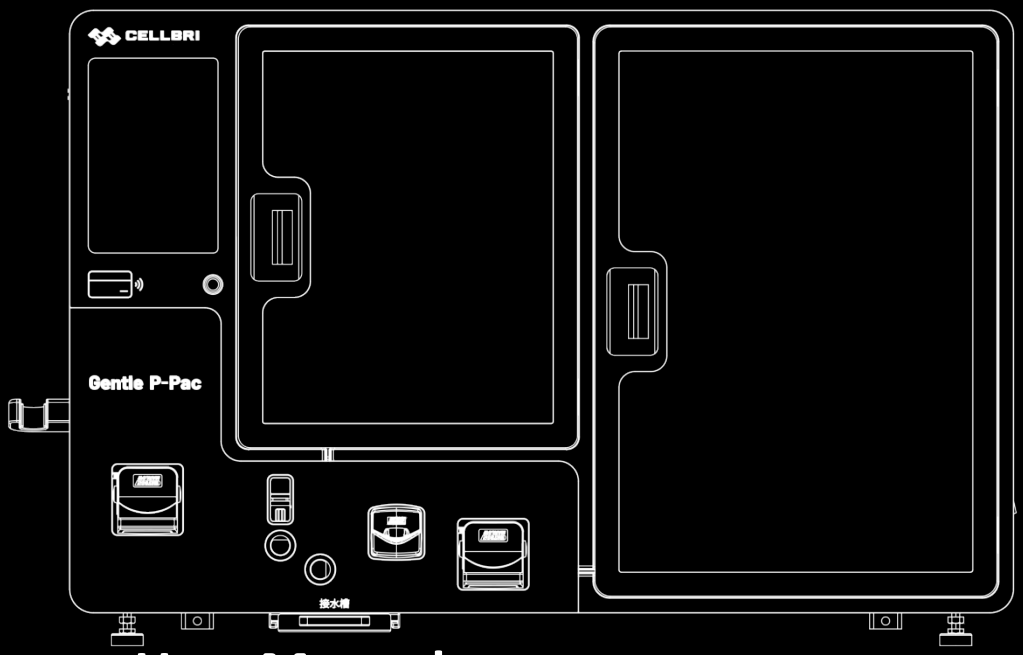
CELLBRI

Gentle P-Pac™

High-precision Automated Fill & Finish System



User Manual

Integration, Co-Creation and Sharing · Developing with Our Customers

User Manual

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The high-precision automated fill & finish system is mainly used for filling, and it is not suitable for clinical and human infusion applications. Biopharmaceutical manufacturers are solely responsible for ensuring the purity, potency, safety, and identity of the finished product and obtaining regulatory approval.

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Cellbri guarantees that any services provided to customers will be done by well trained personnel.

Failure or damage caused by the following aspects are not covered by the warranty

- Failure or damage caused by improper use or human error.
- Failure or damage caused by an unstable or out-of-range power input.
- Failure or damage caused by fire or earthquake.
- Failure or damage caused by improper operation or maintenance by unqualified or unauthorized

maintenance personnel.

- Failure or damage caused by the use of components or accessories not approved by Cellbri.
- Others not caused by the instrument or component itself.

Warning: During any use, if you encounter problems that cannot be handled, please contact Cellbri. To prevent any accident, do not dissemble the machine.

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.

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

Note: 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.

RF Exposure Compliance

This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

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

Revision History

Revision Version	Date	Description
V01	February 07, 2024	Initial version of the user guide for instrument

*The information in this Guide is subject to change without notice.

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1 Introduction

About this chapter

This chapter contains important user information that must be read before operating the Gentle P-Pac high precision automated fill & finish system, as well as information about user documentation.

In this chapter

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1.1	Important user information	**Error! Bookmark not defined.**
1.2	About this Guide	**Error! Bookmark not defined.**

1.1 Important user information

1.1.1 Before operating, please read this guide

Before installing, operating, or maintaining this equipment, all users must read the user guide.

When operating this equipment, always keep the user guide at hand.

Do not operate this equipment in any way not mentioned in the user guide or related user guides. Otherwise, you may risk injury to personnel or damage to cells or cell handling equipment due to contact with hazardous materials or mechanical reasons.

In addition, before operating the system, all users must carefully read the operation manual for the specific application.

1.1.2 Intended Use

Gentle P-Pac is a high-throughput, high-precision, automated closed liquid dispensing system designed to be used with specific disposable sterile dispensing consumables. It is suitable for pharmaceutical institutions, bio-research centers, pathology research institutions, *etc*., and is applicable for dispensing a variety of cell suspensions such as immune cells, viruses, and stem cells. Gentle P-Pac equipment can only be used in conjunction with Gentle P-Pac software, processes, and disposable dispensing consumable kits.

The Gentle P-Pac automated cell handling system is intended for research or cell product manufacturing in GMP environments and should not be used for clinical surgery or diagnostic purposes.

Product Name	Gentle P-Pac High-precision Automated Fill & Finish System
Product Size	Gentle P-Pac
Registrant/Manufacturer	Shenzhen CellBri Bio-Innovation Technology Co., Ltd
Manufacturing Address	Fenghuang Subdistrict, Guangming District, Shenzhen | Hengtaiyu Building, 3A Block, 3A-201, 3A-301, 3A-401, 3A-501, 3A-601
Manufacturing Date	Refer to the nameplate for detailed information
Shelf Life	5 years
Overvoltage Category	II

1.1.3 Advantage of Automation

The Gentle P-Pac system enables efficient automatic cell packaging and venting, transforming tedious manual operations into automated production, reducing a large number of manual repetitive operations, long exposure times and risk of contamination, improving product reliability, repeatability and promoting compliance with good manufacturing practices in practical applications.

1.2 About this Guide

1.2.1 Purpose of the guide

This operating instruction gives you the information you need to safely install, operate, and maintain Gentle P-Pac equipment.

1.2.2 Applicability of the guide

This guide covers Gentle P-Pac equipment and software only.

Please refer to the quick operating manual provided with the application for instructions on how to install disposable tubing kits and perform liquid dispensing with Gentle P-Pac equipment.

Gentle P-Pac equipment, together with disposable tubing kits and application software, are collectively referred to as Gentle P-Pac processing systems.

2 Safety Instructions

About this Chapter

This chapter describes the information and symbols on safety precautions, system labels, and other safety labels attached to products.

Strictly follow the relevant operation requirements of this guide to avoid injury to the operator, damage to the equipment, or cell products processed by the equipment.

Before installing, operating, or maintaining a system, be aware of the hazardous conditions described in this guide.

In the Chapter

Section		Page number
2.1	Safety Precaution	**Error! Bookmark not defined.**
2.2	Symbols and Abbreviations	**Error! Bookmark not defined.**
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2.1 Safety Precaution

This user Guide contains safety instructions regarding the safe use of the product. Symbols that warn of potential hazards or convey important safety information may be affixed or printed on the equipment.

2.1.1 General Precautions

- Please read all user guides before using.
- If you are unsure about the use of Gentle P-Pac equipment, please contact our technical representative.
- Only trained users are allowed to operate this system to ensure safe and effective use.
- Only approved technicians may install, modify, maintain or repair Gentle P-Pac equipment. The equipment and disposable tubing kits are designed not to be modified or used for unintended purposes by the user or third parties.
- Always use appropriate personal protective equipment when operating and maintaining this product.
- Before use, please check that all functions of the equipment are running normally and in good working condition.
- The equipment should only be used for its intended purpose, otherwise it may compromise the performance and safety of the equipment or result in incorrect results.
- Failure to use the product as described in this User Guide may result in personal injury or damage to equipment. Please ensure that anyone using the product is aware of the general laboratory safety practices and the safety information provided in this User Guide.
- It is recommended to connect and operate disposable tubing kits in a clean environment that meets the applicable regulatory requirements (see the application Quick Operation manual)
- Read and understand all applicable safety data sheets (SDS) and use appropriate personal protective equipment (gloves, protective clothing, goggles, etc.) before handling chemicals.
- Gentle P-Pac equipment comes with a single-use dispensable tubing kit sterilized with ethylene oxide (EO), which may cause allergic reactions. Make sure that the operator is not allergic to ethylene oxide (EO) before using the Gentle P-Pac equipment tubing kit.

2.1.2 Transportation and Installation

- The equipment must be kept upright during transportation.
- If equipment needs to be moved to another location, it is the responsibility of the laboratory manager to ensure that the equipment is installed safely.
- Be sure to connect the equipment to a reliably grounded power supply.
- Always use an original or certified power cord. Do not use adapters or extension cords.
- The equipment will not restart automatically in the event of an interruption or mechanical interruption caused by a power failure.
- Do not expose the equipment to direct sunlight or strong light sources, liquids or corrosive substances, physical impact or vibration of heavy objects, magnets, and magnetic or electromagnetic fields.

2.1.3 Operation

- Please operate the equipment on a flat, stable, level and clean surface.

2.1.4 Single-use of Disposable consumables

- Be sure to combine the Gentle P-Pac disposable consumables from the manufacturer with the Gentle P-Pac equipment. Disposable consumables are aseptically packaged and for single use only.

- Please follow local waste disposal regulations and dispose of used single-use consumable kit waste.
- The user shall be solely responsible for any consequences arising from the use of packages other than those specified in this User Guide.

2.1.5 Cell Product Processing

- In the event of spills or leaks, follow your internal Standard Operating Procedures (Sops) for waste disposal.
- Wear gloves and protective clothing for handling.

2.1.6 Peripheral Devices

- Only code scanner provided by the manufacturer can be used.
- Clean the code scanner and associated power cables with an antistatic cloth and antibacterial solution for surface disinfection.

2.1.7 Equipment Safety

- Do not remove the protective cover.
- If you remove the protective equipment plate or disable the interlocking device, you may be in serious danger.

2.1.8 Physical Injury

Dangerous Substance

- No potential dangerous substances shall be placed within 30cm of the equipment.

Movement and Lifting

- The equipment can only be moved and installed by the personnel or supplier specified in the user manual. Improper lifting may cause back pain or permanent damage to the person.

Considerations before lifting or moving the equipment:

- Depending on the weight, moving or lifting may require two or more people.
- If you decide to move the equipment after it has been installed, do not attempt to do so without the assistance of others.
- Make sure you can safely and securely grasp the equipment.
- Ensure that there are no obstacles in the path of the equipment's movement.

