

ALLEX[®] Mini

Fully Automated Nucleic Acid Extraction System

Instruction For Use



Thank you for purchasing the
AIIEx[®] Mini Automated Nucleic Acid Extraction System.
This user manual provides essential guidelines and precautions
to ensure the effective and safe operation of the system.
Please read it carefully before operation.

Initial Inspection

Please perform a thorough inspection of the instrument and all accessories when you first open the packaging. If you find any damage or if any components are missing, please get in touch with GeneAll Biotechnology or your local distributor for immediate assistance.

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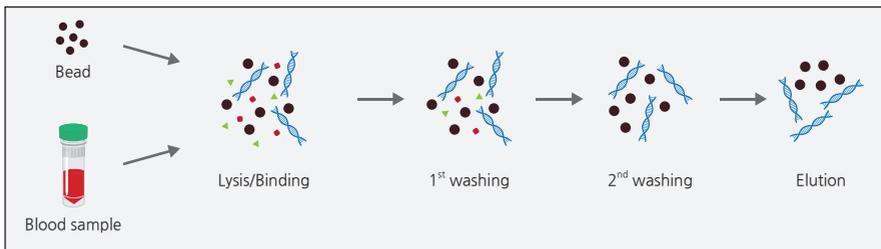
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Content

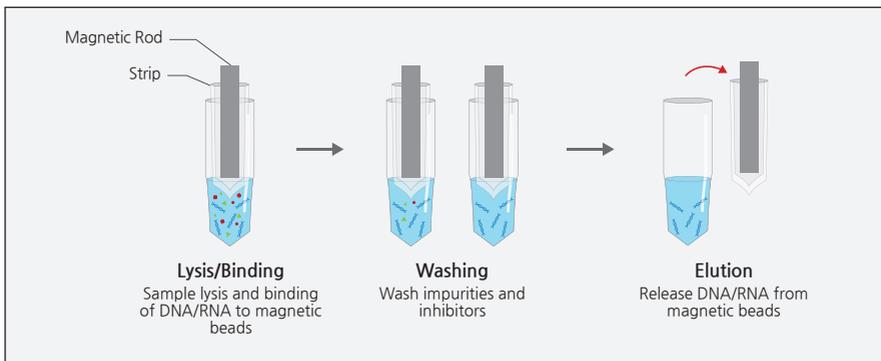
1. Introduction	4
1.1. Purpose of Use	4
1.2. Key Features	5
2. Safety Information	5
2.1. General Safety Precautions	5
2.2. Safety Precautions	5
2.3. Installation Precautions	5
2.4. Maintenance Precautions	6
3. Specifications and Components	7
3.1. Product Specifications	7
3.2. Components	7
3.3. Component Names	8
4. Installation	9
5. Program	10
5.1. Menu Structure	10
6. Nucleic Acid Extraction	12
6.1. Loading the Nucleic Acid Extraction Kit	12
6.2. Selecting a Protocol	13
6.3. Running the Protocol	15
6.4. Completion of Nucleic Acid Extraction Process	17
6.5. Use of Emergency Stop	17
7. Additional Functions	19
7.1. View Protocol List	19
7.2. Barcode Verification	19
7.3. Decontamination	19
7.4. Recovery	20
8. Settings Menu	21
9. Registration Information	21

1. Introduction

The AllEx® Mini is a compact, efficient nucleic acid extraction device designed for genetic analysis applications in hospital genetic testing, animal disease diagnostics, quarantine centers, and plant research institutes. Utilizing a dedicated nucleic acid extraction kit, it enables the extraction of high-purity nucleic acids from a wide range of samples, including human-derived specimens. The AllEx® Mini features an innovative Single Cartridge system, column-shaped strip handling, and automatic processes to ensure accuracy, speed, and cost-effectiveness.



[Figure 1-1] Principle of Silica Coated Magnetic Beads Extraction



[Figure 1-2] Process of Silica Coated Magnetic Beads Extraction

1.1. Purpose of Use

The AllEx® Mini is a fully automated nucleic acid extraction device that uses the dedicated AllEx nucleic acid extraction kit to extract up to 12 nucleic acids simultaneously in a short time, with no reagent waste. It efficiently processes various samples, including human-derived specimens.

