For research, or production of cell, gene, or cellular tissue products.

赛桥生物

Gentle Flex Pro

High Throughput Cell Processing System

High Throughput Multi-Functional Fully Enclosed Automated Cell Processing System

User Guide

User Guide

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

Disclaimer: To the extent permitted by law, Shenzhen Cellbri Bio-Innovation Technology Co., Ltd. and its subsidiaries shall not be liable for any special, incidental, indirect, punitive, or multiple damages related to this document, including its use. In all cases, users of the instrument must comply with all operating instructions in this manual. If deviations from the operating requirements and precautions in this manual result in instrument malfunction, errors, damage, loss, or other consequences, neither this company nor its subsidiaries shall be held responsible.

The high throughput multi-functional fully enclosed automated cell processing system is only intended for applications such as cell separation, concentration, washing, and incubation. It is not suitable for clinical and human infusion applications without official permission. Biopharmaceutical manufacturers shall be responsible for ensuring the purity, efficacy, safety, and identity of the final product and obtaining appropriate regulatory approvals.

Warranty:

The company provides a 12-month warranty service for the product (main unit) and a 6-month warranty service for accessories. The warranty period begins from the date of product shipment to the customer. If the instrument malfunctions within the warranty period, the customer should promptly notify Shenzhen Cellbri Bio-Innovation Technology Co., Ltd. for repair, adjustment, or replacement of the faulty instrument or parts. We guarantee that any service provided to the customer will be carried out by personnel who have received specialized training.

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

- Failures or damages caused by improper use or human error.
- Failures or damages caused by unstable or out-of-range power input.
- Failures or damages caused by force majeure events such as fires and earthquakes.
- Failures or damages caused by unauthorized personnel operating or improperly repairing the instrument.
- Failures or damages caused by the use of parts or accessories not approved by Cellbri.
- Other issues not caused by the instrument or its components themselves.
- Warning: In case of any issues during use that you cannot address, please contact us promptly. To prevent any accidents, do not open the machine for operation.

Revision History:

Revision	Date	Description
V01	6/10/2022	New document: User guide for new work
V02	2/9/2023	Updated manual cover, address, and email information Chapter 5: Troubleshooting and weighing calibration content

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Contents

Chapter 1 Product Information

Before using this product, please read and understand the information in the "Safety" annex of this document.

Product Description

Product Name: High Throughput Multi-Functional Fully Enclosed Automated Cell Processing System

Product Model: Gentle Flex Pro

Product Structure and Composition: The High Throughput Multi-Functional Fully Enclosed Automated Cell Processing System (referred to as 'Gentle Flex') consists of five main components: the mechanical structure platform, centrifugal unit, fluid path control unit, temperature control unit, and electrical measurement and control platform.

Gentle Flex is a fully automated, digital, fully enclosed, and flexible cell processing instrument capable of executing various cell processing steps for different cell types. It is suitable for use in pharmaceutical companies, research centers, and pathology research institutions.

The system requires the use with a disposable cell processing kit. The disposable cell processing kit is specifically designed for cell processing and is suitable for cell processing steps, including cell separation, buffer exchange, cell washing and concentration, and dispensing.

Gentle Flex employs user-programmable software. The open design and integrated modules of the software allow users to monitor cells in real-time, making it easier to optimize protocols.

Functions

The Gentle Flex Pro High-Throughput Multi-Functional Fully Enclosed Automated Cell Processing System can be used for various workflow processes including cell separation, cell concentration, cell washing, and preparation dispensing.

- Disposable chamber with low shear force reduce cell damage and maintain cell viability
- High-throughput, large-volume cell processing capability
- Integrated sampling port provides real-time sample collection
- Cell separation process can handle blood sample ranging from 50mL to 400mL
- Seamless transition from protocol development to GMP manufacturing within the same system
- High-precision sample processing and dispensing

System Overview

Instrument Description
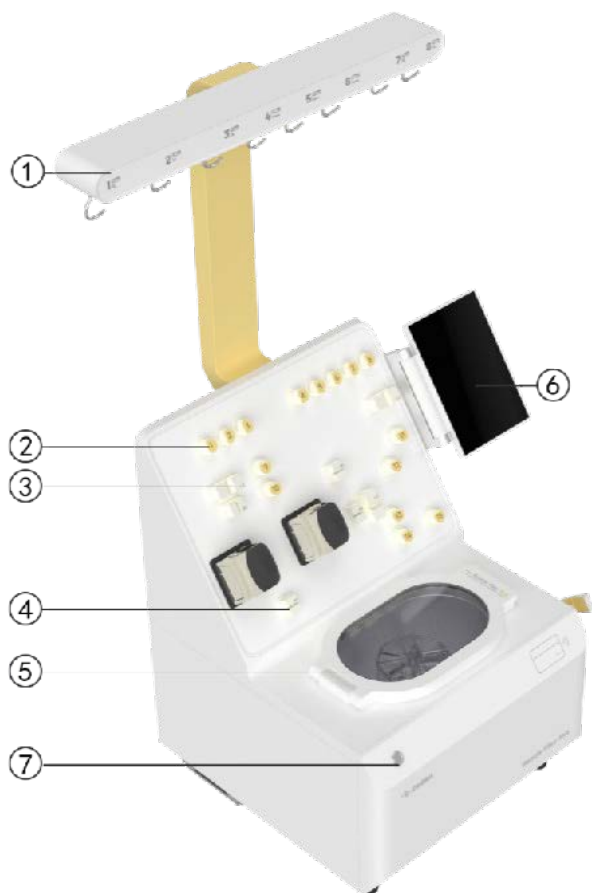
Figure 1 Instrument - Front View

①Weighing Module　②Pinch Valve　③Bubble Sensor　④Pressure Sensor　⑤Centrifugal Module ⑥Screen　⑦Power Button

Figure 2 Instrument - Rear View

Instrument Dimensions
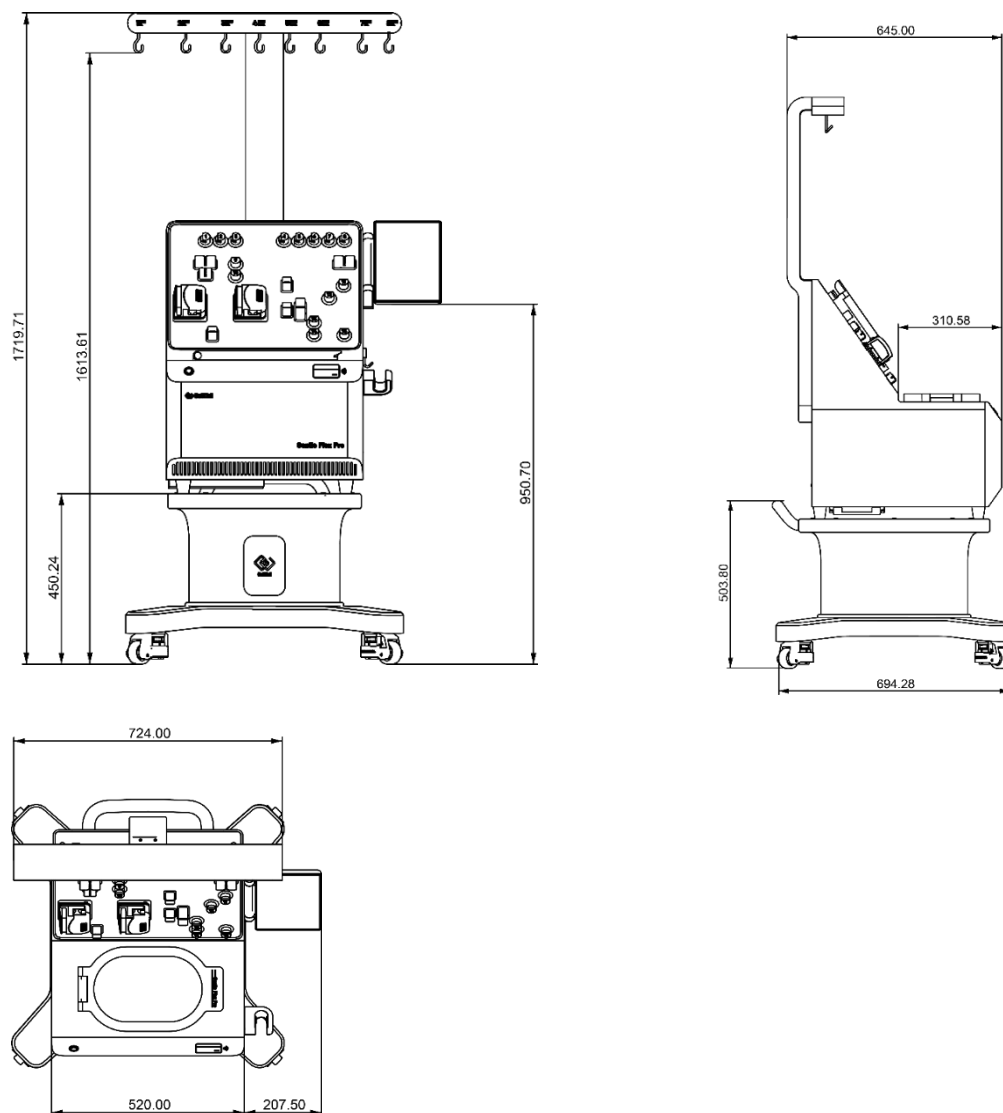
Working Space

The Gentle Flex Pro instrument works in a space that is required to have a height of approximately 172 cm, a maximum width of 72.4 cm, and a depth of 69.4 cm.

Instrument Weight

The weight of Gentle Flex Pro is 81.5kg.

Instrument Performance

Category	Performance	Values
Electrical		
	Supply voltage	100–240 V AC, 50/60 Hz
	Rated power consumption of the machine	450VA
	Maximum rated input current	3.15 A
	Overvoltage category	II
	Fuse	2 x 3.15 A
Sound level		
	Maximum sound level	70dBA (measured at 1 m from the instrument)
	Typical sound level	62dBA (measured at 1 m from the instrument)
Environmental range		
	Operating ambient temperature	15°C~30°C
	Storage & transportation temperature	-40 ~ 55°C
	Relative humidity	45%-75%, non-condensing
	Atmospheric pressure	860hpa-1060hpa
	Indoor use only	√
	Not recommended for humid areas	√
	Intended for ISO Class 5 environment	√
Operating limits		
	Centrifuge speed	0~1000g (3000rpm)
	Flow rate	Standard: 10~300mL/min
	System pressure	100kPa
	Centrifugal chamber temperature	4°C~37°C
	Fluid density	1.0~1.1g/mL
	Minimum operating volume	50mL
	Minimum separation recovery volume	50mL

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	Centrifugal chamber volume	800mL
	Maximum bag weight per rod	3 kg
External interface		
	Purpose	For connection for equipment program upgrade and control
	Connector	USB2.0 port and RJ-45 port
Operation mode		
	Operation mode type	Continuous operation
Centrifugal motor		
	weight	6.2kg
	direction	anticlockwise
	Rated Output	3800RPM

Permissible Chemical Substances for Cleaning the Instrument Surface

Chemical substances	Concentration	Maximum exposure time
Water for injection	100%	5 minutes
Ethanol	75%	5 minutes
VHP (Vaporized Hydrogen Peroxide)	35%	12 hours

Chapter 2 Installation and Setup

Packaging Contents

- Gentle Flex Pro instrument
- Convenient cart
- <mark>Chinese standard power cord （Prohibit the use of power cords not provided by the manufacturer）</mark>
- Fuse
- Certificate of Conformity
- Warranty card
- T-handle Allen wrench
- RFID card
- Gentle Flex Pro User Guide

Damage Inspection

This instrument has undergone rigorous testing before shipping. To avoid any impact during transportation, the instrument is packaged securely. Upon receipt of the instrument, carefully inspect the packaging to determine if there is any damage as follows:

- Inverted or deformed external packaging;
- Obvious traces of moisture on the external packaging;
- Obvious signs of impact on the external packaging;
- Signs of tampering with the external packaging.

