

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

Frequently Asked Questions



Q What is DXT Data Management?

A DXT Data Management is a software-only product that is used to seamlessly integrate with the Lovo Cell Processing System. The customer is required to provide the hardware, operating system, and database. DXT is compatible with select Microsoft Windows operating systems and Microsoft SQL Server versions. The user interface supports Chrome and Edge web browser.

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

A Lovo software version 4.0 requires the use of DXT. A customer-specific software agreement must be executed prior to Lovo instrument software being upgraded and DXT being installed.

Q What are the main benefits of DXT Data Management?

A DXT Data Management supports compliance with 21 CFR Part 11/EU Annex 11 and use in GxP setting, with the following key features:

- 1. Automatic procedure record capture and off-instrument long-term storage**
Procedure record information is automatically formatted into a non-editable report and securely stored off-instrument for long-term access. DXT capacity, while unlimited is dependent on the server capacity. Authorized DXT users can download these records at any time. Even after deletion from the Lovo instrument (due to its 200-record memory limit), which overwrites the oldest procedure records as new ones are created, records remain accessible to authorized DXT users.
- 2. Centralized Access**
Single repository to access procedure information for all Lovo instruments registered to a DXT instance.
- 3. Protocol Management**
Remotely distribute protocols to a single Lovo or across an entire site. Manage protocols individually and confirm protocol identity with a dedicated protocol signature.
- 4. Control and Monitor Access with User Authentication**
DXT integrates with Active Directory for user authentication on Lovo and DXT. Users are assigned specific roles and role-based access on both Lovo and DXT, limiting access to the instrument (Operator or Administrator) and DXT functionality.
- 5. Comprehensive Audit Trails**
Track user activity within the procedure, protocol creation, changes, and transfers, and logins to DXT and Lovo instruments.
- 6. Real-Time Instrument Visibility**
Access a real-time instrument status overview/dashboard.

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 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 can be exported using DXT and provided to Fresenius Kabi for troubleshooting.

Q Is the Lovo procedure record information 21 CFR Part 11 and EU Annex 11 compliant?

A DXT supports 21 CFR Part 11 and EU Annex 11 compliance* (see LTR-001149 for details).

*excludes electronic signatures.

Is DXT validated?

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

A

Where is DXT installed? How is DXT accessed?

Q DXT is an on-premise solution, installed on an end-user provided server on the same network the 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.

A

What are the technical requirements for implementing DXT?

Q For detailed requirements, please reference Chapter 2 of the DXT Administrator's Guide (SW version 3.11).

A

DXT Data Management System Requirements			Additional System Features
Operating System	Windows 11 Pro	Windows Server 2022	
Database Management System (DBMS)	SQL Server 2022 Express	SQL Server 2022	
Processor	8 Cores	8 Cores	
Memory	16 GB	16 GB	
Disk Size*	500 GB SSD	500 GB SSD	

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

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

What is the DXT fee structure?

Q Lovo software version 4.0 requires the use of DXT. The fee structure is based on the number of Lovo instruments (per Lovo) connected to a DXT instance. There are different rates for standalone versus integration with third-party software options. A customer-specific software agreement must be executed prior to Lovo instrument software being upgraded and DXT being installed.

A

Q What DXT deployment options are available?

A DXT is available in two development options:

1. Standalone

Receive and store information and view/print standard reports

2. Integrated with Third-Party Software

Standalone capabilities plus consulting, development support, and testing of DXT integration with customer's 3rd party software

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

A If an instrument loses connection to DXT during a procedure, it will continue operating locally. Once the connection is restored, the undelivered procedure records will be sent to DXT and the status will update. However, because Lovo relies on DXT for Active Directory login, if the connection with DXT is lost, users must use the emergency username and password, defined during setup, to access the instrument during the disruption.

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 FK_NAHotlineSupportTechServices@fresenius-kabi.com. For requests outside the U.S., please contact your local market unit for details.

Q Can you connect the instrument wirelessly?

A The Lovo instrument is configured for wired configuration by default. Wireless can be selected instead of wired for installation. If you need to convert your instrument to wireless after installation, there is a service fee.

Q Any special ports that must be opened on the network for device to communicate?

A Yes. The Lovo communicates to DXT using port 9170.

Q How do we manage user authentication on the Lovo?

A Lovo supports two user roles: admin and operator. User roles are controlled through Active Directory groups that are configured in DXT. Users log in with their Active Directory credentials, and their role determines the interface they see. Operators access only the operator screen, while admins have access to administrative functions.

Q Can you control the Lovo instrument(s) remotely?

A No, but you have status visibility of procedures using the DXT Overview, which provides real-time updates throughout the lifecycle of a procedure from install check to procedure completion.

Q When are records sent to DXT from the Lovo?

A Records are sent at the end of the procedure.