1.2. Key Features

- **Single Cartridge System:** Optimizes cost by minimizing reagent waste.
- **Automatic Strip Mounting/Dismounting:** Prevents test failures and sample waste.
- **Automatic Barcode Scanning:** Enables quick and accurate test selection.
- **Recovery Function:** Ensures successful test completion even during unexpected power outages or equipment issues

2. Safety Information

2.1. General Safety Precautions

Proper use of the device not only ensures high-quality nucleic acid extraction results but also promotes user safety. Please thoroughly understand and follow these instructions when using the device.

2.2. Safety Precautions

- 2.2.1. Before connecting the power supply, ensure the incoming power meets the specified voltage requirements (100 - 240 VAC).
- 2.2.2. Use a grounded power source and power cable when operating this device.
- 2.2.3. Do not use this device for purposes other than nucleic acid extraction.
- 2.2.4. Do not connect or operate the power switch with wet hands to avoid the risk of electric shock.
- 2.2.5. This device handles human-derived samples, which may pose a biological hazard if in contact with the chamber interior. It is recommended to wear hygienic gloves while using the device and to perform UV light sterilization after use.



2.3. Installation Precautions

- 2.3.1. Install the device on a solid, level surface.
- 2.3.2. Designed for indoor use, this device should be installed away from direct sunlight.
- 2.3.3. Ensure there is a minimum 5 cm clearance from the wall to allow for adequate ventilation. Insufficient ventilation may lead to overheating, malfunction, or even fire.
- 2.3.4. Use a grounded power source.
- 2.3.5. Install at an altitude of no more than 2,000 meters.
- 2.3.6 Do not install the device near sinks or areas with high moisture, as this may lead to malfunction.

- 2.3.7. Avoid installing in dusty environments, as dust is a common cause of device failure.
- 2.3.8. Keep the device away from heat-generating appliances.
- 2.3.9. Install away from devices sensitive to magnetic fields.
- 2.3.10. This device is designed according to Pollution Degree 2 (PD2).

2.4. Maintenance Precautions

- 2.4.1. Follow the maintenance procedures outlined in Section 8 (Maintenance).
- 2.4.2. Do not disassemble the device. Unauthorized disassembly may cause malfunction and could result in serious injury.
- 2.4.3. Warranty service may be denied if a malfunction results from unauthorized disassembly.

3. Specifications and Components

3.1. Product Specifications

Item	Description
Model Name	AlIEx [®] Mini
Sample Processing Capacity	12 samples per run
Dimensions (mm)	270(W) x 330(D) x 330(H)
Weight	14 kg
Power Requirements	90~240 VAC, 50/60 Hz, 3A
Operating Temperature	15~30°C
Operating Humidity	20~80% R.H non-condensing
Interface	5" TFT LCD Touch Screen
Decontamination	UV LED
Barcode	Internal Barcode Reader

