



CLEO™ AP16

Automated Nucleic Acid Extractor

Instruction for use

REF CL2016

For *in vitro* diagnostic use.

For professional use only.



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General Information

The CLEO™ AP16 Automated Nucleic Acid Extractor is a compact benchtop DNA and RNA purification system that uses magnetic separation technology to extract nucleic acids from a variety of samples. Magnetic beads are modified by coating them with silica to provide binding capacity for nucleic acids. Nucleic acids are purified and eluted using several washing and elution steps. CLEO™ AP16 automated extraction system helps to obtain high-quality ultrapure DNA and RNA that can be used directly for further downstream processing.

Important Information

Before using the CLEO™ AP16 system, it is important to read this user manual to familiarize yourself with the instrument. Follow all instructions to ensure proper operation of the CLEO™ AP16 device. Do not use any consumables, accessories, or external equipment other than that specified. Safety warnings must be adhered to at all times to avoid risk in personal injury and/or damage to the instrument. If the equipment is used in a manner not specified by the manufacturer, the protection provided by the equipment may be impaired. The advice given in this manual is intended as a supplement, not for superseding the normal safety requirements in the user's country.

Intended Use

The CLEO™ AP16 system is designed to automatically extract DNA or RNA from samples using magnetic particles.

The CLEO™ AP16 is for *in vitro* diagnostic or research use only.

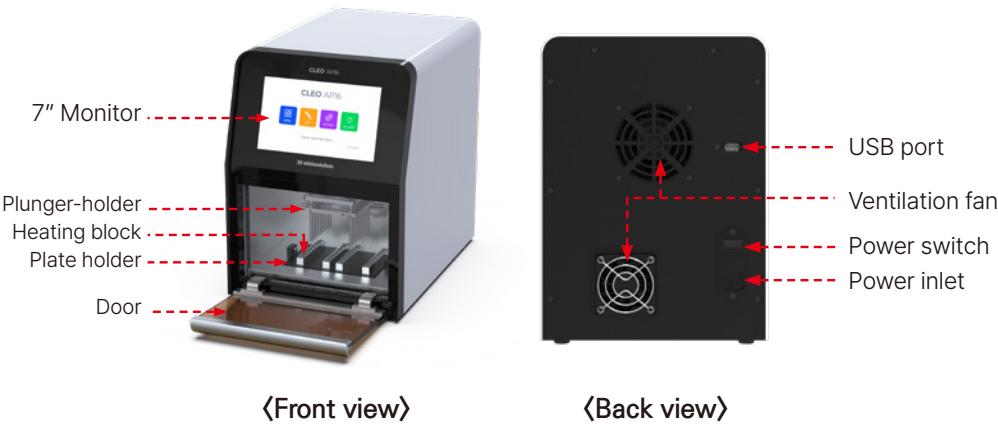
The CLEO™ AP16 can extract up to 16 samples simultaneously.

CLEO™ AP16 Components

Each CLEO™ AP16 is composed of the following components:

- CLEO™ AP16 device 1
- Power cable 1
- User Manual 1

CLEO™ AP16 Overview



CLEO™ AP16 Specifications

Model No.	CL2016
Number of samples	16 Samples
Extraction method	Magnetic bead-based extraction
Sample volume	200 uL - 300 uL
Operating System	Android OS
Input power	100 - 240 VAC (50/60 Hz)
Max. power	500 W
Operating environment	Indoor Use Only
Operating temperature range	10 °C - 35 °C (50 °F - 95 °F)
Storage temperature range	0 °C - 50 °C (32 °F - 122 °F)
Operating humidity range	20% - 80%
Storage humidity range	20% - 80%
Dimensions (L×W×H)	326 X 229 X 310 mm
Net weight	8.6 kgs

Unpacking and Installation

The following items are packaged within the CLEO™ AP16 shipping container:

- CLEO™ AP16 device
- Power cable
- CLEO™ AP16 manual

1. Hardware installation

- 1) Place the CLEO™ AP16 device on a flat surface.
- 2) Open the door and remove any packaging materials inside.
- 3) Plug the power cord into a wall outlet and turn on the power from the socket.
- 4) Turn the power on by operating the power switch on the back of the device.
- 5) When the device is properly powered, the display screen on the front of the device turns on and the device's programs run.
- 6) To power off the device, use the power switch on the back of the device.

