

IVD

# CLEO™ ONE

## User Manual

For *in vitro* diagnostic use.

For use with the CLEO™ COVID-19 Test

**REF** CL0001P

 **wizbiosolutions**  
THE INNOVATION OF GENOMICS

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# Product Information

## Product Name

CLEO™ ONE

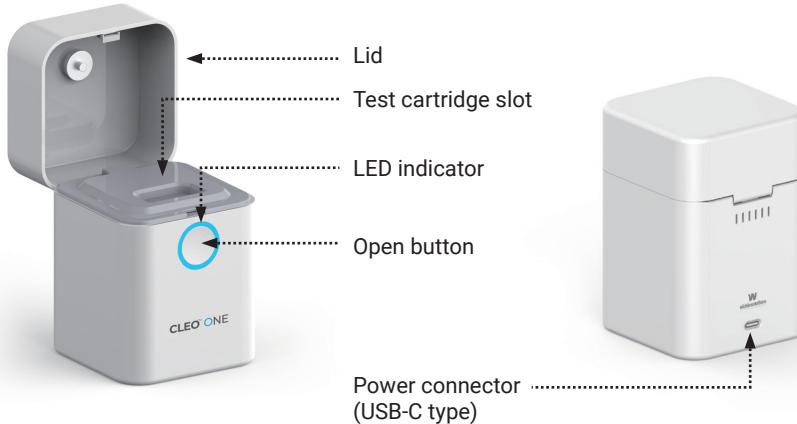
## Intended Use

This CLEO™ ONE system is for nucleic acid amplification of samples.

## CLEO™ ONE Components

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

Component Name	Quantity
CLEO™ ONE device	1
USB-C Power Adapter <ul style="list-style-type: none"><li>• Input: 100 - 240V, 50/60Hz, 2A</li><li>• Output: 12V, 24W</li></ul>	1
Instruction for Use	1



## Specifications

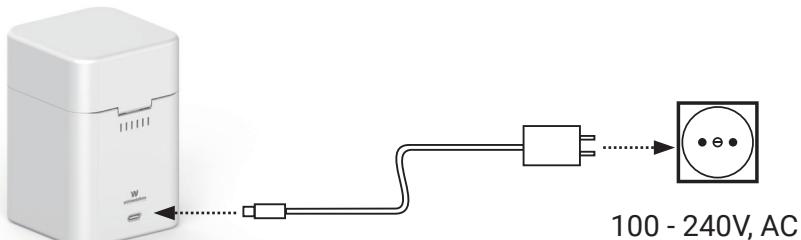
- Model number ..... CL0001P
- Input power ..... 100-240 V~(50/60 Hz)
- Output power ..... 12 Vdc., 2 A
- Operating environment ..... Indoor Use Only
- Operating temperature range ..... 1 °C to 65 °C
- Storage temperature range ..... 5 °C to 50 °C
- Operating humidity range ..... 10% - 80%
- Storage humidity range ..... 10% - 80%
- Dimensions (L×W×H) ..... 72×72×104 mm
- Net weight ..... 165 g
- Temperature ..... 1 °C - 65 °C
- Frequency ..... 2 402 - 2 480 MHz

# Installation

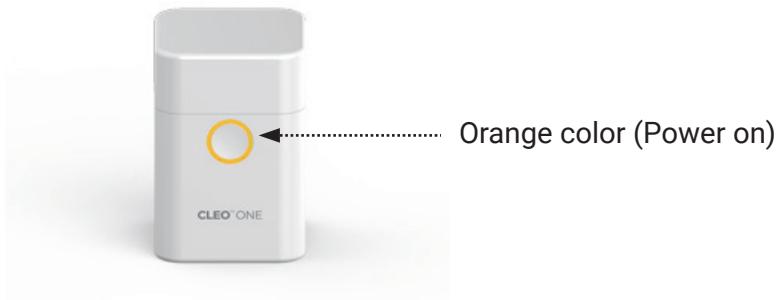
Use only the USB-C power adapter included in the CLEO™ ONE package. Avoid strong direct sunlight and place the CLEO™ ONE device on a flat surface, well-ventilated room around the unit.

