

## General Information

Please carefully compare the contents of this delivery with the enclosed delivery note, the package leaflet or the invoice. We recommend that you keep a copy of this document together with the instructions, so that you can quickly access information about the date and scope of delivery in case of future queries, re-orders or service work. Please be sure to remove all small parts from the packaging material. We wish to inform you that our devices are adjusted at the factory and can be used immediately after installation. Before using the CLEO™ ONE device for the first time, please read the user manual carefully. We recommend that it always be kept with the CLEO™ ONE device.

## Important Information

Before using the CLEO™ ONE 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™ ONE 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 to supplement, not supersede, the normal safety requirements established in the user's country.

## Intended Use

The CLEO™ ONE system is intended to be used to perform for nucleic acid amplification of samples.

CLEO™ ONE system is intended for *in vitro* diagnostic and research use.

The CLEO™ ONE system is a compact molecular amplification instrument with fluorescence detection.

CLEO™ ONE can only be used with the dedicated test cartridge, CLEO™ Test Cartridge. Please refer to the user manual for each test cartridge for available test cartridges.

## Repeat Use

The CLEO™ ONE device is reusable.

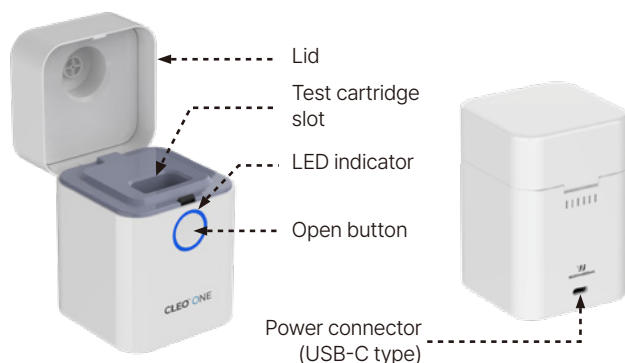
However, if you must dispose of it, this electronic product contains substances that can damage the environment if not handled properly. Therefore, it cannot be disposed of as regular garbage.

## Components

Each CLEO™ ONE system is composed of the following components:

- CLEO™ ONE device ..... 1
- USB-C power adapter (100 - 240V, 50/60Hz, 2A, 12V) ..... 1
- Instruction for Use ..... 1

## CLEO™ ONE Overview



## Specifications

Model number	CL0001P1
Input power	DC 12V, 2A
Max. power	24 W
Operating environment	Indoor Use Only
Operating temperature range	10°C to 35°C
Storage temperature range	0°C to 50°C
Operating humidity range	20% - 80%
Storage humidity range	20% - 80%
Dimensions (L×W×H)	72×72×104 mm
Net weight	165 g

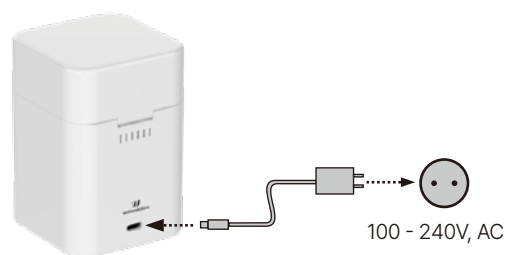
## Installation

Use only the USB-C power adapter included in the CLEO™ ONE package.

Avoid strong direct sunlight and place the CLEO™ ONE device on a flat surface, well-ventilated room around the unit.

Connect the USB power adapter to the USB-C connector on the back of the CLEO™ ONE device and plug the other end of the power cord into an 100 - 240V AC outlet.

Once the CLEO™ ONE device is on, the LED indicator located on the front of the CLEO™ ONE device will turn an **orange color** when it is ready to use.



**CAUTION:** Do not insert the test cartridge into the CLEO™ ONE device when power is off.

## LED Indicator Color Legend

LED color	Orange	Blue	Green	Flash green	Red
State	Power on	System ready	Test ready	Test in progress	System error

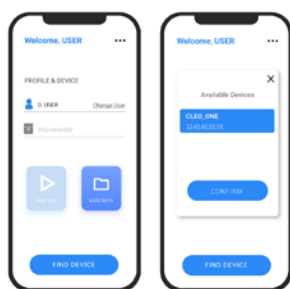
## Bluetooth connect with CLEO™ ONE device

### A. Smartphone App. (for single test)

1. Open the CLEO™ ONE App on your smartphone device.
2. Login by entering your ID and password.

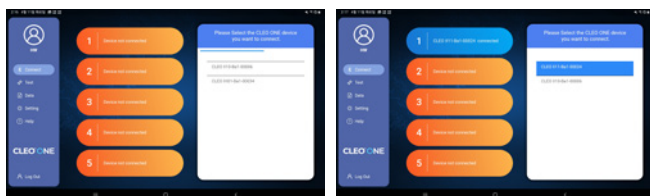
**Note:** If you do not have an account, please create a user account and log in.

