

# Gentle Flex

Automated Fully-closed Cell Processing System

- Centrifugal chamber with temperature control
- Patented FaSe fast separation technology
- Gentle handling with low damage
- Washing by continuous flow centrifugation
- Closed-flow dispensing



# Product Overview

The Gentle Flex is a fully-closed, automated, digital and flexible cell processing instrument which can be used for a variety of cell processing programs for different cell types. It is applicable to major pharmaceutical enterprises, biological research centers, pathological research institutions, hospitals and universities in the cell and gene therapy industry.

## Product Features

- Patented FaSe fast separation
- Gentle cell processing for high viability
- Closed-flow dispensing
- Washing by continuous flow centrifugation
- Centrifugal chamber with temperature control



### PBMC separation

Suitable for whole blood, fresh apheresis blood, cryopreserved apheresis blood, and umbilical cord blood.



### Magnetic bead incubation



### Viral transduction

High viral transduction efficiency



### Concentrated harvest



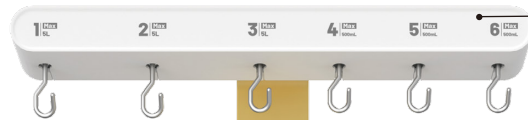
### Cell washing

Washing by continuous flow centrifugation.



### Dispensing

Cryopreservation solution replacement  
Multi-batch dispensing, 3 bags/batch



### Weighing module

Precisely control the volume of liquid in and out

### Pinch valve indicator light

Each pinch valve is equipped with an indicator light to indicate the open and closed state of these valves (the closed state is shown in the figure)

### Pinch valve

Control hydraulic switches and flow paths

### Liquid and pressure sensors

Achieve real-time monitoring of protocol progress and pressure in the tube as well as early warning of risks, while detecting disposables and hardware performance

### Peristaltic pump

Control liquid flow rate and flow direction

### Centrifugal module

The main module of cell processing, which controls the cell processing mode, including centrifugal intensity, mixing intensity, etc.

### Heat dissipation module

Used for heat dissipation of the centrifugal chamber and circuit module

### Intuitive GUI touchscreen

Operation interface, including: basic operation and protocol run, etc.

### Card swiping area

Swipe card and enter password for dual authentication login, which is in compliance with regulatory requirements

### QRcode scanner holder

Used to place the QRcode scanner for inputting disposables information



# Product Advantages

## Multi-functional modules

PBMC separation, magnetic bead incubation, viral transduction, cell washing, cell concentration, washing harvest, cryopreservation solution replacement, and dispensing

## Economical

Functional integration of processes can provide cost savings and reduce waste. The PBMC separation and magnetic bead incubation processes are integrated into one protocol with only one set of consumables; and the concentrated washing, cryopreservation solution replacement, and dispensing processes are integrated into one protocol with a single set of disposables.

## Equipped with sterile sampling kit

Allows for more convenient sampling and counting as the disposables are equipped with sterile sampling kits to easily perform analytical tests without disturbing the final cell bag.

## High-precision dispensing (need to cooperate with high-precision disposables)

10-100mL is dispensed, with an error of N-1 bags  $\pm$  1mL, and the dispensing precision comparable to that of manual is suitable for the seamless transition from manual protocols to automatic procedures.

