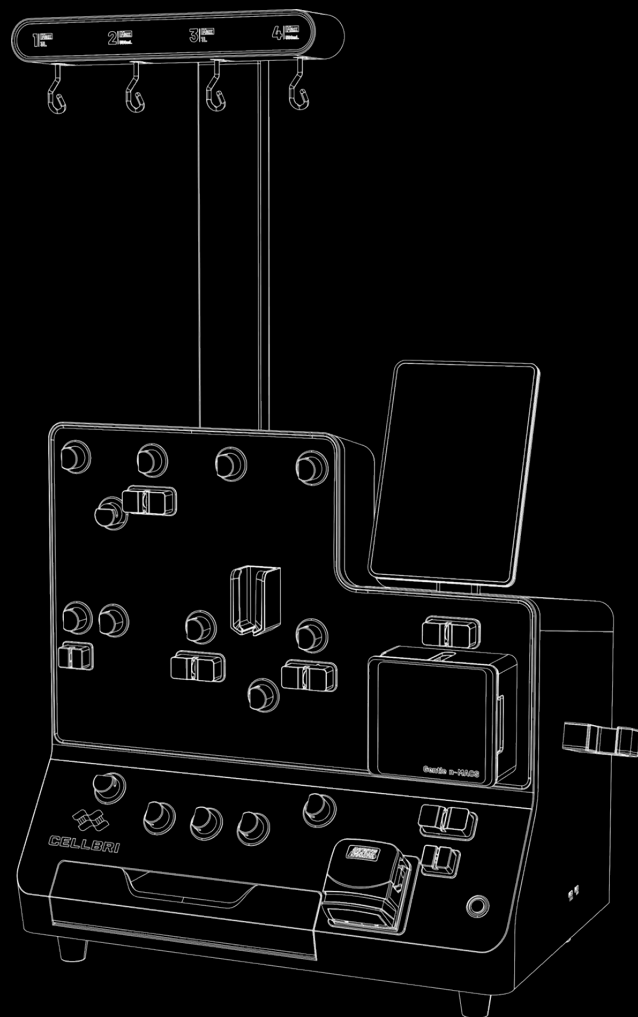


Gentle n-MagS™

Nanomagnetic Bead Fully Automated Sorting System

User Manual





The information in this user manual was correct at the time of printing. However, US CellBri Bio-Innovation Technology LLC continues to improve products and reserves the right to change specifications, equipment, and maintenance procedures at any time without notice.

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Disclaimer

To the extent permitted by law, US CellBri Bio-Innovation Technology LLC and its affiliates shall not be liable for any special, incidental, punitive, multiple, or indirect damages related to this guide, including its use.

The Gentle n-MagS Cell Sorting System is mainly used for cell sorting. Without official authorization, it is not intended for clinical use or reinfusion into the human body.

Biopharmaceutical manufacturers are solely responsible for ensuring the purity, potency, safety, and identity of the final product and obtaining regulatory approval.

During use, if you encounter any problems that cannot be handled, please contact your US CellBri support representative, to prevent any accidents, please do not open, disassemble, or perform any operation on the device.

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1 Introduction

These operating instructions provide you with the information needed to safely install, operate, and maintain your Gentle n-MagS instrument.

Sample Properties

The table below outlines sample property parameters for the Gentle n-MagS instrument.

Property	Specifications
Sample Size	Max. magnetically labeled cells: 1.2×10^9
Sample Source	Fresh apheresis, cryopreserved apheresis
Sample Handling	PBMC samples, washed apheresis samples

Consumable Requirements

The Gentle n-MagS instrument [Nma-Nss-S001] is compatible with a dedicated set of cell processing consumables. Details are listed below:

Product Code	Product Function	Product Model	Description
01020149	Nanomagnetic bead sorting	n-MagS	Dual separation column kit with 40 μm filter
01020180	Nanomagnetic bead sorting	n-MagS	Dual separation column kit with 40 μm filter

2 Safety Precautions

This section describes safety precautions and other information about this product. Strictly adhering to these guidelines reduce risk of injury to the operator, damage to the device, or the cell products handled by the device.

Before installing, operating, or maintaining the system, review this manual.

Getting Started

- **Power-on:** Check the instrument appearance for any damage. After confirming it is intact, connect the power cable and press the power button to start.
- Before using the [Nma-Nss-S001] sorting process, manual depletion sorting effectiveness must be confirmed. If the cell–bead incubation is not optimal, [Nma-Nss-S001] will not be responsible for the sorting outcome.
- Before starting the process, confirm that the protocol, fluid path, and software versions are compatible. Mismatches may result in failed operations.
- It is important to keep the instrument clean between procedures. After removing the consumables, use a lint-free cloth to wipe the instrument surface.

Protocol Precautions

- Key process parameters in the standard protocol require manual confirmation or input. Operators are advised not to leave the instrument unattended during critical steps to avoid long idle states.
- During operation, avoid touching the fluid bags unless prompted.
- During inflow, minimize movement to prevent interference with weight measurement accuracy.
- If the protocol is interrupted due to an error and resumed by skipping steps, ensure the fluid in the tubing panel and bags matches the state before the skipped step.
- It is recommended to inject $\geq 1/4$ of the sample volume of air into the sample bag before starting to reduce sample residuals.
- If clamps are opened prematurely and liquid enters the consumables without reaching the separation column, it is recommended to use the “Basic Operation” to return the liquid. If the liquid has already entered the separation column, replace the consumables to avoid affecting sorting results.
- Poor cell status or aggregation after bead incubation may affect cell recovery rate.
- Magnetic bead-labeled cell residue:
 - **Cell load range:** The recommended maximum is $\leq 1.2E9$ magnetic bead-labeled cells. If it exceeds this, residual magnetic bead-labeled cells in the target fraction cannot be guaranteed.



- o **Bead-cell incubation efficiency:** If incubation is not effective, residual bead-labeled cells in the target fraction cannot be guaranteed.

FCC Regulatory Compliance

- o 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.

