

Cue[®]

Cell Processing System



Cryopreservation Preparation



Electroporation Preparation



Small Volume Culture Media Exchange



For Laboratory Use Only

Key features of the Cue Cell Processing System

- **Flexibility** – User-defined aliquot container number and fill volume
- **All-in-One** – Ability to concentrate and wash in the same procedure as final formulate and fill
- **Precision** – Aliquot volumes ≤ 10 mL
- **Control** – Optional automated temperature control and mixing

Overview

Full Functionality	Concentrate	A cell suspension is processed through the spinner to deplete supernatant volume, resulting in a smaller cell suspension volume and higher cell concentration
	Wash	While the cells remain in the spinner, residual supernatant is replaced with wash solution
	Harvest	Cells are transferred from the spinner to the Bulk Bag
	Dilute	Additional wash solution is added to the Bulk Bag, resulting in a larger cell suspension volume and lower cell concentration
	Formulate	Formulation solution is added to the cell suspension in the Bulk Bag at a defined ratio
	Aliquot	A defined volume of cell suspension is transferred from the Bulk Bag into one or multiple Aliquot containers
	Air Management	Automated and semi-automated air removal from Aliquot bag(s) and/or the Bulk Bag
Partial Functionality	The system can also be configured to utilize a subset of the full functionality. Examples include: <ul style="list-style-type: none"> • Concentrate, Wash, Harvest Dilute • Dilute, Formulate, Aliquot • Aliquot 	
Concentrate & Wash Technology	Spinning Membrane Filtration	
Strategy for Clearing Cells from Tubing	Air Rinse	
Continuous or Batch Processing	Batch	

Protocols and Estimations

Configurability	<ul style="list-style-type: none">Users with administrator privileges may use the Cue Desktop Application Software to access full parameter configurability to design protocols, then import protocols to the Cue instrument.Imported protocols are then available with limited configurability to operators.
Maximum Number of Protocols on Instrument	20
Estimations	During procedure setup, system provides estimations including duration, output cell concentration, output volume, and solution volume usage. Estimates can also be generated via the Cue Desktop Application Software.

Processing Capabilities¹

The Cue system was tested with various fluid types (density range: 1.01 – 1.125 g/mL)

Output Volume Accuracy ±10% or 1 mL, whichever is greater

Flow Rate Accuracy ±30% over a 10 mL period

A subset of protocol parameters and configurable ranges are shown below. For each verified range, configuring the parameter in the protocol design was confirmed to correspond with correct adjustment of the parameter on the instrument and correct execution of any associated calculations.

	Configurable	Verified
Source Volume	1 – 9,999 mL	10 mL – 1L
Source Processing Rate	2 – 100 mL/min	2 – 100 mL/min
Wash Buffer Types	Up to 2	N/A
Formulation Buffer Type	1	N/A
Formulation Flow Rate	2 – 100 mL/min	2 – 100 mL/min
Final Product (End in Bulk) Volume	10 – 2,500 mL	10 mL – 1L
Final Product (Aliquot) Volume	0 – 2,500 mL (0.1 mL increments)	2 – 500 mL
Aliquot Number	0 – 100	0 – 10
Aliquot Bag Type	Users define and attach the desired aliquot bag type(s) to the primary consumable set. There are no aliquot bags pre-attached to the consumable set.	N/A

Cell Processing Data – Cue Software 1.1 Product Quality Test Results¹

Jurkat cells (immortalized T-cell line) were seeded in G-Rex[®]100M-CS culture vessels at $0.5 \times 10^6/\text{cm}^2$ in RPMI Media + 10% FBS + 1% Pen/Strep + and cultured for 7 – 8 days. On harvest day, excess culture media was removed through the tubing connected to the media removal conduit. Cells were resuspended in the remaining media and collected into a bag through the tubing connected to the cell recovery conduit. The harvested cells (Source) were processed on the Cue system using a full functionality protocol that included the following steps:

1. Concentrate cells in spinner
2. Wash cells in spinner with Phosphate-Buffered Saline (PBS) + 0.5% BSA
3. Harvest cells in PBS + 0.5% BSA from spinner and transfer to Bulk Bag
4. Dilute cell suspension in Bulk Bag with PBS + 0.5% BSA to target 50×10^6 cells/mL
5. Formulate cell suspension in Bulk Bag 1:1 with CryoStor[®] CS10 to target 25×10^6 cells/mL and 5% final DMSO Concentration
6. Aliquot formulated cell suspension into 2 to 3 bags with a target fill volume per bag of 20 mL

Cell count and viability was determined using Nexcelom Cellometer Auto 2000 AO/PI Assay2

