ScaleReady

For Laboratory Use Only

Lovo® Automated Cell Processing System

Flexible and precise closed-system cell washing and volume-reduction

With data driven insights and reporting powered by DXT® Data Management System

DXT
Move Efficiency Forward

scaleready.com

Lovo supports your unique selection prep, thaw wash, or harvest wash processes.

Immunomagnetic Selection Prep[1]

Remove platelets, incubate with beads, and remove unbound beads in a single procedure for fast and automated processing

Fresh Leukapheresis Wash[2]

Remove platelets with precision and resuspend your cells in a preferred buffer for any custom manufacturing process

Culture Harvest & Media Exchange[3]

Volume-reduce or exchange media for your expanded products with high cell recoveries and washout efficiency

Thawed Wash & DMSO Removal[4]

Wash cryopreserved products to remove DMSO and resuspend cells in your preferred buffer or culture media

Increase operational efficiency

Cells continually flow in and out of Lovo's spinning membrane module, minimizing overall processing time. Lovo handles source volumes up to 22 L and processes a standard apheresis product in approximately 11 minutes.[3]

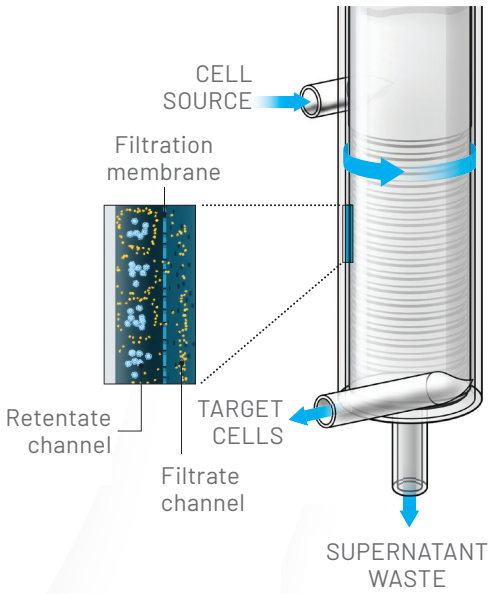
Customize protocols to fit your process

Lovo's software has been designed to support your unique processes and technologies. Up to 10 protocols can be saved on the device and each wash cycle may be customized even further.

Improve product consistency and quality

Capture precisely the cells you need, optimizing recovery while maintaining viability — even for fragile cells. The membrane's 4 µm pores enable >98% TNC recovery and <2% decrease in viability when targeting 99.9% supernatant removal.[3]

Proprietary spinning membrane filtration technology



Choose filtered to further your goals.

Whether you're focused on early stage trials or ramping up to full commercialization, Lovo's spinning membrane filtration technology enables fast, precise, and flexible procedures that help increase your lab's overall operational efficiency and processing consistency without compromising product quality.[2] You can rely on Lovo and the ScaleReady team to work with you to address your lab's biggest challenges in developing cutting-edge cell therapy manufacturing solutions.

The Partnership of Data & Compliance

DXT® for use with the Lovo Cell Processing System

DXT
Move Efficiency Forward

Lovo

DXT

End User

Electronically transfer procedure record data | Anytime, Anywhere Access

DXT is a Data Management Software application designed to receive, store and transmit procedure information

Information is transferred from Lovo to the DXT Data Management Software via a wired or wireless connection and can then be transferred to your external systems