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

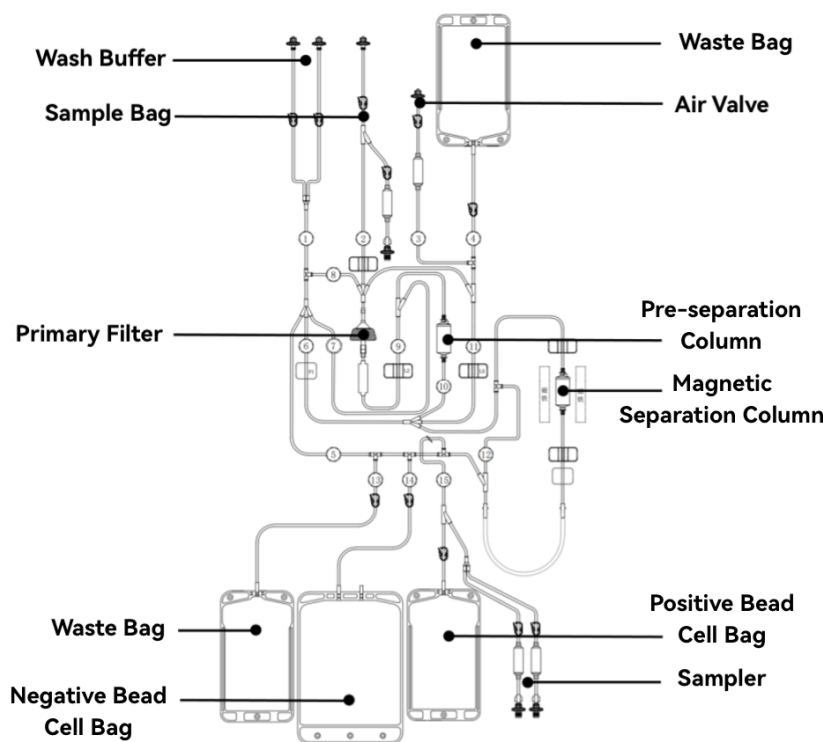
- o This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate 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.

This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. This equipment should be installed and operated with minimum distance 20 cm between the radiator and your body. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

3 System Overview



The image above is a schematic diagram of the tubing kit for the cell sorting process of the Gentle n-MagS instrument. The consumables for the Gentle n-MagS process include fluid path tubing, fluid bags, first stage filter, pre-sorting column, magnetic sorting column, and sterile sampling kit.

Fluid Paths

No. 1 is connected to the wash solution bag

No. 2 is connected to the sample bag

No. 3 is the exhaust valve

No. 4 is connected to the waste liquid bag.

Fluid paths No. 1 and No. 2, the No. 3 exhaust valve, No. 4 tubing, the waste liquid bag, and the magnetic bead-labeled/unlabeled cell bags are all included in the kit.

The fluid bags for paths No. 1 and No. 2 as well as the sample bag must be provided by the user.

The first stage filter is a 40 μm filter used for removing cell clumps. The pre-sorting column is designed to disperse aggregated cells and adsorb relatively adherent cells. The magnetic sorting column is used to capture magnetic bead-labeled cells.

Fluid path

No. 13 is connected to the waste liquid bag

Path No. 14 is connected to the unlabeled magnetic bead cell bag for collecting unlabeled bead cells.

Path No. 15 is connected to the magnetic bead-labeled cell bag for collecting labeled bead cells. This section of tubing is equipped with two sterile sampling kits for adjusting the density of labeled cells in-line. All three fluid bags are included in the kit.

4 System Preparation

Cell Sample Bag Preparation

Transfer the cell sample to be sorted into a sterile fluid bag that supports aseptic connection in advance. It is recommended that the sample volume not exceed one-third of the fluid bag's capacity.

Note: A single sorting run should not exceed 1.2×10^9 magnetic bead-labeled cells.

Cleaning Solution and Culture Medium Preparation

If non-target cells are not collected, prepare 450 mL of washing solution.

If non-target cells are collected, prepare 500 mL of washing solution.

Note: Recommended formula for washing solution: PBS ($\text{Ca}^{2+}/\text{Mg}^{2+}$ -free) + 2 mM EDTA + 0.5% w/v HAS.

Consumables Preparation

Prepare the consumables, and 01020149 check whether the consumables are intact 01020180 or undamaged.

Note: If the consumables are damaged (such as cracks in the sorting column and pre-sorting column, damage to the primary filter pipeline, etc.), please contact your CellBri technical support specialist.

Auxiliary Equipment Preparation

The Gentle n-MagS [Nma-Nss-S001] protocol requires a barcode scanner, sterile tubing welder, and heat sealer.

Barcode Scanner

The barcode scanner is provided with the instrument and is used for entering kit information.

Note: When scanning the consumable QR code, keep the scanner at approximately 30cm for optimal recognition.

Sterile Tubing Welder and Heat Sealer

The sterile tubing welder and heat sealer must be prepared by the user and are used for aseptic connection and heat sealing of the tubing for sample bags, washing solution, and culture medium.

5 System Operation

The operation of the magnetic bead sorting protocol on the Gentle n-MagS™ instrument consists of four parts:

- Instrument Initialization
- Consumables Installation
- Protocol Operations
- Protocol Completion

Instrument Initialization

Device Startup:

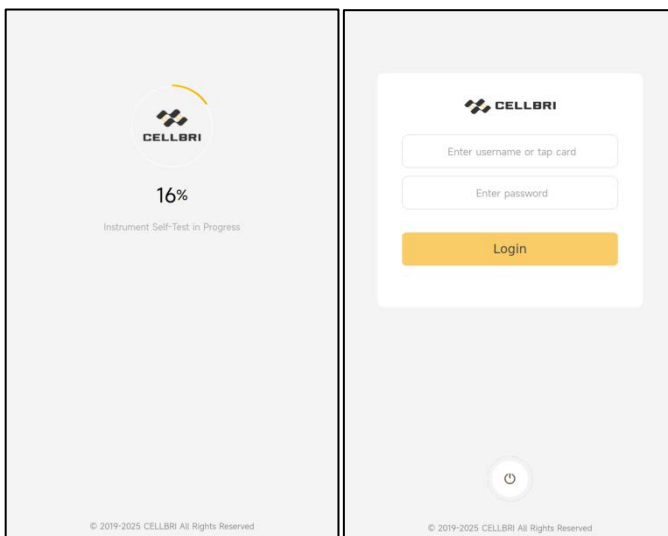
1. After connecting the power cable, switch on the power switch located at the back of the instrument.
2. Press the power button at the bottom right corner on the front panel to start the instrument.