2.1.9 Electrical safety

Fuse installation

- Before installing the equipment, please ensure that the fuse is installed correctly, and the fuse voltage matches the power supply voltage.
- Make sure to use fuses that are consistent with the specifications of the fuse. Mismatched fuse specifications may damage the power system of the equipment and even cause a fire.

Ensure proper power supply

To ensure the safe operation of the equipment:

- Insert the unit plug into a power socket with sufficient current capacity.
- Ensure that this equipment is connected to a power socket with grounding protection.
- Ensure that the voltage of the power supply is within the specified range of the equipment.
- Never operate the equipment when the grounding device is disconnected. The safe operation of the equipment requires grounding continuity.

Power cord

- Connect the device to the power socket using a verified power cord.

Turn off the power

- For example, before leaving the equipment unused for a long time or cleaning the equipment, please make sure to completely disconnect the power and unplug the power cord.

Protective grounding

- To ensure the normal operation of the equipment and the personal safety of the operators, the grounding continuity of the equipment body, frame and panel should be checked regularly.

2.1.10 Electromagnetic compatibility

This equipment must comply with the following standards and requirements regarding electromagnetic compatibility when in use:

- It is recommended to evaluate the electromagnetic environment before using the equipment. The user must ensure that the electromagnetic environment meets the normal operation of the equipment.
- This equipment shall not be close to or stacked with other equipment. If it is necessary to be close to or stacked, it shall be observed and verified to operate normally under its configuration of use.
- Using accessories and cables other than the internal components, spare parts, and cables provided or sold by the manufacturer may result in an increase in the equipment's electromagnetic emissions or a reduction in its immunity.
- It is prohibited to use the equipment near strong radiation sources (such as unshielded RF sources), otherwise the equipment may not function normally.
- The equipment is susceptible to electromagnetic interference during its operation. Electromagnetic interference may cause the equipment to malfunction, so do not use equipment that can generate strong electromagnetic waves while the device is in operation.
- During the operation of the equipment, it will radiate electromagnetic waves to the outside. Do not install or use electromagnetic sensitive equipment near the device.
- The equipment contains extremely powerful permanent magnets, and a strong magnetic field can cause serious personal injury to individuals carrying implanted or attached medical devices (such as heart stents and prostheses); in addition, a strong magnetic field can also cause damage to tools, equipment, or personal items containing steel, iron, or other magnetic materials, such as erasing information from magnetic media and causing credit cards to fail.

2.1.11 Chemical safety

- To reduce the hazards of chemicals, please ensure that all laboratory personnel are aware of and master the general safety guidelines for the use, storage, and waste of chemical substances.

- Before storing, handling, and using any chemicals or hazardous substances, please read and understand the safety data sheet (SDS) provided by the chemical manufacturer.
- Minimize contact with chemicals. When handling chemicals, please wear appropriate personal protective equipment (such as goggles, protective gloves, or protective clothing).
- Try to avoid inhaling chemical substances. Only open chemical reagents in well-ventilated equipment (such as fume hoods)..
- Regularly check for chemical substance leaks. If a leak occurs, please follow the cleaning procedures recommended in the SDS.
- Handle chemical waste in the fume hood.
- Make sure to use primary and secondary waste containers. (The main waste container holds the direct waste, and the secondary container must be able to contain the leaks from the main container. Both containers must be compatible with the waste and meet the container storage requirements of local regulations.).
- After emptying the waste container, seal it with the supplied lid.
- Differentiate and label (if necessary, by analysis) the chemical waste produced in your laboratory.
- Make sure that the waste is stored, transferred, transported, and disposed of in accordance with local regulations.

2.1.12 Biohazard

- Bio samples processed on the equipment may be substances with biological hazards. When handling substances with biological hazards, appropriate decontamination methods should be used.
- Biological samples such as tissues, body fluids, infectious pathogens, and blood from humans and other animals may spread diseases.
- Please carry out all work in facilities equipped with appropriate safety equipment (e.g. physical protective devices). Safety equipment also includes other items for personal protection, such as gloves, coats, shoe covers, boots, respirators, masks, safety goggles or eye shields.
- Individuals should be trained in accordance with applicable regulations and the requirements of the company/institution before using potential biohazardous materials.
- Please strictly follow the requirements of local regulations during the operation.

2.1.13 Cleaning and disinfection

You can only use the cleaning and disinfection methods specified in this user manual.

The operator (or other person in charge) is responsible for ensuring that the following requirements are met:

- Do not use cleaners that can react with the components of the equipment or the materials contained in the equipment, as the use of such substances may cause dangerous situations.
- If you need to use a cleaning or disinfection method other than the one recommended by the manufacturer, please confirm with the manufacturer that this method will not damage the equipment.

2.2 Symbols & Abbreviations

2.2.1 System Tags

The system tags are on the back of the equipment, which are used to mark the product and show electrical data, regulatory compliance, and warning signs. The system tags have the following symbols and contents:

Symbol/Text	Description
Product Name	High-precision Automated Fill & Finish System
Product Size	Gentle P-Pac
Power Input	AC100-240V，50/60Hz，450VA
Place of Origin	Shenzhen, China
SN	Serial Number (Equipment Name - 202XXXXXX)
	Production Date: 202X-XX
	Warning! Before using this system, please read the guide. Unless otherwise specified in the guide, do not open any protective covers or replace components.
Registered/Manufacturing Enterprise	Manufacturer's Name, Address, Telephone, Website

2.2.2 Standard safety symbols

Symbol	Meaning
	Danger warning. Please refer to the safety guide for more safety information.
	Electrical shock risk
	Potential biohazard
	Caution: risk of hand pinching

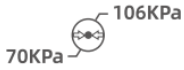
2.2.3 Control and connection symbols

Symbol	Meaning
	On (power-on)
	Off (power is off)
	Protective wire terminal (main ground)

2.2.4 Equipment identification symbols

Symbols and descriptions	Meaning
	Product serial number
REF	Manufacturer's product catalog number
	Manufacturing date
	Equipment requires recycling through specialized channels
	Users need to consult the user manual

2.2.5 Transport identification symbols

Symbols and descriptions	Meaning
	The temperature range that the transport packaging should maintain
	The humidity range that the transport packaging should maintain
	The atmospheric pressure range that the transport packaging should maintain
	Packaging should be placed on a single layer only
	Do not roll the transport packaging during handling
	The transport packaging should be kept upright during transportation
	The transport packaging is afraid of rain
	Fragile items are packed in the transport package, handle with caution
	Prevent exposure to the sun

2.3 Emergency procedures

Describe how to shut down Gentle P-PAC in an emergency, as well as the procedure for restarting Gentle P-PAC.

In addition, this section also introduces the consequences of a power failure.

2.3.1 Controlled closure

When the Gentle P-PAC device and software are running, follow the following steps to stop the procedure:

Step	Operation
1	Click the termination button on the touch screen to terminate the program
2	Close all the tube clamps on the disposable kit
3	Click OK to confirm the termination of the program
4	Click the login option in the upper left corner of the screen to exit the login
5	Click on the shutdown button on the display
6	Shutdown complete. Please turn the power switch on the back of the device to the OFF (off) position (O)

2.3.2 Power failure

- When a power failure occurs in Gentle P-PAC, the program will be immediately interrupted.
- In order to prevent liquid leakage, please close all the tube clamps on the disposable kit.
- All the program data collected before the power failure is stored in the log file..

Note: Connecting Gentle P-PAC to an uninterruptible power supply (UPS) helps prevent operational interruptions and data loss.

2.3.3 Restart after emergency stop or power outage

When the power is restored after a power outage or emergency shutdown, please perform the following operations as needed:

Step	Operate
1	Make sure all the pipe clamps on the disposable kit are closed
2	Restart Gentle P-PAC
3	Use the basic operation function to recycle the cells in the pipeline

3 System Description

About this chapter

This chapter provides an overview of the Gentle P-PACTM Cell Sorting System and control software.

In this chapter

Section		Page number
3.1	Device description	**Error! Bookmark not defined.**
3.2	User interface	**Error! Bookmark not defined.**
3.3	Data privacy and security	**Error! Bookmark not defined.**
3.4	Important instructions of the disposable kit	**Error! Bookmark not defined.**
3.5	QRcode scanner holder	**Error! Bookmark not defined.**

3.1 Description of Gentle P-PAC

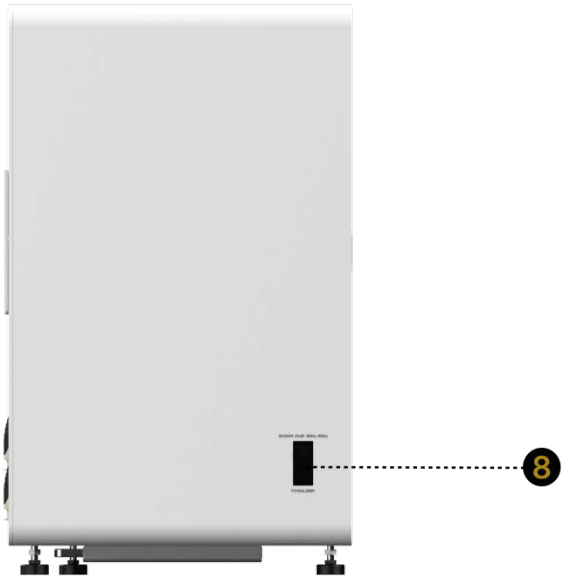
3.1.1 Main Components

Gentle P-Pac is mainly composed of the following components:

- Liquid transport device: Tube clamp valves * 22, Peristaltic pump * 3, and the flow rate of the peristaltic pump is 5-300 mL/min.
- Sensors: Liquid sensors * 5, Temperature sensor * 1, Hall sensor * 2.
- Card swipe module: Swipe user login cards and consumables cards.
- Touchscreen display: 10.1 "TFT touch screen.
- Temperature controlled mixing compartment： The temperature control range is 2 ℃ - 8 ℃, and the mixing volume is 150 mL-3000 mL.
- Software: Linux system, with multiple built-in fixed programs, and programmable according to requirements.
- Embedded computer system for process automation. This includes Ethernet and USB communication ports.

