IVD CE

Integrated Nucleic Acid Testing Device

Product Instruction

Contents

Important Notice

1. Important security operation information

Users need to have a complete understanding of how the device works before operating it safely. Please read the instruction carefully before running the device.

	Anyone is prohibited from operating the device before reading the instruction. If individual who did not operate the device as instructed, the heat generated by the device during operation may cause serious burns, and electrical shock accidents may occur. Please carefully read the following safety guidance, and implement all of these precautions.

2 . Safety

The following basic safety precautions shall be observed during the whole processes of operation, maintenance and repair of this device. Failures to comply with these measures or the warnings noted in this instruction may damage the protection provided by the device and misuse the intended range of the device.

	This device conforms to the relevant requirements of IEC61010(EN 61010-1).This device is a product for indoor use.
	Please read the instructions carefully before operating the device, otherwise personal injury may occur. This device can only be operated by qualified personnel trained in how to install and use electrical equipment.
	Operators ought not to disassemble or repair the device, doing so will cause the device disqualify for the warranty and may also endanger yourself to an electric shock. If the repair is required, our company is responsible for the repair.

Before connecting the power supply, ensure that the voltage of the power supply matches the voltage required by the device. Meanwhile, ensure that the rated load of the power outlet is not less than which the device required.

The power cord must be replaced if damaged. Other required replacement parts have to match the original type and specification. Do not hang anything on the power cord when this device is in use. Do not place the power cord where people move around randomly.

Be sure to hold the plug when plugging or unplugging the power cord. Ensure that the plug fully inserted into the socket, and do not pull the power cord when pulling out. If the supplied power adapter does not fit your local outlet, replace or add a suitable power adapter to ensure that the power supply matches the conditions required by the instrument.

The device should be storage in environment of low humidity and dust. Storage should avoid direct sunlight and strong light source, while the room should be well ventilated and without corrosive gas or strong magnetic field interference., Storage should be away from heating, furnace and all other heat sources. Do not place the device in damp or dusty places. Do not place the device where will be difficult to terminate the operation when radical circumstances occurred.

Device power supply should be turned off when operations ended. When the device will not be used for a longer period, the cable should be unplugged and the inactive device should be covered with a soft cloth or plastic paper to prevent dust from entering it.

Under the following circumstances, the power plug of the device should be removed from the power socket immediately. And please contact the supplier or trained maintenance personnel to handle below cases:

- Reaction liquid dropped into the device;
- Watered;
- Dropped damages;
- Alienation of functions and capabilities.

3. Electromagnetic compatibility

The device has been tested and meets the electromagnetic compatibility (EMC) technical standards.

The device complies with the emission and disturbance resistance requirements specified in this section of IEC 61326.

a) This device can generate and radiate radio wave energy and may interfere with wireless communication if not installed and used in accordance with the instruction. The use of the device in residential areas may cause harmful interference, and the user shall be responsible for solving the interference problem. If the device does cause harmful interference to other equipment, it only occurs when starting the device. It is recommended to take one or more of the following measures to overcome this interference:

- Reposition the placement direction or location of the disturbed device.
- Increase the spacing between the two devices.
- Connect the device to an independent sockets that do not share circuits with other equipment.
- Consult the manufacturer or field technicians for help.

b) Do not use devices that can generate and radiate radio wave energy (e.g., mobile phones, radio transceivers, etc.) close to the device. Otherwise, interference of electromagnetic waves may cause failure of this device.

C) You are advised to evaluate the electromagnetic environment before using the device.

	Warning: This device is designed and tested as class II device in IEC 60601-1. In the home environment, this device may cause radio interference and need to take protective measures.
	Warning: The device may cause damaging electrostatic discharge in a dry environment with artificial materials (artificial fabrics, carpets, etc.), which may lead to incorrect conclusions.
	Warning: Do not use the device near strong radiation sources (such as unshielded RADIO frequency sources); otherwise it may interfere with the normal operation of the device.
	Warning: Uses of accessories and cables other than those originally provided by the manufacturer of this device may result increased device interference or decreased its immunity to outside interference.
	Warning: Multiple devices should not be used closely to or stack one on another. If multiple devices must be used at the same time, operations should be observed to verify whether it can work properly or contact the manufacturer for solutions.
	Warning: Interference generated during the operation of this device may adversely affect the operation of other electronic devices.
	Warning: the Type-C port has no practical function and is only for debugging by manufacturer and professional institutions.

FCC Warning

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 inter-ference.

(2) This device must accept any interference received, including interference that may cause undesired operation.

NOTE 1: 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 andon, 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.

NOTE 2: Any changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

4. Device maintenance

The device should be cleaned regularly with a clean soft cloth dipped in a small amount of anhydrous alcohol module and hot cover, to ensure that the microfluidic chip and module contact is sufficient, good thermal conductivity, avoid pollution.