The positions of the power and instrument switches are shown in the diagram below:



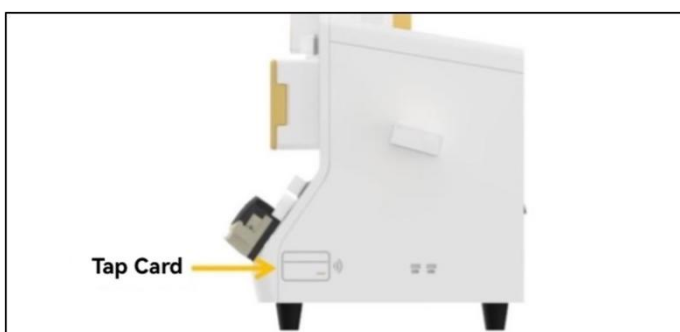
Device Self-Test:

After powering on, the instrument performs a self-test (left image). Upon successful completion, it enters the login interface (right image).



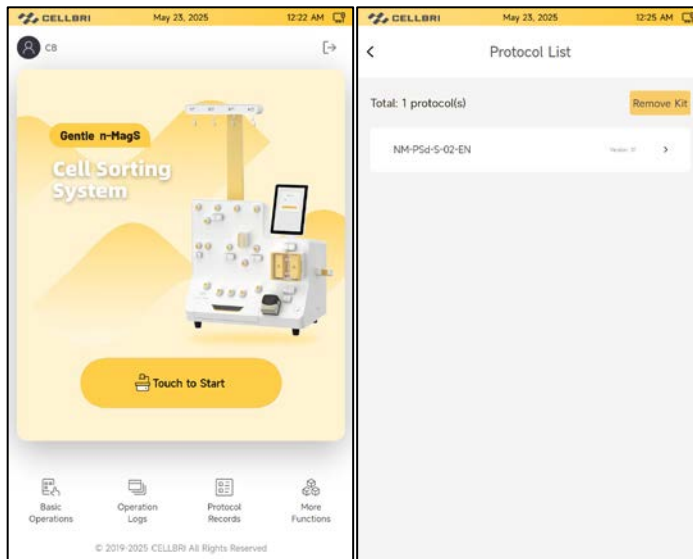
Log in to Enter the Main Interface:

Tap the card to obtain the username, enter the password, and select **Login** to access the main interface.



Enter the Protocol Selection Page:

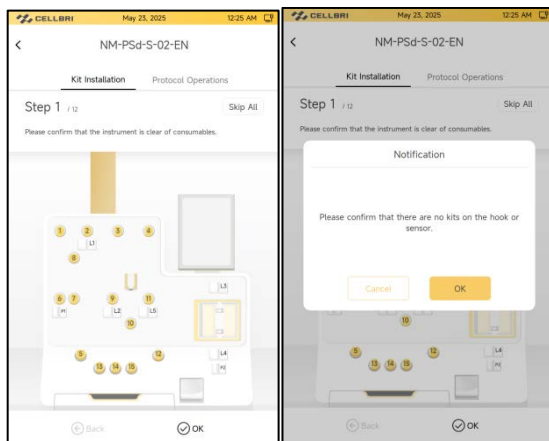
Select **Select Protocol** to display the list of protocols (as shown below), then select “Nma-Nss-S001”:



Consumables Installation

Pre-installation Check:

1. Confirm that there are no reagents or consumables on the hooks or in the sensors.
2. Select **OK** to proceed to consumables installation initialization.

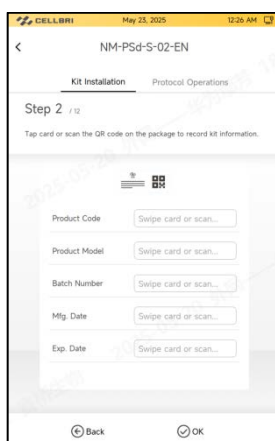


Kit Information Entry:

1. Open the outer packaging of the kit.
2. Use the barcode scanner to scan the QR code on the packaging or place the blue card from the kit package onto the card reader area of the instrument to register the kit information.

After scanning/swiping, the kit information will be displayed automatically.

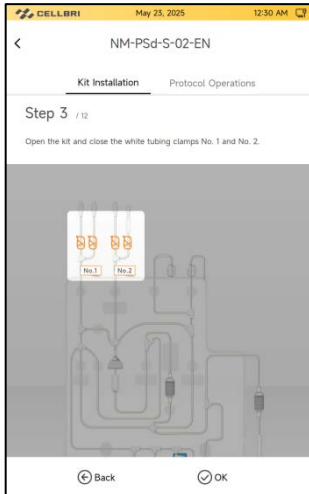
3. Select **OK** to proceed.



Pre-installation Preparation:

1. Remove the kit from packaging.
2. According to the diagram, close the clamps on the fluid paths of valves No. 1 and No. 2.
3. Aseptically connect the wash solution to fluid path No. 1 and aseptically connect the cell sample to be sorted to fluid path No. 2.

4. Hang the fluid bags onto the corresponding hooks, then select **OK** to proceed.

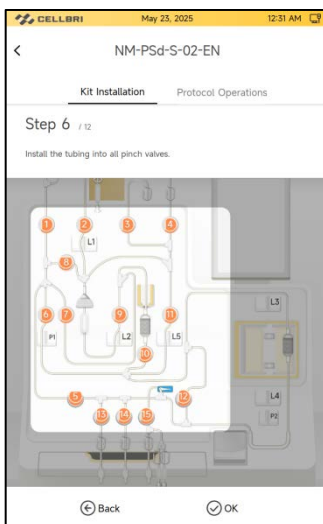


Tubing Installation:

This step is for installing tubing into pinch valves only. Do not install the tubing into sensors (L1–L5; P1–P2) at this stage.