[Table 3-1] Specification

3.2. Components



AlIEx[®] Mini system



1 User Manual



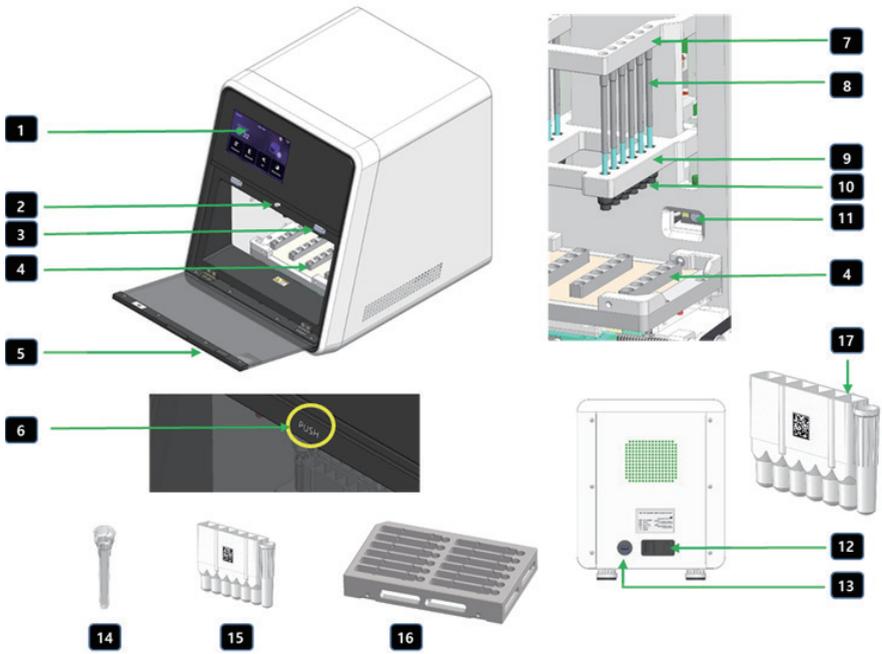
1 220 V Power Cable for AlIEx[®] Mini system



Cartridge + Adaptor

[Figure 3-1] Components

3.3. Component Names



1 Display	7 Magnet Rod Arm	13 USB Port (used for update only)
2 Door Sensor	8 Magnet Rod	14 Strip
3 Door Catcher	9 Strip Arm	15 Cartridge
4 Heat Block	10 Strip Finger	16 Cassette
5 Door	11 Barcode Reader	17 Strip Pocket
6 Door Open Switch	12 Power Switch	

[Figure 3-2] Component Names

4. Installation



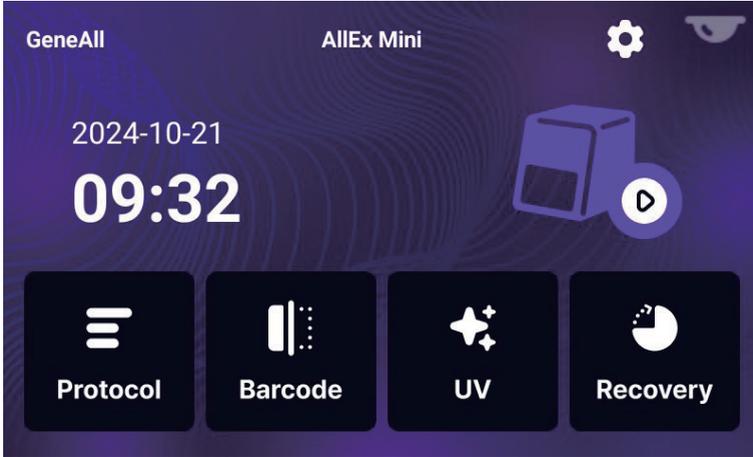
[Figure 4-1] Packing Case

- 4.1. Clear the installation area for the AllEx® Mini.
- 4.2. Ensure that an appropriate power outlet is nearby.
- 4.3. Rotate the four locking clasps on the case to unlock it.
- 4.4. Lift the top cover of the case to open it.
- 4.5. Remove all components from the case.
- 4.6. Carefully lift the device and place it on a table.
- 4.7. Remove the plastic wrapping.
- 4.8. Check all components for any signs of damage.
- 4.9. Place the AllEx® Mini on a sturdy, level table.
- 4.10. Connect the power cable to the device.
- 4.11. Press the power switch to turn on the device.
- 4.12. Wait until the system initialization process is complete.
- 4.13. Confirm that the main menu appears on the screen.
- 4.14. Press the Door Open Switch to open the door.
- 4.15. Remove the cassette containing an empty cartridge from the heat block.
- 4.16. Close the door by pressing it until you hear a click.
- 4.17. Remove the protective film from the LCD display.
- 4.18. Remove the protective film from the door.
- 4.19. Installation is complete.