If there is any damage, please contact Cellbri or the local distributor immediately. If the external packaging is intact, unpack it in the presence of designated personnel of Cellbri or the local distributor, and perform an inspection:

- Check that all components are complete according to the packing list inside the package;
- Inspect the appearance of all components for cracks, damage by impact, or deformation.

After unpacking, if there is any damage during handling or if you find that the configuration is incomplete, please contact Cellbri or the local distributor immediately.

Instrument Installation

- Remove the external packaging.

⚠️ Place the Gentle Flex Pro instrument on the provided cart, and ensure the cart is on a level surface. If using a mobile device, the user is responsible for ensuring all safety hazards and functional risks are addressed, including adequately supporting the weight of the instrument and having sufficient wheelbase to maintain stability for both the cart and the instrument.

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• Reserve enough working space for the Gentle Flex (see page 7 for "Working Space") and ensure easy access to the instrument's power switch and convenient power cord plugging and unplugging.

• Ensure the floor is flat and level within ±0.4 inches (10mm).

⚠ The Gentle Flex Pro instrument weighs 81.5Kg. Be cautious and seek help as necessary when handling or moving the instrument. Lift the instrument, and secure it on the rubber feet at the bottom of the instrument.

⚠ Confirm the reliability of the power supply before use.

⚠ Ensure the location where you place the instrument does not disconnect the power cord from the power source.

⚠ Warning! Do not place the equipment in a location where it is difficult to access the disconnecting instrument. Keep at least 25CM from the wall behind the equipment and do not place any items obstructing within 30CM to the right of the equipment.

⚠ Caution: Check for electromagnetic interference in the vicinity before using the equipment.

⚠ If using a backup main cable, ensure it is rated for at least 10A.

Note: Adequate protective grounding device is required for this instrument.

Figure 5 Rear View of the Instrument

1. Insert the power cord into the power input interface, then turn on the power switch.

Instrument Power "ON"

1. Turn on the power switch located on the rear of the instrument.
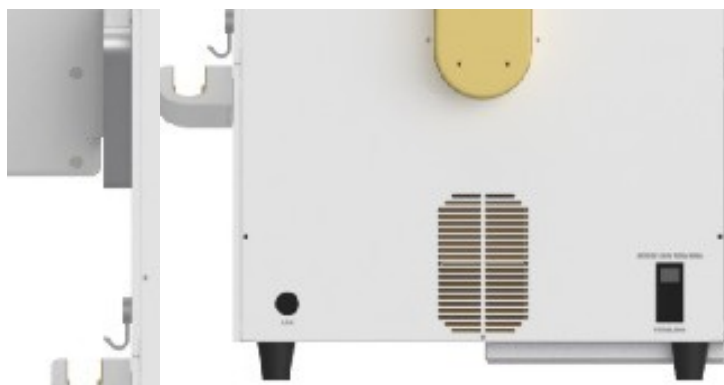
2. When the instrument is powered on, the instrument button lights will arrange sequentially. If the hood is closed, the instrument will automatically check if a disposable cell processing kit is installed.

Instrument Power "OFF"

1. Use the power-off button on the software's main interface to turn off the instrument.
2. Use the power switch to turn off the instrument.
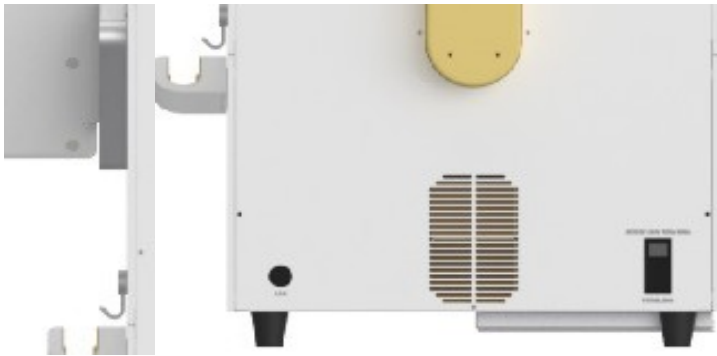
⚠ There is no automatic recovery program. In case of a power outage event, please refer to page 43 for "Restart After Shutdown".

Functions Introduction

1. Power-on test: If there is an abnormality, an error code will be displayed when reaching 100%. If there is no abnormality, it directly enters the login interface.

| Self-test in progress | Self-test completed with abnormalities |

CN	EN
正在进行设备自检	Instrument self-test in progress
设备自检异常那个，请联系售后服务	Instrument self-test exception. Please contact after-sales service.
错误代码：1001、1002、2001、2002、2003	Exception code: 1001, 1002, 2001, 2002, 2003

2. Swipe card to get the username, input the password, and click [L] to enter the main interface.

CellBri Gentle Flex Pro High Throughput Multi-Functional Fully Enclosed Automated Cell Processing System
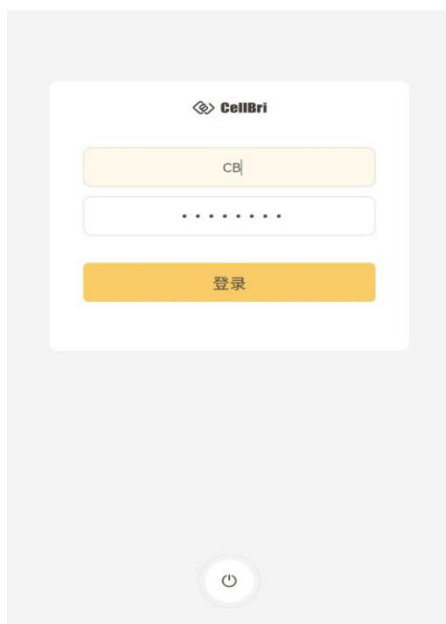
Login interface

CN	EN
登录	Login

3. Click [Select a Protocol] to access the protocol list interface, click [Operation Log] to view the operation logs, click [Basic Operation] to access the basic operations interface, and click [More] to access more functions including user management and system settings.

Main interface

CN	EN	CN	EN
为人类健康而奋斗	Strive for Human Health	操作日志	Operation Log
选择工艺	Select a Protocol	工艺记录	Protocol Record
基础操作	Basic Operations	更多功能	More

Basic Operations Function

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1. Sample In/Out

Select the needed peristaltic pump and choose the sample inlet port, sample outlet port, line, and flow rate, and enter the required volume. You can choose whether to enable the bubble sensor based on your specific needs (if the bubble sensor is enabled, it will use the detection of bubbles in the fluid path as the stopping criterion). Click 'Start' button to start the sample in/out operation.

2. Centrifugation

Enter centrifugation speed, centrifugation time, and set acceleration (high speed - 80, medium speed - 40, low speed - 15, custom speed - 1-200). Click 'Start' button to initiate centrifugation.

2.1 Click the "Open Centrifugal Chamber Lid" button to unlock the centrifugal chamber lid.

2.2 During centrifugation, click the settings button to adjust the centrifugation acceleration and deceleration.

Basic Operations - Sample In/Out

Basic Operations - Centrifugation

CN	EN	CN	EN
基础操作	Basic Operations	实时数据	Real-Time Data
进出样	Sample In/Out	当前体积	Current Volume
离心	Centrifugation	离心转速（rpm）	Centrifugation Speed (rpm)
混匀	Mixing	离心时间（s）	Centrifugation Time (s)
孵育	Incubation	加速度（rpm）	Acceleration (rpm)
参数设置	Parameter Settings	减速度（rpm）	Deceleration (rpm)

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进样口	Sample Inlet Port	速度设置	Speed Setting
出样口	Sample Outlet Port	高速	High Speed
流速（mL\min）	Flow Rate (mL\ min)	中速	Medium Speed
体积（mL）	Volume (mL)	低速	Low Speed
线路	Line	自定义	Custom
序列号	Serial Number	转速	Rotate Speed
气泡传感器	Bubble Sensor	运行时间	Run Time

3. Mixing

Please set the mixing time, high speed time, low speed time, high speed, low speed, acceleration, and deceleration. You can click the slider button of one-way mixing based on your needs (selecting one-way mixing will only mix in one direction). Click "Mix" button to start mixing.

Basic Operations - Mixing

4. Incubation

Please set the incubation temperature and time. After setting, click the "Start" button to start the incubation.