1. Install the corresponding tubing into pinch valves No. 1–15 as shown in the diagram.
2. Ensure that the tubing is clamped to the bottom of the pinch valve and can be moved freely up and down.
3. Select **OK** to proceed.

Note: Avoid pulling or bending the tubing inside the pinch valves during installation. Make sure the tubing is clamped to the bottom; otherwise, the function of the valve and fluid flow may be affected.



Sorting Column Installation:

1. According to the tubing diagram, insert the sorting columns into the designated slots.
2. Close the compartment cover.
3. Select **OK**.



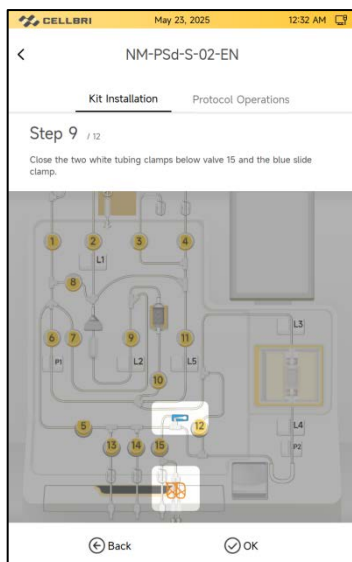
Sensor Tubing Installation:

1. Insert all sensor tubing highlighted in the image into the bottom of the sensor slots.



2. Close the blue slide clamp and sampling tube clamps highlighted in the image.

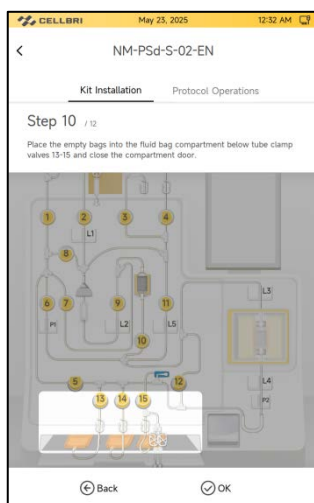
Note: The blue slide clamp must be positioned close to the three-way tubing connector as shown in the diagram, to prevent cross-contamination of the magnetic bead-labeled cell collection tubing (No. 15) by unlabeled cells.



Collection Bag Placement:

1. Place the fluid bags according to the diagram and close the compartment door.
2. Select **OK** to proceed.

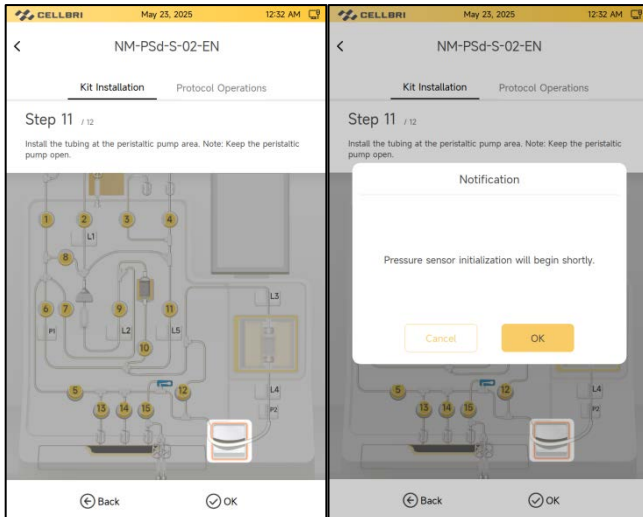
Note: Bag No. 13 is for waste liquid, No. 14 is for unlabeled magnetic bead cells, and No. 15 is for magnetic bead-labeled cells.



Pressure Sensor Initialization Preparation:

1. Open the peristaltic pump and install the pump segment tubing into the position shown in the diagram, keeping the pump in the open position.
2. After selecting **Confirm**, a pop-up will indicate "Pressure sensor initialization will begin shortly."
3. Select **Confirm** again to proceed to Pressure Sensor Initialization.

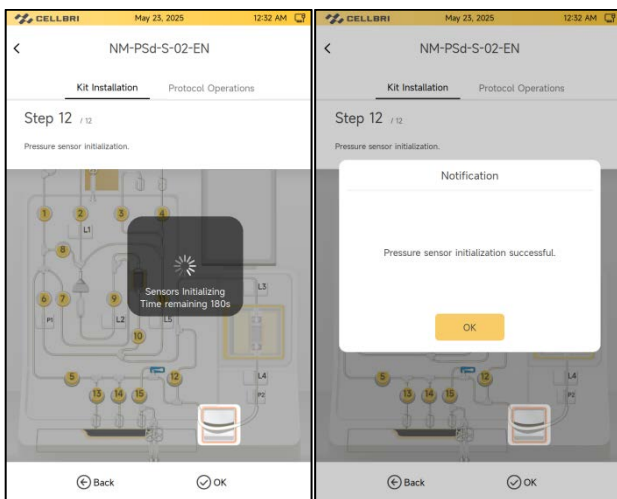
Note: Do not close the peristaltic pump until prompted, to ensure that the tubing pressure remains within the expected range.