3.1.2 Schematic diagram

Main components of the Gentle P-Pac:

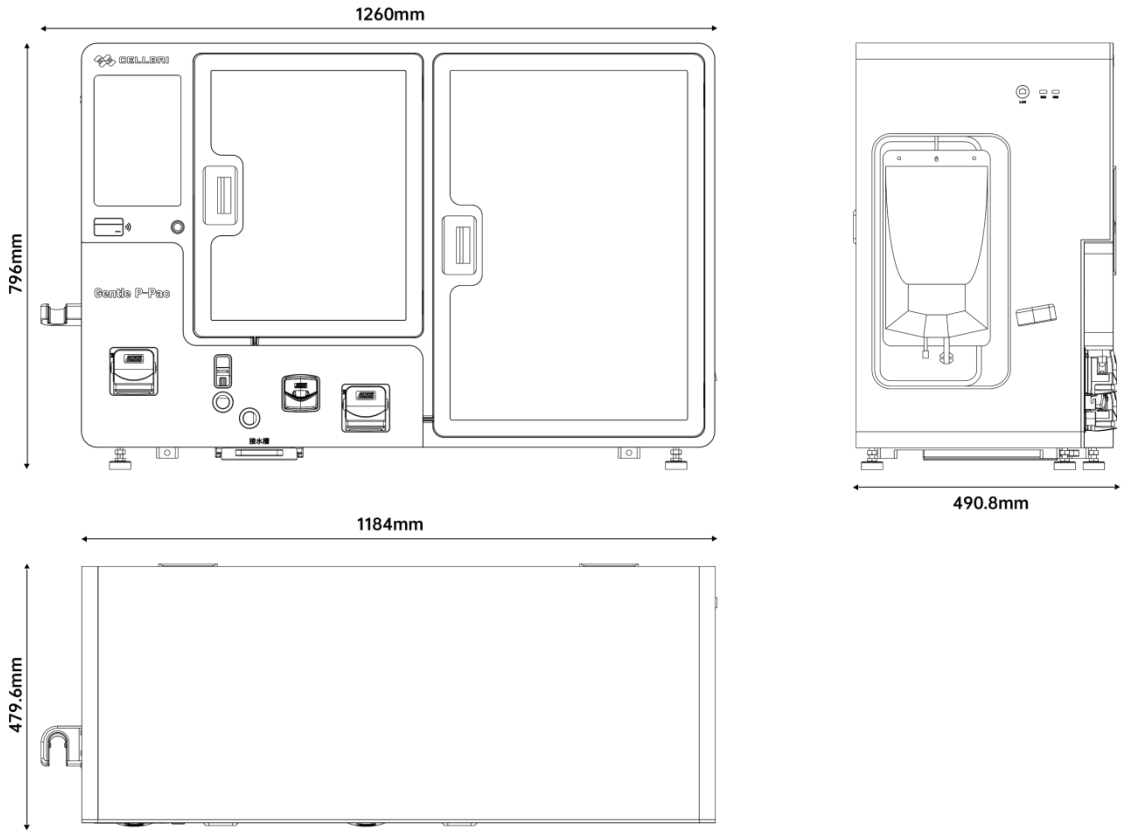


Components	Description
①Touchscreen	A user interface is provided for operating and controlling the dispensing process.
②Temperature controlled module in mixing chamber	Samples can be mixed in an environment of 2-8 ℃.
③Power Switch	Click for 1 second to boot, press and hold for 5 seconds to shut down.

④mixing compartment	Samples can be dispensed while being mixed.
⑤Liquid Sensor	Identify bubbles and liquids for process control in automated processes.
⑥Tube clamp valves	Control the automatic opening and closing of disposable consumables pipelines.
⑦Preparation dispensing module	The placement area of the final product
⑧Power Supply	Power switch/power input port.
⑨Sink	Collect condensate.

3.1.3 Size

The Gentle P-Pac has a working space with a height of approximately 479.6mm, a maximum width of 1260mm, and a depth of 490.8mm, weighs 100kg. For specific dimensions. The specific dimensions are shown in the following image:



3.1.4 Back panel component

Back panel component of Gentle P-Pac ：

Conponent	Description

1	A fan (air outlet) used for cooling the equipment. The fan will operate as soon as the equipment is turned on.

3.2 User Interface

The touchscreen is utilized to control the process functioning and present an interface for users to input information and query records.

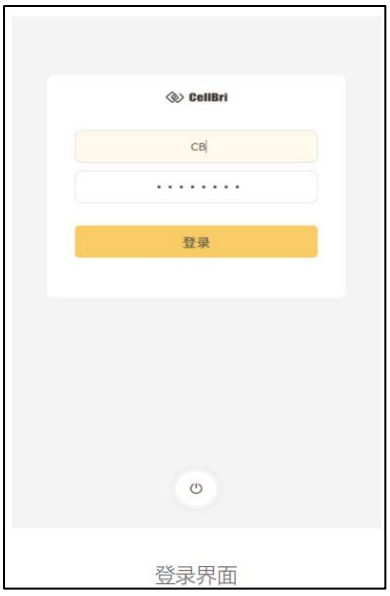
3.2.1 Power-on detection and login interface

After the Gentle P-Pac is powered on, it will first carry out a boot self-check. When it reaches 100%, it will enter the login interface, as shown in the following figure.

(If there are exceptions, an error code will be displayed after reaching 100%. Please contact the after-sales service.)

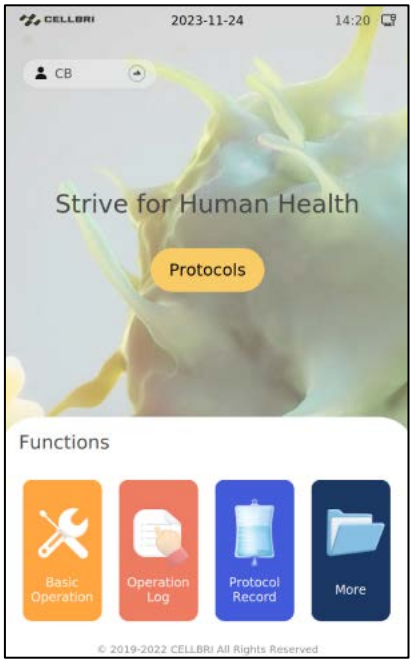
自检运行中

自检完成存在异常



登录界面

3.2.2 Main interface of the touchscreen



Swipe the card to obtain the user name, enter the password, and click on "Login" to enter the main interface:

Step	Description
1	User display
2	Choose protocol
3	Display the column of the main menu (basic operations, operation logs, process records, more functions).

3.2.3 Basic Operation Function

In addition to the process of the operating system, the main interface of the touchscreen also has some basic operating functions, as shown in the following table:

Menu	Description
Basic operation	Temperature control, inflow setting, mixing setting, tubing control
Operation log	Available for viewing and exporting
Process record	Available for viewing and exporting
More functions	Including user management, system settings, permission management, system log, pressure sensor calibration

- Basic operation

1. Temperature control: Please set the value and time for temperature control, and click the start button to perform the temperature control operation.

2. Inflow setting: Input the required volume, and you can choose whether to complete the inflow in full (if YES, the bubble sensor detects the bubble in the liquid tubing as the stop criterion), and click the start button to inflow liquid.

3. Please set the start position of mixing, the end position of mixing, the pressing-in time, the waiting time after pressing-in, the pulling-out time, and the waiting time after pulling-out. You can choose whether to reset after termination according to your requirements (If YES, it will automatically reset to the position of 0 after mixing ends). Click the start button to perform the mixing operation.

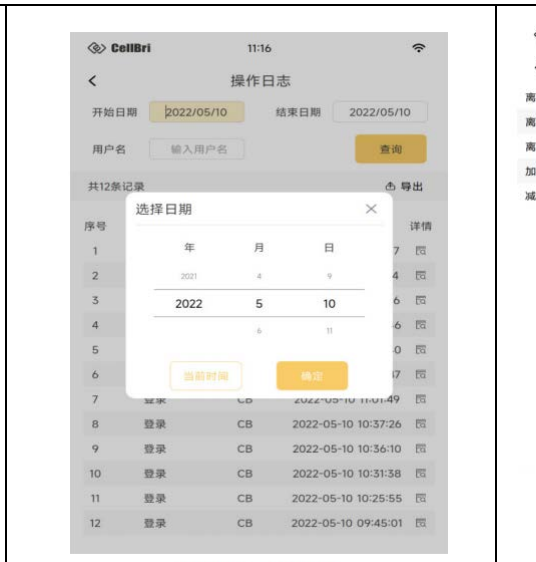
4. Tubing processing: Select the required peristaltic pump number, flow direction, and flow rate, and input the required time. You can select the corresponding valve number according to the situation requirements (valve 21 is connected to the mixing bag, and valve 22 is connected to the exhaust valve). Click the start button to perform the tubling processing operation.(图

片？）

- Operation log

Click on the operation log to enter the log interface, select the corresponding time, and click on the search to view the operations performed by the user, as shown in the following figure:

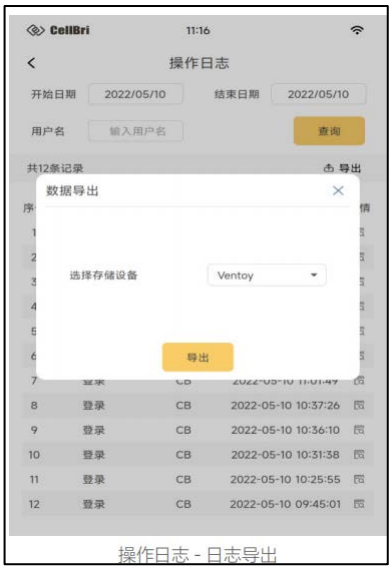
操作日志界面



操作日志 - 日期选择

操作日志 - 日志详情

Operational logs can be exported to the storage device. Click the 导出 button to batch export the retrieved process records to the storage device, and a user password verification is required during export.