2. Updating software

- In the case of a device software update, check the updated version of the device on our website (www.wizbiosolutions.com), then check whether it is updated by comparing it with the device's software version in the <SETTING> ► <Device Info> of the program.
- If a software update is needed, download the software from the website, save it to USB memory, and then insert the USB memory into the USB port on the back of the device.
- Update the software by selecting the <Update> in the <SETTING> menu.
- **CAUTION:** Do not turn off the device while the update is in progress.
- Once the software update is complete, your device will automatically run the updated version.
- If you are unsure about software updates, please contact the place where you purchased the device or our technical support team. (support@wizbiosolution.com)

Menu Guide

1. Operation Menu

- MENU: Select items to extract (WizMag™ products only)
- EDIT: Editing extraction protocols
- SETTING: Modify the setting
- UV LIGHT: UV light for sterilization

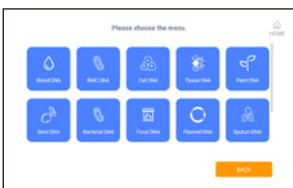


<Main Menu>

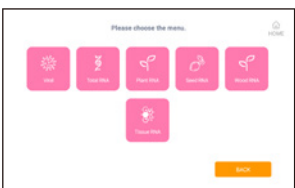
2. Extraction Menu (WizMag™ Kit only)



<Select DNA or RNA>



<DNA items>



<RNA items>

3. Edit Menu

- Use the EDIT menu when using a modified protocol.
- You can proceed with extraction by changing the value of each applicable Step.

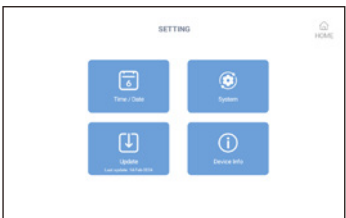
Step	1	2	3	4	5	6	7	8
Step	Load	Bind	Bind	Wash	Wash	Wash	Elute	Discard
Well #	1	6	1	1	2	3	4	1
Wash Time	00:00	00:00	00:00	00:00	00:00	00:00	00:00	00:00
Dry Time	00:00	00:00	00:00	00:00	00:00	00:00	00:00	00:00
Elute Time	00:00	00:00	00:00	00:00	00:00	00:00	00:00	00:00
Centrifuge Time	00:00	00:00	00:00	00:00	00:00	00:00	00:00	00:00
Volume (µL)	500	300	500	700	700	700	700	700
Wash Speed	Fast	Medium	Fast	Fast	Fast	Fast	Fast	Fast
Centrifuge Speed	Strong	Strong	Normal	Normal	Normal	Normal	Normal	Normal
Temperature	OFF							OFF

At the bottom of the table are buttons for 'RESET', 'ADD', 'DELETE', 'LOAD', 'SAVE', 'RUN', and 'HOME'.