5. Program

5.1. Menu Structure

5.1.1. Main Menu



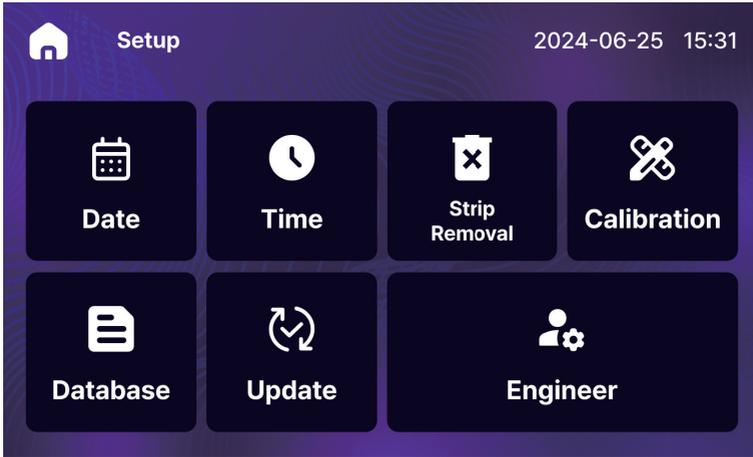
[Figure 5-1] Main Menu Screen

 <p>Run Protocol: Executes protocol for nucleic acid extraction</p>	 <p>View Protocol List: Displays a list of available protocols</p>
 <p>Check Barcode: Scans and verifies the barcode for accurate test</p>	 <p>Decontamination: Activates the UV LED for decontaminating the chamber, reducing biological hazards</p>
 <p>Recovery: Resumes a protocol that was interrupted unexpectedly, allowing the process to continue from the last completed step</p>	 <p>Control Chamber Light: Turns the interior lighting on or off to aid visibility within the chamber</p>
 <p>Go to Settings: Opens the settings menu for adjusting device configurations</p>	 <p>Return to Previous Screen: Navigates back to the previous menu or screen for ease of access</p>

[Figure 5-2] Main Menu Structure

5.1.2. Settings Menu

The Settings Menu provides access to various device configurations and maintenance tools.



[Figure 5-3] Setup Screen

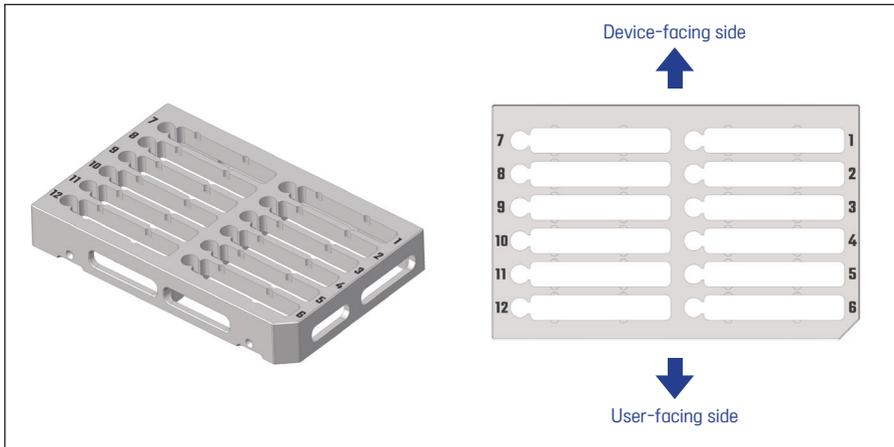
 Date	Edit Date: Adjust the system date	 Time	Edit Time: Adjust the system time
 Strip Removal	Attempt Strip Removal: Used if the strip does not automatically eject	 Calibration	Automatic Calibration of Strip Arm and Magnet Rod Arm Position: Calibrates the position of the strip arm and magnet rod arm for optimal performance
 Database	Check Consumable Usage Time: Displays the usage time of consumable parts	 Update	Software Update: Allows for software upgrades and changes to various configuration settings
 Engineer	Engineer Mode: A restricted menu for authorized technicians to manage device settings. Unauthorized access is prohibited for safety reasons		 Return to Main Menu: Returns to the main menu