Pressure Sensor Initialization:

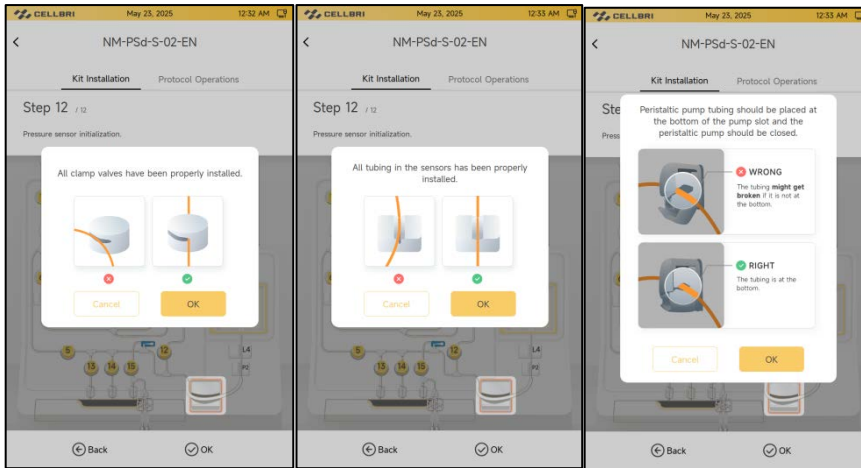
This process takes 180 seconds. After the countdown ends, a pop-up window will display “*Pressure sensor initialization completed successfully.*”

1. Select **Confirm**, then place the pump segment tubing as shown in the diagram and close the peristaltic pump cover.
2. Select **Confirm** again to proceed to Kit Installation Verification.



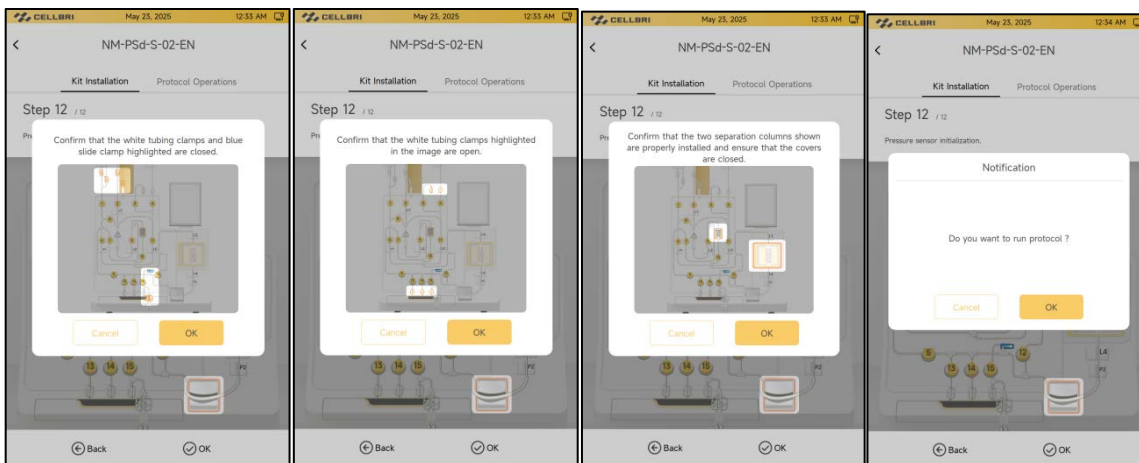
Kit Installation Verification:

1. According to the diagram below, recheck the tubing at the pinch valves, sensors, and peristaltic pump.
2. Ensure that the tubing is properly inserted on the inner side of the pinch valve and remains unobstructed; sensor tubing is at the bottom of the groove and remains unobstructed; peristaltic pump tubing is at the bottom of the pump slot and the peristaltic pump panel is closed.
3. After confirming everything is correct, select **Confirm**.



Tubing Clamp Status Confirmation:

1. Confirm that the clamps highlighted in the image are in the correct open or closed positions, then select **Confirm**.
2. Confirm that the separation columns are correctly installed and the cover is closed, then select **Confirm**.
3. A pop-up will then prompt whether to proceed to protocol operation; select **Confirm**.



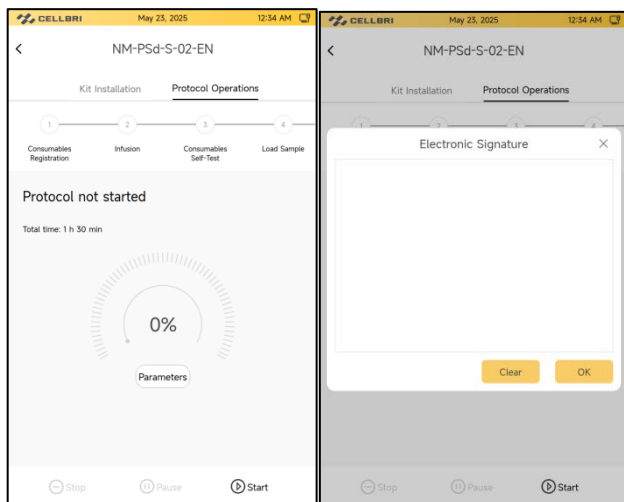
Protocol Operation

After completing the consumables installation, begin the protocol operation by following the instructions below.

Start Protocol Operation:

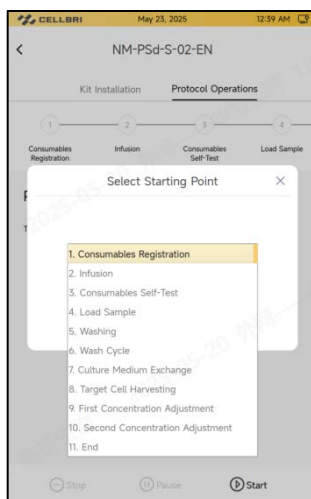
1. Entering the **process operation** interface, select **Start**.
2. Complete the electronic signature then select **OK**.

The system automatically displays the *Select Starting Point* pop-up.