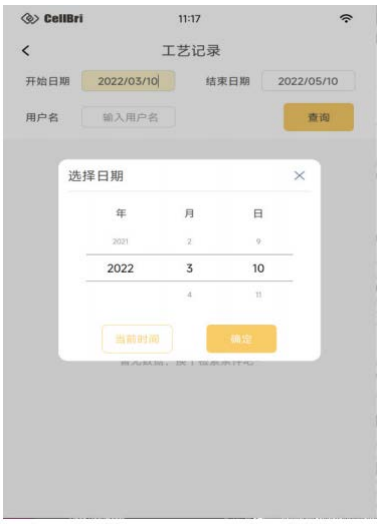


操作日志 - 日志导出

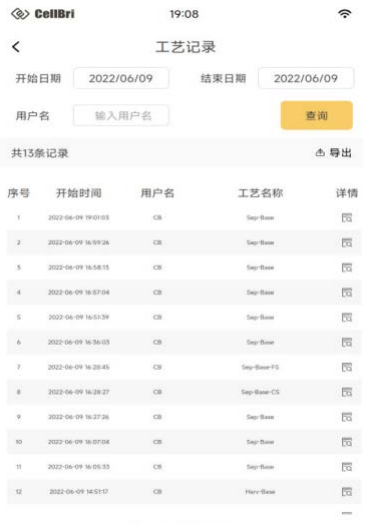
- Process record

Click on the process record to enter the process record interface, select the corresponding time, and click on the search to view the detailed process data that has been completed. See the following figure for details:

工艺数据

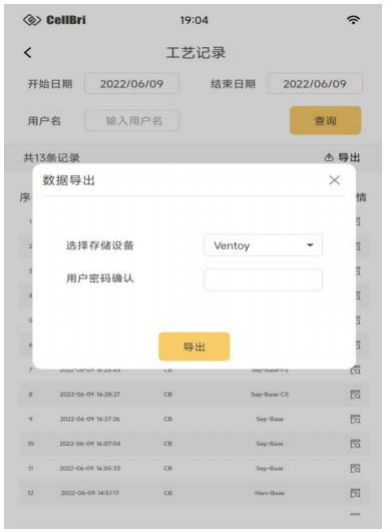


日期选择



工艺记录界面

Process records can be exported to the storage device, and the retrieved process records can be exported in batches. User password verification is required during export. Click the 导出 button in the process details interface to export a single process record, and user password verification is required during export.



工艺记录 - 工艺详情导出

工艺详情界面

- More functions

More functions include user management, system settings, permission management.

1) Click on "User Management" to enter the user management interface. The administrator can click the "+" button to add ordinary users, or click the "delete" button to delete ordinary users, and can also modify their own password and user name or modify the password and user name of ordinary users.

Note: User name rules: The length of the user name must be between 2 and 16.。

Password rules: The password must start with a capital letter and can only contain letters, numbers, and underscores. The password length must be between 8 and 16.

Users with higher permissions can create or deactivate IC cards for ordinary users with lower levels: Click to create an IC card, place the IC card in the RFID sensing area after the pop-up box, and the system will automatically enter the card number, and click OK to create an IC card. Click to deactivate the IC card, place the IC card in the RFID sensing area after the pop-up box, the system will clear the card number information in the database, and clear the user information of the IC card.

2) Click on the system settings to enter the system settings interface. You can set the sleep time, local IP, and local gateway for the system. After inserting a USB drive with an upgrade package, clicking on software upgrade and firmware upgrade will perform the corresponding upgrade operation, and you can view the current software version number on the system settings page.

3) Click on permission management to enter the permission management interface. It is possible to modify the permissions for user groups with a lower level than oneself (Super user: has all permissions, management user: cannot perform permission management, ordinary user: cannot perform permission management, system settings, and user management).

3.3 Data privacy and security

All exports of data (e.g., logs and configurations) from the Gentle P-Pac equipment system must be controlled.

3.3.1 System protection

Storage devices and terminals used for exporting files, logs, and sensitive data from the Gentle P-Pac equipment system must be protected with commercially available regular anti-malware and anti-virus software. Our company will not be liable for any subsequent problems and/or data privacy issues caused by the presence of malware in the storage device.

The internet connection at the site where users finally use the equipment must comply with international security standards, and be fully protected by commercially available regular firewalls and anti-virus systems. Our company will not be responsible for any data loss and/or data privacy and network security threats if there are vulnerabilities or compliance issues in the user's enterprise network.

3.3.2 Local user's authentication and authorization

All user accounts and operations are managed by the administrator account. We will provide the user with an administrator account after the equipment is installed and debugged. Of course, the user must establish and implement the norms for the use and management of the equipment by themselves.

As a part of the equipment workflow, the information system will store the user's name, but our company will not use this information for any other purpose. Please decide for yourself whether to provide your real name as user account information. It is recommended to consider both personal privacy and the need for a unique identifier for the account.

If the administrator makes any changes to the relevant configurations regarding the software security, making the software more vulnerable to security problems, our company will not assume any responsibility for the consequences resulting therefrom. All security settings are highlighted in

different ways on the user interface.

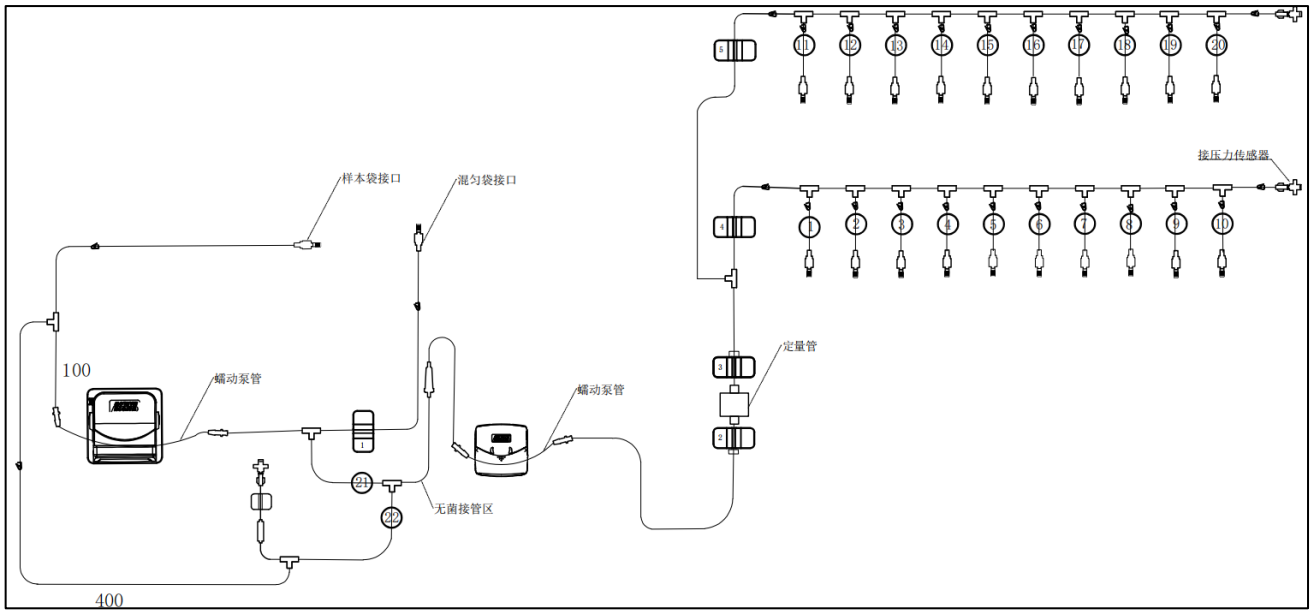
3.3.3 Data Confidenciality

Gentle P-Pac equipment may collect relevant information for system diagnosis and support, but our company will not use this information for any other purpose. However, the user is responsible for ensuring the privacy of sensitive data is not leaked, such as the donor ID in the logs. It is recommended that users collaborate with our company to prevent the leakage of sensitive information.

3.4 Important instructions of the consumable disposable kit

After receiving the consumable package bag, check the sterilization label (blue indicates aseptic), product code, production date, whether it is within the valid period, and whether there is an anti-counterfeiting identification card.

3.4.1 Diagram of common consumable kit



- The Gentle P-Pac disposable sub-packaging consumable kit includes a quantitative tube, tubing, and tubing support plate.
- The Gentle P-Pac disposable sub-packaging consumable kit is equipped with a 0.22μm hydrophobic filter. This filter can be used for aseptic exhaust of the cryopreservation bag.
- There is a two-dimensional code on the consumable packaging bag, which collects the batch information of the consumable and the consumable code, etc.

3.4.2 Points for installing the consumable kit

Please connect and install the disposable kit according to the quick operation guide.

3.5 QRcode scanner holder

The Gentle P-Pac equipment is equipped with a QRcode scanner holder, which is used to read the two-dimensional code information of the consumable kit and the quantitative tube.

4 Installation

About this chapter

This chapter provides on-site requirements and preparation work that need to be performed before the operation of Gentle P-PAC. In addition, it also provides instructions for moving Gentle P-PAC.

About delivery and installation

- Gentle P-PAC will be stored in a specially made packaging box for transportation.
- Initial installation and system testing must be carried out by the maintenance engineer or application engineer of our company.

Note: Please keep all the original packaging materials. If the system needs to be repackaged for transportation or other purposes, it is necessary to use the original packaging materials to ensure the safety of the system.

In this chapter

Section		Page number
4.1	Installation precaution	**Error! Bookmark not defined.**
4.2	Environment requirements for equipment placement	36
4.3	Movement of equipment	**Error! Bookmark not defined.**
4.4	Wire connection	**Error! Bookmark not defined.**
4.5	Installation of protocol procedures	**Error! Bookmark not defined.**

4.1 Installation precaution

Depending on the weight and volume of the device, at least two people must work together to lift and move the equipment safely.

Position needs to be maintained upright during transport.

If the equipment is moved to another location, the administrator has the responsibility to ensure that it is installed safely.

Packaging content:

- Gentle P-PAC * 1
- National standard power line * 1
- Fuses * 4
- Certificate * 1
- Warranty card * 1
- RFID card * 5
- Gentle P-PAC User's Guide * 1
- QRcode scanner holder * 1

4.2 Environmental requirements for equipment placement

4.2.1 General requirements

The placement position of the equipment must meet the following general requirements:

- The room shall be equipped with an exhaust and ventilation device
- The equipment shall not contact the heat source, such as direct sunlight
- The dust content in the air should be minimized
- Equipment shall not be placed in the vibration environment
- Do not block the air vents behind the equipment

4.2.2 Environmental requirements

Please operate, store, and transport the Gentle P-PAC equipment under the following conditions:

Parameter	Storage and transportation	Operational environment
Temperature	-40℃ to 55℃	From + 15℃ to + 30℃
Relative humidity	From 10% to 90%	From 10% to 90%
Maximum altitude	2000 m	2000 m
Maximum atmospheric pressure	70KPa-106KPa	70KPa-106KPa
Use the location	not applicable	Indoor use only, not recommended in wet locations

4.3 Movement of equipment

If the Gentle P-Pac equipment needs to be moved, the administrator has the responsibility to re-

inspect the equipment based on the requirements described in this guide.