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.



## Connecting with CLEO™ ONE device

Open the CLEO™ ONE App on your mobile smart device.

Connect CLEO™ ONE device to Bluetooth.

It will show a **blue color** LED button when CLEO™ ONE device is ready for the test.



## LED Indicator Color Legend

LED color					
State	Power on	System ready	Test ready	Test in progress	System error

## 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.

## 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

<b>Device does not power on (no LEDs are lit)</b>	Check the following connections: <ul style="list-style-type: none"><li>• Device and USB-C adapter</li><li>• A/C adapter to outlet</li></ul> <u>If problem persists, contact Technical Support.</u>
<b>Bluetooth connection failure</b>	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. <u>If the Bluetooth connection still does not function, please contact Technical Support.</u>
<b>A test cartridge is inserted into the instrument, but the color of the LED indicator does not change to green.</b>	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. <u>If this problem is not resolved, contact Technical Support.</u>
<b>A test tube is inserted into the cartridge, but the test does not start.</b>	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. <u>If the test does not proceed even after completing this process, please contact Technical Support.</u>
<b>If the Bluetooth connection is disconnected during the test</b>	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

 This symbol certifies that the electromagnetic interference from the device is under limits approved by the Federal Communications Commission.	 This symbol identifies that the electronic device meets the safety requirements specified for Class II equipment according to IEC 61140
 This symbol indicates that the device has been tested to applicable standards by Underwriters Laboratory (UL).	 This symbol indicates that caution is necessary when operating the device in order to avoid undesirable consequences.
 This symbol indicates that the device must not be used if the package containing the device is damaged.	 This symbol indicates that the Instructions For Use [IFU] should be consulted.
 This symbol indicates direct current (DC) voltage.	 This symbol indicates that the device should be kept in dry conditions.
 For In Vitro Diagnostics Use.	 This symbol indicates that the device is fragile and shall be handled with care.
 This symbol indicates the date on which the device was manufactured.	 This symbol identifies the manufacturer's catalog number.
 This symbol identifies the manufacturer of the device	 This symbol identifies the manufacturer's serial number.
 Use by date	 Temperature limit

## **Repeat Use**

### **The CLEO™ ONE device is reusable.**

However, if you need to dispose of it, please see the information below.

This electronic product contains substances which could damage the environment if not properly handled. As such, it is not possible to dispose of it in the regular trash.

Please check with your local government or electronics store to verify how to recycle your product. You can also check with your local electronics store to see if they will be able to recycle this product for you.

Depending on the solution chosen, fees may apply.

**[part 15 of the FCC Rules]**

**This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.**

**This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:**

- Reorient or relocate the receiving antenna.**
- Increase the separation between the equipment and receiver.**
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.**
- Consult the dealer or an experienced radio/TV technician for help.**

**Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.**

**This device should be installed and operated with minimum 20 cm between the radiator and your body.**

## Certificate of the Product

Product Name	CLEO™ONE	Seller	
Model Name	CL0001P	Tell.	
Purchaser	Wizbiosolutions Inc.	Manager	
REF.		Name	
Purchase Date		P/N	
Warranty Period	Device : 1 year	Address	

- In the event of a failure, refer the product and this warranty to the vendor where you purchased the device.
- We are not responsible for any disadvantages arising from the loss of the consumer's warranty.

### **Quality Assurance content**

#### **<Warranty Period>**

If a failure occurs in the normal condition of use according to the instructions for use, product labels, etc.,

It is repaired free of charge for one year under the Consumer Protection Act, and accessories are excluded.

If you receive free repair due to failure within the warranty period, please present the product and this warranty to your supplier.

After the warranty period, it is a paid repair.

- The customer is supposed to pay the shipping fee or expenses incurred for the repair.
- This warranty promises free repair under the terms and conditions specified above. Accordingly, under this warranty, It does not limit your rights by law, so if you have any questions about repairs, etc. after the warranty period has elapsed, If so, please contact the place of purchase (+82-070-7609-5054).

# CLEO™ ONE

Molecular Test Device



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#### Technical Support



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