 After instrument initialization, the buzzer will be sounded for about 2 seconds.

7.2.5 The main menu should be displayed on the touchscreen.

Figure 3: Main menu display

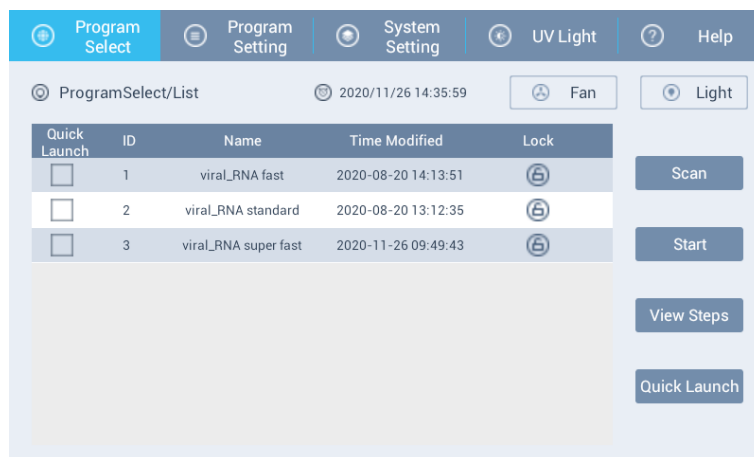


7.3 Run an existing purification program from main menu

7.3.1 Select the “Program Select” on the main menu.

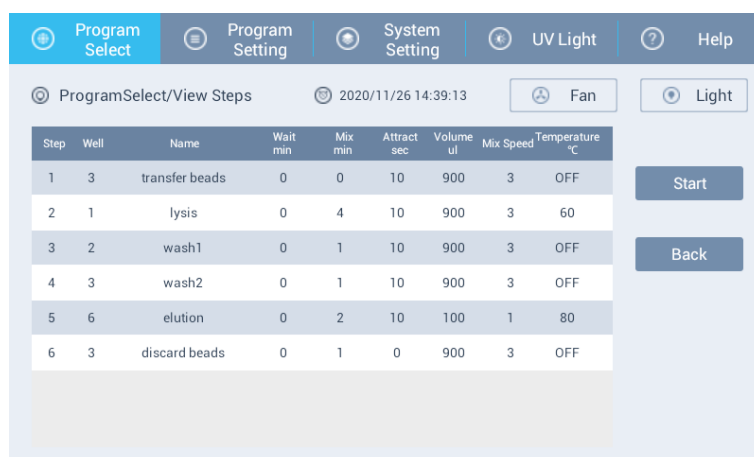
7.3.2 On the “Program Select” display window, highlight the correct program.

Figure 4: Program Select display



7.3.3 Click “View Steps” to ensure the correct run parameters used in the selected program.

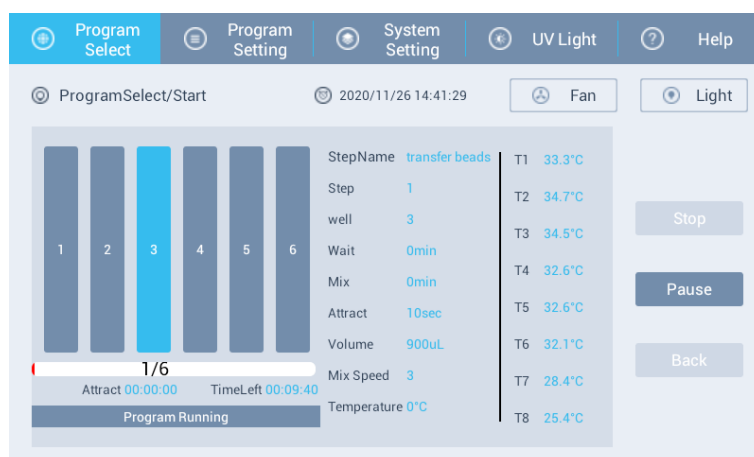
Figure 5: Run parameter display



7.3.4 Ensure the correct running parameter is selected, and then click on “Start” to run the program.

7.3.5 After started a program, the run status window should be display as in figure 6.

Figure 6: Running status display



Note: during the run, one of the six bars will flash which indicates step of extraction in progress.