Enter Kit Registration:

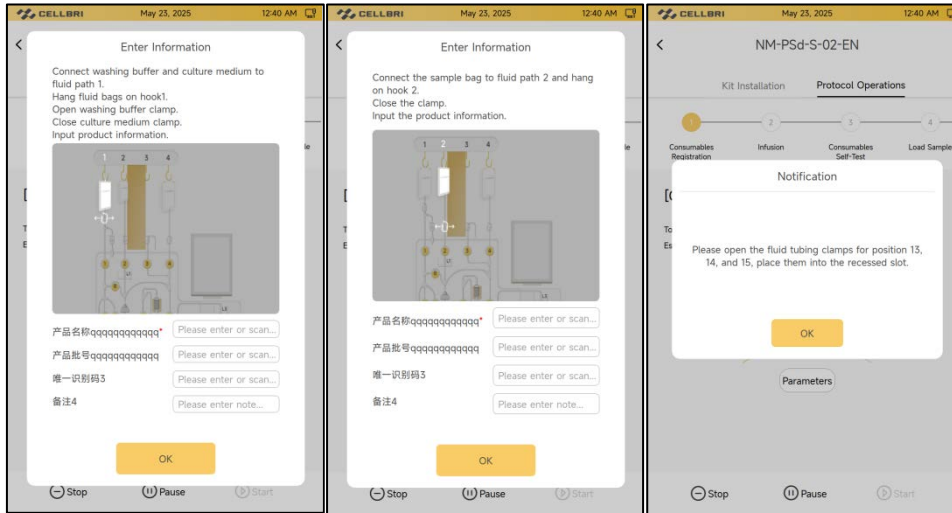
Select 1. Kit Registration then select **OK**.



Information Entry:

1. When prompted, hang the medium and washing solution on **Hook 1**.
2. Open the washing solution clamp.
3. Enter the necessary details.

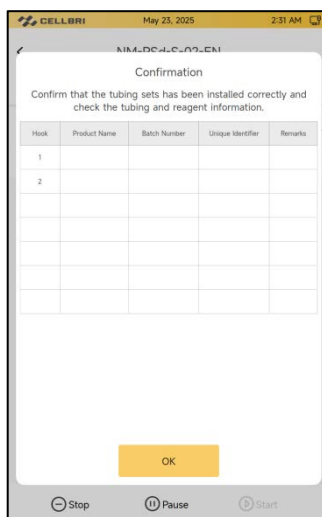
4. Hang the sample bag on Hook 2
5. Close the clamp.
6. Enter the necessary details.
7. Begin the Kit Self-Test.



Kit Information Entry Confirmation:

The system will automatically display an *Entry Information Confirmation* pop-up window. Verify the entered information then select **OK** to proceed.

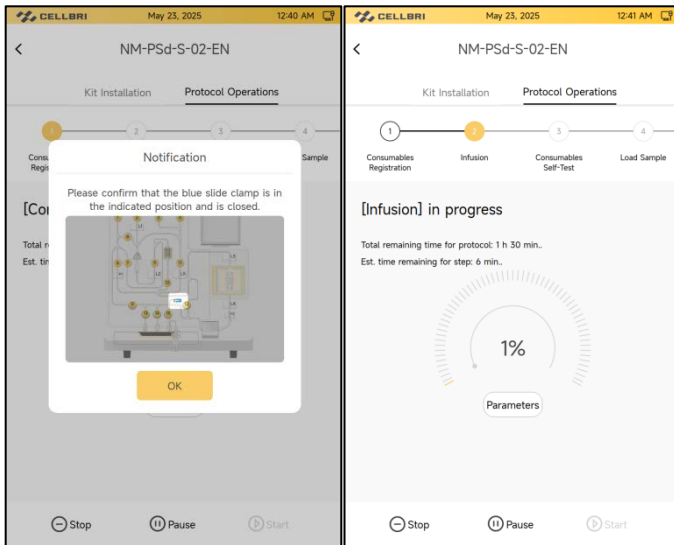
Note: If any incorrect information is found during confirmation, you can select the corresponding entry to modify it.



Infusion:

A pop-up will prompt “Please confirm that the blue slide clamp is in the indicated position and is in the closed state.” After confirming, select **OK** to enter the “Infusion” step.

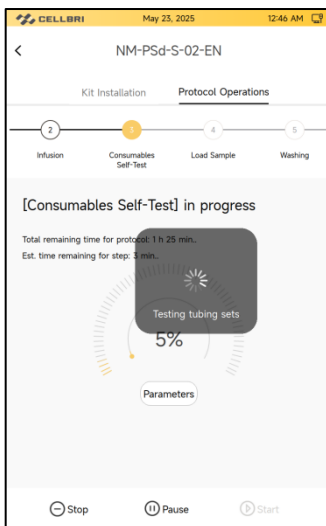
The instrument will proceed automatically according to the protocol. This step mainly flushes and saturates the tubing and sorting columns, removing air from the system and preparing for the subsequent sorting.



Kit Self-Test:

The device enters the "Kit Self-Test" step, during this step it automatically performs a self-check according to the protocol.

This step mainly verifies the status of the kit and whether it has been properly installed. Once the device displays "Kit Self-Test Passed," select **OK** to proceed to the next step.



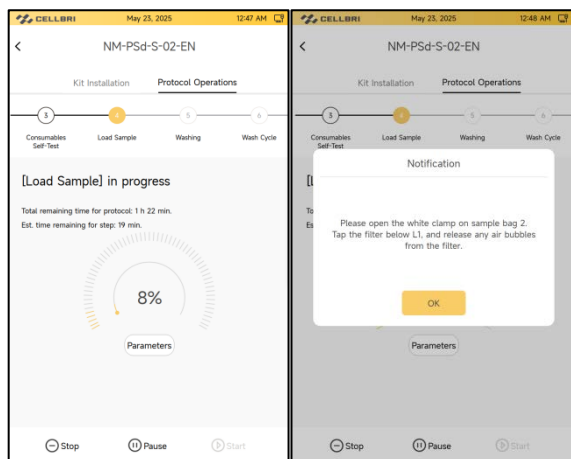
Magnetic Bead Sorting:

The device enters the "Magnetic Bead Sorting" process, which proceeds automatically according to the protocol and includes the following steps:

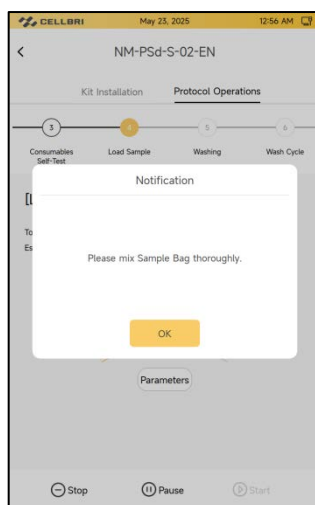
- **Apply Magnetic Field:** The magnet in the sorting column area extends to apply a magnetic field to the sorting column. At this stage, ensure that the magnet is properly extended to avoid sorting failure. A pop-up reminder will prompt the user to input the sample inflow

rate. According to the prompt, tap the filter below Sample Bag No. 2 to remove air bubbles and allow the membrane to be fully wetted by the buffer.