Authorized personnel must install the Gentle P-Pac equipment based on the instructions described in this chapter.

If there are any problems during the installation of the Gentle P-Pac equipment, please contact the authorized after-sales or technical personnel of our company to obtain support.

If you need to transport the system to another site, please contact the authorized after-sales or technical personnel of our company to obtain support.

4.3.1 Lift the Gentle P-Pac equipment

At least five people are required to lift the Gentle P-Pac equipment, follow the following steps:

Step	Operation
1	Make sure that the Gentle P-Pac equipment and any connected attachments are cut off the power.
2	One person stands on each side of the equipment, separately holds one side of the bottom, and puts the other hand on the front or back side of the equipment to ensure stability.
3	Make sure that everyone has firmly grasped the equipment, then lift it from the workbench.

4.3.2 Move the Gentle P-Pac equipment

Please follow the following steps：

Step	Operation
1	Make sure that the Gentle P-Pac equipment and any connected attachments are cut off the power.
2	Lift the Gentle P-Pac equipment and put it on a stable hand trolley capable of bearing its weight.
3	Move the Gentle P-Pac equipment to the environment that meets the placement requirements.
4	Connect the power, and confirm that the equipment powers on normally and displays the login screen.

4.4 Wire connection

When the Gentle P-Pac equipment is shifted to a different position, it has to be reconnected to the power supply and network (optional).

General requirements

- Protective earthing. This device must be connected to the earthed power socket.
- Power cord. You can only use the power cord provided or approved by Cellbri.

- Power voltage. Before connecting the power cord, please make sure that the power voltage of the socket is consistent with the voltage indicated on the instrument.
- Keep the power switch and power cord in a conveniently accessible position. Do not cover or block the power switch and power cord, keep the power switch always in an easily accessible position, and ensure that the power cord with a plug is always easy to disconnect.

4.5 Installation of protocol procedures

The Gentle P-Pac equipment is equipped with standard protocol procedures when it leaves the factory. If subsequent changes or new protocol procedures are required, please contact the authorized personnel of our company to get support.

5 Preparation

About this chapter

This chapter shows the user management of the Gentle P-PAC equipment..

In this chapter

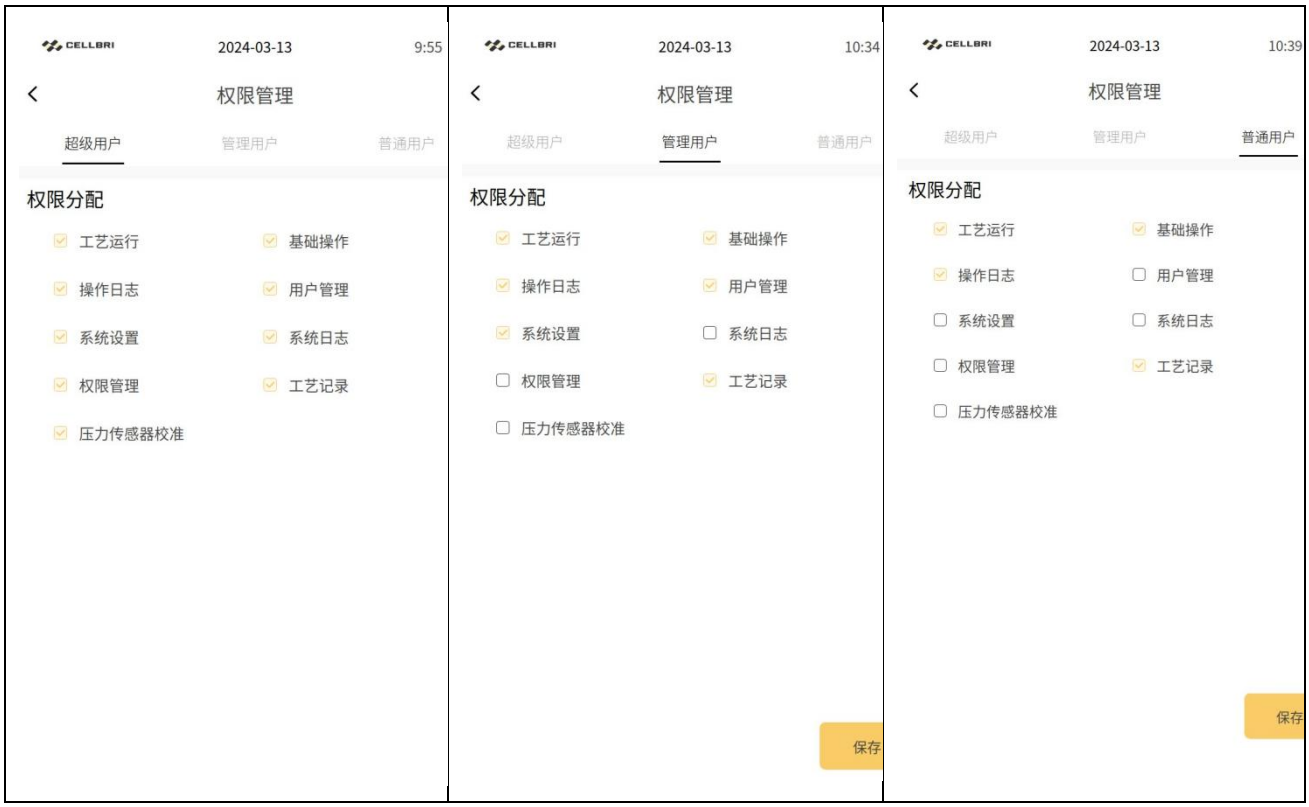
Section		Page number
Error! Bookmark not defined.5.1	User Role Description	40
5.2	User Authentication	**Error! Bookmark not defined.**0
5.3	User Establishment	41
5.4	User Editing	44
5.5	User Deletion	**Error! Bookmark not defined.**

5.1 User Role Description

This section describes user authentication, and provides instructions for creating and modifying user accounts on the Gentle P-Pac equipment. There are three user roles:

- Ordinary user (operator) (laboratory user)
- Administrative user (administrator) (laboratory administrator)
- Super user (supervisor) (senior laboratory user with extended permissions)

The following table shows the activity permissions of each user role:



5.2 User identification

5.2.1 User name and password rules

The length of the user name is between 2 and 16 characters, and the password rules: the password must start with a capital letter and can only contain letters, numbers, and underlines, and the length of the password must be between 8 and 16 characters.

5.2.2Default super user account

The Gentle P-Pac equipment possesses a default super user (there can only be 1 super user):

User ID： admin

Password： SQ123456

5.2.3 Initial startup and login

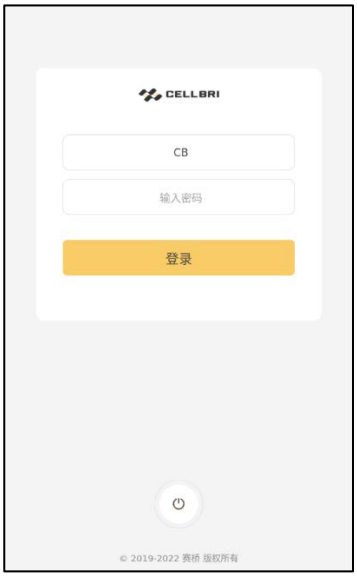
When powering on the Gentle P-Pac equipment for the first time, only the super user can be logged in and create accounts for other users.

5.3 User Establishment

Higher-privileged users can create accounts for low-privileged users, so the super user can create accounts for administrative users and ordinary users, and the administrative user can create accounts for ordinary users. Follow the following steps for details:

Step	Operation
1	Click on“More function”-“User administration”
2	Click on the " + " button in the lower left corner to add users, and enter the user name, real name, password, and user level.
3	Click on "Create IC card", place the IC card in the RFID sensing area after the pop-up box, and the system will automatically enter the card number. Note that do not move the card during the card swiping process until the successful entry is displayed before removing the card.
4	After being confirmed, it returns to the user management interface. At this moment, the new user name

<table>
<tr><td></td><td>is listed, and the role is displayed under the user ID in the left column area.

</td></tr>
<tr><td>5</td><td>Return to the login interface and log in again using the new account and new password.
 
</td></tr>
</table>

6	After successful login, it automatically enters the main interface.

Note: Once a user is saved, its username cannot be edited again. The username of a deleted user cannot be used continuously.

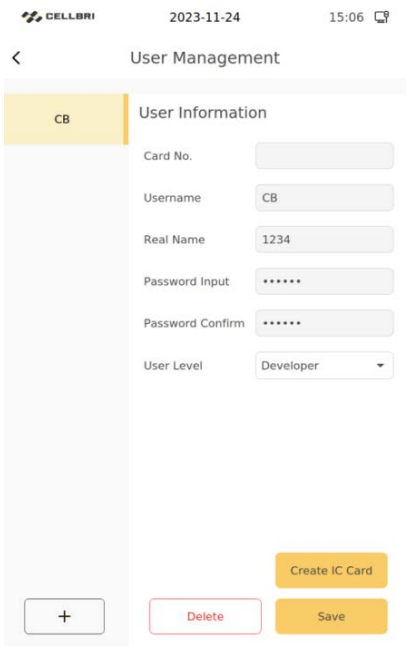
5.4 User Editing

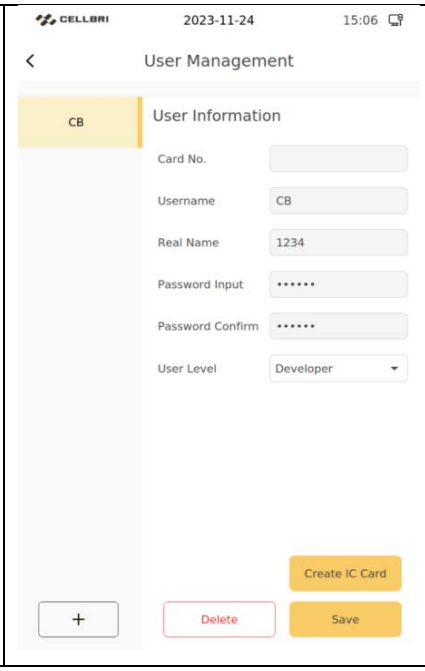
Management users and super users can enter the "user management" interface to edit users, follow the below steps:

Step	Action
1	Enter the interface of "More Functions" - "User Management", click on the user to be edited, and you can modify the card number, password, user level, etc. of the user.
2	Click " Save " to save the changes, and return to the login interface for verification.