Basic Operations - Incubation

CN	EN	高速时间（s）	High-Speed Time (s)
基础操作	Basic Operations	低速时间（s）	Low-Speed Time (s)

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进出样	Sample In/Out	加速度（rpm）	Acceleration (rpm)
离心	Centrifugation	减速度（rpm）	Deceleration (rpm)
混匀	Mixing	实时数据	Real-Time Data
孵育	Incubation	转速	Speed
参数设置	Parameter Settings	运行时间	Run Time
混匀时间（s）	Mixing Time (s)	孵育温度（℃）	Incubation Temperature (℃)
混匀单向	One-Way Mixing	孵育时间（s）	Incubation Time (s)
高速度（rpm）	High Speed (rpm)	温度	Temperature
低速度（rpm）	Low Speed (rpm)		

Others

1.1 Operation Log

Select the corresponding date and click [Query] to view the operations performed by the user.
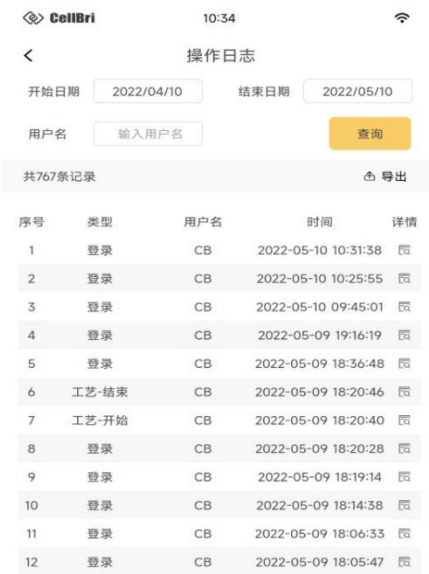
Operation Log Interface

1.3 Select Date

1.4 Log Details

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CN	EN	CN	EN
操作日志	Operation Log	工艺-结束	Protocol-End
开始日期	Start Date	工艺-开始	Protocol-Start
结束日期	End Date	选择日期	Select Date
用户名	Username	年　　月　　日	yyyy-mm-dd
输入用户名	Enter your username	当前时间	Current Date
查询	Query	确定	OK
共 767 条记录	767 logs in total	日志详情	Log Details
导出	Export	离心-开始	Centrifugation-Start
序号	No.	离心转速	Centrifugation Speed
类型	Type	离心时间	Centrifugation Time
时间	Time	加速度	Acceleration
详情	Details	减速度	Deceleration
登录	Login		

1.4 Log Export

Click the 　♤ 导出 　 button to batch export the retrieved operation records to a storage device. User password verification is required during export.
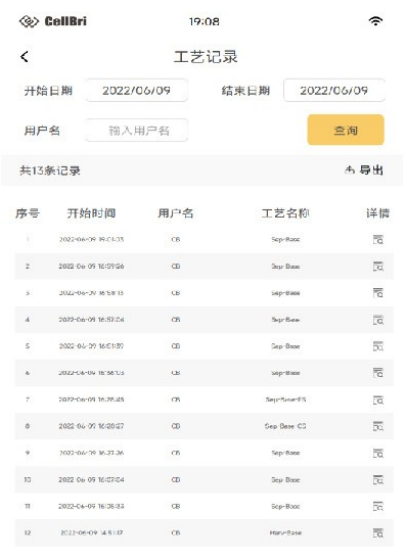
2.1 Protocol **Record**

Select the corresponding date and click [Query] button to view detailed protocol data that has been completed.
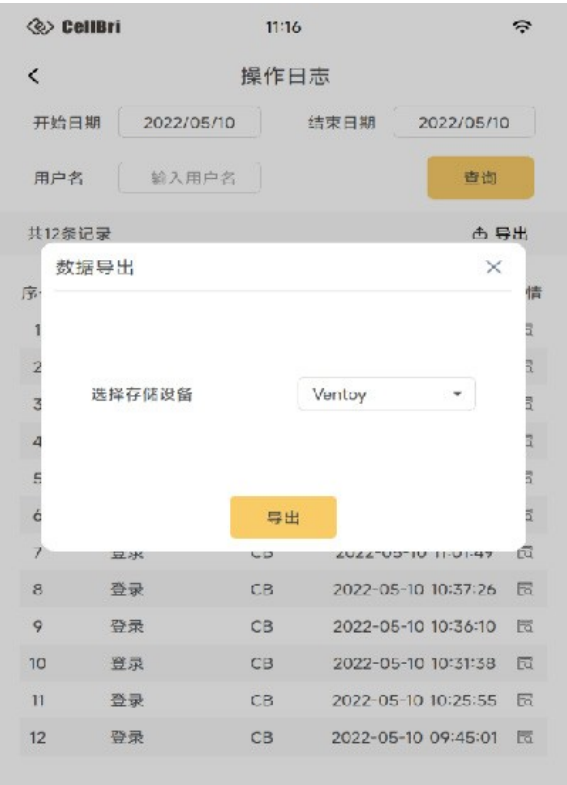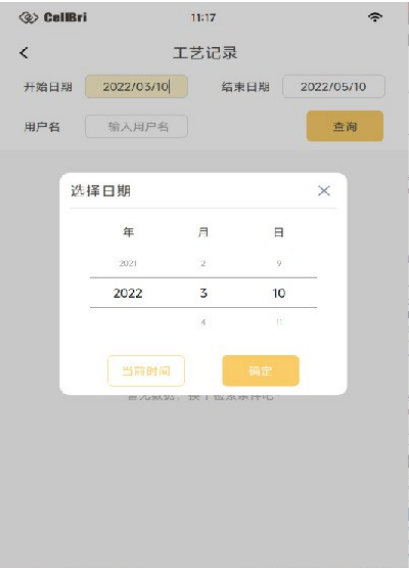
2.2 **Search for** Protocol **Record**

Protocol Record Interface

2.3 **Date Selection**

Date Selection

2.4 Protocol **Record Details**

Protocol **Record** Details Interface

CN	EN	CN	EN
数据导出	Data Export	当前时间	Current Date
选择存储设备	Select a storage device	确定	OK
导出	Export	工艺记录详情	Protocol Record Details
工艺记录	Protocol Record	工艺名称	Protocol Name
开始日期	Start Date	开始时间	Start Time
结束日期	End Date	结束时间	End Time
用户名	Username	操作人	Operator
输入用户名	Enter your username	耗材信息	Consumable Information
查询	Query	工艺处理信息	Protocol Treatment Information
暂无数据，换个检索条件吧~	No data available. Please change your search conditions	样本体积	Sample Volume
共 13 条记录	13 records in total	时间	Time
序号	No.	详细记录	Detailed Record
详情	Details	进出样-开始（1-9-14.7） 目标：210.0mL	Sample In/Out Start (1-9-14.7) Target: 210.0mL
选择日期	Select Date	进样本	Sample In
年　　月　　日	yyyy-mm-dd		

2.5 Protocol **Record Export**

You can click the button in the search interface to batch export the retrieved protocol records. User password verification is required during export. You can click the button in the protocol details interface to export individual protocol record. User password verification is required during export.
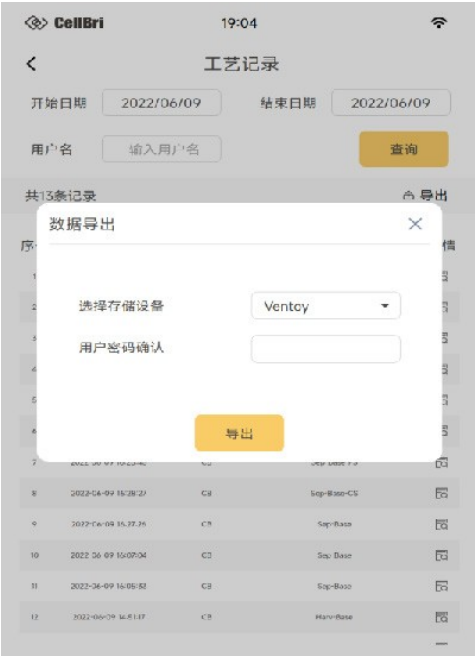
Protocol Record - Protocol Details Export

CN	EN	CN	EN
数据导出	Data Export	用户密码确认	User Password Confirmation
选择存储设备	Select a storage device	导出	Export

3. More Functions

Click "User Management" to access the user management interface. Click "System Settings" to access the system settings interface. Click "Permission Management" to access the permission management interface. Click "Weighing Debugging" to access the weighing debugging interface.

CN	EN	CN	EN
数据导出	Data Export	用户管理	User Management
选择存储设备	Select a storage device	系统设置	System Settings
用户密码确认	User Password Confirmation	权限管理	Permission Management
导出	Export	称重调试	Weighing Debugging
更多功能	More Functions		

4. User Management

4. Administrators can click the '+' button to add general users, or click the [Delete] button to delete general users, modify their own passwords and usernames, or modify the passwords and usernames of general users.

(Username rules: Username length must be between 2-16 characters. Password rules: Passwords must start with an uppercase letter and can only contain letters, numbers, and underscores. Password length must be between 8-16 characters.)

Users with higher permissions can manage users with lower permissions. Click [Create IC Card], and place the IC card in the RFID sensing area. The system will automatically record the card number. Click [Confirm] to create an IC card for the

User Management Interface

general user. Click [Cancel IC Card] and place the IC card in the RFID sensing area. The system will clear the card number information from the database and clear the user information on the IC card.

CN	EN	CN	EN
用户管理	User Management	密码确认	Password Confirmation
用户信息	User Information	用户等级	User Level
卡号	Card Number	开发用户	Development User
使用者	User	删除	Delete
密码输入	Password Input	保存	Save

5. System Settings

You can set the system's sleep time, local IP, and local gateway. After inserting a USB drive with an upgrade package, clicking "Software Upgrade" or "Firmware Upgrade" will perform the corresponding upgrade action. You can view the current software version number on the system settings page.

System Settings Interface

CN	EN	CN	EN
语言设置	Language Settings	开	On
简体中文	简体中文	保存	Save
本地 IP	Local IP	设备条码	Instrument Barcode
屏幕休眠	Screen Sleep	软件版本	Software Version
从不	Never	升级	Upgrade
本地网关	Local Gateway	固件升级	Firmware Upgrade
调试日志	Debug Log	主控板	Main Control Board

6. Permission Management

You can modify permissions for user groups with lower permissions than yourself (Super Users: Have all permissions, Manage Users: Cannot manage permissions, General Users: Cannot manage permissions, system settings, or user management).


Permission Management Interface

CN	EN	CN	EN
权限管理	Permission Management	操作日志	Operation Log
超级用户	Super User	用户管理	User Management
管理用户	Manage User	系统设置	System Settings
普通用户	General User	权限管理	Permission Management
权限分配	Permission Assignment	硬件调试	Hardware Debugging
工艺运行	Protocol Run	工艺记录	Protocol Record
基础操作	Basic Operations		

7. Weighing Calibration

You can perform calibration actions on the corresponding weighing sensor. (Taking weighing sensor 1 as an example) Click the [Calibrate] button. In step 1, confirm that there are no items on hook 1 and click [Confirm] to enter step 2. Follow the prompts to hang a 500g weight. In step 2, click [Confirm] to start the 5-second calibration process. After 5 seconds, the step 3 prompt window will automatically pop up. Follow the prompts to remove the 500g weight and place a 50g weight on hook 1. In step 3, click "Confirm" to start the 5-second verification process. After 5 seconds, if completed successfully, a popup will appear indicating calibration is successful. **(The calibration process requires one 500g weight and one 50g weight)**
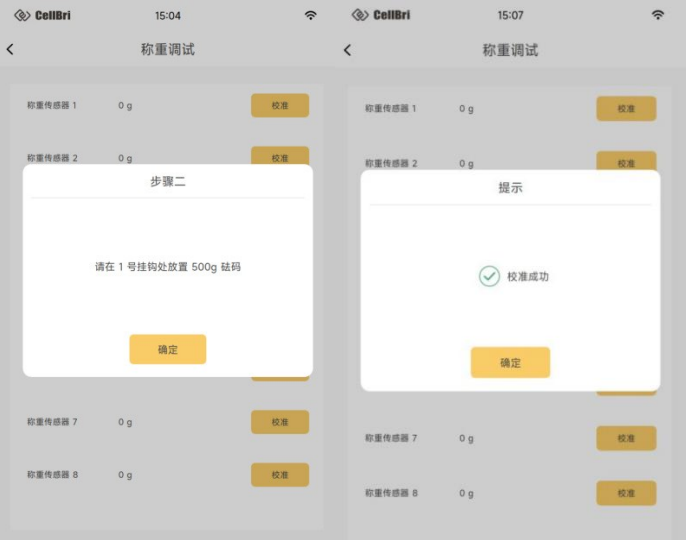
CN	EN	CN	EN
称重调试	Weighing Debug	确定	OK
称重传感器	Weight sensor	步骤二	Step 2
校准	Calibrate	请在 1 号挂钩处放置 500g 砝码	Please place a 500g weight on hook 1
步骤一	Step 1	提示	Prompt
请确认 1 号挂钩无任何物品	Please confirm no items on hook 1	校准成功	Calibration Successfully
取消	Cancel		

