

DXT[®] Data Management for use with the Lovo[®] Cell Processing System

Frequently Asked Questions

Q: What is DXT Data Management?

A: DXT is a Data Management Software application designed to receive, store and transmit procedure record information from the Lovo instrument. Information is automatically transferred from the Lovo to the DXT software via a wired or wireless connection using the local network. DXT generates non-editable procedure reports, which can be printed to PDF, exported to Excel, and transferred to 3rd party software (e.g., laboratory information management system (LIMS)). DXT also synchronizes the instrument date/time with the local network's settings.

Q: What are the main benefits of DXT?

1A: Automatic procedure record capture

- With DXT, procedure record information is automatically formatted into a non-editable report, which may be downloaded by authorized DXT users.
- Without DXT, procedure record information must be transcribed manually from the Lovo instrument touch screen.

2A: Off-instrument procedure record storage

- The Lovo instrument's memory card can store a maximum of 200 procedure records. Once the memory capacity is reached and a new procedure is started, the system will replace the oldest procedure record with the new procedure record.
- With DXT, a procedure record deleted from the Lovo instrument is still available through DXT.
- Without DXT, a deleted procedure record is no longer accessible, unless it was previously exported via USB and is then only accessible in an editable format (see below).

3A: Single repository to access procedure information for all instruments registered to a DXT instance

Q: What does the DXT interface and procedure record printed to PDF look like?

A: Please see appendixes A-C located at the end of this document.

Q: Is DXT required for use with the Lovo Cell Processing System?

A: The Lovo instrument can be operated without DXT. Without DXT, users will manually transcribe procedure record information, and an Administrator will set the date and time directly on the instrument. All other instrument functionality is not impacted by DXT implementation.

Q: Can I use a USB to export Procedure Records without enabling DXT?

A: The Lovo instrument supports export of procedure records to USB, but the exported file format is editable XML and therefore not suitable for official documentation purposes. Without DXT, a user should manually transcribe procedure record information and only use the USB export to obtain files to send to Fresenius Kabi for troubleshooting.

Q: Does DXT transfer log files?

A: Each procedure generates a procedure record file and one or more log files. Log files are password-protected files that can only be accessed by Fresenius Kabi. Log files are not transferred by DXT. To provide log files to Fresenius Kabi for troubleshooting, a user must manually export the log files to USB.

Q: Is Lovo procedure record information 21 CFR Part 11 compliant?

A: DXT supports 21 CFR Part 11 compliance (see TID-061190 for details). Without DXT, Lovo does not generate an electronic record and 21 CFR Part 11 is therefore not applicable (see LTR-000771 for details).

Frequently Asked Questions (cont.)

Q: Is DXT validated?

A: DXT has been developed and validated by Fresenius Kabi using procedures based on best practices for software application development.

Q: Where is DXT installed? How is DXT accessed?

A: DXT is an on-premise solution, installed on a computer on the same network Lovo is connected to. DXT is a web-based application that can be accessed by any computer connected to the local network. Authorized users login to DXT using their Active Directory Username and Password.

Q: What are the technical requirements for implementing DXT?

A: For detailed requirements, please reference Chapter 2 of the DXT Administrator's Guide (SW versions 3.7 and above)

DXT Data Management System Requirements			Additional System Features
Operating	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	

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

Q: Is DXT included with the purchase of a Lovo instrument?

A: DXT is sold separately from the Lovo instrument.

Q: What is the DXT fee structure?

A: DXT is licensed on a per-instrument basis. There is a one-time, per environment (Development, Production, etc.) implementation fee and an annual, per-instrument software license fee. A minimum 2-year software agreement is required.

Q: What DXT tiers are available?

A: DXT is available in two tiers:

1. Standalone - Receive and store information, generate and print standard reports
2. Integrated with 3rd Party Software - Standalone capabilities plus consulting, development support, and testing of DXT integration with customer's 3rd party software

Q: What if my institution waits to implement DXT, such that procedure records are already stored on the Lovo instrument at the time of DXT implementation?

A: Procedure records that are stored on the instrument's memory card and have not been previously delivered to DXT will be sent upon initial connection and registration.

Q: What if the Lovo instrument's connection to DXT is lost during a procedure?

A: If an instrument loses connection and procedures are completed while the system is disconnected, the undelivered procedure records will be sent to DXT when the connection is re-established.

Q: Who should I contact for DXT troubleshooting? (U.S.)

A: Contact Technical Hotline & Support by calling 800-937-5060 prompt 1 or by email Data.Management@fresenius-kabi.com. For requests outside the U.S., please contact your local market unit for details.