5.5 User Deletion

Management users and super users can enter the "user management" interface to delete users, follow the below steps:

Step	Action
1	Enter the interface of 'More Functions' - 'User Management', click on the user to be deleted 
2	Click on " Delete ", at this time, a prompt appears showing "Are you sure to delete this account?", after clicking on confirm, this user will be deleted, and it shows that the deletion is successful. （需补图，询问提示框和删除成功的提示框）
3	Click on "confirm" to be completed, and after being completed, it automatically returns to the "user management" interface.


CELLBRI
2023-11-24
15:06
User Management
CB
User Information
Card No.
Username
CB
Real Name
1234
Password Input
Password Confirm
User Level
Developer
Create IC Card
+
Delete
Save

6 Equipment Operation

About the chapter

This chapter shows how to operate the Gentle P-PAC equipment.

If you need protocol-specific operation manual, please contact us.

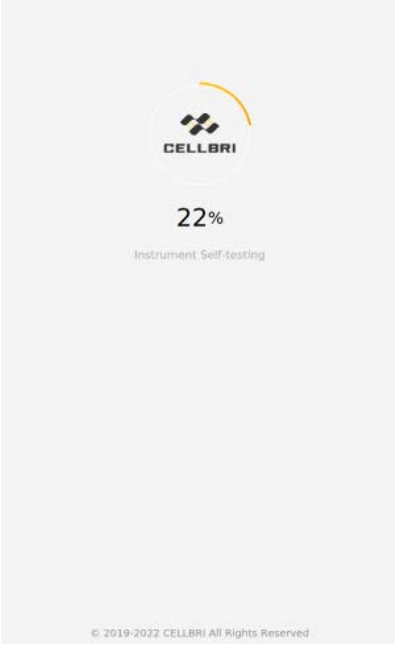
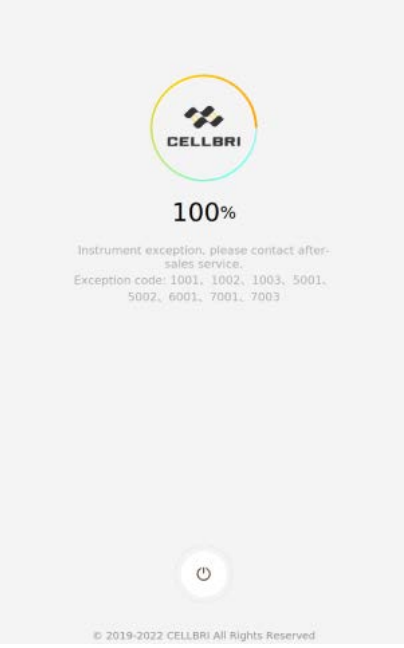
In this chapter

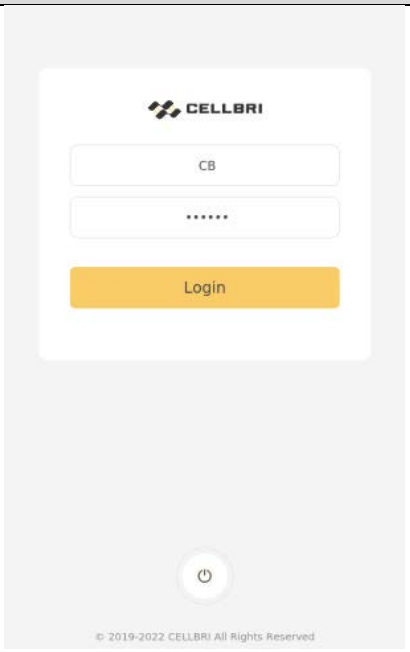
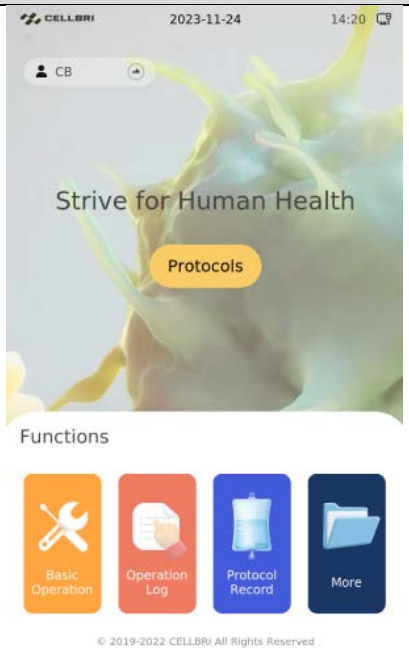
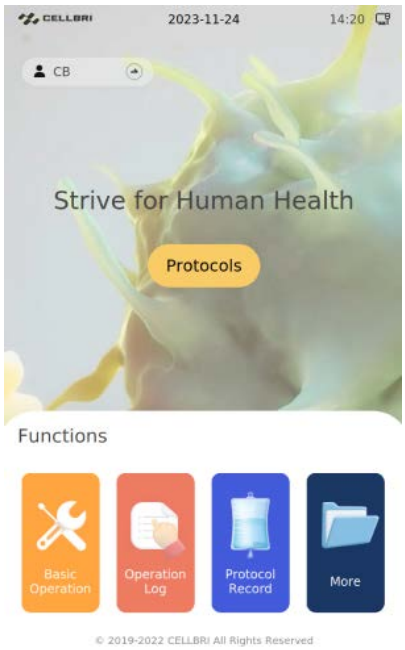
Section		Page number
6.1	Startup and Shut Down	44
6.2	Protocol Documents	**Error! Bookmark not defined.**1
6.3	System Setting	55

6.1 Startup and shut down

6.1.1 Start up the Equipment

Follow the below steps to start up the Gentle P-PAC equipment and log in:

Step	Operation
1	Turn on the power switch(ON) located on the rear of the instrument.
2	Power-on test: If there is no abnormality, it directly enters the login interface; If there is an abnormality, an error code will be displayed when reaching 100%, Please contact the Cellbri technical personnel.  
3	Swipe card to get the username, input the password, and click ‘ Login ’ to enter the main interface.

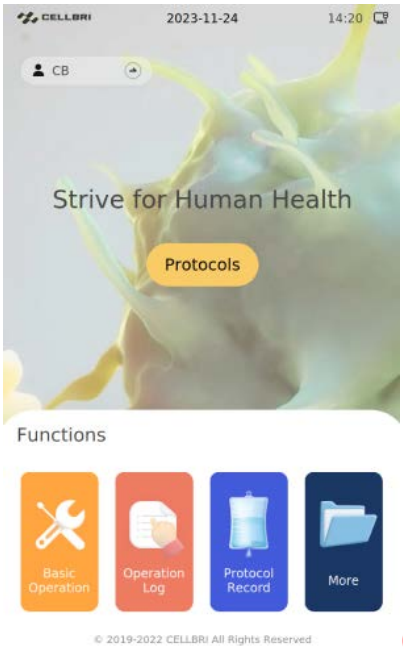
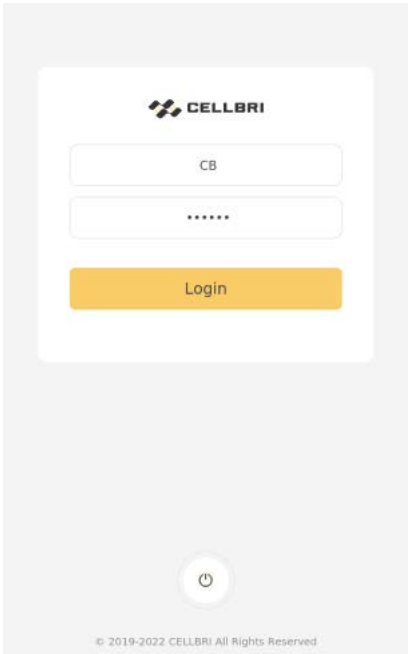
Step	Operation
	 
4	Click the “Protocols”on main interface to access the protocol interface. Then click on the target process to enter the process operation.  (需补图-工艺列表)

6.1.2 The initial login to the equipment

When initially logging in the device, the temporary super user password provided by cellbri must be used.

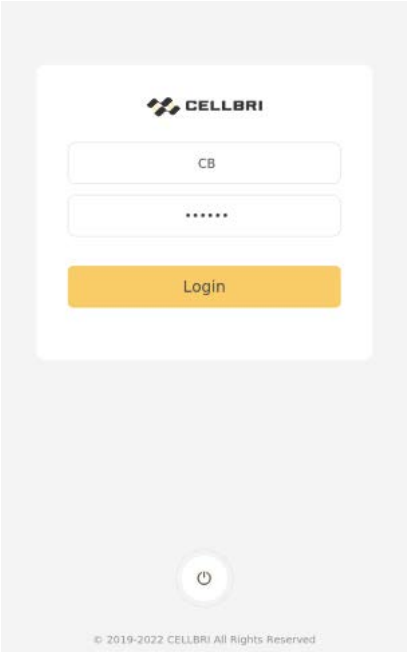
6.1.3 Log out

Follow the below steps to log out：

Step	Operation
1	Click on your username in the upper left corner of the main interface. Prompt: "Do you want to exit the login interface?"  (需补图，退出的确认弹框)
2	Click OK, after logging out, the screen displays the login interface.  (需换图，此时不应该显示用户名和密码)