## Harvest by continuous flow centrifugation

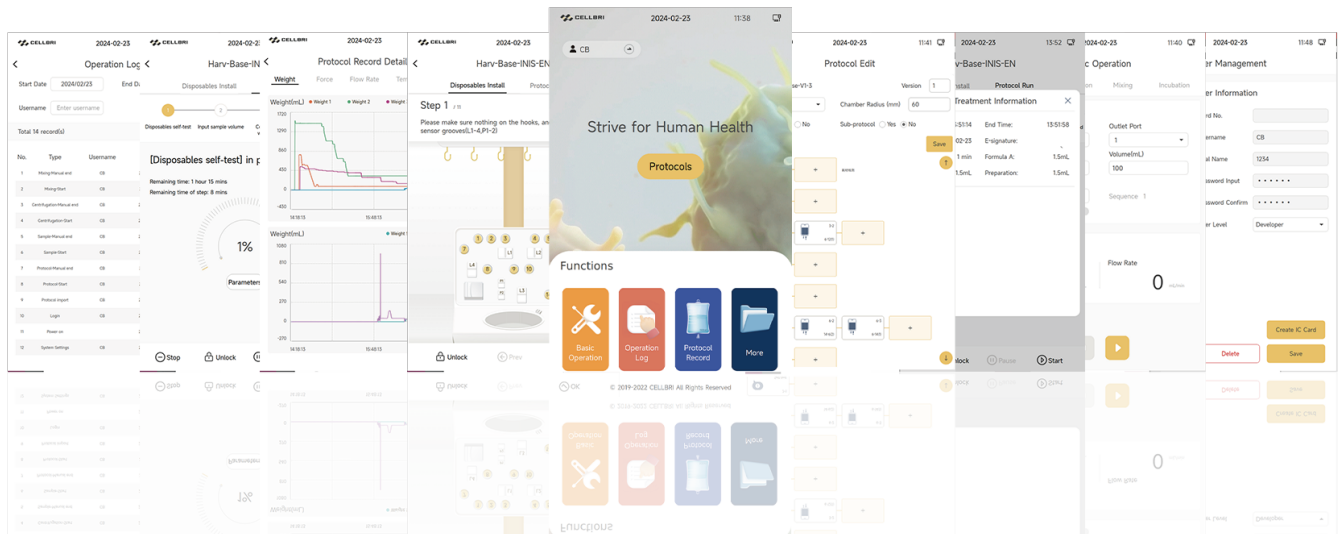
Harvest by continuous flow centrifugation, with shorter processing time, higher processing efficiency, and higher instrument utilization

## Temperature control

The centrifugal chamber has the temperature control function, 4-37°C

## Compliance with regulatory requirements

The software design complies with 21 CFR part 11, with the functions of permission management, audit trails, and electronic reporting.



## Functional Parameters

### PBMC separation

Support 4 sample types	Whole blood, fresh apheresis blood, cryopreserved apheresis blood, and umbilical cord blood
Maximum number of cells in single processing	1E10
Sample volume range that can be processed	10mL - 150mL
Ficoll dosage	200mL
PBMC recovery	40% - 80% (varying according to sample type)
Final output volume	30mL - 250mL
Total process time	About 90min

### ● Ultra-fast sedimentation density gradient centrifugation technology (FaSe technology)



#### Efficient

Complete PBMC separation and extraction with two cycles of washing within 90 minutes.



#### Flexible

Culture and magnetic bead incubation can be directly conducted.



#### Low damage

Centrifugation uses low shear force, and cell viability remains unchanged before and after separation.



#### High performance

Mononuclear cell recovery and purity are superior to manual techniques.

### Concentrated harvest and dispensing

Sample type	Cultured cells
Maximum number of cells in single processing	2E10 (Tcell)
Maximum sample volume	5L
Recovery	90%±10%
Minimum concentrated volume	10mL
Number of final collection bags	Multi-batch dispensing, 3 bags/batch
Final collection volume	30mL-5L
Washing method	Centrifugal mixing and washing, and washing by continuous flow centrifugation
Maximum flow rate	120mL/min

Collection method	Volume range	Dispensing precision
Tube	10 mL–100 mL	±0.5 mL
Filter	10 mL–100 mL	±1 mL

- Note:
- Final collection performance depends on user operation/product configuration.
  - The above indicators refer to when the dispensing volume is < 100mL; if the dispensing volume is > 100 mL, then the calculation is based on the relative error of the indicator.
  - The total volume error of the final collection is better than ±3 mL; when the total volume of the final collection is greater than 100 mL, the total volume error is better than ±3%.
  - The confidence level is 95%.

# We Can Provide

## ● Automated protocol development services

CellBri offers flexible protocol customization services as per the varied protocol requirements of customers. This allows customers to define their own production lines, and ensures effective human-machine collaboration while facilitating a transition from manual protocols to automated procedures. In the future, the planned automated protocol procedure will be integrated into the enterprise production management system, making it convenient for users to integrate data and carry out effective information management.