DXT Purchase & Implementation Process Outlined

#	Step	Details
1	Meeting with Fresenius Kabi Data Management Team + Customer To schedule a meeting, email Data.Management@fresenius-kabi.com	Key Attendees include Lovo Administrators (Process Development, Manufacturing Engineers), IT and Quality Agenda topics typically reviewed during initial introductory meeting include: • Overview of DXT • Technical requirements • DXT available license options • Q&A
2	Customer provides implementation decisions for estimate generation	# of LOVO instruments, standalone or integrated, and wired/wireless connection type to generate estimate
3	Fresenius Kabi Data Management Team provides total cost estimate based on customer's implementation decisions	Estimate includes implementation and annual license costs
4	Customer confirms that they would like to move forward with DXT project	Customer confirms payer, site location, Lovo instrument S/Ns for DXT implementation, and connection type (wired or wireless). See Implementation Plan. Customer confirms they can meet the technical requirements to implement DXT and the desire to move forward including the number of instruments that will be included
5	Fresenius Kabi Data Management Team provides DXT Software Agreement for review, and final execution	Customer reviews Software License Agreement, which includes final pricing, and executes
6	Customer submits PO	PO covers Implementation Fee and first year Annual License Fee
7	Installation Preparation Activities	<ul style="list-style-type: none"> • Process order for DXT Software (The DXT software will be shipped once Fresenius Kabi confirms the agreement has been fully executed) • Complete and process License & Certificate Request forms. An SSL certificate is required to secure the communication with Lovo. Fresenius Kabi must provide the certificate used for the connection. • Provision DXT server and install prerequisites • Create Active Directory service accounts and user groups • Deploy certificate
8	Configure Connection Type (if needed).	If necessary, a Fresenius Kabi Field Service Engineer will visit the Customer's site to update the Lovo instrument(s) to the desired connection type (wired or wireless) prior to DXT installation.
9	Fresenius Kabi Contracts group issues invoice for Implementation Fee and 1 st Year Annual Fees	Customer receives invoice and submits internally for processing.
10	Fresenius Kabi Data Management Team provides Virtual Training	Fresenius Kabi provides training for Administrators and users of DXT <ul style="list-style-type: none"> • Administrator training covers system configurations and device connectivity • User training covers the use of DXT to access procedure reports
1-year & Agreement Renewal	Fresenius Kabi generates billing for annual license fee on the 1- year anniversary of the effective start of the Software Agreement	Amendment renewal process begins 90 days prior to agreement expiration date

APPENDIX A - Lovo Procedure Listing Screen

Reports > Lovo Procedure Listing 145 Records Found From: 8/1/2019 To: 8/1/2021 Filters

Report Type: Lovo Procedure Listing Export

Search Search

Search Procedure Record Key, Procedure ID, Source ID, or Disposables/Consumables Reference or Lot Number

Site	Procedure Start Time	Instrument Serial Number	Procedure Record Key	Protocol	Procedure ID	Source ID	User ID	Source Volume	Retentate Volume	Alerts	Result
Chicago	9/16/2019 10:47:38 AM	FK5001	20190916104738_FK5001_PR	Standard Wash	P19100108	S19200108	5018	150	68	8	COMPLETE
Chicago	9/18/2019 9:36:47 AM	FK5001	20190918093647_FK5001_PR	RBC Lys Select Prep	P19100107	S19200107	5003	447	150	3	COMPLETE
Chicago	9/18/2019 4:40:56 PM	FK5001	20190918164055_FK5001_PR	RBC Lys Select Prep	P19100106	S19200106	5003	439	200	5	TERMINATE_KIT_FAIL
Chicago	9/18/2019 4:58:12 PM	FK5001	20190918165812_FK5001_PR	RBC Lys Select Prep	P19100105	S19200105	5045	439	200	5	TERMINATE
Chicago	9/18/2019 5:25:21 PM	FK5001	20190918172520_FK5001_PR	RBC Lys Select Prep	P19100104	S19200104	5022	439	200	4	TERMINATE
Chicago	9/18/2019 5:44:36 PM	FK5001	20190918174436_FK5001_PR	RBC Lys Select Prep	P19100103	S19200103	5022	439	200	2	TERMINATE_KIT_FAIL
Chicago	9/18/2019 5:53:35 PM	FK5001	20190918175335_FK5001_PR	RBC Lys Select Prep	P19100102	S19200102	5019	439	200	5	COMPLETE

APPENDIX B - Procedure Results Screen

Reports > 20190918093647_FK5001_PR Print

Details

Notes Key
 * Operator Editable Values
 ** Final Cycle Retention
 *** Event Types: 0: Procedure Event, 1: Alert/Alarm, 2: User ID Change, 3: Note Added

GENERAL PROCEDURE INFORMATION

Protocol	RBC Lys Select Prep	Protocol Description	Mobilized Aph <60e9 WBCs - RBC Lys and Select Prep - 3min RBC Lysis Cycles 1>2, 30min Circ Incubet Cycles 3>4; 5-Cycle
Procedure ID	P19100107	Procedure Record Key	20190918093647_FK5001_PR
Procedure Result	COMPLETE	Time Zone	UTC -04:00
Procedure Start Time	9/18/2019 9:36 AM	Procedure End Time	9/18/2019 11:44 AM
Source Processing Start Time	9/18/2019 9:50 AM	Source Processing End Time	9/18/2019 11:34 AM
User ID (Start)	5003	User ID (End)	5003
Site	Chicago	Region	Midwest