[Figure 5-4] Configuration of the Settings Menu

6. Nucleic Acid Extraction

6.1. Loading the Nucleic Acid Extraction Kit

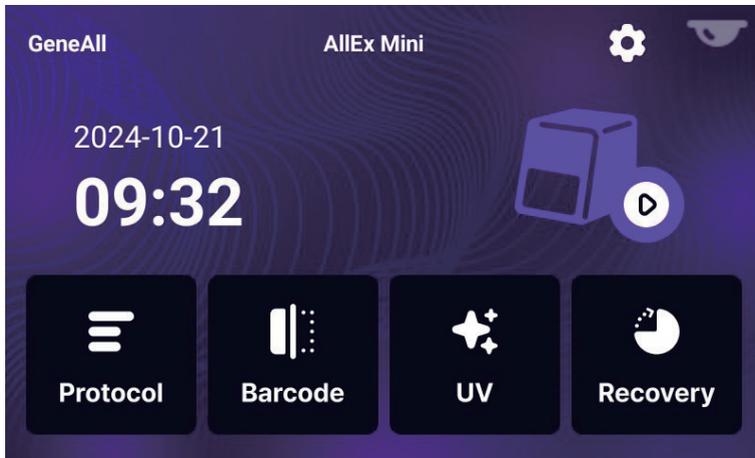
- 6.1.1. Review and follow the instructions provided in the nucleic acid extraction kit's manual.
- 6.1.2. If a cassette is already inside the device, open the door and remove the cassette from the cassette loader.
- 6.1.3. Place the cassette on the laboratory workbench.
- 6.1.4. On the workbench, open the extraction kit packaging and remove the cartridge.
- 6.1.5. Prepare the cartridge according to the instructions provided in the kit manual.
- 6.1.6. Confirm the cartridge positions in the cassette, ensuring that Position 1 faces the interior of the device and Position 6, with a beveled corner, faces the user.



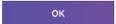
[Figure 6-1] Cassette

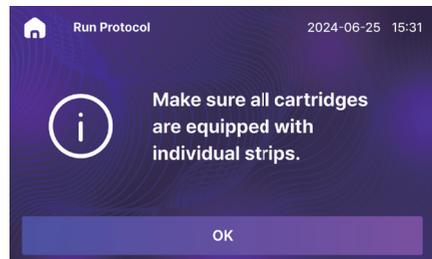
- 6.1.7. To ensure accurate barcode scanning, insert the cartridges starting from Position 1.
- 6.1.8. Check each cartridge's strip pocket to ensure a strip is present; insert a strip if it is missing.
- 6.1.9. Once all necessary cartridges are loaded into the cassette, open the device door and place the cassette onto the heat block in the cassette loader.
- 6.1.10. It is recommended to use both hands to securely place the cassette onto the cassette loader.
- 6.1.11. Close the door by lifting it and pressing firmly until it is securely shut.

6.2. Selecting a Protocol



[Figure 6-2] Main Menu

- 6.2.1. Tap  to start the extraction process.
- 6.2.2. A prompt appears to confirm that strips are loaded in all cartridges.
- 6.2.3. Once strip loading is confirmed, tap .



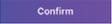
[Figure 6-3] Strip Confirmation Prompt

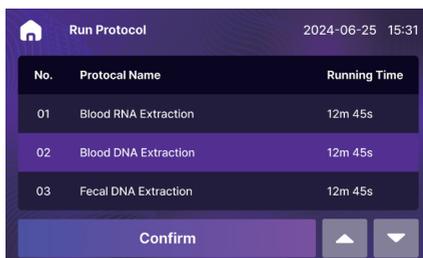
- 6.2.4. When barcode scanning begins, a prompt appears to indicate the process.



