

# SONY



## CGX10 Cell Isolation System

### Technical Specifications

The CGX10 Cell Isolation System is a fully closed system for GMP-compliant cell production and cell sorting applications. The system provides high quality cell isolation based on the presence of specific markers. The CGX10 offers two operational modes, one for the operator, for routine use, which is compliant with 21 CFR Part 11 guidance, and another for the process developer, to maximize operational efficiency. This versatility makes transition from research to manufacturing smooth. Moreover, full touch screen operation, a small footprint, and mobility with caster wheels enable adoption into your GMP facility as needed.

Sony Biotechnology Inc.



# Technical Specifications

<b>Technology</b>	Cell isolation	Closed microfluidics cell isolation technology with patented hydrodynamics control technology
	Closed/sterile	Single-use, sterile, closed tubing kit and fluid bag connected by sterile welder. Tubing kits are sterilized with EOG (ethylene oxide gas).
	Automation	Fully automated system setup technology without any beads or non-sample particles. Automatic clog detection and recovery function are provided.
	Ease of use	Guided setup and operation for routine and GMP use, including auditable electronic records, comprehensive user privileges and touch screen control
<b>System Specification</b>	Dimensions	W: 27.6 in (70 cm) x D: 29.5 in (75 cm) x H: 60.6 in (154 cm) without system status indicator pole (H: 69.3 in (176 cm) with system status indicator pole)
	Weight	397 lb (180 kg) main unit only, dry weight
	LCD panel	15.6" touch screen (main), sub monitor can be connected (duplicate mode)
	Power supply	100–240 V, 50/60 Hz, 2 sockets
	Power consumption	1,000 W (two independent 500-W circuits)
	External interface	External connector (for mouse, keyboard or data storage device) and video (external display) connector. There is also a LAN port (RJ45).
	Operating temperature	15°C to 25°C
	Relative humidity	20% to 60%
<b>Optics</b>	Excitation lasers	488 nm, 638 nm, 405 nm, 561 nm
	Detectors	V1, V2                    450/50 nm, 525/50 nm B1, B2, B3, B4        525/50 nm, 600/60 nm, 695/50 nm, 785/60 nm R1, R2                    665/30 nm, 785/60 nm
	Detection parameters	8 fluorescence + 2 scatter
<b>Functional Specification</b>	Sample input	Sterile Tubing Kit (Standard): 1–25 mL Sterile Tubing Kit (Process Development): depends on user's selection
	Sort output devices	Sterile Tubing Kit (Standard): collection bag (max 100 mL) Sterile Tubing Kit (Process Development): depends on user's selection
	Temperature control	Active temperature control to manage input sample and sort output reservoirs independently across the range of 4°C to 34°C (using an electric cooling method)*
	Agitation unit	For sample reservoir and collection bag
	Event rate	Designed to deliver up to 100,000 eps
	Sorting speed	Designed to achieve purity of about 97% and efficiency of approximately 70% at 15,000 events/s. The yield obtained is based on Poisson's statistics. Higher threshold events per second can be achieved without affecting purity but with a decrease in yield based on Poisson's statistics.
<b>Software</b>	GUI	Dual Mode full touch screen operation; Process Development Mode and Standard Operation Mode
	Electronic records	Features facilitating compliance per 21 CFR Part 11 guidance
	Output data file structure	Flow Cytometry Standard (FCS) 3.0 or 3.1
<b>Sort Modes</b>	Purity mode	Prioritizes purity (achieve purity of about 97%)
	Enrichment mode	Designed to increase throughput while maintaining high yield (speed up to 100,000 eps)
	Yield mode	Improves yield by limiting purity compared to purity mode
	Custom purity mode	Offers adjustable balance between purity and yield (sort efficiency)
<b>Compliance</b>	Operating system	Microsoft® Windows® 10 IOT
	Safety standards compliance	UL, CE, CSA

\* Actual temperature is influenced by ambient temperature.

## Fluorochrome Guide

FSC and BSC (488 nm, 561 nm)



FSC (638 nm)



405-nm laser		488-nm and 561-nm laser (colinear)				638-nm laser	
V1 450/50 nm	V2 525/50 nm	B1 525/50 nm	B2 600/60 nm	B3 695/50 nm	B4 785/60 nm	R1 665/30 nm	R2 785/60 nm
● VioBlue®	● VioGreen™	●● FITC	●● PE	●● PerCP	●● PerCP-Cy™ 7	● APC	● APC-Cy7
● Pacific Blue™	● Brilliant Violet 510	●● Alexa Fluor® 488		●● PerCP-Cy™ 5.5		● Alexa Fluor® 647	● Alexa Fluor® 750
● Brilliant Violet 421™				●● PE-Cy™ 5			
● Alexa Fluor® 405				●● PE-Cy 5.5			

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The CGX10 Cell Isolation System and related products are intended for use by trained laboratory technicians in research, process development or manufacturing environments all related to Advanced Therapy Medicinal Products (ATMP) or regenerative medicine, including cell and gene therapy. The CGX10 instrument and related products are for ex vivo cell separation processing only, and are not intended for therapeutic, diagnostic, or human in vivo applications. Any clinical application of the cells is exclusively within the responsibility of the user of the CGX10 instrument and related products. For the manufacturing and use of cells in humans, regulations must be followed. The CGX10 Cell Isolation System and related products are not sold as medical devices.

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All other trademarks are property of their respective owners. The CGX10 Cell Isolation System is classified as a Class 1 laser product.

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