<EDIT>

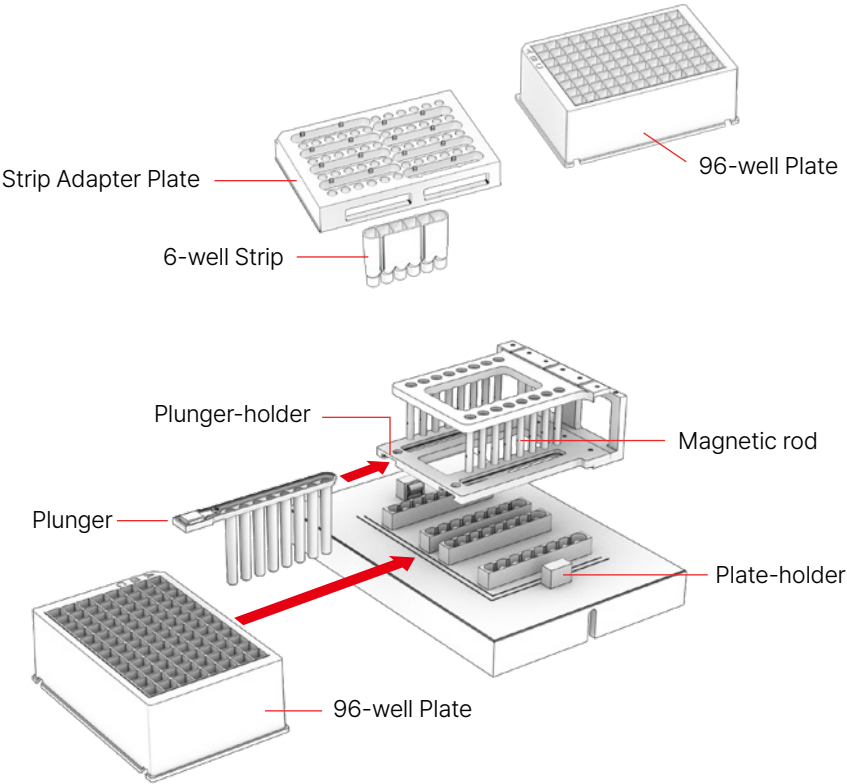
4. Setting Menu

- Time/Date: Select timezone and Date
- System: Check system information.
- Update: Software version check and Software update.
- Device Info: Check the device information.



<SETTING>

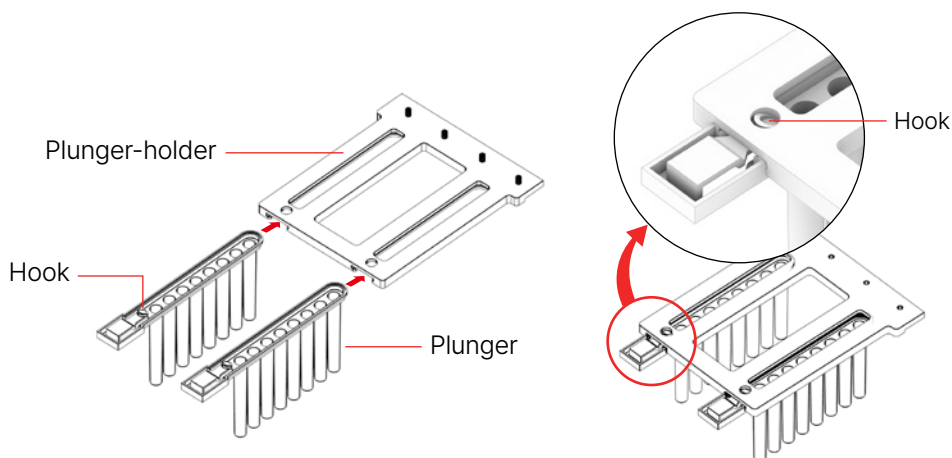
Name of each part



Item	Description
Plunger	Mixing of magnetic beads and samples, protection of magnetic rod, disposable
96-wll Plate	Nucleic acid extraction of 16 samples per 96-well plate, disposable
6-well Strip	Nucleic acid extraction of 1 sample per 6-well strip, disposable
Strip Adapter	Use by combining 6-well strips. Up to 8 strips can be combined.
Plunger-holder	Plunger mounting holder
Plate-holder	96-well Plate or Strip Adapter Plate mounting holder

NOTE: The Plunger and the 96-well Plate should be placed on the same side when processing extraction (See illustrations above). Inadequate installation of the 96-well Plate & Plunger may damage the machine.

How to mount the Plunger



After combining Plunger and Plunger-holder

NOTE: Using non-recommended consumables may affect the device performance.

Operation Procedure of CLEO™ AP16

1. How to START the CLEO™ AP16

- 1) Power on by pressing the power switch on the back of the device. When the self-check completes successfully, the menu screen appears.
CAUTION: Do not insert the Plunger and Plate before powering on the instrument. it may damage your device.
- 2) Insert the sample you want to extract into the sample well of the 96-well Plate or 6-well Strip.
(Refer to the manual for each WizMag™ Nucleic Acid Extraction Kit).
- 3) Open the door and load the 96-well Plate and Plunger according to the instructions.
- 4) When using a 6-well Strip, load the Strip Adapter Plate first, then insert the 6-well Strip into the Adapter. (Refer to page 8.)
CAUTION: Make sure the Plate and Plunger are in the correct position.
- 5) Close the door.
- 6) Select the <MENU> button and choose the <ITEM>.
- 7) Press <RUN> to begin the extraction.