6.1.4 Shut down the equipment

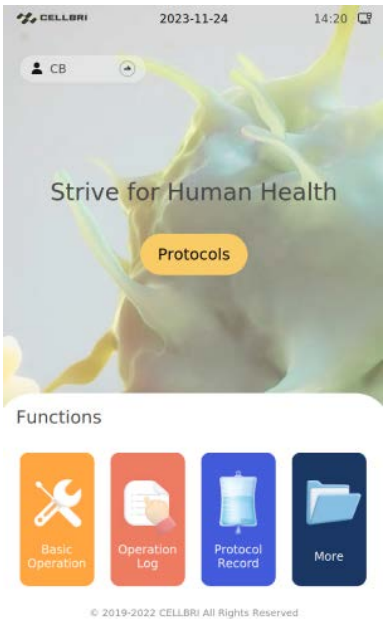
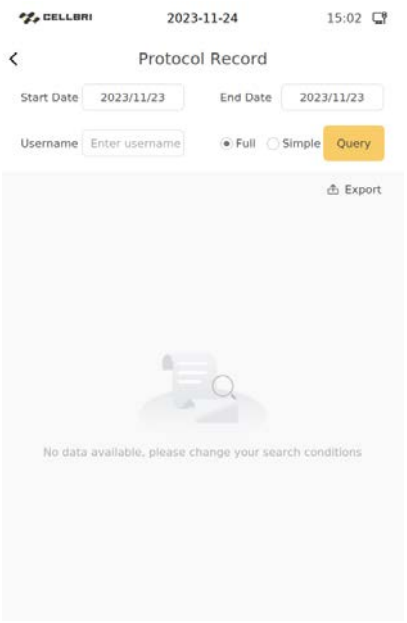
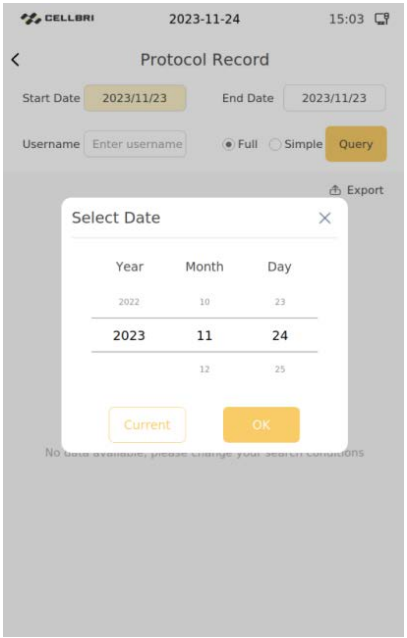
Follow the below steps to shut down the Gentle P-PAC equipment：

Step	Operation
1	Click " ", prompt "Are you sure to shut down the system?". Then click OK, and the device is powered off.  (需换图，不应显示用户名和密码，同时需补提示图)
2	Turn off the power switch(OFF) located on the rear of the instrument.

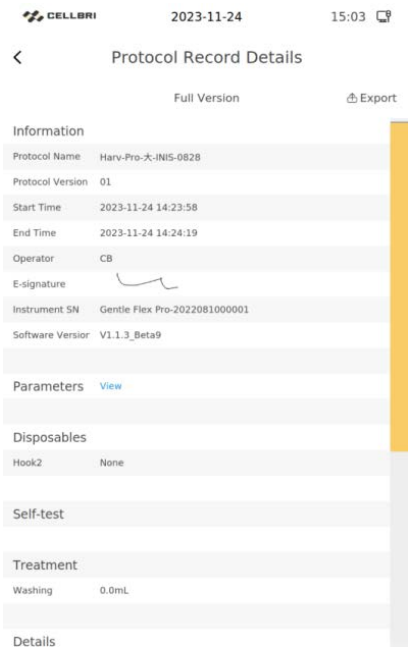
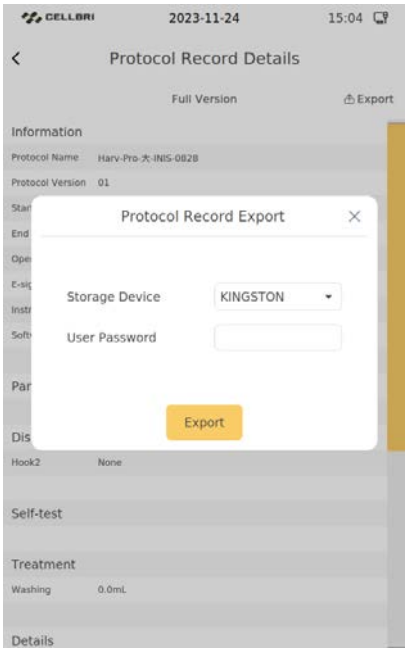
6.2 Protocol Documents

6.2.1 Protocol Record

The equipment automatically records information such as time, samples, reagents, parameters during the operation process, and generates process records. The specific operation steps for viewing and exporting are as follows:

Step	Operation
1	Click the “Protocol Record”on main interface to access the protocol record interface.  
2	Choose the start date and end date, input the user name, and then click on “ Query ” to search for the process record.  If you click on "Current Date", it will automatically select the date of the day.

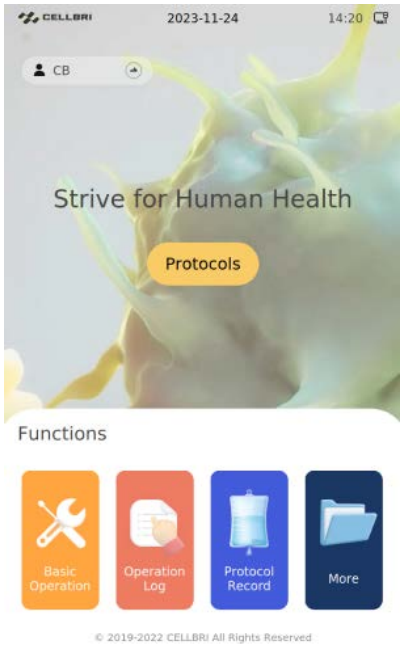
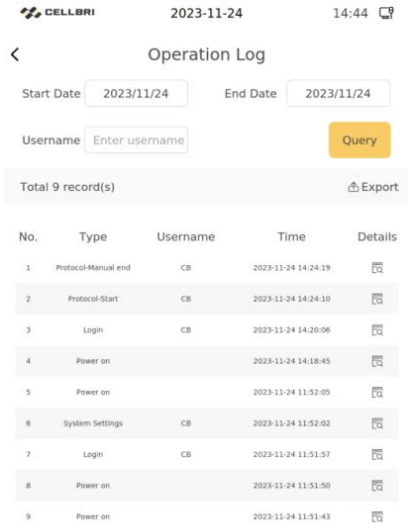
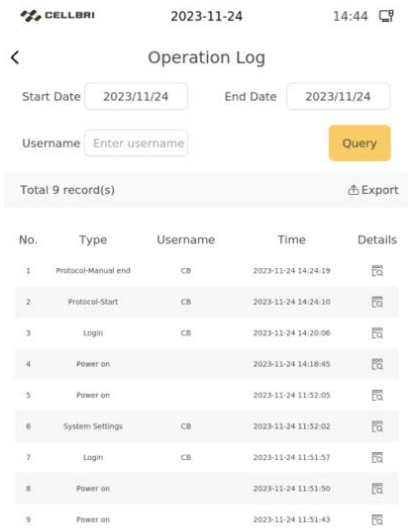
<table>
<tr><td>3</td><td>Click on "Details" to check the specific records, and pull the yellow bar up and down to scroll and look through.

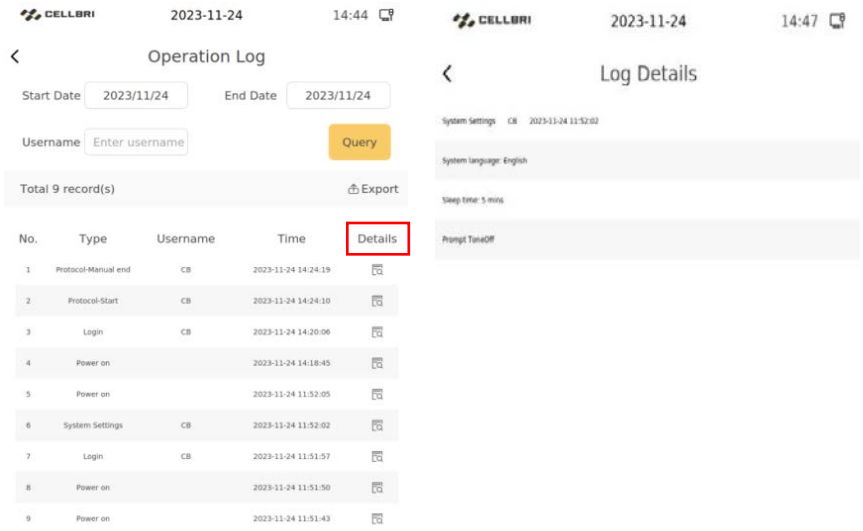
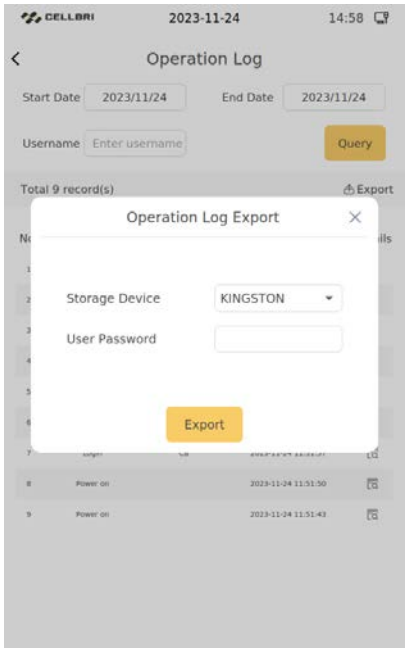

</td></tr>
<tr><td>4</td><td>Insert the USB drive into the USB port of the equipment，then click the “ Export ” in the search interface to batch export the retrieved protocol records.
User password verification is required during export. You can click the “ Export ” in the protocol details interface to export individual protocol record. User password verification is required during export. (补充工艺记录导出图片)
 
</td></tr>
</table>

6.2.2 Operation Log

The equipment automatically records every step of the performed operations into the operation

log. In the "operation log" interface, users can browse the recorded operation data, and also perform operations such as querying and exporting for historical operations. The specific operations are as follows:

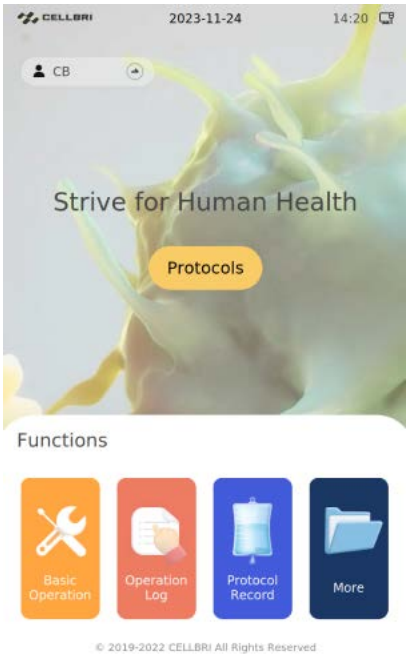
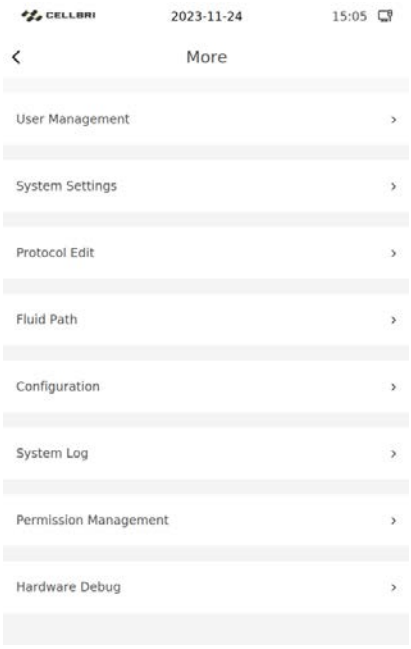
Step	Operation
1	Click the “Operation Log” on main interface to access the operation log interface.  
2	Choose the start date and end date, input the user name, and then click to “ Query ” to search for the operation log.  If you click on "Current Date", it will automatically select the date of the day.