## ● Disposable cell processing kit

Cat#	Size	Application
01020207	GS11-150	Compatible with Gentle Flex for PBMC separation of 10-150mL of blood samples, magnetic bead incubation and washing, etc.
01020205	GH11-5L	Compatible with Gentle Flex for concentrated harvest of cells within 5L and dispensing, cell replacement and washing, magnetic bead incubation and washing, etc.

## ● Disposable cell processing Protocol

Cat#	Protocol software	Application
090100001	Harv-Base cell harvesting	Used for cell concentration, washing, solution replacement, addition of cryopreservation solution, and dispensing
090100002	Sep-Base PBMC separation	For platelet removal, concentration, and separation of mononuclear cells from peripheral blood
090100003	Sep-Base-CS PBMC separation	For platelet removal, concentration, and separation of mononuclear cells from cryopreserved apheresis blood
090100004	Sep-Base-FS PBMC separation	For platelet removal, concentration, and separation of mononuclear cells from fresh apheresis blood
090100008	VTrans viral transduction	For the transfer of viruses into cells
090100009	Beadsin magnetic bead incubation	For magnetic labeling of PBMC

# Product Specifications

## Specification parameters

Size 21.7×24.6×68.5 in.

Weight 140.7lb

## Power consumption parameters

Power supply 100-240 VAC,50/60 Hz

Power 450V

## Port parameters

USB 2.0x2

Ethernet port 100Mbit/s

## Main unit parameters

Monitor 10.1-inch TFT capacitive touch screen

Centrifugal chamber With the centrifugal chamber of disposable tubing, the maximum centrifugal force can reach 520g

Sensors Pressure sensor, liquid sensor, temperature sensor, weighing sensor, liquid leakage sensor, and Hall sensor

Centrifugal chamber temperature control 4°C-37°C

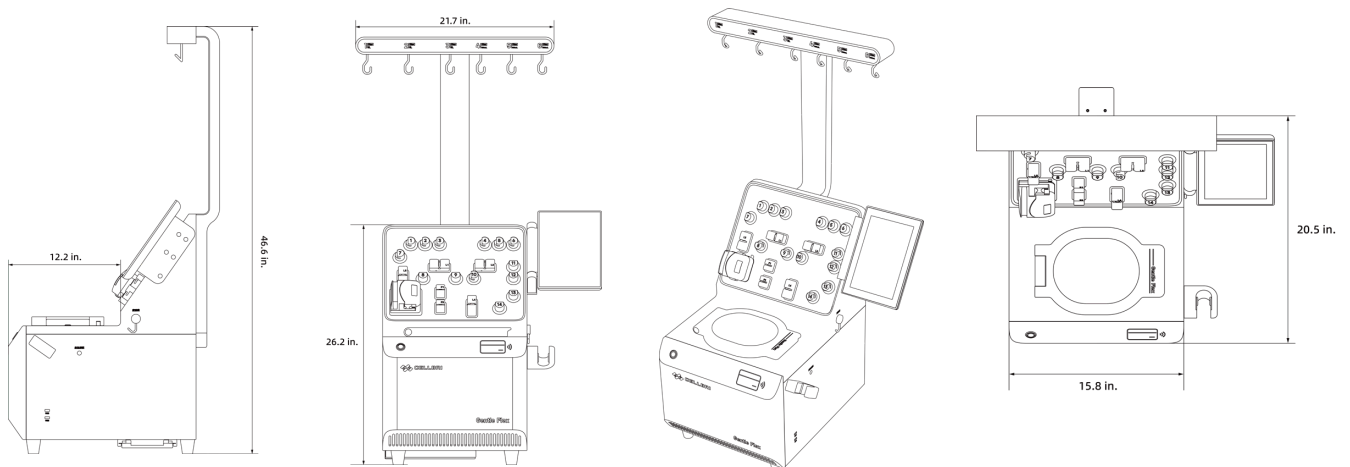
Hook 8 pieces

Liquid delivery devices Pinch valve, and peristaltic pumps with a rate of 10-400mL/min

Consumables Single-use fully closed disposables, minimizing the risk of contamination

Software Linux operating system, with a variety of built-in standardized protocols, which can develop customized protocols according to customer needs

Barcode scanner Convenient to input the information of various reagents



# Cell and Gene Therapy Productivity Transformer

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