- 8) When extraction is complete, a sound and completion notification will appear. Select <OK> in the pop-up window.
- 9) Take out the plunger.
- 10) Take out the 96-well Plate. For a 6-well Strip, take out the Strip first, then take out the Strip Adapter Plate.
- 11) Extracted nucleic acids can be used immediately.

NOTE: The <RUN> does not work in the situations below.

- When the UV lamp is turned on
- When the door is open

2. How to PAUSE the CLEO™ AP16

- 1) During the extraction, press the <PAUSE> button to stop the CLEO™ AP16 if necessary. In the pause status, a pop-up guide appears on the display.
- 2) The magnetic rods and plunger will move up to the top together.
- 3) Close the door of CLEO™ AP16, and press <START> to resume the extraction.

NOTE: The <PAUSE> does not work in the situations below.

- During the drying and transferring process of the magnetic bead.
- The UV Lamp is on.

3. How to Use the UV Lamp

- 1) After the extraction is finished, press the <UV LIGHT> on the menu, and the sterilization will start automatically.
- 2) The sterilization will continue for 30 minutes. To stop the UV light, press the <UV TUNE OFF> on the display.

NOTE: The <UV LIGHT> does not work in the situations below.

- The door is open.
- During the extraction process.

4. How to Shutdown the CLEO™ AP16

- 1) Before turn off the CLEO™ AP16, please make sure the Plates and Plungers are removed from the device.
- 2) Turn off the main switch at the back of the device.

Device Safety Precautions



- Read this manual carefully before using the device and follow all recommended safety precautions to avoid personal injury or damage to the device.
- Check the rated voltage before use. If the rated voltage is not followed, the device may be damaged.
- Do not insert anything other than consumables permitted for this machine into the machine. It may cause device failure or incorrect results.
- To prevent contamination of the device from biohazardous substances, strictly adhere to UV sterilization during and after operation of the device.
- Keep the device dry, dust-free, and well-ventilated on all sides. Do not place near heat sources.
- Unplug the device before cleaning.
- Do not force the device to open or attempt repairs. The device may be damaged. If you have any questions, please contact customer support.
- When the device is not in use, turn it off by unplugging it from the wall outlet.
- When not in use for a long time, cover the device with a cloth to protect it from dust.
- Any significant incidents related to the device should be notified to the competent authorities and manufacturers.
- If a cybersecurity threat is detected when connecting to a USB memory to your device, stop using the product and contact Wizbiosolutions Inc. or your customer service representative
- Do not look directly into the UV light. Danger to the eyes.
- Do not insert plungers and well plates before powering on the instrument. Damage will occur to the device.
- Do not use this device in proximity to sources of strong electromagnetic radiation (e.g. unshielded intentional RF sources), as these can interfere with proper operation.
- This equipment is designed for use in a PROFESSIONAL HEALTHCARE FACILITY ENVIRONMENT. It is likely to perform incorrectly if used in a HOME HEALTHCARE ENVIRONMENT. If it is suspected that performance is affected by electromagnetic interference, correct operation may be restored by increasing the distance between the equipment and the source of the interference.
- CLEO™ AP16 emits UV rays.
- RF communication equipment should be used no closer than 30cm to any part of CL2016.

Cleaning & Maintenance

- Power off the device before cleaning. Do not use or fill wells with caustic cleaning solutions.
- If a foreign object enters the test tube slot, gently wipe it off with an alcohol-moistened cotton swab. Then, open the device cover and let it dry completely before use.
- Never turn over if foreign objects get inside. It may cause equipment failure. Please contact our technical support team.

Warranty

The free warranty period for this product is 1 year from the date of purchase. If a defect occurs in the device during the free warranty period, Wizbiosolution Inc. will repair or replace the product free of charge. However, defects arising from the following matters are excluded from the scope of the free warranty.

- Improper use or misuse
- Unauthorized repairs/replacements or modifications.
- Damage caused by disaster
- Corrosion caused by inappropriate solvents or samples.

Electronic Compatibility

1. Electromagnetic Emission

This equipment is manufactured to operate in the electromagnetic environment described below.

The customer or user should verify if this equipment is operated in such environment.

