

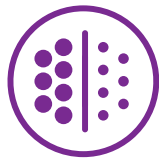
# Lovo<sup>®</sup>

## Automated Cell Processing System

Precise closed-system cell washing and volume reduction  
**With data driven insights and reporting powered by  
DXT<sup>®</sup> Data Management System**



Immunomagnetic  
Selection Prep<sup>1</sup>



Fresh  
Leukapheresis Wash<sup>2</sup>



Culture Harvest &  
Media Exchange<sup>3</sup>



Thawed Wash &  
DMSO Removal<sup>4</sup>



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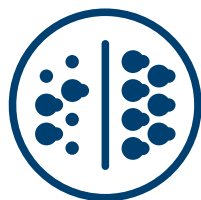
For Laboratory Use Only



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

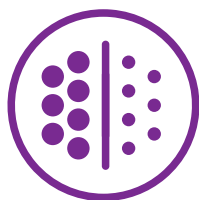
## Immunomagnetic Selection Prep<sup>1</sup>

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



## Fresh Leukapheresis Wash<sup>2</sup>

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



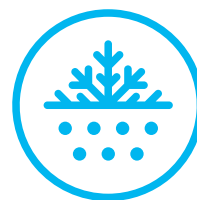
## Culture Harvest & Media Exchange<sup>3</sup>

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



## Thawed Wash & DMSO Removal<sup>4</sup>

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.<sup>3</sup>

## Increase product consistency and quality

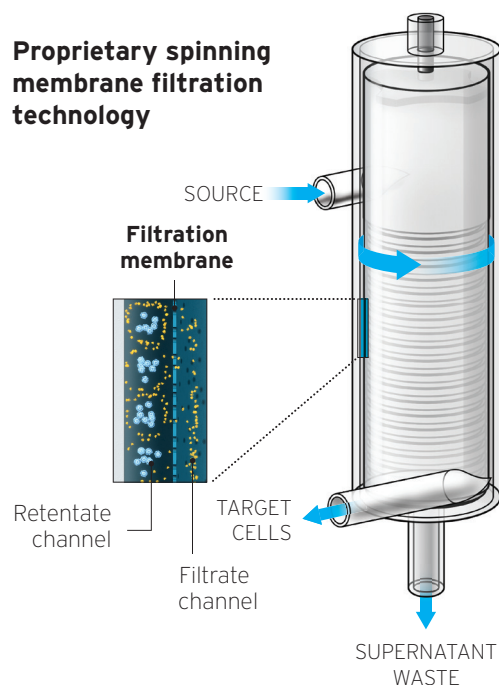
Capture precisely the cells you need, optimizing recovery while maintaining viability – even for fragile cells. The membrane's 4µm pores enable >98% TNC recovery and <2% decrease in viability when targeting 99.9% supernatant removal.<sup>3</sup>

## Customize specific protocols to support your cell therapy manufacturing needs

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.

## 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.<sup>2</sup> You can rely on Lovo and the Fresenius Kabi 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



### 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 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

### Additional System Features

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

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

### 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 Report - Lovo**

**Times (hh:mm:ss)**

Estimated Total	Measured	Passed
01:17:02	01:47:40	00:43:11

**Volumes (mL)**

Estimated Total	Measured
204	204
200	200
2386	2382

**Supernatant Removal**

Estimated Total	Measured
89.8725	0.13

**Incubation**

Estimated Duration (HH:MM:SS)	Measured Automated Duration (HH:MM:SS)	Measured Total Duration (HH:MM:SS)	Estimated Volume (mL)	Measured Volume (mL)
00:03:00	00:03:00	00:03:00	400*	408

**Theoretical Retentate Composition**

Cells	Supernatant	Solution 1	Solution 2	Total
100	81.1	0.1	0	100

**PROCEDURE PARAMETERS**

General Parameters	Source Rise Parameters
Source Rise Rate (BPM): 600	Source Rise Volume (mL): 40
Final Product Media Susp. Rate (mL/min): 100	Pause After Source Rise: Enabled
High Pressure Limit (mmHg): 550	IP Top Port Rise Volume (mL): 20
Low Pressure Limit (mmHg): 20	IP Bottom Port Rise Volume (mL): 10
Disposable Kit Prime Solution: Solution 1	Final IP Bottom Port Rise Volume (mL): 10

**Source Prime Parameters**

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

**Container Information**

Type	Location	Cap (mL)
Source: New	On-Site*	1000*
Final Filter: Original*	On-Site*	2000*
Retentate: Original*	On-Site*	800*

Values on the Electronic Procedure Record Report with an asterisk (\*) are operator-editable values.

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

**PROCEDURE NOTES**

User ID	Date / Time	Description
User 1	4/13/2021 11:12 AM	Kit Install Complete
User 1	4/13/2021 11:12 AM	Changed User ID to rnmk
User 1	4/13/2021 11:13 AM	Alert 2016 Unable to Pressurize Kit 5 6

**PROCEDURE EVENTS**

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



# Lovo Automated Cell Processing System

## Instrument features

### Cell types

Fresh, cryo-preserved, and 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<sup>1</sup> 50 mL - 50 L

### Wash-out range

Up to 99.9999%<sup>2</sup>

### System components

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

<sup>1</sup> Actual lowest achievable volume will depend on cell type, cell concentration, and source volume.

<sup>2</sup> Based on theoretical wash-out from system estimator. Actual lowest achievable volume will depend on cell type, cell concentration, and source volume.

## 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.



Code	Item	Quantity
6R4900	Lovo Cell Processing System	N/A
X6R4909A	Lovo Cell Processing Disposable Kit with Bag Access - 4µm (Compatible with Lovo software version 3.0 or greater)	6 units/case
X6R4906A	Lovo Cell Processing Disposable Kit - 4µm (Compatible with Lovo software versions 2.0 or greater)	6 units/case
X6R4930	Lovo Cell Processing Kit - 0.8µm	6 units/case
X6R4902	Lovo Ancillary Bag Kit	20 units/case
X6R4907	Lovo Pouch Kit	6 units/case
X6R4917	Lovo Valve and Filter Disposable Kit	6 units/case
YM020	20mm Vialok® Vented Vial Access Device	100 units/case

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, DXT Administrator's Guide and DXT User's Guide for a complete list of warnings and precautions associated with the use these products.

For additional information, please visit [chooselovo.com](https://www.chooselovo.com)



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