CE English

Integrated Nucleic Acid Testing Device

User Manual

PM003

For veterinary use only

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Important Notice

1. Important safety operation information

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

	It is prohibited to operate the device before reading these instructions. If the device is not operated 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. Failure to comply with these measures or the warnings noted in these instructions may damage the protection provided by the device and affect its intended range of use.

	This device conforms to the relevant requirements of IEC 61010-1 and IEC 61010-2-101 (EN 61010-1 and EN 61010-2-101). This device is 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 the installation and use of electrical equipment.
	Operators must not disassemble or repair the device, as doing so will invalidate the device warranty and may also result in electric shock. If repair is required, please contact the manufacturer.

	Before connecting the power supply, ensure that the voltage of the power supply matches the voltage required by the device. Also ensure that the rated load of the power outlet is not less than that required by the device. The power cord must be replaced if damaged. All replacement parts must match the original type and specification. Do not hang anything on the power cord when this device is in use. Place the power cord away from foot traffic. Be sure to hold the plug when plugging or unplugging the power cord. Ensure that the plug is fully inserted into the socket when plugging in, and do not pull the power cord when unplugging. 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 device.
	The device should be stored in an environment with low humidity and dust. Store away from direct sunlight and strong light sources. The room should be well ventilated and free from corrosive gas or strong magnetic field interference. Keep away from heating, stoves 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 access and disconnect the device in an emergency.
	Turn off the power supply to the device when it is not in use. When the device will not be used for an extended period, the cable should be unplugged and the device covered with a soft cloth or suitable plastic cover, to prevent dust from entering it.

Under the following circumstances, immediately remove the power plug of the device from the power socket and contact the supplier or trained maintenance personnel to deal with the situation:

- Liquid spilled on the device
- Device is exposed to rain or water
- Device is dropped or casing is damaged
- The functions of the device have changed significantly

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 .

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

- Reorient or relocate the disturbed device
- Increase the spacing between the two devices
- Connect the device to an independent socket that does not share a circuit with other equipment
- Consult the manufacturer or field technician for assistance

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

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

	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 supplied by the manufacturer of this device may result in increased device interference, or decrease its immunity to outside interference.
	Warning: The device should not be used close to or stacked with other devices. If it must be used close to or stacked with other devices, its operation should be observed to verify that it works properly in the configuration in which it is used.
	Warning: Interference generated during the operation of this device may adversely affect the operation of other electronic devices.

4. Device maintenance

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

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

The power must be disconnected when cleaning the device.
The device surface must not be cleaned with corrosive cleaning agents.

5. After-sales service

The service lifetime of this device is 2 years. (This service period is valid if the usage precautions are observed and regular maintenance is correctly performed.)

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

a) Warranty

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

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

Warranty products must be sent by the user to the company for repair. The cost of sending the device to the maintenance department shall be borne by the user. The manufacturer will bear the shipping cost for returning the device to the user.

For repairs outside the warranty period, the company will charge the cost of the repairs to the user.

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 technology: Microfluidics refers to the science and technology involved in systems that microtubes (tens to hundreds of micrometers in size) to process or manipulate tiny volumes of fluids (ranging from nanoliters to attoliters). It 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, and also known as lab-on-a-chip devices and micro total analysis systems.

1.2 Isothermal nucleic acid amplification technology: this is the general term for a class of molecular biology technology that expands the copy number of a particular DNA or RNA fragment at a particular temperature. At present, the main isothermal amplification technologies include: rolling circle nucleic acid amplification, loop-mediated isotemperature amplification, strand displacement amplification, nucleic acid sequence-based amplification and helicase-dependent amplification. They all share common characteristics: constant temperature, high efficiency, special, no need for special equipment.

2. Intended use

The product is intended to be used in combination with Pluslife test cards for in vitro amplification and qualitative detection of various pathogens from animal nucleic acid samples. The device is for veterinary use only.

3. Device characteristics

■ The thermal circulation system adopts metal film heating technology, which has stable and reliable performance.

■ The temperature changes rapidly, and the heating and cooling rate is no less than 10°C/min.