If the surface of this device is stained, it can be cleaned with soft cloth with water.

Power must be cut off when cleaning the device.

Device surface is not strictly cleaned with corrosive cleaning agent.

5. After-sales service

The service lifetime of this equipment is 2 years. (Observe the use precautions, and with correct & regular maintenance, this service period is valid.)

There may be safety or performance issues when the 2-year use period expires. Please consult with the corresponding technical support personnel.

a) Warranty

Within one month from the date of delivery, the manufacturer will be responsible for the replacement of the device due to material and manufacturing defects.

This device is guaranteed for 12 months from the date of delivery in case of material or manufacturing defects. During the warranty period, the company will repair or replace the device proved to be defective.

Warranty products must be sent by the user to the company for repair. Users will be responsible for the freight of the device sent to the maintenance department, while the manufacturer will bear the freight of returning the instrument to the user.

For repairs beyond the warranty period, the company will properly charge the cost of repairs.

b) Scope of Warranty

The above warranty is not suitable for damage caused by inappropriate maintenance, operating in conditions that do not meet the requirements, unauthorized repair or modification.

Chapter I Overview

1. Technical introduction

1.1 Microfluidic Technical: Microfluidic (Microfluidics) refers to the science and technology involved in processing or manipulating tiny fluids (volume is nanoliter to attoliter) systems using microtubular (dimensions of tens to hundreds of micrometers), is an emerging interdisciplinary discipline involving chemistry, fluid physics, microelectronics, new materials, biology and biomedical engineering. Because of the characteristics of miniaturization and integration, microfluidic devices are commonly referred to as microfluidic chips, also known as Chip Laboratory (Lab on a Chip) and micro-Total Analytical System.

1.2 Isothermal nucleic acid amplification technology : it is the general term for a class of molecular biology techniques that expand the copy number of a particular DNA or RNA fragment at a particular temperature. At present, the main constant temperature amplification technologies include: rolling loop nucleic acid amplification, loop-mediated isotemperature amplification, chain substitution amplification, nucleic acid sequence-dependent amplification and depolymerase amplification. They all share common characteristics: constant temperature, high efficiency, special, no need for special equipment.

2. Main uses and scope of application

It can be used with adaptive microfluidic chip for in vitro amplification detection of sample gene nucleic acid.

3. Device characteristics

■ Thermal circulation system adopts metal film heating technology, which has stable and reliable performance;

■ The temperature changes rapidly, and the rising and cooling rate is no less than 10℃/min;

■ Match the microfluidic chip independently developed by Guangzhou Pluslife Biotech Co., Ltd..

Chapter II Features

1. Normal working conditions

Environmental temperature: 15℃ ~ 30℃

Relative humidity: ⩽70%

Power supply: 5V⎓3A

Input power: 10W

2. Transportation and storage conditions

Temperature: -20℃ ~ 55℃

Relative humidity: ⩽80%

3. Parameters

3.1 Basic parameters

Sample size: 1

Dimensions (mm)(length × width × height) : 101×86×63

Weight (g) : 210g

3.2 Performance parameters

Sample module operating temperature range: 30℃ ~ 75℃

Maximum heating rate of sample module: ⩾ 10℃/min

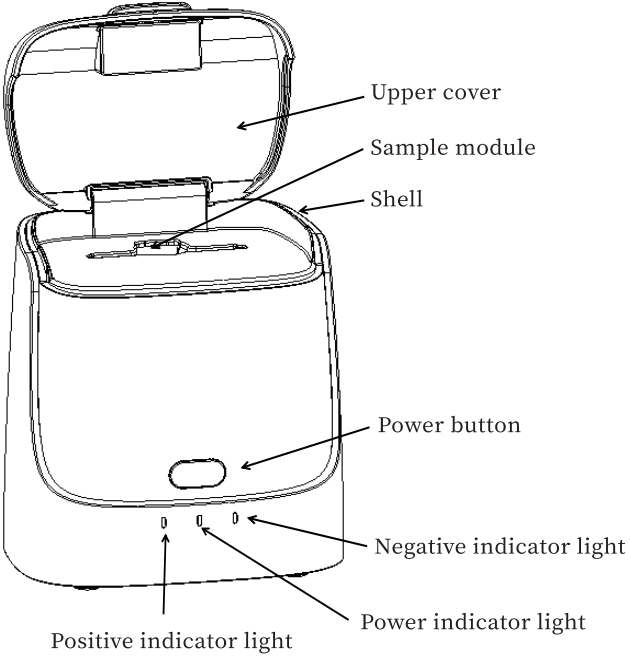
Maximum cooling rate of sample module: ⩾ 5℃/min