3	Click on "Details" to check the specific log. 
4	Insert the USB drive into the USB port of the equipment, then click the "Export" in the search interface to batch export the retrieved operation log. User password verification is required during export. You can click the "Export "in the protocol details interface to export individual operation log. User password verification is required during export. 

6.2.3 System Log

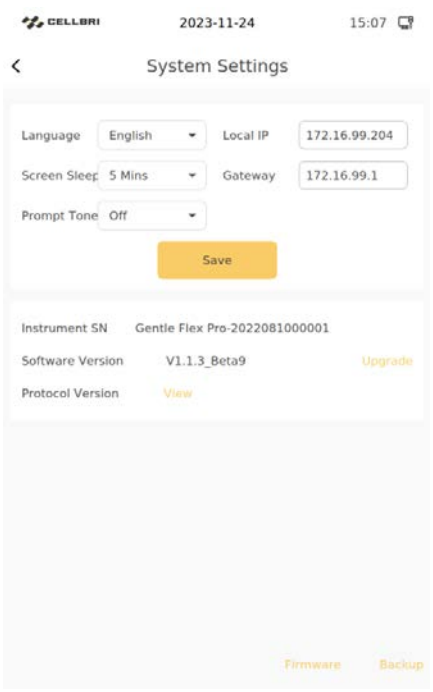
The system log contains technical information such as sensor values, and after being exported, it

can be used to diagnose faults or performance issues. The specific operation for exporting are as follows:

Step	Operation
1	Click the “Operation Log” on main interface, then click the “System Log”to access the system log interface.  
2	Choose the start date and end date, input the user name, and then click to “ Query ” to search for the operation log. (需补图)
3	Insert the USB drive into the USB port of the equipment，then click the” Export “in the search interface to batch export the retrieved operation log. User password verification is required during export. You can click the” Export “in the protocol details interface to export individual operation log. User password verification is required during export. (需补图)

6.3 System setting

System Settings Interface	Operation



6.3.1 Language

Users can set the language to Chinese or English.

6.3.2 Screen Sleep

Users can set the time for Screen Sleep Time after stopping operation. The optional time are: never, 5 minutes, 10 minutes, 20 minutes, 30 minutes, 1 hour, 2 hours, and 4 hours.

6.3.3 Local IP、Gateway

Turn on the equipment to automatically obtain the local IP and gateway, and users can also set it manually.

6.3.4 Software/Firmware Upgrade

1) Prepare the firmware for upgrade and a USB drive formatted as FAT32, and copy the software/firmware upgrade package to the USB drive;
2) Insert the USB drive into the USB interface of the device;
3) Click "Software/Firmware Upgrade" (if the upgrade package does not exist in the USB drive, it will prompt "The upgrade package does not exist");
4) A prompts "Whether to upgrade to the XXXX version", click OK;
5) It prompts that the software upgrade is successful, and the device will automatically restart.

7 Maintenance

About this chapter

This chapter explains the instructions for cleaning the Gentle P-PAC.

Any modifications, adjustments, maintenance, or repairs to Gentle P-PAC should be performed by the technically authorized personnel of our company.

Only spare parts and accessories approved or provided by our company can be used for maintenance.

In this chapter

Section		Page number
7.1	Maintenance	**Error! Bookmark not defined.**
7.2	Cleaning	**Error! Bookmark not defined.**
7.3	Cleaning before planned maintenance service	**Error! Bookmark not defined.**
7.4	Warranty	**Error! Bookmark not defined.**
7.5	Power Supply and Fuse	**Error! Bookmark not defined.**

7.1 Maintenance

Based on the application situation of Gentle P-Pac, users need to develop and implement proper equipment maintenance plans.
The maintenance that users need to do includes cleaning the outer surfaces of the following components:

- The Gentle P-PAC equipment
- Power cord

Notes: If a liquid leak occurs, or you use the refrigeration module of Gnetle P-PAC, cleaning imediately is necessary.

Arrange regular maintenance together with our company to guarantee that the equipment gets the correct maintenance operations. Any modification, adjustment, maintenance or repair of Gentle P-PAC should be performed by the technically authorized personnel of our company.

Only the spare parts and accessories approved or provided by our company can be used for repair.

7.2 Cleaning

Please follow the following steps to clean the outer surface of the Gentle P-PAC equipment：

Step	Operation
1	Shut off the power and withdraw the power plug from the power socket
2	Soak the gauze, bandage or soft paper with warm water to clean all the outer surfaces. Dry the wet surfaces with dry soft paper, and repeat the wiping operation as needed.
3	Use the sterilization solution (e.g. 75% ethanol) to disinfect all the surfaces.
4	In the event of liquid overflow or leakage into the interior of the equipment, please contact the manufacturer in time, and do not turn on the power or run the equipment
5	Please deal with the waste by following the validated standard operating procedures and local regulations.

7.3 Cleaning before planned maintenance/service

To ensure the protection and safety of maintenance personnel, all equipment and work areas must be clean and free of any hazardous contaminants before a maintenance engineer begins the maintenance.

7.4 Warranty

Shenzhen Cellbri Bio-Innovation Technology Co., Ltd. (hereinafter collectively referred to as "the Company") provides a 12-month warranty service for the main unit of the product and a 6-month warranty service for the accessories of the product. The warranty period starts from the date when the product is delivered and transported to the customer. If the equipment fails within the warranty period, the customer should promptly notify the Company to repair, adjust, or replace the faulty equipment or

components.

The Company guarantees that professionals who have received professional training will provide relevant services to users.

The following failures or damages are not covered by the warranty:

- Failures or damages caused by improper use or human negligence.
- Failures or damages caused by unstable or out-of-range power input.
- Failures or damages caused by force majeure such as fires and earthquakes.
- Failures or damages caused by improper operation or maintenance by unqualified or unauthorized maintenance personnel.
- Failures or damages caused by the use of components or accessories not approved by Shenzhen Cellbri Bio-Innovation Technology Co., Ltd.
- Other failures or damages not caused by the device or component itself.

In the process of use, if you encounter any problem that cannot be handled, please contact us in time. In order to prevent any unexpected situations, do not open or disassemble the device or perform any operations.

7.5 Power Supply and Fuse

7.5.1 Power supply

Specifications: AC 100 - 240V, Frequency 50/60Hz, 450 VA.

7.5.2 Fuse

Specifications: Dimensions 5x20mm, F6.3AL250V, glass quick-acting fuse.

If necessary, replace the fuse as follows:

1) Turn off the power and unplug the cable plug from the device power socket on the back of the device.

2) Remove the fuse cover.

3) Remove the faulty fuse.

4) Ensure that the specifications of the replacement fuse (voltage, current, size, type) are correct.

5) Insert the new fuse and close the fuse cover.

8 Troubleshooting

About this chapter

This chapter describes the alarms or errors that may occur during the use and the relevant information about troubleshooting.

In this chapter

Section		Page number
8.1	General Troubleshooting	**Error! Bookmark not defined.**

8.1 General Troubleshooting

General Troubleshootingof Gentle P-Pac is following：

Components	Fault	Corrective Actions
Power supply	Instrument is not powered on	Check the power switch and the instrument switch
	Fuse is damaged	Replace the fuse
Peristaltic pump	Excessive or insufficient flow	Check if all white manual clamps are opened.
		Check if the input and output bags are correctly connected to the tubing of the disposable dispensing consumable kit.
		Check if the pump tubing is damaged, and correctly installed.
		With the power off, check if there is any foreign matter blocking inside the peristaltic pump.
		Contact the service representative of our company.
Temperature control	Refrigeration unit does not work when turn on it.	Restarting the system
		Contact the service representative of our company.
	Refrigeration machine makes too much noise.	Contact the service representative of our company.
Pinch valve	The light does not come on when the pinch valve is turned on.	Manually control the opening and closing of the valve to check the status of the valve indicator light. If there are still problems, please contact our company.

Note: Some faults can be corrected by restarting the system. You can press the power switch on the side of the device to turn off the power, wait for 2 minutes, and then restart to confirm whether the fault has been removed. If it still remains unsolved, please turn off the power of the device and contact our company or the dealer in a timely manner.

9 Regulation information

Some of the regulations or standards referred to or quoted by this system are as follows：

- IEC 61010: 2010+A1: 2016
- IEC 61010-2-051: 2018
- IEC 61010-2-081: 2019
- IEC 61010-2-011: 2019
- IEC 61326-1: 2020
- RoHS, Directive 2011/65/EU
- REACH Regulation (EC) 1907/2006
- WEEE Directive 2012/19/EU
- Toxic Substances Control Act
- California Proposition 65
- 21 CFR Part 11
- FCC Part 15C
- IEC 62304: 2015
- ISO 15223-1: 2021

Appendix A: Product documentation and technical support

Customer service and technical support

Please visit www.cellbri.com to obtain the latest service and support information

- Product support information
- Product frequently asked questions
- Software, patches, and updates
- Train on applications and devices
- Orders and web support
- Product documents
- User guides, operation guides, and protocols

Note: For the documentation information of reagents and chemicals produced by other manufacturers, please contact the relevant manufacturers.

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Gentle P-Pac High-precision Automated Fill & Finish System is only used for liquid dispensing. It is not suitable for clinical and human infusion applications without official approval. Biopharmaceutical manufacturers should be responsible for ensuring the purity, potency, safety, and identity of the final product and obtaining appropriate regulatory approvals.

Important License Information

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Using this product indicates that the user has accepted all the terms and conditions of the applicable limited-use license labels.

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