- **Load Sample:** Valves 2, 9, 10, and 14 open. As the cells in Sample Bag No. 2 flow through the sorting column, bead-labeled cells are retained in the column by magnetic force, while unlabeled cells flow directly into Bag No. 14. The process continues until all sample has been loaded.

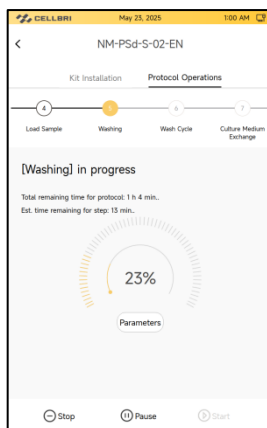


- **Backflush Sample Bag:** Valves 1, 5, 11, and 2 open. The nanobead sorting buffer from Cleaning Solution Bag No. 1 flows into Sample Bag No. 2. A pop-up will prompt: "Manually mix the sample bag." After manual mixing, select **OK** to continue sample loading.



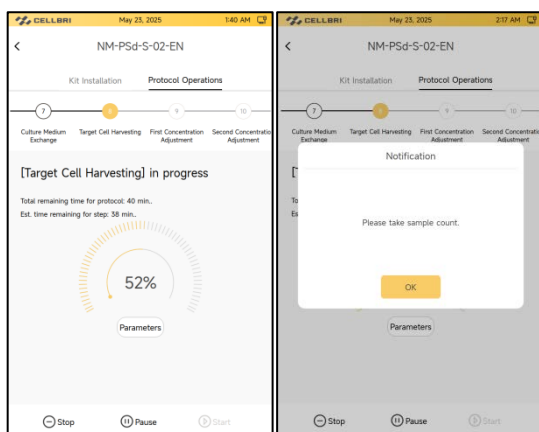
Washing:

Residual unlabeled magnetic bead cells in Sample Bag No. 2, the primary filter, and the separation columns are flushed into Liquid Bag No. 14.



Collecting Unlabeled Target Cells:

According to the pop-up prompt, use the heat sealer to seal off Liquid Bag No. 14 and collect the target cells that are not labeled with magnetic beads.



Collecting Non-Target Cells Labeled with Magnetic Beads:

A pop-up will prompt you to choose between "Collect non-target cells" or "Do not collect non-target cells". Make selection.

Note: If "Do not collect non-target cells" is selected, the process will end, and a pop-up will prompt: "Sorting is complete, please collect the target cells from Bag No. 14."

If "Collect non-target cells" is selected, the process will continue and proceed to the **Non-target Cell Collection** step.

Non-target Cell Collection:

- The magnetic field in the sorting column area will be deactivated, entering the preparation stage for non-target cell collection.
- A pop-up will prompt: "Please open the blue slide clamp". After opening, select **Confirm**. The default formulation volume for non-target cells is **50 mL**.

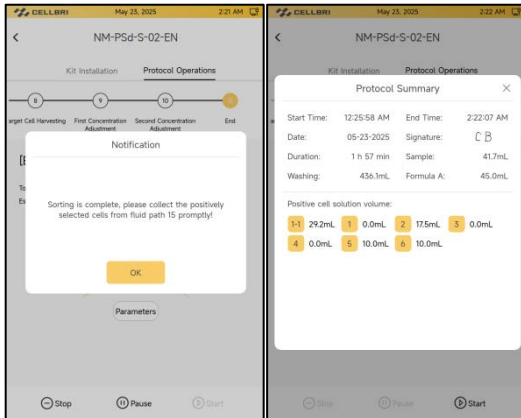
Process Completion:

A pop-up window will prompt: *"Sorting is complete. Please collect the non-target cells from Bag No. 15."*

After collecting the cells, select **OK**.

The system will automatically display the Protocol Summary, including: start time, end time, processing date, operator signature, processing duration, sample volume, wash solution volume, and negative bag volume.

Select the "x" in the upper right corner to return to the main interface.



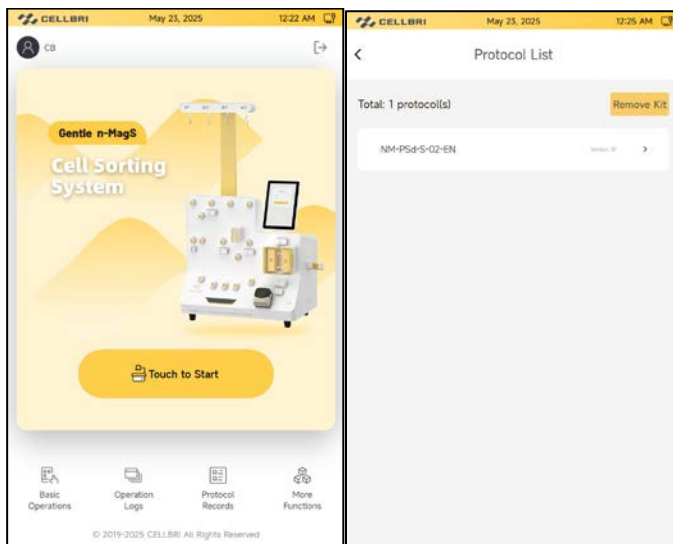
Protocol Completion

Final Product Collection:

According to experimental requirements, heat seal and remove the final product bag for subsequent experiments.