Radiated disturbance according to CISPR 11	Group 1 Class A	This equipment is not intended for use in residential environments and may not provide adequate protection to radio reception in such environments.
Mains terminal disturbance voltage according to CISPR 11	Group 1 Class A	
Harmonic current emission IEC 61000-3-2	Class A	The CL2016 is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Voltage Fluctuation/-Flicker IEC 61000-3-3	Complied	

2. Electromagnetic Susceptibility

This equipment is manufactured to operate in the electromagnetic environment described below.
The customer or user should verify if this equipment is operated in such environment.




















Test of Electronic Interference Resistance	IEC 61326-2-6 Test Level	Electromagnetic Environment Guideline
Electrostatic Discharge (ESD) according to IEC 61000-4-2	Discharge by 4 kV direct contact 8 kV of Air-gap discharge	The floor should be wooden or cemented floor or ceramic tile floor. In case that the floor is made of chemical compound materials, the relative humidity should be at least 30%
Radiated RF Electromagnetic Field immunity according to IEC 61000-4-3	3 V/m 80 MHz-6 GHz 80% AM at 1 kHz	The CL2016 series is suitable to use in professional healthcare environment.
Electrical Fast Transient/Burst according to IEC 61000-4-4	± 1 kV for power supply lines 100 kHz repetition frequency	The quality of supplied power should be suitable for general business site or hospital environment.
Surge according to IEC 61000-4-5	± 0.5 kV line to line ± 1 kV line to earth	The quality of supplied power should be suitable for general business site or hospital environment.
Immunity to conducted disturbances induced by RF fields according to IEC 61000-4-6	3 V 0.15-80 MHz 80% AM at 1kHz Power supply line	The strength of RF field in the frequency range within 150 kHz~80 MHz, the strength of the RF field is smaller than 3 V
Voltage dips/ Voltage interruption according to IEC 61000-4-11	0 % U_T ; 0.5, 1 cycle and 70 % U_T ; 25/30 Cycles Single phase: at 0° 0 % U_T ; 250/300 cycle	The quality of supplied power should be suitable for general business site or hospital environment. For the user to operate the equipment continuously even the electric power supply is interrupted, it is recommended that the uninterruptable power supply device (UPS) or batter is prepared.
Magnetic field of supply frequency (50/60Hz) according to IEC 61000-4-8	3 A/m	The magnetic field of power frequency should be coincided with the general value found in the business site or hospital environment

Note: U_T is the AC voltage of the power before using test level

Troubleshooting




Error	Possible cause	Comments and suggestions
The CLEO™ AP16 device does not start	The CLEO™ AP16 device is not connected to the power outlet.	Check that the CLEO™ AP16 device is connected to the main power.
	The power switch at the back of the CLEO™ AP16 device is not powered ON.	Power ON using the power switch at the back of the CLEO™ AP16 device.
	The CLEO™ AP16 device is in standby mode.	Press the ON/OFF button to take the CLEO™ AP16 device out of standby mode.
The touchscreen does not respond	The CLEO™ AP16 device is in standby mode (the status indicator is blue).	Press the ON/OFF button on the Operational Module.
	Hardware failure	Contact Wizbiosolutions Technical Services.
UV light does not light up	Door is open	UV light cannot operate while the door is open. Close the door again.
	UV light is broken	Contact Wizbiosolutions Technical Services.
Door does not open	Mechanical failure.	Contact Wizbiosolutions Technical Services.
Magnetic rod function failure	Stain on the magnetic rod	Ensure the Plunger is installed before each extraction. Use a clean and wet paper towel to wipe it off carefully. Do not use any solvent or detergent to clean the magnetic rods.
	The magnetic rod comes off from the magnetic rod holder	Contact Wizbiosolutions Technical Services.

Symbols Glossary

Symbol	Meaning	Symbol	Meaning
	CE Marking		Catalog number.
	For <i>In Vitro</i> Diagnostics Use.		Serial number.
	Caution		Authorized EC Representative in the European Community
	Date of manufacture		Restriction of Hazardous Substances in Electrical and Electronic Equipment
	Manufacturer		Waste stream disposal status
	Consult instruction for use		Unique Device Identification
	Keep dry		Temperature limit
	Fragile, handle with care		Protective earth (ground)
	This way up		Protect from sunlight
	Handle with care		

Technical Support



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