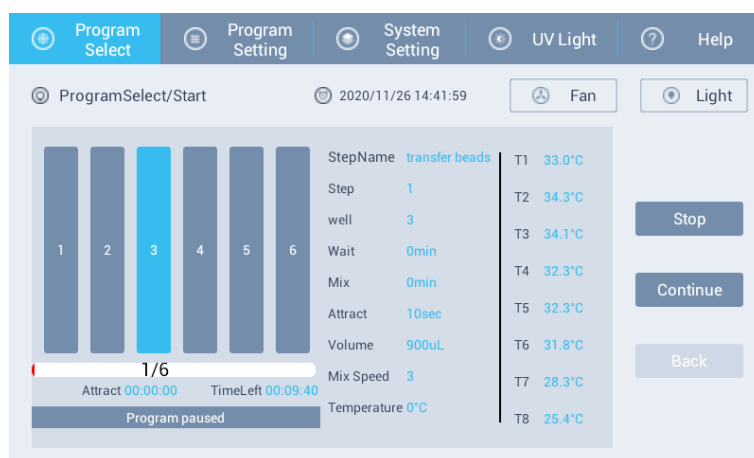
Note: Do not turn on the FAN when the instrument is running.

7.3.6 Pause and stop the running program

7.3.6.1 The program could be paused by click on "Pause" on the display as showed on figure 6 in step 7.2.4.

7.3.6.2 After paused the program, two options will be displayed on the touchscreen window as following:

Figure 7: Paused status display

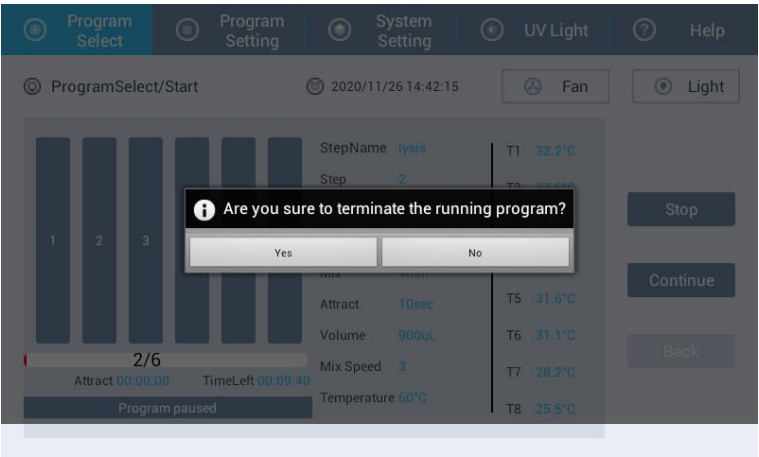


7.3.6.2.1 Click "Continue" to resume the program.

7.3.6.2.2 **Click "Stop" to abort the program.**

7.3.6.2.3 After click "Stop", the following message will be displayed, then click "Yes" to abort the run.

Figure 8: Pop-up box for aborting the program

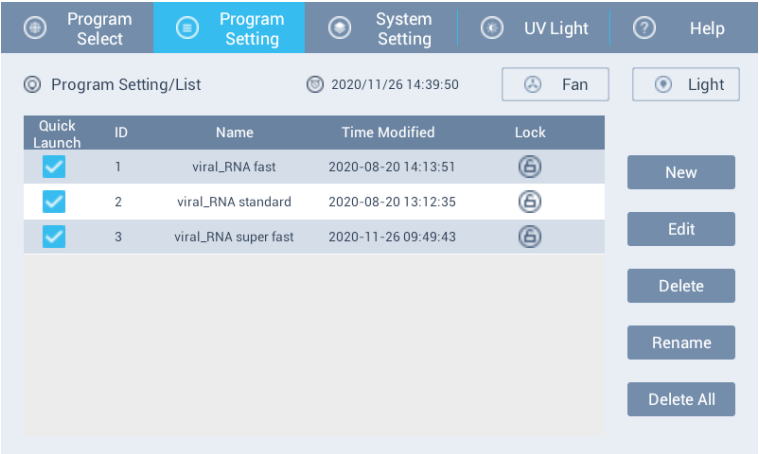


Note: To stop a program run, pause the running program must be initiate first, then abort (stop) the running program.

