

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

| | | |
|---------------------------------|-----------------------------|--|
| Technology | 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 |
| System Specification | 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% |
| Optics | 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 |
| Functional Specification | 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. |
| Software | 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 |
| Sort Modes | 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) |
| Compliance | 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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