[Figure 6-4] Barcode Scanning Prompt

6.2.5. If a protocol is identified via barcode, the scanned protocol will be displayed. If multiple protocols are available, a list of executable protocols appears

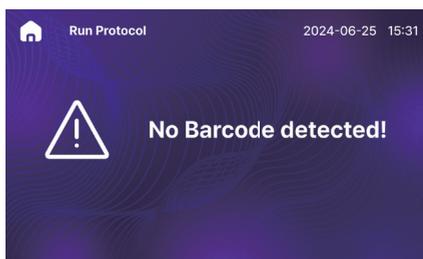
6.2.6. Tap   to focus the protocol you want to use then tap  to go to the protocol confirmation screen.



[Figure 6-5] Executable Protocol List

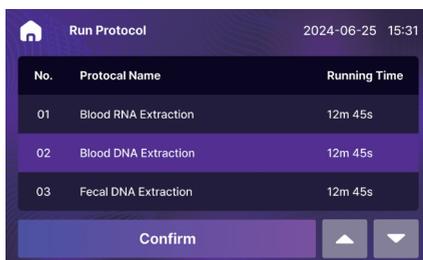
6.2.7. If the barcode is missing or unreadable, a message will appear indicating that barcode information is not available.

6.2.8. After a 3-second "No Barcode detected" message, all available protocols will be displayed for user selection.



[Figure 6-6] No Barcode Information Notification

6.2.9. Tap   to focus the protocol you want to use then tap  to go to the protocol confirmation screen.



[Figure 6-7] User Protocol Selection Screen

6.2.10. If only one protocol is identified via barcode scanning, the protocol confirmation screen appears automatically.

6.2.11. Tap  to exit to the main menu, or tap  to initiate the protocol and begin nucleic acid extraction.



[Figure 6-8] Protocol Confirmation Screen

6.3. Running the Protocol

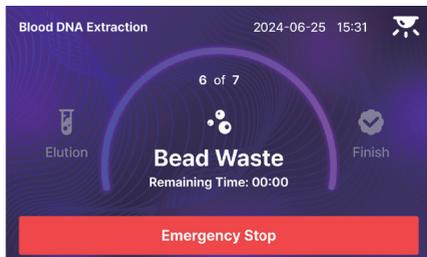
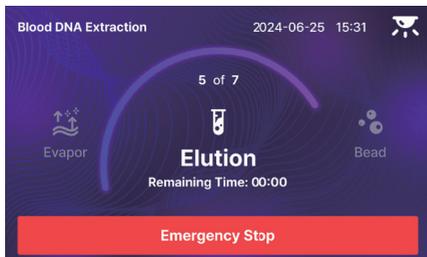
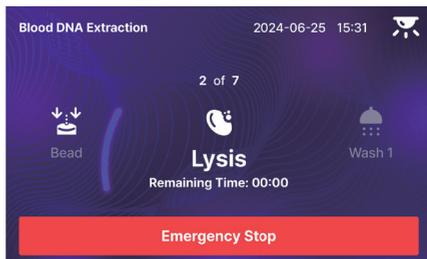
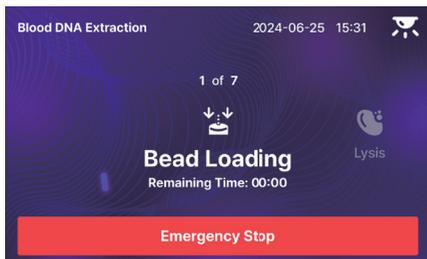
6.3.1. Initialization Process

