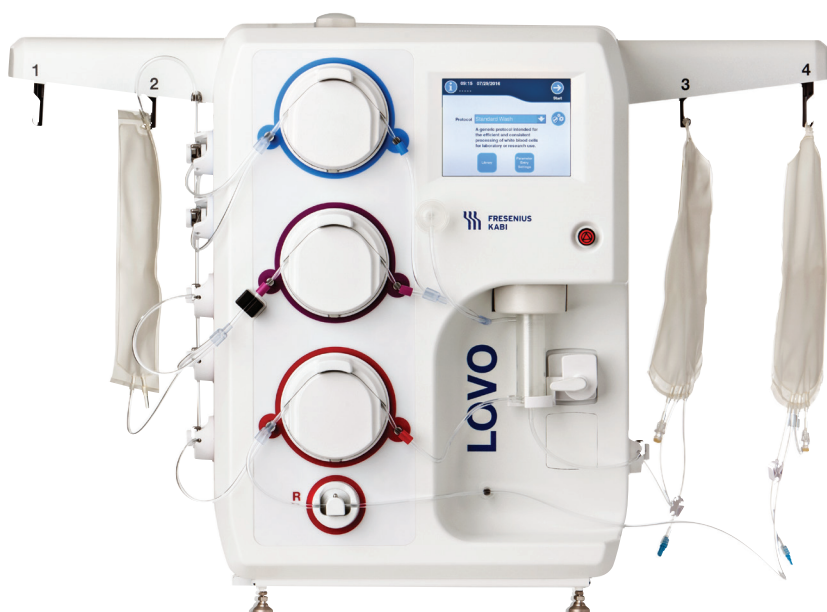


DXT[®] for use with the LOVO instrument

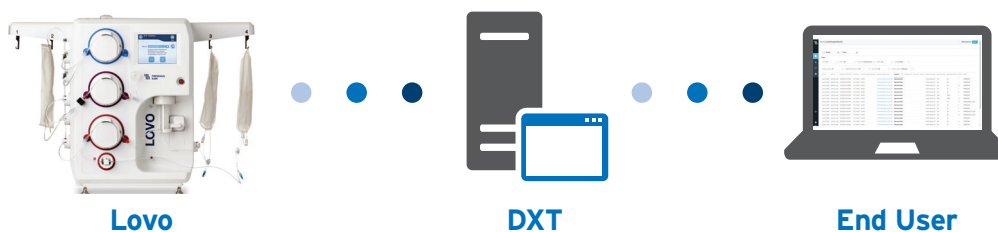
The Partnership of Data & Compliance

What is DXT?

- A software application designed to receive, store and transmit procedure information
- Information is transferred from Lovo to the DXT software via a wired or wireless connection and can then be transferred to your external systems
- Supports 21 CFR Part 11 compliance



Electronically transfer procedure record data | Anytime, Anywhere Access



DXT
Move Efficiency
Forward

DXT for use with the LOVO instrument

Seamlessly view and store electronic data

Procedure Report - Lovo			
Times (hh:mm:ss)	Estimated Total	Measured	Location
Source Processing	01:17:52	01:47:40	Paused
Duration		00:43:11	Automated
		01:20:49	Paused
		00:00:00	Paused
Volumes (mL)			
	Estimated Total	Measured	
Solution 2 (mL)	304	314	
ACK buffer			
Final Product/Retentate (mL)	200*	200	
Filtrate (mL)	2386	2362	
Target Minimum Final Product Volume	160		
Supernatant Removal			
	Estimated Total		
% Washout	99.9728		
Residual (mL)	0.13		
Incubation			
	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			
	Percentages (%)		
Cells	18.8		
Supernatant	<1		
Solution 1	0.1		
Solution 2	0.1		
Total	100		
PROCEDURE PARAMETERS			
General Parameters			
Spinner Idle Rate (RPM)	600	Source Rinse Volume (mL)	40
Final Product Media Sup. Rate (mL/min)	100	Pause After Source Rinse	Disabled
High Pressure Limit (mmHg)	500	Pause After Source Rinse Text	Mix Source
Low Pressure Limit (mmHg)	20	IP Top Port Rinse Volume (mL)	20
Disposable Kit Prime Solution	Solution 1	IP Bottom Port Rinse Volume (mL)	10
		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*	1500*
Final Filtrate	Original*	On Scale*	2500*
Retentate	Original*	On Scale*	800*
Procedure Record Key			
20210323112429_WC12345_PR	Fresenius Kabi	Printed On:	Page:
	Location	10/07/2021 12:57:52 PM	2 of 6

Supports 21 CFR Part 11 compliance

Access Procedure Data, Anywhere, Anytime.

What is included?

- Non-editable Procedure reports documenting programmed parameters, procedure results, calibration and events times (exportable to PDF or Excel)
- Procedure listings providing a historical view of procedures from all devices (exportable to Excel)

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->rmkm	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

DXT System Requirements

Operating System	Windows 10 Professional	Windows Server 2019
Database Management System (DBMS)	SQL Server 2017 Express	SQL Server 2017
Processor	2 cores @ 2.3 GHz	4 cores @ 2.3 GHz
Memory	8 GB	8 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

- Lovo communicates wirelessly or wired
- LIMS interface compatible
- Support provided by Fresenius Kabi team

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 of these products.

The LOVO Cell Processing system is for laboratory use only. Unless the user has obtained advance clearance or approval from the appropriate regulatory agency, cells processed on this system are not intended for diagnostic purposes, direct transfusion, or for use in the production of therapeutic products or vaccines for clinical use. For applications requiring regulatory clearance or approval, users may request the required LOVO technical documentation from Fresenius Kabi to support their submissions.

Trademarks referred to are property of their respective owners.