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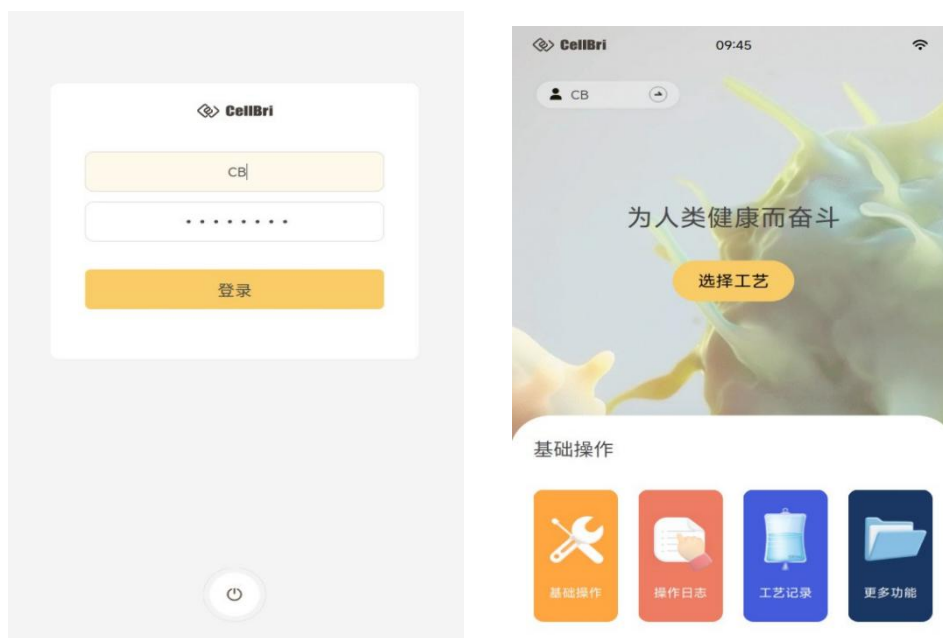# Chapter 3 Introduction to Operations of Routine Applications

Basic Operations

Power On

Connect to the power supply, press the power button on the left side of the instrument to power it on. The instrument will automatically go through the power-on initialization and then enter the home page.

User Login

Enter the username and password to log in.

CN	EN	CN	EN
登录	Login	操作日志	Operation Log
为人类健康而奋斗	Strive for Human Health	工艺记录	Protocol Record
选择工艺	Select Protocol	更多功能	More
基础操作	Basic Operation		

Protocol Program Run

Click "Select Protocol " to select the protocol program you want to run. Take the PMBC Separation Standard Program as an example:

Disposables Installation

1. Please confirm that there are no reagent disposables on the hooks, then click [Confirm].

CellBri Gentle Flex Pro High Throughput Multi-Functional Fully Enclosed Automated Cell Processing System
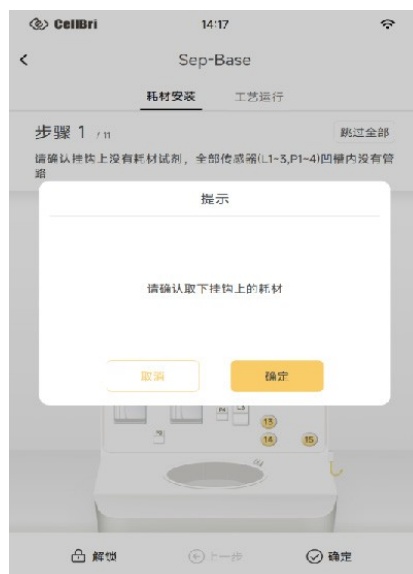
CN	EN
耗材安装	Disposables Installation
工艺运行	Protocol Run
步骤 1	Step 1
跳过全部	Skip All
请确认挂钩上没有耗材试剂，全部传感器（L1~3，P1~4）凹槽内没有管路	Please confirm that there are no consumable reagents on the hooks and no tubing in the grooves of all sensors (L1~3, P1~4)
解锁	Unlock
上一步	Previous
确定	OK
提示	Prompt
请确认取下挂钩上的耗材	Please confirm removal of consumable reagents from the hooks.
取消	Cancel
步骤 2	Step 2
打开管路外包装，扫描仪扫描包装二维码，录入管路信息	Open the outer packaging of the tubing and scan the barcode on the packaging with a scanner, enter the tubing information
产品编码	Product code
请输入或扫码	Please enter or scan barcode
产品型号	Product Model
产品批号	Batch Number
生产日期	Date of Manufacture
有效日期	Use By Date

2. Open the outer packaging of the tubing consumables and scan the barcode with a scanner, enter the tubing

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information (tubing packaging and barcode images). After scanning, the page will display the consumable information.

3. Install the tubing support plate according to the diagram onto the corresponding tube clamp valves.

4. Close all tube clamps on the tubing 1-8 and place the tubing on the top of the instrument's backboard.

5. Confirm that the tube clamps on tubing 1-8 are all closed. Click "Confirm" to automatically proceed to the installation of tube clamp values 1-8.

6. Install the corresponding tubing into the tube clamp valves (1-8) as shown in the tubing diagram. Then, click "√".
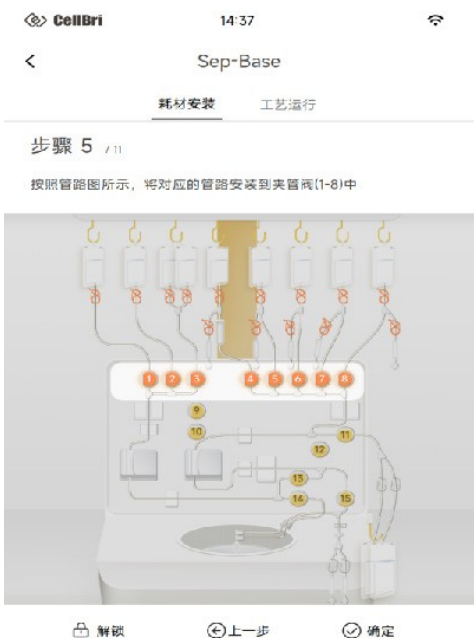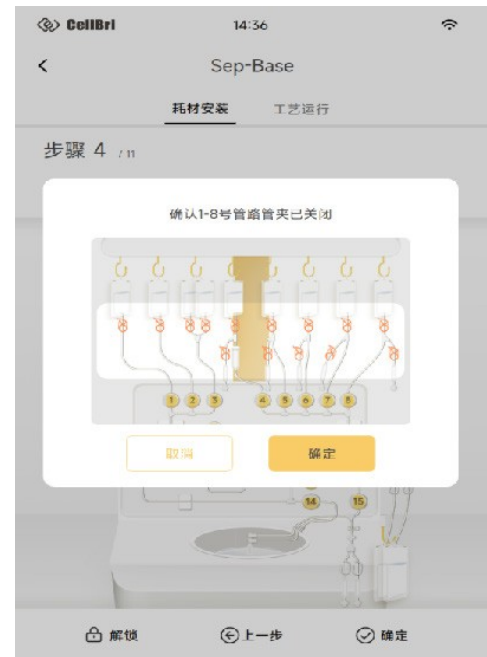

CN	EN	CN	EN
耗材安装	Consumable Installation	步骤 4	Step 4

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工艺运行	Protocol Run	关闭 1-8 号管路上的全部管夹，将管路放在仪器背板上方	Close all tube clamps on the tubing 1-8 and place the tubing on the top of the instrument's backboard
步骤 3	Step 3	确认 1-8 号管路管夹已关闭	Confirm that the tube clamps on tubing 1-8 are all closed
将管路托板按照图示安装到液路面板	Install the tubing support plate according to the diagram onto the fluid path panel	取消	Cancel
解锁	Unlock	步骤 5	Step 5
上一步	Previous	按照管路图所示，将对应的管路安装到夹管阀（1-8）中	Install the corresponding tubing into the tube clamp valves (1-8) as shown in the tubing diagram
确定	OK		

7. Open the peristaltic pump and install the peristaltic pump tubing at the indicated position, keeping the pump in the open state.

8. Install the tubing into the corresponding bubble sensor and pressure sensor as indicated in the tubing diagram, ensuring that the tubing inside the sensor is pressed to the bottom of the groove.
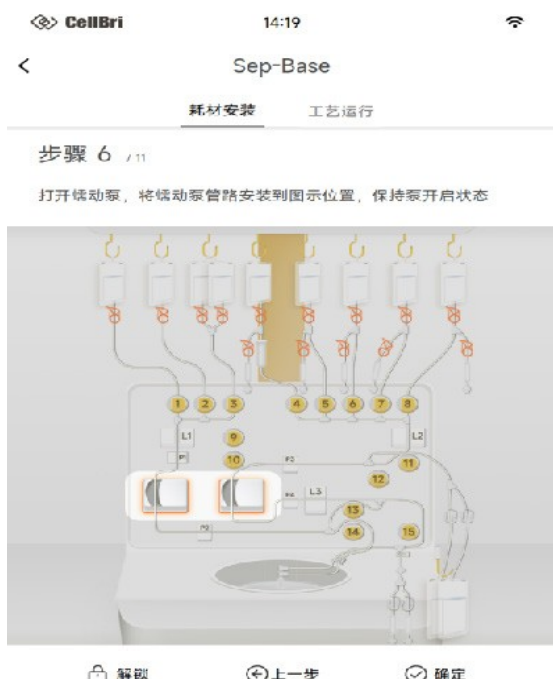
9. Install the spin cup.