7.4 Operational program of instrument is following Reagent program, create new program by below steps

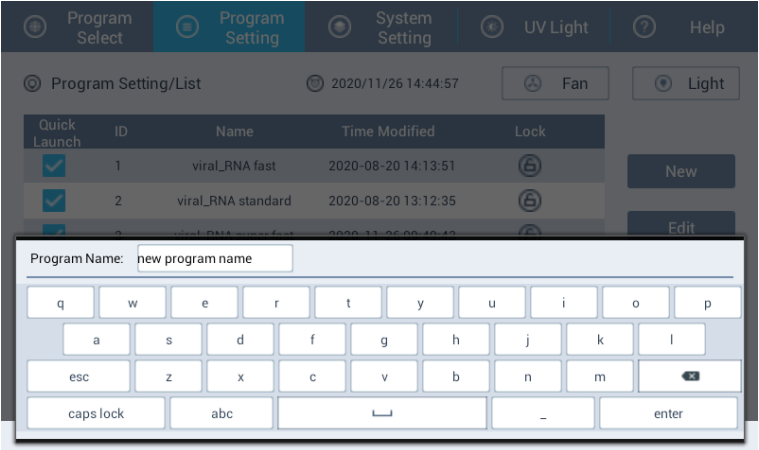
7.4.1 In the main menu, select "Program Setting", then click on "New".

Figure 9: New program display



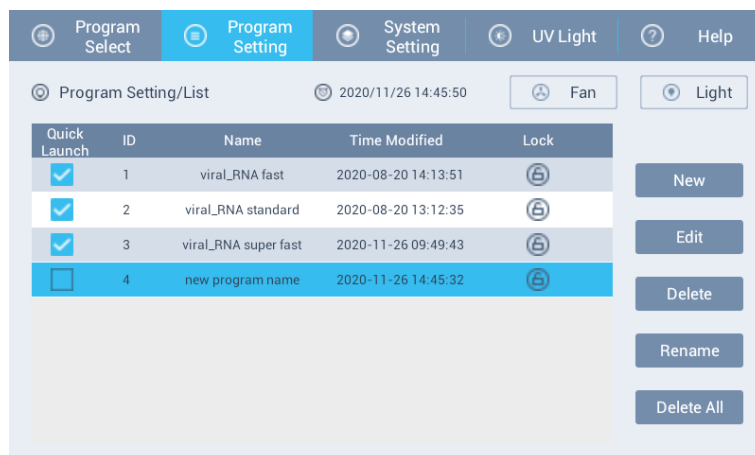
7.4.2 On the following display, create a program name by using the key board displayed on the touchscreen, the click on "Enter".

Figure 10: Naming a new program display



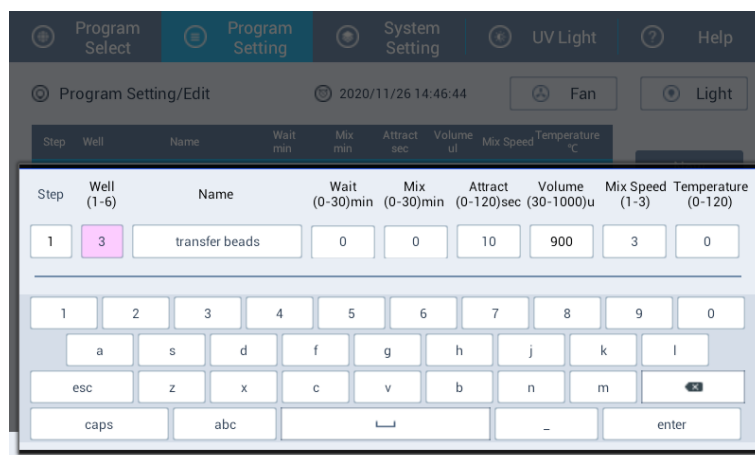
- 7.4.3 Highlight the new created program, and then click on “Edit” to create each run parameter.

Figure 11: Setting display



- 7.4.4 Enter the information for all the required fields in the following display, then click “Enter” to create each step.

Figure 12: Information display



7.4.5 The definition of each parameter for creating a new program

7.4.5.1 Step

Enter a numerical number in the “Step” field. Each number represents the current step in the program.

7.4.5.2 Well

The wells in column 1 to 6 of the 96-well sample prep plate will be selected. Each column represents a specific run parameter.