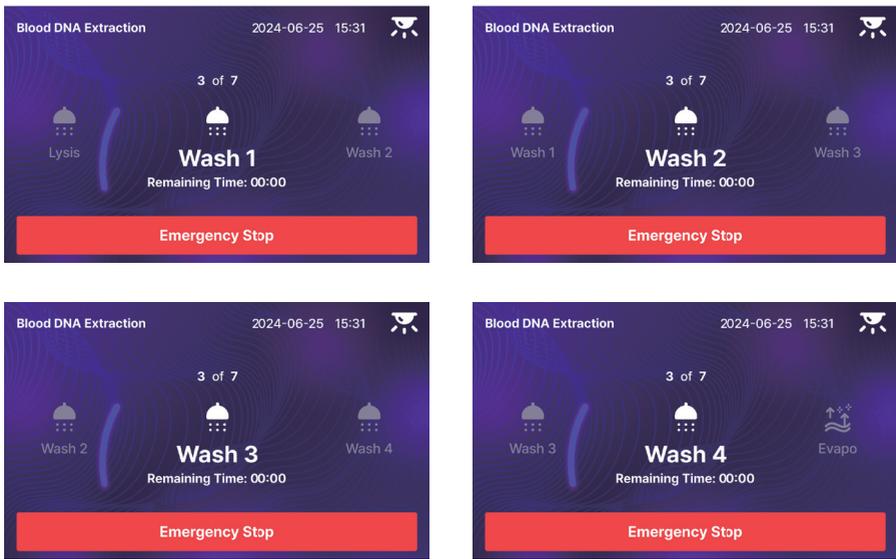
Before executing the protocol, the device initializes the strip arm, magnet rod arm, and cassette loader to ensure they are correctly aligned and positioned at their starting locations. Once the initialization is complete, the protocol steps will proceed as outlined on the display screen.



[Figure 6-9]

6.3.2. Protocol Step Progress Screen

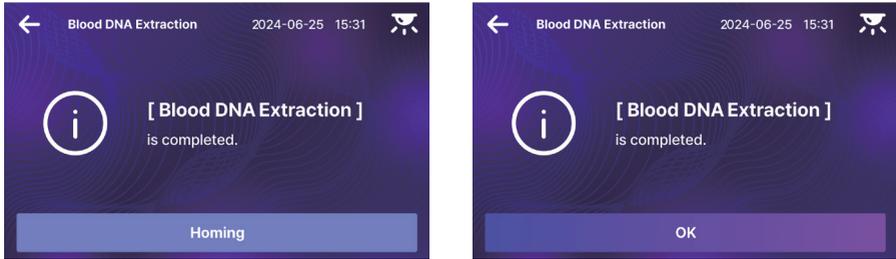




[Figure 6-10]

The progress screen displays the current protocol step in real-time, showing the status of the nucleic acid extraction process.

6.3.3. Protocol Step Completion Screen



[Figure 6-11]

Tap **OK** to go back to the main menu. Each screen guides the user through the protocol steps to ensure the process is running smoothly and that results are achieved as expected.

6.4. Completion of Nucleic Acid Extraction Process

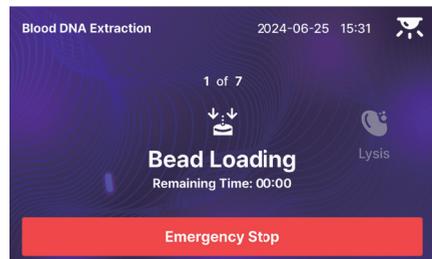
- 6.4.1. Open the door and check if all strips have been removed and placed in the strip pocket of the cartridge. If any strip remains on the strip finger, navigate to the settings screen and initiate the Strip Removal function.
- 6.4.2. Remove the cassette from the cassette loader, transfer it to the lab workbench, and collect the extracted nucleic acid. Dispose of the cartridge according to internal waste disposal regulations.
- 6.4.3. Close the door and perform a UV sterilization process for decontamination.
- 6.4.4. Power off the equipment.

6.5. Use of Emergency Stop



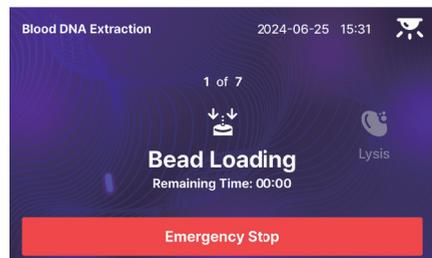
If it becomes necessary to stop the equipment operation after the extraction process has started, you can immediately tap  to halt the operation. Once the situation is resolved, the operation can resume from where it left off, minimizing reagent and sample loss.

- 6.5.1. In the event of an emergency stop situation during the extraction process, tap  .



[Figure 6-12] Protocol Step in Progress

- 6.5.2. The equipment will stop immediately, and a red emergency stop screen will flash.