9.1 Click the "Unlock" button to open the centrifugal chamber lid.

9.2 Install the bottom groove of the spin cup into the adapter, rotate it 90° clockwise until you hear a

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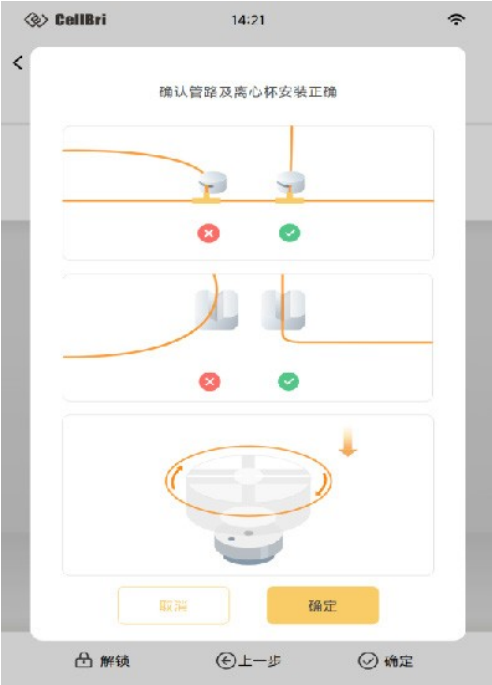| CN	EN
耗材安装	Consumable Installation
工艺运行	Protocol Run
步骤 6	Step 6
打开蠕动泵，将蠕动泵管路安装到图示位置，保持泵开启状态	Open the peristaltic pump and install the peristaltic pump tubing at the indicated position, keeping the pump in the open state
解锁	Unlock
上一步	Previous
确定	OK
步骤 7	Step 7
按照管路图所示，安装管路图到相应的气泡及压力传感器，确认传感器内管路压到凹槽底部	Install the tubing into the corresponding bubble sensor and pressure sensor as indicated in the tubing diagram, ensuring that the tubing inside the sensor is pressed to the bottom of the groove
步骤 8	Step 8
点击解锁按钮，打开离心仓盖子	Click the "Unlock" button to open the centrifugal chamber lid
将离心杯底部卡槽安装到适配器，顺时针旋转 90°，听到咔声，安装到位	Install the bottom groove of the spin cup into the adapter, rotate it 90° clockwise until you hear a "click," indicating it is properly installed
取消	Cancel

9.3 Place the spin cup tubing into the tube groove, and close the centrifugal chamber lid.

9.4 Close the blue clips and white tube clamps for the sampling bag tubing on the spin cup tubing.

10. Confirm that the tubing and spin cup are installed correctly, and that the tube clamps for tubing 1-8 and the spin cup sampling port are closed.

CN	EN
将离心杯管路放入管槽中，关闭离心仓盖子	Place the spin cup tubing into the tube groove, and close the centrifugal chamber lid
取消	Cancel
确定	OK

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耗材安装	Consumable Installation
工艺运行	Protocol Run
步骤 9	Step 9
关闭离心杯管路上取样袋管路的蓝色片夹和白色管夹	Close the blue clips and white tube clamps for the sampling bag tubing on the spin cup tubing
解锁	Unlock
上一步	Previous
确认管路及离心杯安装正确	Confirm that the tubing and spin cup are installed correctly
确认 1~8 号管路、离心杯取样口管夹已关闭	Confirm that the tube clamps for tubing 1-8 and the spin cup sampling port are closed

11. Perform a pressure sensor self-test, which takes 3 minutes. After completion, it indicates that the pressure sensor calibration passed.
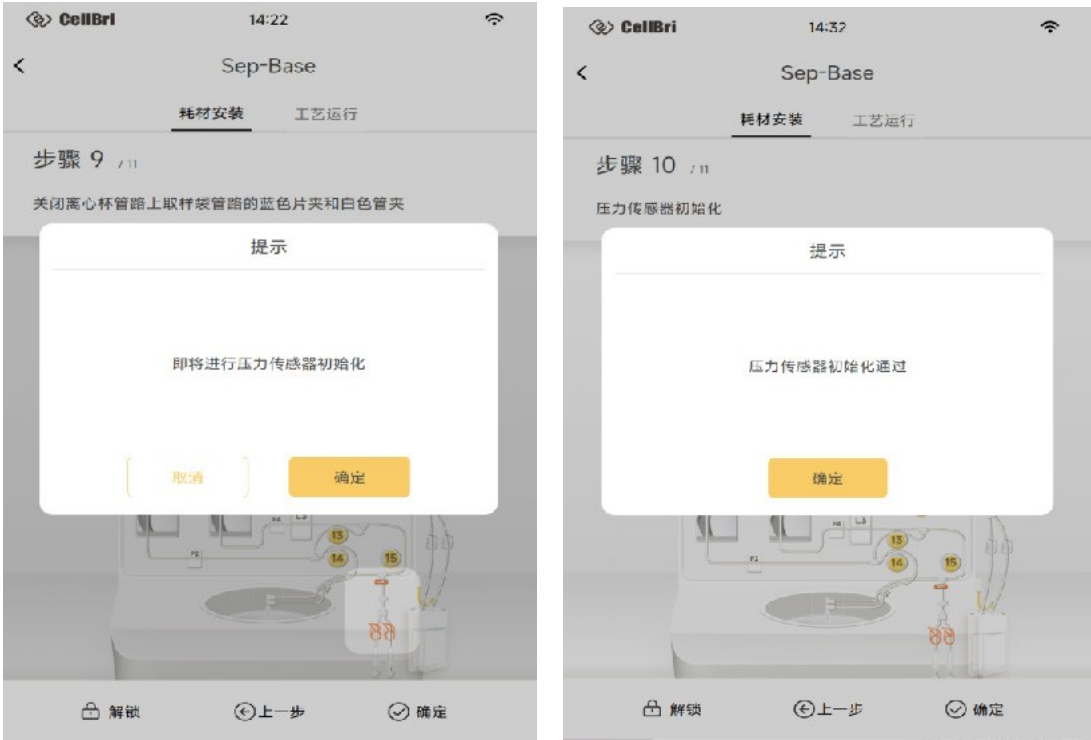
12. After the pressure calibration passes, please close the peristaltic pump and confirm that the pump tubing is correctly installed.

13. Install the corresponding tubing into the tube clamp valves (11, 13-15) as shown in the tubing diagram.

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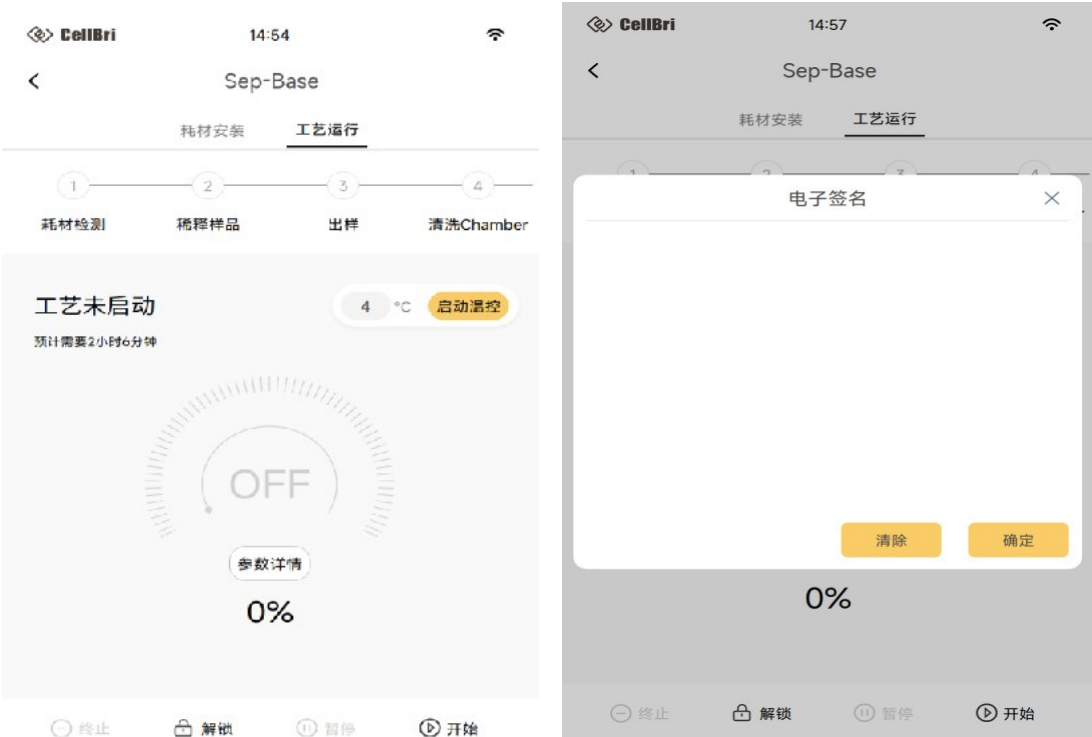| CN	EN
提示	Prompt
即将进行压力传感器初始化	About to perform pressure sensor initialization
取消	Cancel
确定	OK
压力传感器初始化通过	Pressure sensor initialization passed
请确认蠕动管安放正确位置，泵管处于泵槽内最底部，然后关闭蠕动泵	Please confirm that the peristaltic tube is in the correct position, with the pump tube in the lowest part of the pump groove, and then close the peristaltic pump
耗材安装	Consumable Installation
工艺运行	Protocol Run
步骤 11	Step 11
按照管路图所示，将对应的管路安装到夹管阀（11、13-15）中	Install the corresponding tubing into the tube clamp valves (11, 13-15) as shown in the tubing diagram
解锁	Unlock
上一步	Previous

14. Do you want to enter the protocol run? Click "Confirm" to enter the protocol run module.

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CN	EN	CN	EN
提示	Prompt	取消	Cancel
是否要进入工艺运行	Do you want to enter the protocol run	确定	OK

Protocol Run

1. Click the "Start" button to enter the protocol run module and perform electronic signing.

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2. Select the starting step "1. Consumable Test".

CN	EN	CN	EN
耗材安装	Consumable Installation	终止	Terminate
工艺运行	Protocol Run	解锁	Unlock
耗材检测	Consumable Test	暂停	Pause
稀释样品	Sample Dilution	开始	Start
出样	Sample Discharge	电子签名	E-Signature
清洗 Chamber	Chamber Cleaning	清除	Clear
工艺未启动	Protocol not started	确定	OK
启动温控	Start Temp Control	选择起始步骤	Select the starting step
预计需要 2 小时 6 分钟	Estimated to take 2 hours and 6 minutes	1.耗材检测	1. Consumable Test
参数详情	Parameter Detail		

3. Connect washing fluid to the tubing corresponding to valve 3, open the tube clamps corresponding to tubing 3, 5, and 8, hang them on hooks 3, 5, and 8, and input information.

4. The program will automatically perform a 5. Connect resuspension fluid to the tubing

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consumable self-test; after completion, it will prompt "Consumable self-test passed". Click "OK" to proceed to the next step.

corresponding to valve 2, open the tube clamp, hang it on hook 2, and input information.

6. Connect cell separation fluid to the tubing corresponding to valve 1, open the tube clamp, hang it on hook 1, and input information.