7.4.5.3 Name

The name of the function for each step.

7.4.5.4 Wait

The incubation time for each step.

7.4.5.5 Mix

The time in minutes needed to mix the reagents or samples by 8-strip rod comb.

7.4.5.6 Attract

The time in seconds needed to attract magnetic beads by 8-strip magnetic rod. It is recommended to set Attract time for 30 seconds to ensure maximum attraction of magnetic beads.

7.4.5.7 Mix Speed

Mix speed is to control how fast the reagents or sample could be mixed by 8-strip rod comb. There are three mix speeds in the default setting, and speed # 3 is the fastest.

7.4.5.8 Temperature

Set a temperature for each step in the program. Enter "0" to temperature setting indicates heating off. The temperature setting should not be higher than 115°C.

7.4.6 Click "Add" to add the additional step after entering all the required information for each step.

7.4.7 Repeat step 7.4.3 and 7.4.5 to create each step of running parameter.

7.4.8 After adding all the steps, click on "Enter" to complete the program setting.

7.5 Edit the program

7.5.1 Select "Program Setting" from main menu, highlight the program need to be edited, then click on "Edit", the run parameter will be displayed as following:

Figure 13: Setting display

Step	Well	Name	Wait min	Mix min	Attract sec	Volume ul	Mix Speed	Temperature °C
1	3	transfer beads	0	0	10	900	3	OFF
2	1	lysis	0	4	10	900	3	60
3	2	wash1	0	1	10	900	3	OFF
4	3	wash2	0	1	10	900	3	OFF
5	6	elution	0	2	10	100	1	80
6	3	discard beads	0	1	0	900	3	OFF

7.5.2 Highlight the step needs to be modified.

7.5.2.1 Click on "Edit" to modify the parameter in a given step.

7.5.2.2 Click on "Delete" to remove the step from the program.

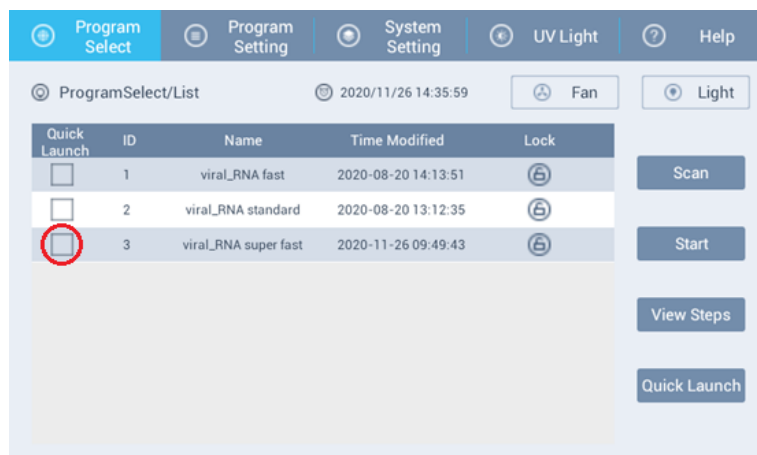
7.5.2.3 Click on "New" to add a new step in the program.

7.5.2.4 Click on "Back" to cancel the modification.

7.6 Quick Launch an existing program

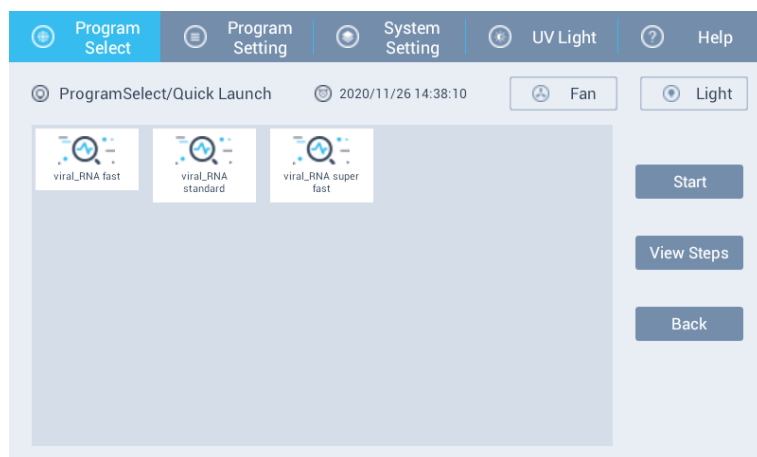
- 7.6.1 From the main menu, select "Program Select", under the "Quick Launch", check the ☐ next to the program to be selected, and then click on "Quick Launch".