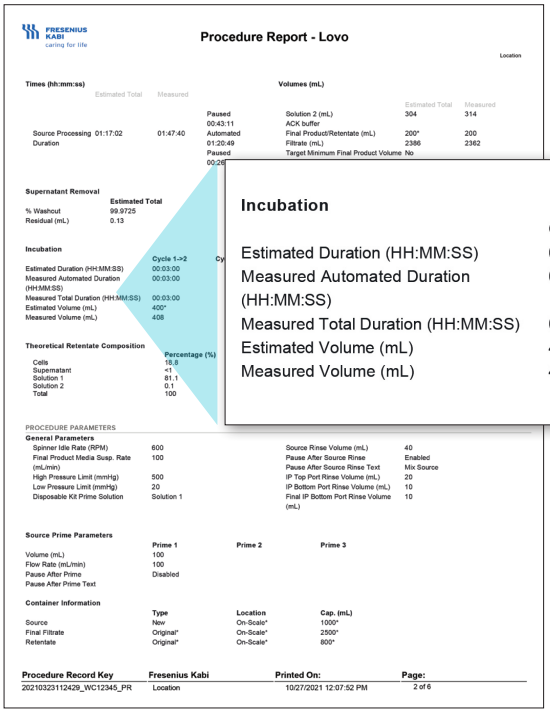
Supports 21 CFR Part 11 compliance

DXT Data Management System Requirements		
Operating System	Windows 11 Pro	Windows Server 2019
Database Management System (DBMS)	SQL Server 2019 Express	SQL Server 2019
Processor	2 cores @ 2.3 GHz	4 cores @ 2.3 GHz
Memory	8 GB	16 GB
Disk Size*	500 GB SSD	500 GB SSD

* The disk size requirements will depend on organizational data retention policy for data immediately accessible through DXT.

Additional System Features

- LIMS interface compatible
- Technical support provided by Fresenius Kabi team


FRESENIUS KABI
caring for life

Procedure Report - Lovo

Location

Times (hh:mm:ss) — Estimated Total / Measured

Volumes (mL) — Estimated Total / Measured

		Paused	00:43:11	Solution 2 (mL)	304	314
				ACK buffer		
Source Processing Duration	01:17:02	01:47:40	Automated	Final Product/Retentate (mL)	200*	200
			01:20:49	Filtrate (mL)	2386	2362
			Paused	Target Minimum Final Product Volume	No	
			00:26			

Supernatant Removal

	Estimated Total
% Washout	99.9725
Residual (mL)	0.13

Incubation

	Cycle 1->2	Cy
Estimated Duration (HH:MM:SS)	00:03:00	
Measured Automated Duration (HH:MM:SS)	00:03:00	
Measured Total Duration (HH:MM:SS)	00:03:00	
Estimated Volume (mL)	400*	
Measured Volume (mL)	408	

Theoretical Retentate Composition

	Percentage (%)
Cells	18.8
Supernatant	<1
Solution 1	81.1
Solution 2	0.1
Total	100

PROCEDURE PARAMETERS

General Parameters

Spinner Idle Rate (RPM)	600	Source Rinse Volume (mL)	40
Final Product Media Susp. Rate (mL/min)	100	Pause After Source Rinse	Enabled
		Pause After Source Rinse Text	Mix Source
High Pressure Limit (mmHg)	500	IP Top Port Rinse Volume (mL)	20
Low Pressure Limit (mmHg)	20	IP Bottom Port Rinse Volume (mL)	10
Disposable Kit Prime Solution	Solution 1	Final IP Bottom Port Rinse Volume (mL)	10

Source Prime Parameters

	Prime 1	Prime 2	Prime 3
Volume (mL)	100		
Flow Rate (mL/min)	100		
Pause After Prime	Disabled		
Pause After Prime Text			

Container Information

	Type	Location	Cap. (mL)
Source	New	On-Scale*	1000*
Final Filtrate	Original*	On-Scale*	2500*
Retentate	Original*	On-Scale*	800*