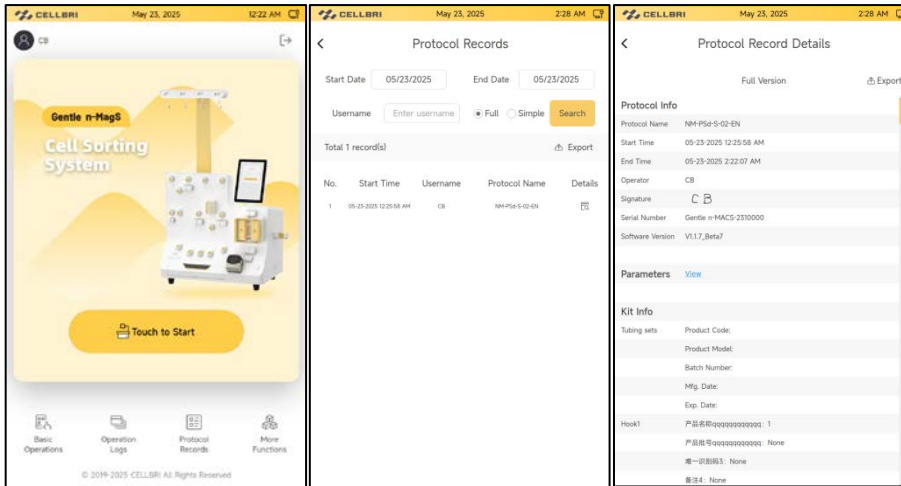
Kit Removal of the Equipment:

1. Follow the onscreen prompts to close all white tubing clamps to prevent fluid flow. From the main interface, select **Select Protocol**, then select **Remove Kit** in the upper right corner. All valves will open and light up to facilitate tubing removal.
2. After removing the tubing kit, select **OK**. A pop-up will appear “Please confirm whether removal is complete.” After confirming, all valves will close and the system will return to the protocol list screen.



Review And Export Process Records:

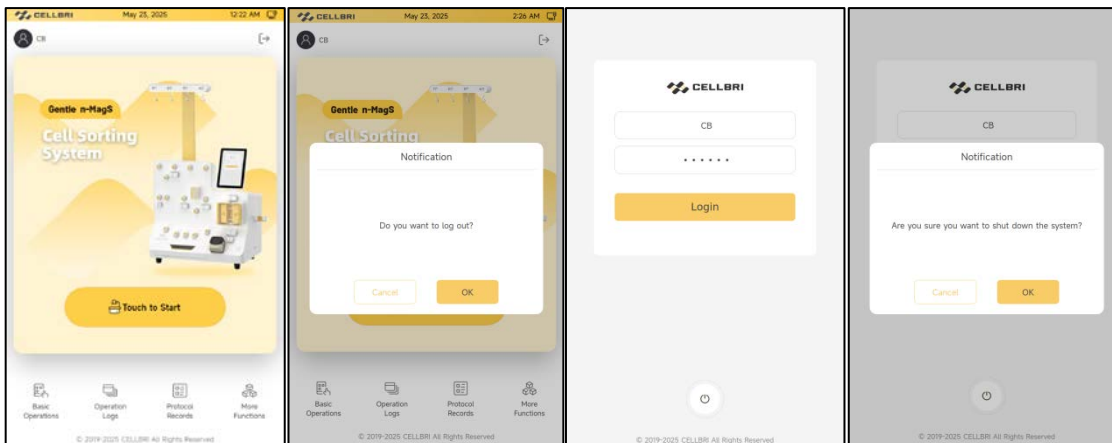
1. Insert a USB flash drive into the USB port of the instrument.
2. Select **Protocol Records** on the main interface.
3. Select the start and end dates of the protocol.
4. Select **Query** to display the protocol records.
5. Select **Details** for the corresponding protocol to review its record.
6. Select **Export** in the upper right corner to export the protocol record.



Shutdown:

After completing the operation, log out from the top left corner of the main interface and shut down the instrument, or press and hold the power button for 5 seconds to turn it off.

Note: After shutdown via software, the power indicator light remains on because it is connected to the power switch. The indicator will turn off only after the rear physical power switch is turned off.



6 Troubleshooting and FAQ

What should I do if the pressure sensor alarm is triggered during the consumables self-test?

Please troubleshoot as follows:

1. Check if the tubing at the pressure sensor is correctly installed.
2. Confirm that the tubing at the pressure sensor is installed at the appropriate step according to the system guidance.
3. Inspect the tubing for abnormalities such as bending, twisting, or stretching.
4. Check whether the tubing clamps are in the correct open or closed state as indicated by the system.

Can the kits/consumables be reused?

Kits/consumables are not reusable. Reuse may lead to decreased cell sorting yield and risk of contamination of target cells.

Note: Some malfunctions may be resolved by restarting the instrument. You can press the power switch on the side of the device to shut it down, wait for 2 minutes, and then restart it to check whether the issue is resolved. If the problem persists, please shut down the device and contact our company or distributor promptly.



Appendix A: Product Documentation and Technical Support

Please visit **www.cellbri.com** for the most up-to-date documentation including:

- Product support information
- Product FAQs
- Software, Patches, and Updates
- Training for applications and devices
- Order management and web support
- Product Documentation
- User Manuals and Protocols
- Analytical reports and certificates
- Safety Data Sheets (SDSs / MSDSs)

Note: For documentation related to reagents and chemicals produced by other manufacturers, please contact the respective manufacturers.

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Appendix B: License Information

Important Licensing Information

This product may contain one or more limited-use license labels.

Use of this product constitutes acceptance by the user of all terms and conditions of the applicable limited-use license label(s).

Trademark

Unless otherwise specified, all trademarks mentioned in this guide are the property of US CellBri Bio-Innovation Technology LLC. All Rights Reserved and its subsidiaries.

Revision History

Revisions	Date	Description
V01	April 2025	First edition

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

The information in this user manual was correct at the time of printing. However, US CellBri Bio-Innovation Technology LLC continues to improve products and reserves the right to change specifications, equipment, and maintenance procedures at any time without notice.

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