Measure		Result
Procedures	Sample Size	n=10
Source	Cell Type	Jurkat Cells
	Volume	70.5 ±10 mL
	Cell Count	1.56 ±0.12 × 10 ⁹
Wash Buffers	Solutions	Solution 1: PBS with 0.5% BSA Solution 3: BioLife Solutions CS10
Formulation	Formulation Ratio	Ratio 1:1 (Cell Suspension : CS10)
	Target Post-Formulation Concentration	25 ×10 ⁶ cells/mL
Post-Formulation	Viable Cell Recovery	98.3 ±4.9 %
	Actual Post-Formulation Concentration	25.8 ±2.9 × 10 ⁶ cells/mL
	Source to Post-Formulation Viability Change	-0.6 ±2.1 %
Aliquots	Target Final Volume	20 mL (n = 25)
	Actual Final Volume	19.6 ±0.9 mL
	Viability Variability	1.1 ±0.7 %
	Concentration Variability	10.8 ± 4.6 %
Time	Automated Source Processing	22.0 ± 1.8 min

Instrument Specifications

Active Temperature Control	Yes (On/Off)
Active Temperature Control Range	3 – 22°C
Mixing Control	Yes (On/Off)
Mixing Angle Range	5 – 30°C
Mixing Rate Range	0.1 – 1Hz
Syringe Pump Flow Rate Range	2 – 200 mL/min
Pumping Mechanism	Syringe pumps with plunger position tracking for volume accuracy. The syringe pump is part of the single-use primary set and includes a 0.2-µm air filter for functionally closed, pneumatic actuation by hardware air pump.
Dimensions (W × D × H)	35.3" × 18.8" × 32.6"* (*max height) 89.7 cm × 47.8 cm × 82.8 cm* (*max height)
Weight	94 lb. 42.6 kg.
Product Code	6R5000 – Cue Instrument & Accessories

Cue Desktop Application Software

Included with Instrument Purchase	Yes
Enables Protocol Design and Management	Yes
Enables Offline Procedure Estimator	Yes
Enables Viewing/Storing Procedure Records	Yes

Primary Set Consumable Specifications¹

Single-Use, Functionally Closed Set	Yes
Filtrate Bag Volume	2,500 mL May be replaced via tube welding.
Bulk Bag Volume	600 mL May be replaced via tube welding.
Filtrate and Bulk Bag Material	PVC
Tubing Material	PVC
Tubing Dimensions	0.118" (ID), 0.178" (OD), 0.03" (Wall Thickness) 3.0 mm (ID), 4.52 mm (OD), 0.76 mm (Wall Thickness)
Sampling Sets Included	Yes, 3 sampling sets per primary set
Sampling Set Volume Capacity	~5.5 mL
Sampling Set Enables Closed System Sampling	Yes
Sterilization Method	E-beam Irradiation
Product Codes	X6R5004 – Cue Primary Set – 4µm 4 sets/case

Manifold Set Consumable Specifications¹

Single-Use, Functionally Closed Set	Yes
Number of Tubing Leads	8
Tubing Material	PVC
Tubing Dimensions	0.118" (ID), 0.178" (OD), 0.03" (Wall Thickness) 3.0 mm (ID), 4.52 mm (OD), 0.76 mm (Wall Thickness)
Sterilization Method	E-beam Irradiation
Product Code	X6R5002 – Cue Manifold Set – 8-lead 10 sets/case

The Cue Cell Processing System is for laboratory use only and may not be used for direct transfusion. Appropriate regulatory clearance is required by the user for clinical use.

For applications requiring regulatory clearance or approval, Users may request the required Cue technical documentation from Fresenius Kabi to support their submissions.

Refer to the Cue Cell Processing System User's Guide for a complete list of warnings and precautions associated with the use of this device.

For additional information, please visit scaleready.com/cue.

References

¹Source: Cue SW 1.1 Product Quality Test Results: 224-DER-078600 [A]

scaleready.com

Contact us: info@scaleready.com

ScaleReady is a Joint Venture formed by Bio-Techne, Fresenius Kabi, and Wilson Wolf. Combining selected offerings from the three partners, the ScaleReady manufacturing platform combines tools and technologies for cell culture, cell activation and expansion, gene editing, and cell processing.

All products are for research use or manufacturing purposes only. Cue is manufactured by Fresenius Kabi.
Copyright © 2023 ScaleReady USA, LLC. All rights reserved. Trademarks referred to are property of their respective owners.

biotechne®

 FRESENIUS
KABI

WILSONWOLF™

 ScaleReady