Figure 14: Launching an existing display



- 7.6.2 The following window will be displayed.

Figure 15: Quick launch display



- 7.6.3 Highlight the program icon.

- 7.6.3.1 Click on "Start" to run the selected program.
- 7.6.3.2 Click on "View Steps" to confirm the run parameters.
- 7.6.3.3 Click on "Back" to cancel the Quick Launch.

7.7 Delete the program

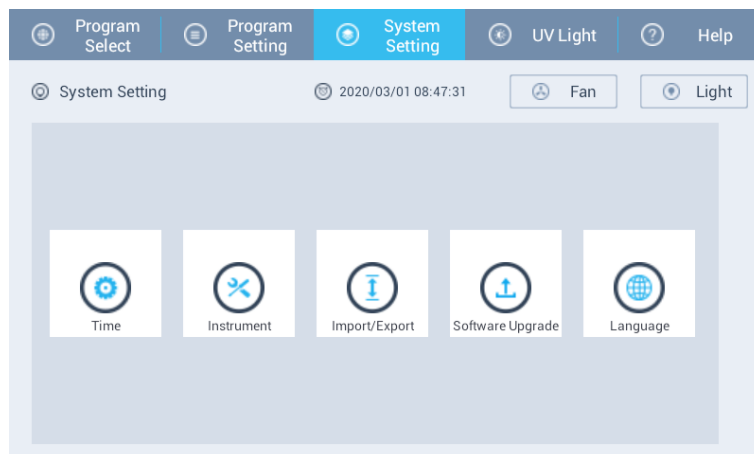
- 7.7.1 Select "Program Setting" from main menu.
- 7.7.2 Highlight the program on the display, and then click on "Delete" to remove the program permanently.

7.8 System Setting

- 7.8.1 Select the "System Setting" on the main menu, and then enter password "910" to

selection each icon displayed on the following window.

Figure 16: System setting display



7.8.1.1 Time setting

Click on the "Time" icon, enter the information in each box accordingly on the following window, then click on "Save" or click on "Back" to cancel the time setting.

7.8.1.2 Instrument

This feature is not available in this version of software.

7.8.1.3 Import/Export

This feature is not available this version of software.

7.8.1.4 Software Update

This feature is not available this version of software.

7.8.1.5 Language

English is the current language for this version of software.

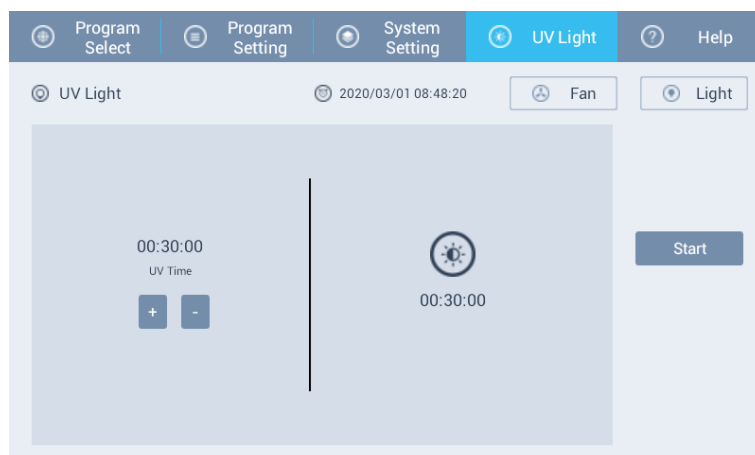
7.9 UV decontamination

UV decontamination should be performed daily. It helps to reduce the possible pathogen contamination of the Automated Nucleic Acids Extraction System ANDiS 350.

Note: Before starting the UV irradiation procedure, ensure that all samples, eluates, reagents, consumables have been removed from the worktable. Closed the instrument door. Once the UV irradiation procedure has been started, it will continue for a defined period of time.