7. Connect sample to the tubing corresponding to valve 4, hang sample bag on hook 4, open the tube clamp, and input information.

CN	EN
信息录入	Information Input
连接清洗液到 3 号阀管路，打开 3 号，5 号和 8 号管路	Connect washing fluid to the tubing corresponding to valve

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|	
对应管夹，分别挂到 3 号，5 号和 8 号挂钩，并录入信息	3, open the tube clamps corresponding to tubing 3, 5, and 8, hang them on hooks 3, 5, and 8, and input information.
产品名称	Product Name
请输入或扫码	Please enter or scan barcode
产品批号	Batch Number
唯一识别码	UDI
备注	Note
确定	OK
提示	Prompt
耗材自检通过	Consumable test passed
连接重悬液到 2 号阀对应管路。打开管夹，挂到 2 号挂钩，并录入信息	Connect resuspension fluid to the tubing corresponding to valve 2. Open the tube clamp, hang it on hook 2, and input information.
连接细胞分离液到 1 号阀对应管路，打开管夹，挂到 1 号挂钩，并录入信息	Connect cell separation fluid to the tubing corresponding to valve 1, open the tube clamp, hang it on hook 1, and input information
连接样品到 4 号阀管路，4 号样品袋挂到对应挂钩上。并打开管夹，并录入信息	Connect sample to the tubing corresponding to valve 4, hang the No.4 sample bag on the corresponding hook. Open the tube clamp, and input information.

8. Confirm the input information; changes or additions can be made in this step.

9. Enter the sample volume, range: 10-400 mL.

10. Enter the diluent volume, range: 0-100 mL.

11. A prompt will appear for sample mixing; the program will automatically perform PBMC

separation, including PBMC layer extraction and PBMC washing.
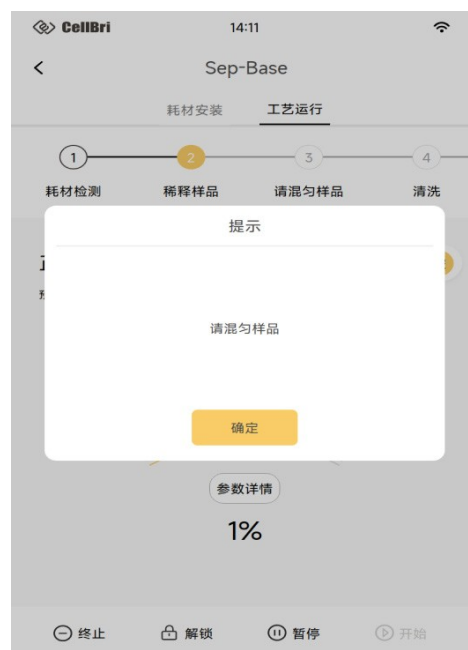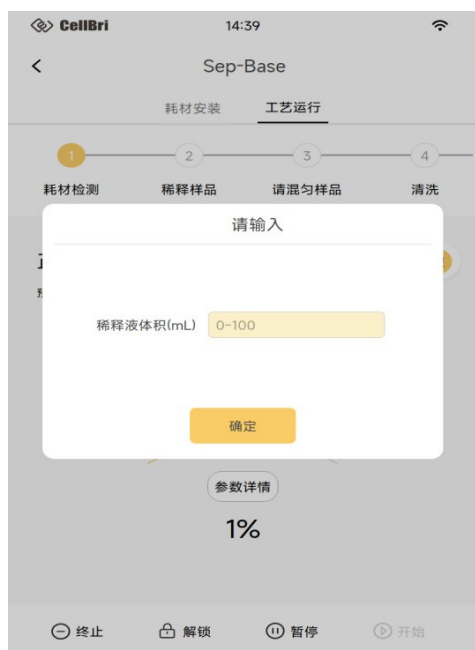
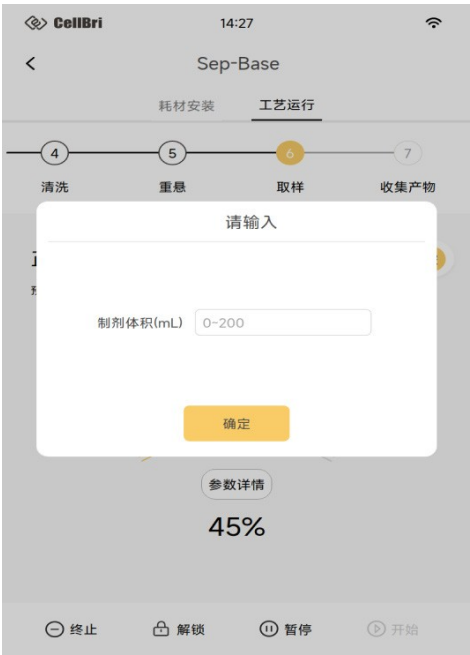| CN	EN	CN	EN
录入信息确认	Input information confirmation	细胞分离液	Cell Separation Fluid
确认管路安装正确，检查已录入的管路和试剂信息	Confirm that the tubing installation is correct, and check the input tubing and reagent information	样品	Sample
挂钩	Hook	确定	OK
产品名称	Product Name	参数设置	Parameter Settings
产品批号	Batch Number	样品体积（mL）	Sample Volume (mL)
唯一识别码	UDI	请输入	Please input
备注	Note	稀释液体积（mL）	Diluent Volume (mL)
清洗液	Washing Fluid	提示	Prompt
重悬液	Resuspension Fluid	请混匀样品	Please mix the sample

12. After washing, a prompt will appear to enter the re-suspension volume, range: 0-150 mL.

13. After resuspension, a prompt will appear to count the sample; click "OK".

14. Enter the preparation volume, range: 0-200mL.

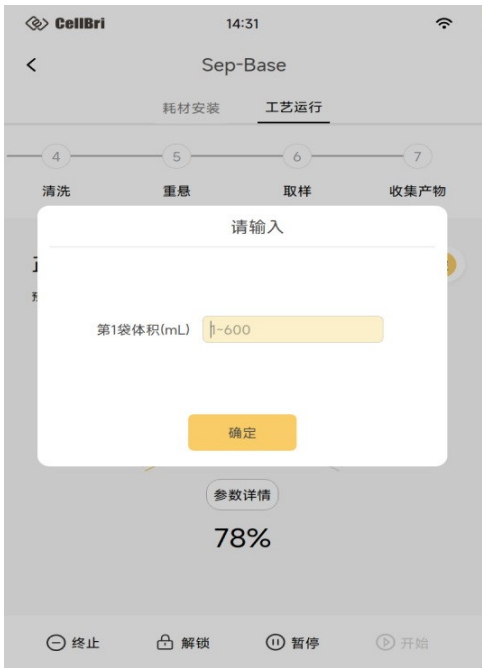15. A prompt will appear to input the number of dispensing bags, range: 1-3.

CN	EN	CN	EN
参数设置	Parameter Settings	请输入	Please input
重悬体积（mL）	Resuspension Volume (mL)	制剂体积（mL）	Preparation Volume (mL)
确定	OK	分装袋数	Dispensing Bag Count

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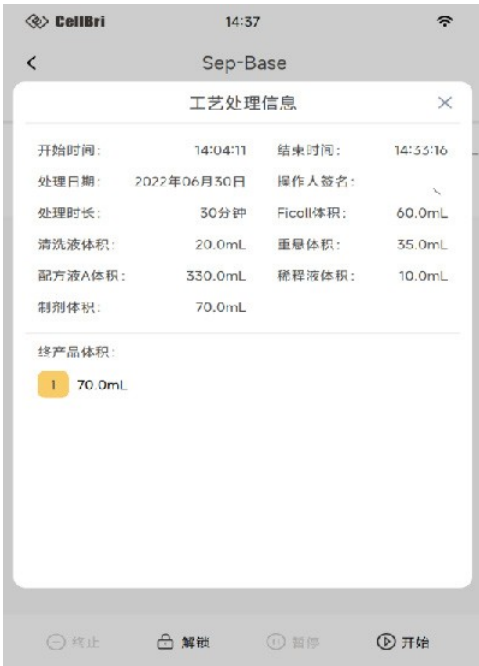
16. Input product bag information.

17. Enter the preparation dispensing volume for the first bag.

18. After preparation is complete, the protocol will end, and a box will pop up, showing the protocol run information.

CN	EN	CN	EN
请连接 6-1 的产品袋，并录入信息	Please connect the product bag 6-1 and input information	结束时间	End Time
产品名称	Product Name	处理日期	Treatment date:
产品批号	Batch Number	操作人签名：	Operator Signature:
唯一识别码	UDI	处理时长：	Treatment Duration:

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备注	Note	Ficoll 体积：	Ficoll Volume:
请输入或扫码	Please enter or scan barcode	清洗液体积：	Washing Fluid Volume:
请输入备注	Please enter note...	重悬体积：	Resuspension Volume:
确定	OK	配方液 A 体积：	Formula Fluid A Volume:
请输入	Please input	稀释液体积	Diluent Volume
第 1 袋体积（mL）	1st Bag Volume (mL)	制剂体积	Preparation Volume
工艺处理信息	Protocol Treatment Information	终产品体积：	Final Product Volume:
开始时间	Start Time		

19. Consumable removal: Click the "Remove Consumable" button in the protocol list to remove the tubing from the tube clamp valve. Open the peristaltic pump, rotate the spin cup counterclockwise by 90°, remove the spin cup, and remove the entire set of tubing consumables.

Power Off

Click the "Back" button next to the username to log out to the main interface, then click the power off button. The instrument will automatically run power-off program. Then, automatically turn off the power.

Instrument Routine Maintenance

It is generally recommended to disinfect and clean the exterior of the instrument after the program running has completed. You can spray 75% ethanol on a soft, dust-free paper or sterile gauze and gently wipe away dust from the hardware components such as pinch valves, peristaltic pumps, and the centrifugal chamber. Be cautious not to use excessive liquid to prevent it from seeping into sensitive parts. You can use a dry, sterile gauze to timely remove excess liquid.

Chapter 4 Maintenance

User Maintenance Plan

Users are responsible for defining and implementing an appropriate instrument maintenance plan for the Gentle Flex Pro based on their specific usage conditions.

⚠ Warning! Regular maintenance should be scheduled in coordination with Shenzhen Cellbri Bio-Innovation Technology Co., Ltd. and its authorized agents to ensure the proper operation of the instrument. Any modifications, revisions, maintenance, or repairs to the Gentle Flex Pro should be performed by technicians authorized by Shenzhen Cellbri Bio-Innovation Technology Co., Ltd.

⚠ Warning! Only parts and accessories approved or provided by Shenzhen Cellbri Bio-Innovation Technology Co., Ltd. can be used for maintenance.

⚠ Warning! No maintenance or servicing of any components of the instrument should be carried out while it is in operation.

