

# Curate<sup>®</sup> Cell Processing System

Designed for the manufacturing of cell therapies, with maximum ease of use, and a focus on minimal manipulation, the Curate Cell Processing System consists of a fully automated fluid control system that integrates seamlessly with a single use disposable cassette, while maintaining a fully closed fluid path.

The result is a solution that gently and reliably delivers maximum leucocyte recovery paired with industry leading purity and critical quality metrics.

### Automated Run Monitoring

The Curate uses 4 independently controlled pumps to provide pulse free flow between 100-1000mL/hr. The system manages and monitors fluid movement by integrating flow rate, gravimetric sensor information, valve positions and sensor status information to ensure a high-quality cell product. This system actively monitors these parameters and can auto-execute a save sample if deviations beyond nominal tolerances are detected.

Capable of highly efficient separation, wash and concentration, the system actively monitors the run every 1/10 second to detect and respond to thresholds or other error condition detection and will activate a “save sample” protocol if relevant thresholds are exceeded.

### Hardware

The Curate utilizes an embedded PC running a hardened windows IOT environment interfaced to a glove compatible 7-inch touch screen display at 800x400 resolution. The system’s drive has 12Gb of memory – enough to store data for >1000 runs.

The system comes with a 2-D compatible barcode scanner and has an additional screen and haptic touch button to guide the user through the accessioning process and provide real time status and error information during a run.

Fluid movement is monitored in real time using load cell equipped hangars. Input and waste hangars feature 0-4.5 Kg dynamic range load cells, and the product collection position features a higher sensitivity load cell with a 0-1.0 Kg dynamic range to aid accuracy in concentration mode.

The design supports up to 2000 mL of input material and up to 5000 mL of waste fluids, and the apheresis/Leukopack processing protocol Supports up to 400mL inputs.



# Technical Specifications

## Software & Connectivity

The Curate software has been designed to be 21.CFR part 11 compliant and all data is TLS 1.2 encrypted.

Three modes of operation are supported

- Separate/Wash
- Separate/Wash plus concentration
- System Test Routine to support IQ/OQ operations

Data Output: PDF Run Reports, .CSV data;

Supported compatibility: OPC/UA, Webservices, sFTP transfers via ethernet connectivity.

## Sterilization & Biocompatibility

Consumable:

The single use closed fluid path consumable cassette is manufactured using compliant materials and is sterilized using Ethylene Oxide.

Instrument:

Designed with a fully closed fluid path, the curate system can also be surface sterilized with disinfectant sprays as needed to ensure bio-safety.

## Compliance

The Curate Cell Processing System is compliant with electrical safety per IEC61010-1 and electromagnetic compatibility per IEC 61326-1. The software is designed in accordance with IEC 62304.

The Curate consumable is designed and manufactured in substantial accordance with ISO 13485, ISO 14971, ISO 10993-1, ISO 11135, ISO 11737-1, ISO 11607-1. Please contact us directly for technical documentation.

For Research Use Only.

155C-10017 Rev A

Component	Specification
<b>Consumable</b>	
Macro-fluidic cassette	Sterile fluid path with integrated 20µm nylon prefilter
Deterministic Cell Processing Array (Patents, Pats. Pending)	3.5 million micro-posts positioned ±1µm Separation efficiency >96% Platelet removal >99% RBC Removal >90% Wash Efficiency >3 Log
Cell Size (Leukocytes)	4-22µm
Overall Leukocyte recovery	~90%*
Output Volume(s)	
Separate/Wash Mode	~85% of Input volume
Concentration Mode(s)	45 mL or 100 mL
Maximum Input cellularity	150e6 WBC/mL or 10% Hematocrit
Minimum Input cellularity	None

<b>Instrument</b>	
Reduced Pulsatility RPM Monitoring Pumps (4)	100-1000 ml/Hr ±10%
Input sample throughput	400 mL/Hr±10% <sup>†</sup>
High Pressure Valves (14)	0-80 PSI ±5%
High Sensitivity Gravimetric Sensors (1)	0-1000 gram. Linearity 0.99 ±2.0%
Gravimetric Sensors (6)	0-5000 gram. Linearity 0.99 ±2.0%
Pressure Sensors (2)	0-45 PSI dynamic range
IR Bubble Sensors (4)	10 Hz Sample Rate
CPU/Operating System with integrated touch screen	2.0GHz CPU 12GB HD, running Win IOT 800 x 480 resolution
Status screen with haptic "next" button (1)	120 x 460 pixels
USB 3.0 Ports (6)	Up to 5Gb/sec
Ethernet Connections (2)	CAT6 Up to 10Mb/sec

<b>Installation</b>	
Dimensions (HxWxD)	64 x 74 x 67 cm (25x29x26 in.)
Weight	39 Kg (86.4lbs)
Input Voltage	90-264VAC at 47-63Hz
Current	< 6A (RMS) at 115V AC < 3A (RMS) at 230V AC
Power Consumption	<200W
Fuses	5A at 250V AC

Performance data based on Curate Beta System.

\* Includes ~7% loss to prefiltering.

† Sample processing rate of 600ml/Hr. following 24 min priming cycle.

Curate Biosciences  
2715 Loker Avenue West  
Carlsbad, CA, 92010



[customerservice@curatebio.com](mailto:customerservice@curatebio.com)  
1-888-784-2297, 805-456-8977  
[techsupport@curatebio.com](mailto:techsupport@curatebio.com)  
1-888-784-6618