7.9.1 Select "UV Light" from main menu. The following window will be displayed.

Figure 17: UV Light display



7.9.2 Click on "+" and "-" symbol to setting the time period of UV irradiation. The default setting for UV decontamination is 30 minutes.

8 Technical Specifications

8.1 General specifications

3D Biomedicine Science & Technology Co., Ltd. reserves the right to change any specifications without prior notice as part of our continue product development program. The general specifications are presented in the Table 1:

Table 1: General specifications of instrument

General specifications of Instrument	
Overall dimention	400mm x 400mm x450mm
weight	35Kg
Operating Condition	Indoor use only. +5°C to +35°C. Maximum relative himidity 80% for temperature up to 31°C
Main power supply	100-240 Vac, 50/60 Hz. Normal automatic voltage detection
operation system	Android system with 17-inch touch screen

8.2 Performance specifications

The performance specification of instrument is presented in Table 2:

Table 2: Performance specifications of instrument

Performance specifications of Instrument	
Processing volume	30µl-1000µl
Capacity	16/32 per run
Collection efficiency of the particles (In door use)	> 95%
Magnetic rod	8 rod in one fram
Plate type	96-well deep plate
Tip combs (polypropylene-disposable)	8 tip combs in one fram
Heating block temperature	Adjustable from room temperature to 115°C/240°F
Contamination prevention	Decontamination with build-in UV light

9 Troubleshooting

Serial no.	Observation	Actions
------------	-------------	---------

1	Black screen after powered on	Unplug the power cord and then Re-plug it
		Check the fuse under the power socket on the back of the instrument. Replace the fuse if necessary.
		If the observation persists, contact 3DMed or the distributor(s)
2	The machine makes an abnormal sound after power on	If the abnormal sound is observed during the first time run after initial installation, ensure the Phillips screws which used to holding the mixing sleeve had been removed. If not, remove the screws.
		Check 8-strip rod comb and make sure it has been monted properly.
		Reload the 96 well deep plate and make sure the A1 position of the 96-well plate is in the left upper corner of plate slot.
		If the observation persists, contact 3DMed or the distributor(s)
3	Motor initialization failure	Contact 3DMed or the supplier
4	Temperature module failure	Contact 3DMed or the supplier
5	UV light could not be turn on	Reinstall the light
		Replace the UV light burb
		If the observation is persists, contact 3DMed or the distributor(s)
6	Magnetic rods do not work properly.	Pause the program and ensure the Magenetic rob is installed properly, then continue the program. If the observation persists, contact 3DMed or the distributor(s)
7	Magnetic rods fall off.	Contact 3DMed or the distributor(s)
8	System operates improperly	Contact 3DMed or the distributor(s)

10 **Instruction for Replacing Fuse**

The fuse of the instrument is a 250v, 10A fuse. The fuse is installed under the power socket on the back of the instrument. When the fuse needs to be replaced, please follow the instructions below:

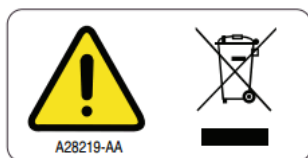
- 10.1** Switch off the power and unplug the power cord.
- 10.2** Remove the fuse's safety cover.
- 10.3** Take out the fuse, check whether the fuse is damaged. If it is damaged, replace with a new fuse.
- 10.4** Plug the power cord and turn on the power.

11 **Accessories**

IFU, power cords, a product certification, an installation acceptance report, a packing list.

12 **Disposal of Instrument**

The symbol of a crossed-out wheeled bin below on the product is required in accordance with the Waste Electrical and Electronic Equipment (WEEE) Directive of the European Union.



The cross-out wheeled bin symbol indicates that this product must not be disposed of with other waste; it must be taken to an approved treatment facility or to a designated collection point for recycling, according to local laws and regulations.

To recycle the instrument under the requirement of WEEE directive, please contact 3DMed or local distributor for proper decontamination information and take back program which will facilitate the proper collection, treatment, recovery, recycling, and safe disposal of devices.



3D Med

Manufacturer: 3D Biomedicine Science & Technology Co., Ltd.
Manufacture Address: 3D Biomedicine Science & Technology Co.,
Limited Block A, Building 2, No. 158 Xinjunhuan Rd.
Shanghai, 201114, China
Tel: (86) 400 021 1661
Email: ivd-support@3dmedcare.com