Instrument Cleaning

All biological contaminants are contained within single-use sterile disposables. However, if necessary, a disinfection procedure can be used to reduce microbial levels on the instrument's surfaces between product batches or in the event of accidental microbial contamination.

After removing the disposable set, the instrument's surface and the centrifugal chamber can be cleaned by the following method:

- Gently spray with 75% medical-grade alcohol.
- Wipe with a lint-free disposable cloth.

⚠ Warning! All functions on the front panel of the instrument are sealed to prevent moisture ingress. The instrument cannot be rinsed or steam sterilized.

Exterior Cleaning

After wiping the instrument's surface with a disinfected non-woven cloth (blue or different color from the product) dipped with 75% medical-grade ethanol, there should be no visible residue marks on the instrument's surface. Both the instrument and the cloth should appear as they did originally.

Transportation

The product can be transported by common vehicles. During transportation, avoid severe impacts, vibrations, and exposure to rain or snow. Packaged medical instruments should be stored indoors at room temperature, in an environment without corrosive gases and with good ventilation.

Check Tubing Sets

Check the instrument housing, flip cover, peristaltic pump, pinch valves, pressure sensors, bubble sensors, and hanging rods for any damage, cracks, corrosion, chemical effects, or wear and tear on a monthly basis. If any such defects are found, cease using the instrument and contact Shenzhen Cellbri Bio-Innovation Technology Co., Ltd. for repairs.

Power Outage Handling

Users can power off the instrument by the following methods:

Use the switch to turn off the instrument or disconnect the power supply.

Press the stop button to immediately stop all instrument functions.

Remove the white plug and insert a 3mm hex key into the hole to trigger the door lock catch.

After the door lock catch pops out, open the door
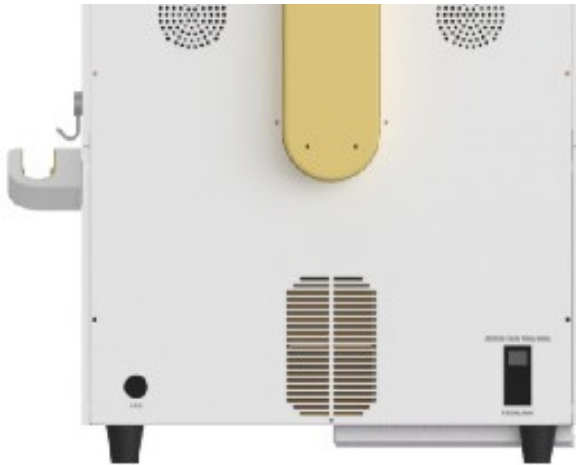
Power Supply and Fuse

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Power Supply

Specifications: AC 110 - 240V, Frequency 50/60Hz, 450 VA.

Fuse

Specifications: Size: 5x20mm, Current: 3.15A, Glass quick-acting fuse.

If necessary, replace the fuse as follows:

1. Turn off the mains supply and disconnect the power cord from the power switch on the rear of the instrument.
2. Remove the fuse cover.
3. Remove the faulty fuse.
4. Check that the fuse for replacement has the correct rating (refer to "Instrument Performance" on page 9).
5. Insert the new fuse and replace the fuse cover.

Chapter 5 Troubleshooting

⚠ Warning! Before performing any procedures described in this Chapter, you must first read and understand all the preceding chapters in the user guide. If you have any questions about the use or maintenance of the instrument, be sure to contact an authorized representative of Shenzhen Cellbri Bio-Innovation Technology Co., Ltd.

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 (see "Fuse" on page 38).
Peristaltic pump	Reduced flow or excessive pressure drop	Check if all manual clamps are open
		Ensure that the input and output containers are connected to the correct fluid tubing on the disposables
		Check if tube connectors are open
		Check the pump tubing for condition and correct placement on the pump roller
		Check for feasible circuit, and correct pinch valve open circuit
	Pump not rotating	Check the instrument status
		Check the power switch and the instrument switch.
		In the event of a power failure, check for obstruction by foreign objects inside the peristaltic pump
		Contact the service representative of Cellbri
Centrifuge	Centrifuge not rotating	Contact the service representative of Cellbri
		In the event of a power failure, check for obstruction by objects inside the centrifugal chamber
	Centrifugation noise	Contact the service representative of Cellbri
	Centrifugation imbalance	Check if the centrifugal chamber is correctly installed
		Check if the centrifugal chamber is filled with liquid and free of leaks
		Check if the workbench is stable

Components	Fault	Corrective Actions
Centrifugal chamber lid	Centrifugal chamber lid cannot be unlocked	Check if the open lid button has been pressed Check if objects are obstructing the rotational position. Note: Instructions on how to manually open the lid to retrieve the disposable toolset or perform maintenance can be found on page 37 under "Power Off and Open Lid"
	Centrifugal chamber lid cannnot be locked	Press the centrifugal chamber lid down completely
		Check if the "Disposable" kit has been correctly loaded with the tubes retained in the tube track
		Check for obstructions
pinch valve	Valve not fully closed	Perform the disposable kit loading/unloading sequence multiple times (see "Disposables Installation" on page 23)
	Slow valve closure	Replace the disposable kit and check performance
	Loud noise during valve closure	Replace the disposable kit and check performance
Hanging rod	Incorrect weighing	Check if the hook is loose; tighten the hanger
		Check if the hook-mounted weight exceeds the weight limit
		Check pump calibration Check if there are no flow restrictions in the output line

Note: Some faults can be corrected by restarting the instrument. To do this, turn off the instrument using the power switch or power on/off switch on the back of the instrument, wait for 2 minutes, and then turn the power on again as described in the Instrument Power "On" section in Chapter 3.

Chapter 6 Compliance

Gentle Flex Pro instrument complies with the following standards:

1. IEC 61010: 2010+A1: 2016
2. IEC 61010-2-051: 2018
3. IEC 61010-2-081: 2019
4. IEC 61010-2-010:2019
5. IEC 61010-2-020:2016
6. IEC 61326-1: 2020
7. RoHS, Directive 2011/65/EU
8. REACH Regulation (EC) 1907/2006
9. WEEE Directive 2012/19/EU
10. Toxic Substances Control Act
11. California Proposition 65
12. 21 CFR Part 11
13. FCC Part 15C

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Chapter 7 Safety Instructions

This chapter provides information on the process of initiating emergency shutdown and the consequences of power outage.

Instrument Emergency Shutdown Events

The instrument will automatically cease running the protocol in the following situations:

- Loss of power
- Humidity sensor detects liquid leakage in the centrifugal chamber area
- Vibration sensor detects an imbalance
- One of the pressure sensors detects sustained pressure exceeding a threshold
- Internal errors can be detected in the centrifuge drive, pump drive, or valves
- Welded or intermittent connection of safety relay contacts
- Centrifugal chamber lid closing sensor opens
- Centrifugal chamber lid locking sensor is incorrect

Emergency Procedures

Instrument emergency shutdown events are designed to ensure the safety of both the operator and the instrument. Whenever possible, the instrument will issue warnings before triggering a shutdown event.

Emergency Shutdown

Use the power switch or disconnect the power supply to turn off the instrument.

Use the power switch or disconnect the power supply to turn off the instrument.

Press the stop button to immediately stop all instrument functions.

Restart After Shutdown

Before restarting the Gentle Flex Pro instrument, ensure that the issues causing the shutdown have been corrected. The instrument can now be restarted; refer to Chapter 3, "Basic Instrument Operations".

Protocol Recovery Process

Once the conditions leading to a failure have been resolved, specific protocol steps can be followed to restart the protocol.

Note: Unless the closed fluid system is breached, the battery will be retained within the system and may potentially recover.

In the manufacturing cases where there is an external run history monitor, you can initiate a qualified protocol in the program at the point where the shutdown trigger event occurred. If this is not possible, manual intervention may be required to relocate the cell-containing fluid to a known bag and execute a custom protocol to recover the cells.

If there is no power or the instrument cannot be used, refer to page 37 for instructions on manually opening the centrifugal chamber lid for disassembly of the disposable kit and manual handling or transfer to another instrument.

Warnings and Precautions

⚠ **Warning**

- Gentle Flex Pro can generate a liquid pressure of up to 400 kPa at maximum flow.
  Restricted users are responsible for ensuring that the volume of liquid pumped into any connected container does not exceed the rated volume of that container. Users should conduct a risk analysis based on the configuration of the connected container or equipment and the protocol they are using.
- The Gentle Flex Pro system should only be operated by well-trained personnel. Users are responsible for ensuring that they have read and understood the user guide.
- If the Gentle Flex Pro system is not used by the method specified by Shenzhen Cellbri Bio-Innovation Technology Co., Ltd., the protection provided by the equipment may be compromised.
- Users must check if the instrument and components are in safe operating conditions before use.
- Shenzhen Cellbri Bio-Innovation Technology Co., Ltd. is not responsible for any harms or damages resulting from the use of the Gentle Flex Pro system that does not comply with the user guide requirements.
- Always use appropriate personal protective equipment (PPE) when operating the instrument or performing maintenance activities.
- The Gentle Flex Pro instrument is not approved for use with flammable or explosive materials or

materials that can cause hazardous chemical reactions.

- The Gentle Flex Pro instrument is not approved for use in potentially explosive atmospheres.
- Do not exceed the operating limits specified in this document and on the system labels. Operating beyond these limits may damage the equipment.
- These sterile disposables are intended to be part of a bio-restraint system but should not be relied upon as the sole means of protection for users and the environment when handling pathogenic microorganisms.
- Do not use the Gentle Flex Pro instrument when the kit cannot work properly or has suffered any damage.
- Caution should be exercised when assembling and loading the kit, connecting input container, and collecting liquid.
- Process samples, unload packages, disconnect and handle output materials, as well as process the components and parts used with care. When operating or interacting with the Gentle Flex Pro instrument, always use appropriate personal protective equipment.
- Before maintenance or service by Shenzhen Cellbri Bio-Innovation Technology Co., Ltd. or approved representatives, including returning the instrument, the system owner must first clean and purify the system and provide documentation for confirmation.
- Before using any cleaning or decontamination methods other than those recommended by the manufacturer, users should consult with Shenzhen Cellbri Bio-Innovation Technology Co., Ltd. to ensure that the proposed methods will not damage the equipment.

Considerations

⚠ Caution

- The Gentle Flex Pro instrument should be used exclusively with disposable cell processing kits. The kits are for one-time use only and should be used within the specified expiration date. Users are responsible for the proper storage, handling, and disposal of the disposable kits.
- If you have any questions about Gentle Flex Pro usage, please contact Cellbri.

Annex A Safety

⚠️ **Warning! General safety.** Failure to use the product with the method as described in this manual may result in personal injury or damage to the equipment. Ensure that anyone using this product is familiar with general laboratory safety regulations and the safety information provided in this document.

• Before using the instrument or equipment, read and understand the safety information provided in the manufacturer's user documentation for the instrument or equipment.

