

Lovo[®] DXT[®]

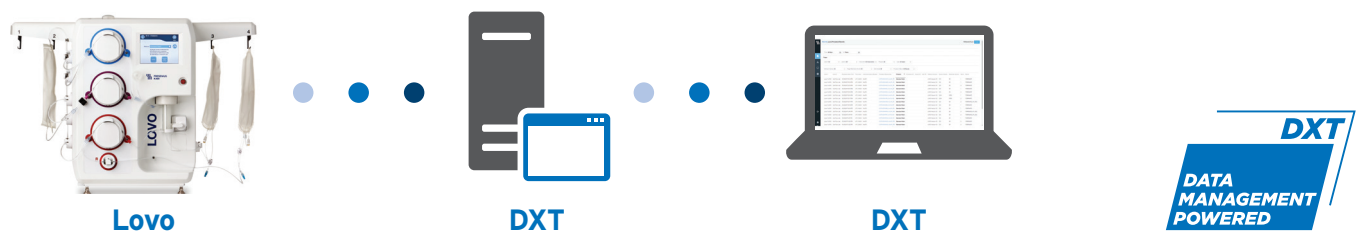
The Partnership of Data & Compliance

What is Lovo 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



Seamlessly view and store electronic data

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)

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caring for life

LOVO Cell Processing System Procedure Record

Procedure Record Key: 20170802163757_21605006_PRR
 Protocol ID: Selection Prep
 Procedure ID: Selection Run 1*
 Source ID: Leukopak

Organization: Fresenius Kabi AG
 Region Name: North America (NAM)
 Location Name: Fresenius Kabi USA
 Location Address: 3 Corporate Drive
 Location City/State: Lake Zurich, IL 60047
 Registration #: N/A

General Procedure Information

Procedure Status	COMPLETE	Time Zone	UTC-06:00
Procedure Start Time	9/22/2017 4:37 PM	Procedure End Time	9/22/2017 5:43 PM
Source Processing Start Time	9/22/2017 4:41 PM	Source Processing End Time	9/22/2017 5:40 PM
User ID (Start)	AVNIE*	User ID (End)	AVNIE*
Instrument Serial Number	W023037	Hardware Controller Software Version	0
Software Version	LOVO Version 3.0		
UDI	(01) 5408000191721 (1) 3.0		
Protocol Description	Remove platelets, concentrate cells, incubate with reagent, remove excess reagent		

Source Product Information

Source Containers	1	Estimated Total Source Volume (mL)	200
Estimated Source Volume Per Container (mL)	200*	Measured Total Source Volume (mL)	202

Source Packed Cell Volume (PCV)

Name	Description
PLT	A generic spec. for platelets.
RBC	A generic spec. for red blood cells.
WBC	A generic spec. for white blood cells.

Final Cycle PCV (%) 8.5 (0.50+00) Recv

Estimates & Results

Total Procedure Duration (HH:MM:SS)	Estimated Total 00:59:56
Source Processing Duration (HH:MM:SS)	00:56:37
Solution 1 (mL)	1912
PBS/EDTA/HSA	
Solution 2 (mL)	0
None	
Final Product/Retentate (mL)	150
Target Minimum Final Product Volume	No
Filtrate (mL)	1930
Supernatant Washout (%)	99.9951
Supernatant Residual (mL)	0.008967

Incubation Estimates And Results

Estimated Duration (HH:MM:SS)	Cycle 1-2
Measured Duration (HH:MM:SS)	N/A
Estimated Volume (mL)	N/A
Measured Volume (mL)	N/A

Alerts

Total Alerts	0
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* Operator Editable Values
 ** Final Cycle Retention
 *** Event Types: 0: Procedure Error, 1: Alert/Nam, 2: User ID Change, 3: Note Added

Signature: _____ Date: _____
 Signature: _____ Date: _____

Procedure Record Key: 20170802163757_21605006_PRR Printed On: 9/13/2018 2:38 PM

Estimates & Results	
Total Procedure Duration (HH:MM:SS)	Estimated Total 00:59:56
Source Processing Duration (HH:MM:SS)	00:56:37
Solution 1 (mL)	1912
PBS/EDTA/HSA	
Solution 2 (mL)	0
None	
Final Product/Retentate (mL)	150
Target Minimum Final Product Volume	No
Filtrate (mL)	1930
Supernatant Washout (%)	99.9951
Supernatant Residual (mL)	0.008967

Events				
User ID	Date / Time	Description	Type***	Alert / Alarm
AVNIE	9/22/2017 4:37 PM	Kit Install Complete	0	
AVNIE	9/22/2017 4:37 PM	Changed User ID->AVNIE	2	
AVNIE	9/22/2017 4:42 PM	Solution(s) Attached	0	
AVNIE	9/22/2017 4:42 PM	Source Container Attached	0	
AVNIE	9/22/2017 4:47 PM	Procedure Resumed/Advanced	0	
AVNIE	9/22/2017 4:47 PM	Source Processing Started	0	
AVNIE	9/22/2017 4:47 PM	First Reduction Started	0	
AVNIE	9/22/2017 4:49 PM	Rinsing Tubing	0	
AVNIE	9/22/2017 4:49 PM	Diluting to desired volume	0	
AVNIE	9/22/2017 4:50 PM	Middle Reduction Started	0	
AVNIE	9/22/2017 4:55 PM	Rinsing Tubing	0	
AVNIE	9/22/2017 4:56 PM	Diluting to desired volume	0	
AVNIE	9/22/2017 4:56 PM	Solution 2 Container Nearly Empty	0	
AVNIE	9/22/2017 4:56 PM	Final Reduction Started	0	

DXT System Requirements

Operating System	Microsoft Windows Server 2016
Database Management System (DBMS)	SQL Server 2016 SP2
Processor	8 cores @ 2.3 GHz
Memory	32 GB
Disk Size*	500 GB SSD

Additional System Features

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

Refer to the LOVO DXT Data Management's System Administrator's Guide for a list of warnings and precautions.

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

The recommended disk size is to maintain two years' worth of data.

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