[Figure 6-13] Emergency Stop Alert

- 6.5.3. If necessary, open the door and perform emergency measures with the equipment in its halted state. Take care to avoid damaging the equipment or reagents, and ensure that the sample is not contaminated.
- 6.5.4. If the situation is resolved by these emergency measures, close the door and tap  to resume the extraction process. However, if the issue cannot be resolved and the cartridge must be removed, tap  to terminate the extraction process.



Even if the extraction process is interrupted in this way, you can use the Recovery function to resume the extraction process. However, the decision regarding the validity of the nucleic acid extraction results obtained by continuing the process is at the discretion of the user.

- 6.5.5. If you need to stop the device operation during the extraction process, you can tap  the device will move to the home position without removing the strip.
- 6.5.6. Use the Strip Removal option in the settings menu to remove the strip.
- 6.5.7. Once the strip is in the strip pocket, remove the cassette from the cassette loader.
- 6.5.8. If the emergency situation has been resolved and it is determined that nucleic acid extraction can safely continue, use the Recovery menu to complete the extraction process.

7. Additional Functions

7.1. View Protocol List



Review the list of protocols stored on the device.

7.2. Barcode Verification

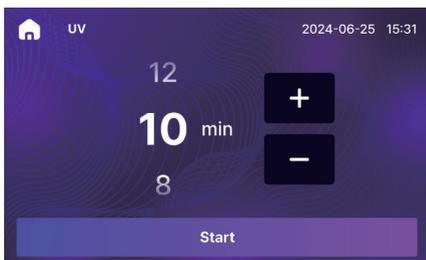


Verify the information on the barcode printed on the cartridge.

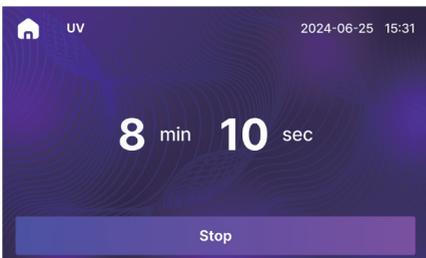
7.3. Decontamination



After nucleic acid extraction is complete, turn on the UV LED to remove contamination.



Tap **+** **-** to set the decontamination duration, then tap **Start** to activate the UV LED.

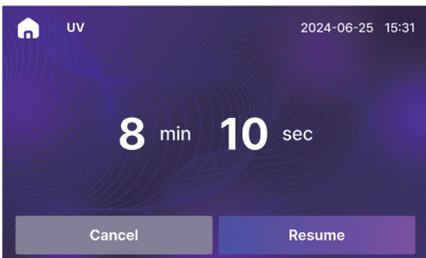


You can stop decontamination at any time by tapping **Stop**.

Tap **Home** to cancel decontamination and return to the main menu.

To resume a paused decontamination process, tap **Resume**.

Tapping **Cancel** again will cancel decontamination and return to the main menu.



7.4. Recovery



Resume an abnormally terminated protocol from the interruption point to complete the nucleic acid extraction. However, the validity of the nucleic acid extracted in this manner is subject to the user's discretion.



If the process was interrupted by an Emergency Stop, resolve the emergency situation and reattach the cartridge.

If the interruption occurred for another reason, check the cartridge's condition and reattach it if there are no issues.

Tap **Up** **Down** to select the protocol to recover, and tap **Confirm** to start the Recovery process.

8. Settings Menu

8.1. Date and Time

8.2. Strip Removal

8.3. Calibration

8.4. Database

8.5. Update

9. Registration Information

Product Name	AllEx® Mini
Item	Automated Nucleic Acid Extraction Device
Registration No.	-
Date of Establishment	2024-11-01
Revision Date	-
Manufacturer	GeneAll Biotechnology CO., LTD. D-1110, Hanam Techno Valley U1 Center, 947, Hanam-daero, Hanam-si, Gyeonggi-do, 12982, Republic of Korea

[Figure 9-1] Registration Information

Memo

Memo



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