• Before handling chemicals, read and understand all applicable Safety Data Sheets (SDS) and use appropriate personal protective equipment (gloves, lab coats, safety goggles, etc.).

Symbols on this Instrument

Symbols that may warn of potential hazards or convey important safety information may be found on the instrument. In this document, hazard symbols are used with one of the following user caution words.

• **Caution!** - indicates potential hazardous situations that, if not avoided, could result in minor or moderate injury. It may also be used to caution against unsafe practices.

• **Warning!** - indicates a potential hazardous situation that, if not avoided, could result in serious injury.

• **Danger!** - indicates an urgent hazardous situation that, if not avoided, could result in serious injury.

Standard Safety Symbols

Symbols and descriptions	
⚠️	Risk of hazard! For more safety information, please refer to the safety manual.
⚡	Risk of electrical shock.
☣️	Potential biological hazard.
🗑️	Indicates compliance with WEEE Directive 2012/19/EU. Warning! Dispose of electronic waste properly to minimize negative impact on environment; do not dispose of electronic waste in unsorted municipal waste. Comply with local city waste regulations for proper disposal. Provide and contact customer service for information on disposal options and responsibilities.

Control and Connection Symbols

CellBri Gentle Flex Pro High Throughput Multi-Functional Fully Enclosed Automated Cell Processing System

Symbols and descriptions	
|	On (Power On)
◯	Off (Power Off)
⏚	Protective conductor terminal (main ground)
~	Alternating current

Instrument Label Symbols

Symbols and descriptions	
SN	Serial number
	Date of manufacture
	Consult instructions for use
ADD:	Address
	No pushing (when the device is running)
	No sitting or lying
	No stepping
	No tilting more than 10°
	Follow the instructions for use

Safety Information for Components Not Manufactured by Shenzhen Cellbri Bio-Innovation Technology Co., Ltd.

Some of the accessories provided as part of the instrument system are not designed or manufactured by Shenzhen Cellbri Bio-Innovation Technology Co., Ltd. For information on the safe use of these products, please refer to the manufacturer's documentation.

Instrument Safety

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⚠ Caution! **Do not dismantle the instrument protective cover**. Disassembling the protective instrument panel or disabling interlocks may result in serious danger, including but not limited to severe electric shock or breakage.

⚠ Caution! **Solvents and pressurized liquids.** When using any pressurized liquids, wear protective eyewear. Exercise caution when using any polymer tubes with pressure:
- If you are using flammable solvents, extinguish any nearby flames.
- Do not use polymer tubes with severe stress or kinking.
- Do not use polymer disposable chamber with tetrahydrofuran or acids and sulfuric acid.
- Note that dichloromethane and dimethyl sulfoxide may cause polymer infusion tubing to swell and significantly reduce burst pressure.
- Note that high solvent flow rates (above 40mL/min) may generate static charges on the tubing surface and may lead to electrical sparks.

⚠ If the centrifugal sample is known to be toxic, radioactive, or contaminated with pathogens that are harmful to the human body, it is necessary to conduct experiments according to the corresponding operating procedures for biological risks and radioactive substances; After the experiment is completed, it is necessary to wait for 5 minutes to confirm that there is no obvious contamination inside the centrifuge chamber before opening the centrifuge chamber cover. If the contamination is obvious, it should be cleaned according to the corresponding operating procedures for biological risks and radioactive substances before determining the usability of the equipment。

It is prohibited to use flammable or explosive materials inside the centrifugal chamber, and materials that react with PVC pipes or centrifugal cups are also prohibited.

⚠ Caution! Do not lean on the instrument. Do not exceed 11.8 inches (300mm) for any operation-related reasons on the instrument. Do not place any potential hazardous materials within 11.8 inches (300mm) of the instrument. The equipment must be placed in a ventilated and dry environment

Body Injury

⚠ Caution! **Moving and lifting injuries.** The instrument can only be moved and positioned by personnel or suppliers specified in the applicable site preparation guide.

Improper lifting could lead to back pain and permanent injury. Considerations before lifting or moving the instrument or accessories:
- Depending on the weight, moving or lifting may require two or more people.
- If you decide to move the instrument after installation, do not attempt to do so without assistance from others and the use of proper moving equipment.

- When moving the instrument along with the cart, do not push the main unit; grasp the cart handle for pushing and pulling.
- Ensure that you can safely and comfortably grip the instrument or accessories.
- Ensure that the path from object to moving object is clear of obstacles.
- Do not lift an object and twist your torso at the same time. Keep a good neutral position when lifting with both legs.
- Participants should coordinate lifting and moving intentions when lifting and handling.
- For smaller packages, do not lift objects out of the box; tilt the box carefully, keep it steady, and have others slide the objects out of the box.

Electrical Safety

Warning! **Fuse installation**. Before installing the instrument, confirm that the fuse is correctly installed, and the fuse voltage matches the power supply voltage. Only replace fuses with the type and rating specified for the protective device. Improper fuse can damage the instrument's wiring system and cause fires.

Warning! Ensure **proper power supply.** To ensure the safe operation of the instrument:
- Plug the system into a properly grounded outlet with sufficient current capacity.
- To avoid the risk of electric shock, this equipment must be connected to a mains supply with protective grounding.
- Ensure the voltage of the power supply is appropriate.
- Do not operate the instrument when the grounding device is disconnected. Proper grounding continuity is required for safe operation.

Warning! Instrument protective bonding. To ensure the safe operation of the instrument, periodically inspect the grounding continuity of the instrument's base, front panel, and bag hanger.

Warning! **Power cord.** Use a correctly configured and approved cord for power supply to your instrument.

Warning! **Disconnect power supply.** To completely disconnect power supply, either disconnect or unplug the power cord, or position the instrument to come near the power cord.

Cleaning and Purification

Caution! Cleaning and contamination. Use only the cleaning and decontamination methods specified in the manufacturer's user documentation. Operators (or other responsible individuals) are responsible for ensuring the following requirements are met:

- Do not use cleaning or decontaminating agents that may react with equipment components or materials contained in the equipment. Using such agents may cause hazardous situations.
- If hazardous substances spill onto the instrument and/or during instrument maintenance or service, replacement, disposal, or loan return, request decontamination forms from the customer service.
- Before using any cleaning or decontamination methods (except those recommended by the manufacturer), confirm with the manufacturer that the suggested method will not damage the equipment.

Electromagnetic Compatibility (EMC) Standards

The design and manufacture of the instrument comply with the following standards and requirements regarding electromagnetic compatibility.

- It is recommended to assess the electromagnetic environment before using the instrument, and users are responsible for ensuring the instrument's EMC environment to enable proper operation.
- This instrument should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the equipment or system should be observed to verify normal operation in the configuration in which it will be used.
- The use of accessories and cables other than those specified may result in increased emission or reduced immunity of the instrument, except for accessories and cables sold by the manufacturer of the instrument as spare parts for internal components.
- Do not use the instrument near strong radiation sources (e.g., unshielded RF sources) as it may interfere with the instrument's proper operation.
- The instrument is susceptible to electromagnetic interference during operation, which may lead to incorrect actions. Please do not use devices that emit strong electromagnetic waves while the instrument is running.
- The instrument emits electromagnetic waves during operation. Please do not install or use electromagnetic-sensitive devices near the instrument.

Chemical Safety

⚠️ Warning! **General chemical handling.** To reduce hazards, ensure that laboratory personnel read and adhere to the general safety guidelines provided for the use, storage, and disposal of chemical substances. Refer to relevant SDS for specific precautions and instructions in the following situations:
- Before storing, handling, or using any chemicals or hazardous substances, read and understand the safety data sheets (SDS) provided by the chemical manufacturer. To obtain SDS, see the "Documentation and Support" section in this document.
- Minimize contact with chemicals. Wear appropriate personal protective equipment, such as safety goggles, gloves, or protective clothing, when handling chemicals.
- Minimize inhalation of chemicals whenever possible. Do not open chemical containers. Only use adequate ventilation equipment, such as a ventilation hood.
- Periodically check for chemical leaks. In case of a leak, follow the manufacturer's recommended cleanup procedures as outlined in the SDS.
- Dispose of the chemical waste in the ventilation hood.
- Ensure the use of primary and secondary waste containers. (Primary waste container holds direct waste,

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while the secondary container contains leaks or spills from the primary container. Both containers must be compatible with the waste and comply with federal, state, and local container storage requirements.)
- After emptying waste containers, seal them with provided lids.
- Describe (analyze when necessary) the waste generated from specific applications, reagents, and substrates that you used in laboratory.
- Ensure that waste is stored, transferred, transported, and disposed of in compliance with all local, state/provincial, and/or national regulations.
- Warning! Radioactive or biohazardous substances may require special handling and may apply to disposal restrictions.

⚠ Warning! **Hazardous waste (from the instrument).** The waste generated by this instrument has potential hazards. Follow the guidelines mentioned in the general chemical handling warnings above.

Biological Hazard Safety

⚠ Warning! **Potential biological hazard.** Depending on the samples used on the instrument, its surface may be considered as a potential biohazardous substance. When handling biohazardous substances, appropriate decontamination methods should be used.

⚠ Warning! **Biological hazard.** Human and animal tissues, body fluids, infectious pathogens, and blood, among other biological samples, have the potential to transmit diseases.
Conduct all work within facilities equipped with proper safety equipment (such as physical protective equipment). Safety equipment may also include personal protective items such as gloves, lab coats, gowns, shoe covers, boots, respirators, face shields, safety goggles, or eyewear. Personnel should receive training according to applicable regulations and company/organization requirements before working with potentially biohazardous materials.
Adhere to all relevant local, state/provincial, and/or national regulations. The following references provide general guidelines for handling biological samples in a laboratory environment:
- U.S. Department of Health and Human Services, Biosafety in Microbiological and Biomedical Laboratories (BMBL), 5th Edition, HHS Publication No.1. (CDC) Revision in November 2009. Available at: https://www.cdc.gov/labs/pdf/CDC-BiosafetymicrobiologicalBiomedicalLaborator ies-2009P.pdf
- World Health Organization, Laboratory Biosafety Manual, 3rd Edition, WHO/CDS/CSR/LYO/2004.11. Available at: www.who.int/csr/resources/publications/biosafety/Biosafety7.pdf

Warning message

⚠ 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.

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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.

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Annex B Documentation and Support

Customer and Technical Support

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

- Global Contact Phone Number
- Product Support Information
- Frequently Asked Questions (FAQs)
- Software, Patches, and Updates
- Training for Various Applications and Instruments
- Order and Web Support
- Product Documentation
- User Guides, Manuals and Protocols
- Certificate of Analysis
- Safety Data Sheets (SDS; also known as MSDS)

Note: For SDS of reagents and chemicals from other manufacturers, please contact the respective manufacturer.

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Official Account of Cellbri

Co-fusion, co-creation, and sharing, be a partner in customer growth