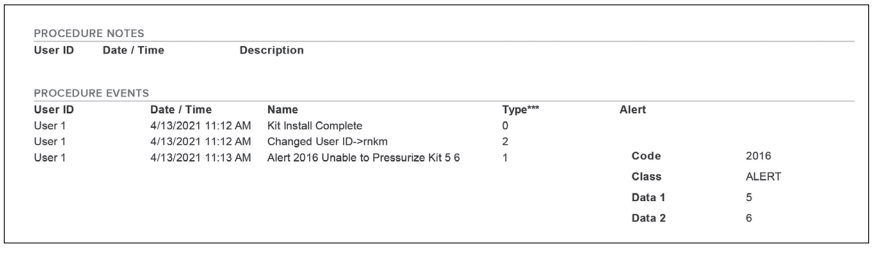
Procedure Record Key	Fresenius Kabi	Printed On:	Page:
20210323112429_WC12345_PR	Location	10/27/2021 12:07:52 PM	2 of 6

Incubation

	Cycle 1->2
Estimated Duration (HH:MM:SS)	00:03:00
Measured Automated Duration (HH:MM:SS)	00:03:00
Measured Total Duration (HH:MM:SS)	00:03:00
Estimated Volume (mL)	400*
Measured Volume (mL)	408

What is included?

- Secure wired or wireless data transfer directly from the Lovo
- Non-editable Procedure reports documenting programmed parameters, procedure results, calibration and events times (exportable to PDF or Excel)
- Filterable procedure listings providing a historical view of procedures from all devices (exportable from DXT to Excel or LIMS)


PROCEDURE NOTES

User ID	Date / Time	Description

PROCEDURE EVENTS

User ID	Date / Time	Name	Type***	Alert	
User 1	4/13/2021 11:12 AM	Kit Install Complete	0		
User 1	4/13/2021 11:12 AM	Changed User ID->rnkm	2		
User 1	4/13/2021 11:13 AM	Alert 2016 Unable to Pressurize Kit 5 6	1	Code	2016
				Class	ALERT
				Data 1	5
				Data 2	6

Instrument features

Cell types

Fresh, cryo-preserved, or culture-expanded white blood cells, including, but not limited to, leukapheresis CD34+ cells, CAR T-cells, TILs, NK cells, and MSCs.

Volume range

Source	Up to 22 L
Output[1]	50 mL – 50 L

Wash-out range

- Up to 99.9999%[2]

System components

- 73 lb, 35.3" × 17.6" × 24.5" (W × D × H) benchtop instrument
- Single-use processing kit with spinning membrane module

[1]Actual lowest achievable volume will depend on cell type, cell concentration, and source volume.

[2]Based on theoretical wash-out from system estimator.

Choose Lovo

To increase the efficiency of your cell therapy manufacturing process

Ordering Information

Description	Quantity	Code
Lovo Cell Processing System	N/A	6R4900
Lovo Cell Processing Disposable Kit with Bag Access – 4µm (Compatible with Lovo software version 3.0 and 3.2)	6 units/case	X6R4909A
Lovo Cell Processing Disposable Kit - 4µm (Compatible with Lovo software versions 2.0, 3.0 and 3.2)	6 units/case	X6R4906A
Lovo Ancillary Bag Kit	20 units/case	X6R4902
Lovo Pouch Kit	6 units/case	X6R4907
Lovo Valve and Filter Disposable Kit	6 units/case	X6R4917
20mm Vialok Vented Vial Access Device	100 units/case	YM020

References

1. Lovo 2.X Blood Run Protocol Report: 223-DER-048957 – Data on file at Fresenius Kabi USA.
2. Lovo 2.X Product Quality Test Results Design Review: 223-DER-048958 – Data on file at Fresenius Kabi USA.
3. Lovo New Membrane Cultured Cell Testing Results: 223-DER-066723 – Data on file at Fresenius Kabi USA.
4. B.Mfarrej, *et al*. Pre-clinical assessment of the Lovo device for dimethyl sulfoxide removal and cell concentration in thawed hematopoietic progenitor cell grafts. Cytotherapy, Volume 19, Issue 12, 1501-1508.

The Lovo 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. Refer to the Lovo Cell Processing System Operator's Manual for a complete list of warnings and precautions associated with the use of this device. For additional information, please visit **scaleready.com/lovo**.

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.

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