DXT Purchase & Implementation Process Outlined

Step	Details
1 Meeting with Fresenius Kabi Data Management Team + Customer	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	Number 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	• Process order for DXT Software (The DXT software will be shipped once Fresenius Kabi confirms the agreement has been fully executed) • Provision DXT server and install prerequisites • Create Active Directory service accounts and user groups
8 Configure Connection to DXT	A Fresenius Kabi Field Service Engineer will visit the Customer's site to upgrade the Lovo instrument(s), set the desired connection type (wired or wireless) and work with the customer's IT to connect to DXT.
9 Fresenius Kabi Contracts group issues invoice for Implementation Fee and First 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 • Administrator training covers system configurations and device connectivity • User training covers the use of DXT to access procedure reports
Annual Invoice and Agreement Renewal	Fresenius Kabi generates an invoice for the annual license fee on the anniversary date of the effective start of the Software Agreement The agreement renewal process begins 90 days prior to agreement's expiration date.

APPENDIX A – Lovo Procedure Listing Screen

Reports > LOVO Procedure Listing								
					11 Records Found	From: 30 Days	To: Today	Filters
Report Type: LOVO Procedure Listing								
				Search				
Site	Procedure Start Time	Instrument Name	Procedure Record Key	Protocol	Procedure ID	Source ID	End User ID	Result
Antioch	3/27/2025 1:15:34 PM	DXTLovo2	20250327131534_DXTLovo2_PR	Incubation and Dilution 4 cycles	procedure1	source1	LOVOoperator	Terminate
Antioch	3/27/2025 1:04:42 PM	DXTLovo2	20250327130442_DXTLovo2_PR	3 Source Containers			LOVOoperator	Terminate

APPENDIX B – Procedure Results Screen

Reports

>

LOVO Procedure Listing

>

20250327131534_DXTLovo2_PR

Print

Download

Protocol Audit Trail

Details

DETAILS

Procedure Record Key

20250327131534_DXTLovo2_PR

Organization

Fresenius Kabi

Protocol ID

Incubation and Dilution 4 cycles

Region

North

Protocol Description

test

Site

Antioch

Protocol Signature

46341

Site Address

—

Procedure ID

procedure1

Site City/State

—

Source ID

source1

GENERAL PROCEDURE INFORMATION

Procedure Status

Terminate

Instrument Check Status

N/A

Disposable Kit Check Start Time

3/27/2025 1:13 PM

Disposable Kit Check End Time

3/27/2025 1:15 PM

Procedure Start Time

3/27/2025 1:15 PM

Procedure End Time

3/27/2025 1:16 PM

Source Processing Start Time

—

Source Processing End Time

—

User ID (Start)

LOVOoperator

User ID (End)

LOVOoperator

Instrument Name

DXTLovo2

Software Version

Version 4.0.27185

Time Zone

UTC -05:00

Software UDI

(01) 00810020441734 (10) 4.0

Hardware Controller Software Version

8

OPERATOR EDITABLE PARAMETERS

ESTIMATES AND RESULTS

CONSUMABLES INFORMATION

APPENDIX C – Printed Procedure Report in DXT



FRESENIUS KABI LOVO Procedure Record

Signature: _____ Date: _____

Procedure Record Key: _____ Printed On: _____ Page: _____

Page 1 of 12



FRESENIUS KABI LOVO Procedure Record

Signature: _____ Date: _____

Procedure Record Key: _____ Printed On: _____ Page: _____

Page 2 of 12



FRESENIUS KABI LOVO Procedure Record

Signature: _____ Date: _____

Procedure Record Key: _____ Printed On: _____ Page: _____

Page 3 of 12



FRESENIUS KABI LOVO Procedure Record

Signature: _____ Date: _____

Procedure Record Key: _____ Printed On: _____ Page: _____

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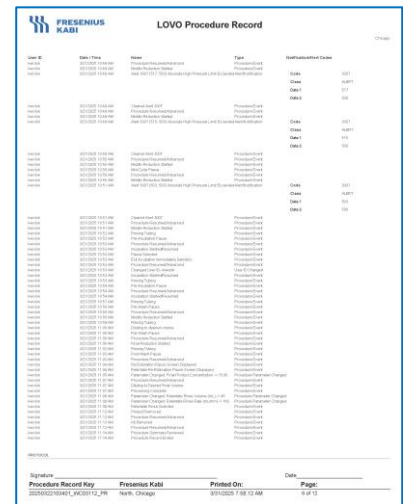


FRESENIUS KABI LOVO Procedure Record

Signature: _____ Date: _____

Procedure Record Key: _____ Printed On: _____ Page: _____

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FRESENIUS KABI LOVO Procedure Record

Signature: _____ Date: _____

Procedure Record Key: _____ Printed On: _____ Page: _____

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The Lovo Cell Processing System is for non-clinical laboratory and research use only. User must obtain appropriate regulatory clearance for clinical use.

Refer to the Lovo Cell Processing System User's Guide and DXT User's Guide for a complete list of warnings and precautions associated with the use of these products.

DXT does not remotely control Lovo.

DXT procedure estimator does not analyze data for a medical purpose.

Protocols are validated on Lovo prior to first use.

Certain devices, software versions, and protocols may not be available depending on approval or clearance by the appropriate regulatory agencies in each country. Contact a Fresenius Kabi representative for questions on the regulatory status in your country.

The information included in this FAQ may change at any time without notice/

For additional information, please visit www.chooselovo.com or email us at cell.therapies@fresenius-kabi.com

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