3. Press 'FIND DEVICE' button at the bottom of the app to connect to the displayed device.
4. When the device and smartphone are properly connected, the color of color of the button on the front of the device changes from **orange** to **blue**.



## B. Tablet App. (for multiple test)

1. Press the 'CONNEX' button in the left menu of the app.
2. From slots 1 to 10, press the slot you want to connect.
3. If you select one of the list of connectable devices displayed in the pop-up window, the device is automatically connected.
4. When the device and tablet are properly connected, the color of the corresponding slot changes from **orange** to **blue**, and at the same time, the color of the button on the front of the device changes from **orange** to **blue**.



## 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.
- Use only the included adapter.
- Do not insert anything other than the CLEO™ test cartridge into the device.
- Do not open the test tube during or after processing steps to avoid contamination of the device with biohazardous substances.
- 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 to repair it. If you have any questions, please contact customer support.
- Turn off the device by unplugging it from the wall outlet when not in use.
- When not in use for a long period of 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 network to your device, stop using the product and contact your Wisbiosolution or service representative.

## Cleaning & Maintenance

- Power off your device before cleaning. Do not use or fill wells with caustic cleaning solutions.
- Wipe the exterior plastic surface with a cloth moistened with isopropyl alcohol. Do not clean the inner wall of the Device.
- If a foreign substance enters the test cartridge slot, gently wipe it with a wet cotton swab with alcohol. After that, open the device cap and dry it thoroughly before use.
- Never turn CLEO™ ONE device over if foreign objects enter it. It may cause equipment failure.

## Troubleshooting

Error	Comments and suggestions
Device does not power on (no LEDs are lit)	Check the following connections: • Device and USB-C adapter • A/C adapter to outlet If problem persists, contact Technical Support.
Bluetooth connection failure	Turn off the device and the app, then turn them on again and try to connect. Check the device list in the app and try to connect. If the Bluetooth connection cannot be established repeatedly, try connecting with another mobile smart device. If the Bluetooth connection still does not function, please contact Technical Support.
A test cartridge is inserted into the instrument, but the color of the LED indicator does not change to green.	The cartridge is not properly inserted into the device. Remove the cartridge and try inserting it again. If the color of the LED does not change immediately, power off the device and start again. If this problem is not resolved, contact Technical Support.
A test tube is inserted into the cartridge, but the test does not start.	The test tube is not fully inserted into the cartridge. Press firmly on the cap of the test tube to fully engage the cartridge support. The device's cover is not completely closed. Close the cover completely by pressing firmly on the cover of the device. If the test does not proceed even after completing this process, please contact Technical Support.
If the Bluetooth connection is disconnected during the test	The test continues even if the Bluetooth connection is cut during the test. After closing the app, open the app again and connect the device via Bluetooth to display the test in progress. Or, when the test is completed, you can check the test results in the app. If the result cannot be confirmed, repeat the test.

## Symbols Glossary

Symbol	Meaning	Symbol	Meaning
IVD	For <i>in vitro</i> diagnostic use	REF	Catalog number.
!	Caution	SN	Serial number.
📅	Date of manufacture	🗑️	Waste stream disposal status
🏭	Manufacturer	UDI	Unique Device Identification
📖	Consult instruction for use	🌡️	Temperature limit
☔	Keep dry	🚫	Do not use if package is damaged
🍷	Fragile, handle with care	🚫	Restriction of Hazardous Substances in Electrical and Electronic Equipment
==	Direct current	EC REP	Authorized EC Representative in the European Community
☀️	Keep away from sunlight		

MFDS License No. : IVD-23-4812



**Wizbiosolutions Inc.**

#1103, 1405, 1406, A-dong, 14, Sagimakgol-ro 45beon-gil, Jungwon-gu, Seongnam-si, Gyeonggi-do, Republic of Korea  
B237~242, 14, Galmachi-ro 288beon-gil, Jungwon-gu, Seongnam-si, Gyeonggi-do, Republic of Korea

E-mail : support@wizbiosolution.com

TEL : +82 70 7605 5066

website : www.wizbiosolution.com



**CMC Medical Devices & Drugs, S.L.**

C/ Horacio Lengo N18, CP 29006, Málaga-Spain