Chapter II Features

1. Normal working conditions

Environmental temperature: 15°C–30°C

Relative humidity: ≤70%

Power supply: 5V ⎓ 3A

Input power: 15W

2. Transportation and storage conditions

Temperature: -20°C–55°C

Relative humidity: ≤80%

3. Parameters

3.1 Basic parameters

Sample size: 1

Dimensions (mm) (length × width × height): 101 × 91 × 65

Weight (g): 210g

3.2 Performance parameters

Sample module operating temperature range: 37°C–70°C

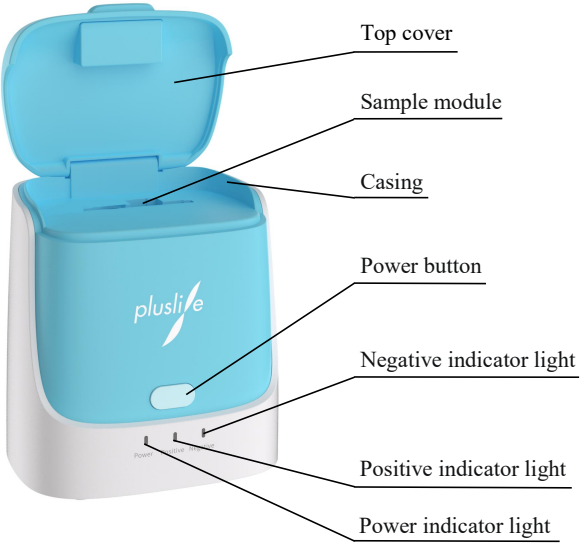
Maximum heating rate of sample module: ≥ 10°C/min

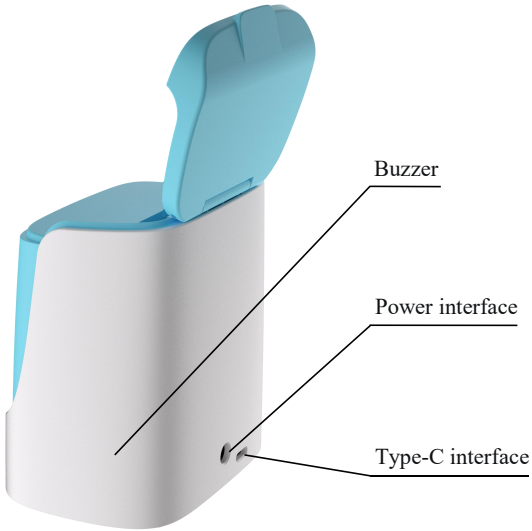
Temperature control accuracy of sample module: ±0.5°C

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

4. Device structure and indicator light status

4.1 Schematic diagram of the device construction



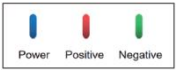

Buzzer
Power interface
Type-C interface

Type-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 stops flashing and turns blue, the preparation is complete and the test can be started. The power indicator light will flash blue during the test.
	When the positive indicator light is on, the sample is determined to be positive.
	When the negative indicator light is on, the sample is determined to be negative, or the sample concentration value is too low to be detected.
	When the negative and positive indicator lights are both on, this indicates invalid test result. It may also indicate insufficient sample volume, suppressed reaction, sampling error or sample contamination during the test process.
	When the power indicator flashes red and the beeper sounds simultaneously, this indicates that the device is in error state.

Chapter III Operation Introduction

1. Pre-amplification preparation

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

Figure 1

2. Start of amplification

Insert the reaction card into the device and close the top cover. Press the power button to start amplification.

3. Error

When the power indicator flashes and the buzzer beeps simultaneously, the device is in Error state, press the button for 3 seconds to end the test.

4. End of amplification

After amplification, you can start the next test. For the next test, press the power button to eliminate the last test result (the power indicator is steady on), insert the reaction card to be tested, and then press the power button for the next normal test.

Press the power button for 3 seconds to turn off the device.

Precautions

1. Do not press the power button during amplification, otherwise an invalid result may occur.
2. If power to the device fails while it is running a test, the test will fail and should be repeated with a new sample.
3. The device top cover must not be opened during operation, otherwise the test result may be affected.
4. Do not pick up the device while a test is in progress to avoid interrupting data transmission by the device.
5. Do not use non-original plugs or cables for testing.
6. Testing must be performed on a flat and clean surface.

Manufacturer

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Explanation of symbols

	CE Mark		Model
	Consult instructions for use		Keep dry
	This way up		Caution
	Manufacturer		Authorized representative in the European Community
	Potential biosafety risks		The product should not be discarded as unsorted waste but must be sent to separate collection facilities for recovery and recycling.

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