

# **CLEO**<sup>™</sup>AP48

Automated Nucleic Acid Extractor

# Instruction for use

REF CL2048

For in vitro diagnostic use. For professional use only.



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#### **General Information**

The CLEO™ AP48 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™ AP48 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™ AP48 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™ AP48 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™ AP48 system is designed to automatically extract DNA or RNA from samples using magnetic particles.

The CLEO™ AP48 is for *in vitro* diagnostic or research use only.

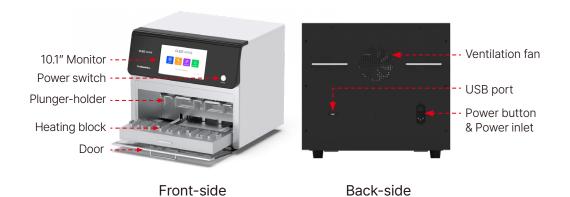
The CLEO™ AP48 can extract up to 48 samples simultaneously.

The CLEO™ AP48 system is a closed type system.

### **CLEO™ AP48 Components**

Each CLEO™ AP48 is composed of the following components:

### **CLEO™ AP48 Overview**



# **CLEO™ AP48 Specifications**

Model No CL2048
Number of samples 1 - 48 Samples
Extraction method Magnetic bead-based extraction
Sample volume 0 uL - 1,000 uL
Operating System ———————— Android OS
Input power 100 - 240 VAC (50/60 Hz)
Max. power 510 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)
Storage temperature range
Operating humidity range

# **Unpacking and Installation**

The following items are packaged within the CLEO™ AP48 shipping container:

- CLEO™ AP48 device
- · Power cable
- CLEO™ AP48 manual

#### 1. Hardware installation

- 1) Place the CLEO™ AP48 device on a flat surface.
- 2) Open the door and remove any packaging materials inside. <u>Caution:</u> Operating the device without removing the inner packaging may cause the device to malfunction. Always check that the inner packaging or plate is inserted before operating the device.
- 3) Connect the power cable to the power inlet on the back of the device. Turn on the power button on the back of the device, then turn on the power switch on the front of the device.
- 4) Connect the power cable to the power cable input on the back of the device, and plug the power code into the power source.
- 5) Turn on the power switch on the front of the device to turn on the display.
- 6) When the device is properly powered, the display screen on the front of the device turns on and the device's programs run.
- 7) When the device is on, pressing the power switch will turn off the front display.
- 8) To completely turn 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>
   CDevice 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<sup>™</sup> products only)
- · EDIT: Editing extraction protocols
- · SETTING: Modify the setting
- · UV LIGHT: UV light for sterilization



<Main Menu>

### 2. Extraction Menu (WizMag™ Kit only)







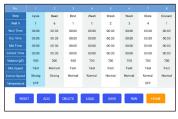
<Select DNA or RNA>

<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.



<EDIT>

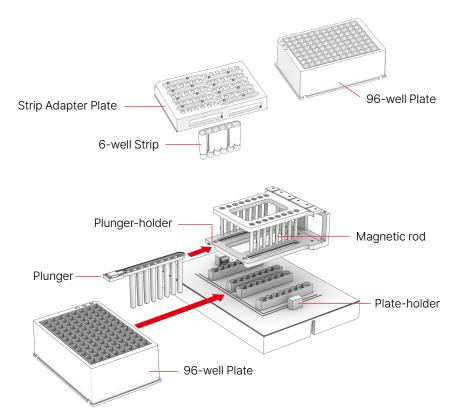
### 4. Setting Menu

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



<SETTING>

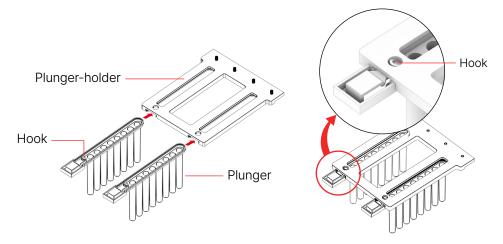
# Name of each part



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		

<u>NOTE:</u> 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™ AP48**

#### 1. How to START the CLEO™ AP48

- Turn on the power button on the back of the device, and then tune on the
  power switch on the front of the device. The device will start booting and
  self-check 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™ AP48

- 1) During the extraction, press the <PAUSE> button to stop the CLEO™ AP48 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<sup>™</sup> AP48, 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™ AP48

- 1) Before turn off the CLEO™ AP48, 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™ AP48 emits UV rays.
- RF communication equipment should be used no closer than 30cm to any part of CL2048.

# 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.

# **Troubleshooting**

Error	Possible cause	Comments and suggestions	
The CLEO™ AP48 device does not start	The CLEO™ AP48 device is not connected to the power outlet.	Check that the CLEO™ AP48 device is connected to the main power.	
	The power switch at the back of the CLEO™ AP48 device is not powered ON.	Power ON using the power switch at the back of the CLEO™ AP48 device.	
	The CLEO™ AP48 device is in standby mode.	Press the ON/OFF button to take the CLEO™ AP48 device out of standby mode.	
The touchscreen does not respond	The CLEO™ AP48 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 o carefully. Do not use any solvent or deterger 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
IVD	For <i>In Vitro</i> Diagnostics Use.	REF	Catalog number.
<u>(i</u>	Caution	SN	Serial number.
W	Date of manufacture	X	Waste stream disposal status
	Manufacturer	UDI	Unique Device Identification
[]i	Consult instruction for use	1	Temperature limit
*	Keep dry		Protective earth (ground)
Ţ	Fragile, handle with care	*	Protect from sunlight
<u>11</u>	This way up		Handle with care

#### **Technical Support**



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