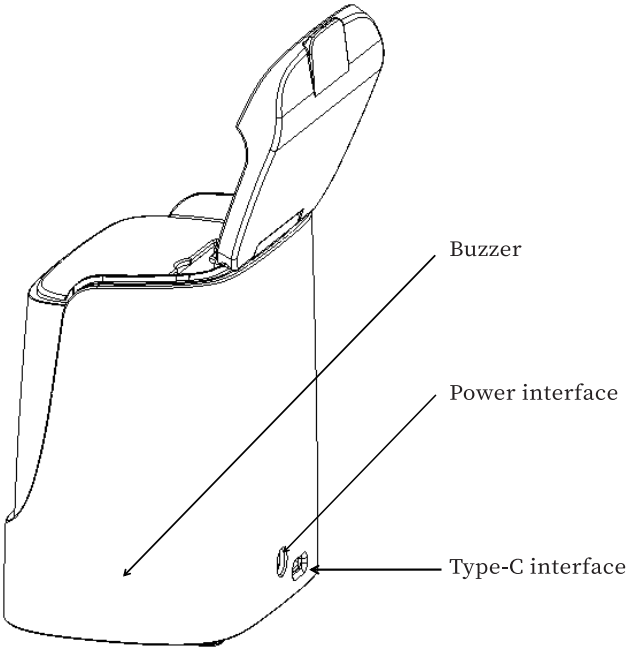
Temperature control accuracy of sample module: ±0.5℃

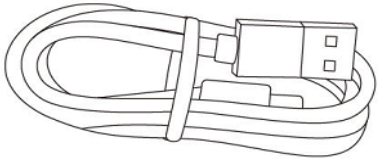
Sample module temperature uniformity: ±1.5℃(after 5mins)

4. Device structure and indicator lamp status

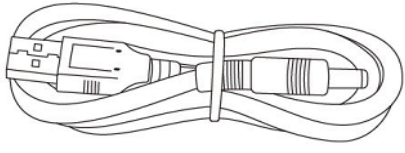
4.1 Schematic diagram of the device construction:



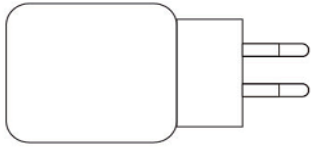

Buzzer
Power interface
Type-C interface



USB-A to USB-C Cable

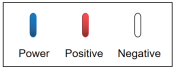
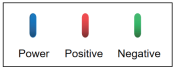
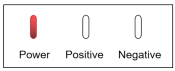


DC Power Cable



Power Adapter

4.2 Indicator light status:

	Power indicator light flashing, temperature preparation stage (measurement cannot be started)
	When the power indicator light stopped flashing and turnsblue, the preparation is complete and the test can be started. The power indicator light will be flashing blue during the test.
	When the positive indicator light is on, the sample is determined as positive.
	When the nagative indicator light is on, the sample is determined as negative, or the sample concentration value is too low to be detected.
	When the negative & positive indicator light are both on, the test result is invalid; or insufficient sample volume, suppressed reaction, sampling error, sample contamination may occurred during the process.
	When the power indicator flashes red and the buzzer rings synchronously means the device ran into errors.

Chapter III Operation Introduction

1. 1Pre-amplification preparation

Connect power supply, press the power button to start the device and enter warm-up status. After 2mins, the warm-up is completed, in the standby state (Figure 1).

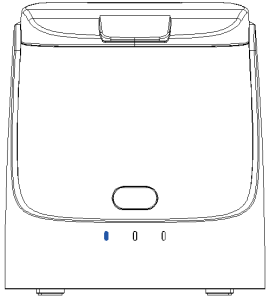


Figure 1

2. The begin of the reaction

Insert the reaction Card into the device and close the upper cover, press the power button to start amplification.

3. Amplification anomaly treatment

When the power indicator flashes, the buzzer rings synchronously and the device is abnormal, press the button for 3 seconds to end the experiment.

4. End amplification

After amplification, you can start the next test directly, or press the button for 3 seconds to turn off the device.

User Prohibitions

1.Do not press the power button during the amplification. If do so, invalid result may occur.

2. When the device encounters external power failure, the on-going test fails, and the test should be re-sampled.

3. The device cover should not be opened during the operation. If do so, this action will impacts the test results.

4. Do not pick up the instrument during the test in order to avoid interruption of instrument transmission.

5. Non-original-provided plugs or cables are not available for testing.

6. The test should be tested on a flat and clean surface.

Manufacturer

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Explanation of symbols

	CE Mark		Afraid of rain
	Consult instruction for use		Temperature range
	Upward		Warning
	Manufacturer		European union representative
	Potential biosafety risks	IVD	IVD product
	Waste product must be taken to the appropriate facility	UDI	Unique Device Identification
	FCC Certification		