FRESENIUS KABI

Lovo® Software 4.0 with DXT®

Connectivity. Traceability. Scalability.

Lovo Cell Processing System for use with DXT Data Management System

- Supports **21 CFR Part 11 Compliance** for electronic records
- Supports **larger source volumes** for starting material
- Provides **secured interface** between Lovo and customers' computer system
- Enables users to **perform procedure estimations** prior to procedure setup

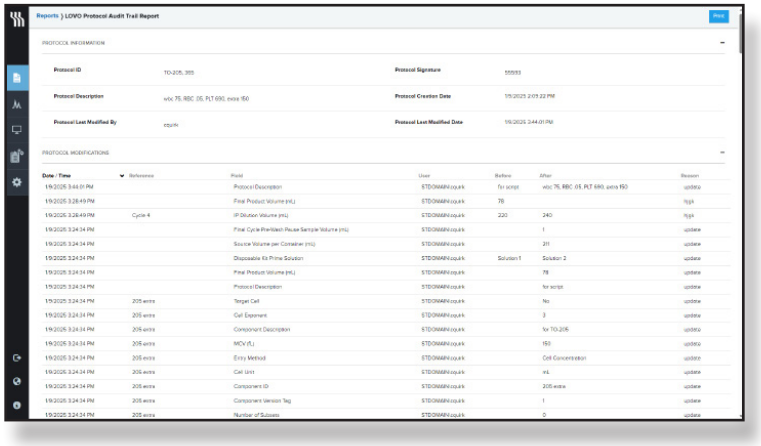
For Laboratory Use Only.



Optimize Efficiency with Advanced Cell Processing Solutions

The Lovo Cell Processing System and DXT Data Management Solution empower you to optimize protocol management and enhance operational efficiency–all while ensuring seamless adherence to cGMP regulations.

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

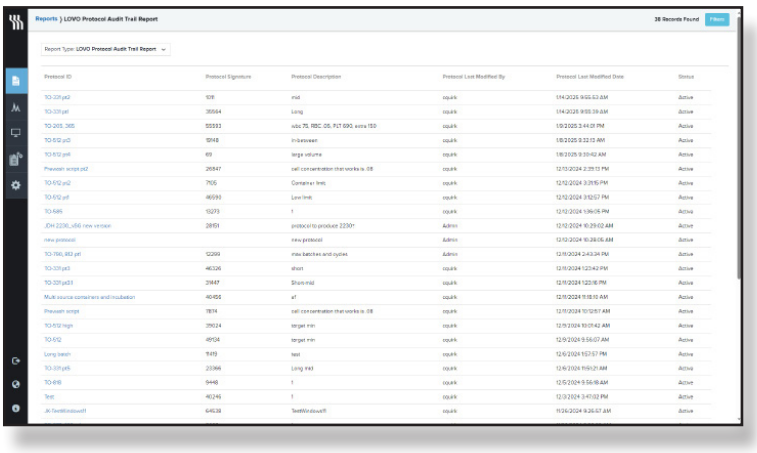


GMP Compliance

- DXT supports 21 CFR Part 11 compliance
- Integration with active directory for user authorization on Lovo and DXT
  - Users are assigned specific roles to limit access to instrument and DXT functionality (either Operator or Administrator)
- Audit trails maintained to track:
  - Protocol Creation and changes
  - Protocol Transfers
  - Procedure Records
  - User Logins to DXT and Lovo instruments

Protocol Management[1]

- Create and manage protocols directly through DXT's software, saving unlimited protocols (DXT) and up to 30 on the instrument
- Distribute protocols directly to a single Lovo or an entire site, at the click of a button
- Perform procedure estimations remotely prior to procedure setup





Software Functionality Comparison

Current Lovo with DXT	Lovo 4.0 with DXT
Time sync with Lovo instrument	Time sync with Lovo instrument
Integration with external computer system	Integration with external computer system
X	Offline protocol management
X	Offline procedure estimations
X	Download logfiles remotely
Electronic procedure record transfers (exportable to PDF)	Electronic procedure record transfers (exportable to PDF)
X	User authentication on the Lovo instrument
X	Audit trails (protocol changes and distribution, user logins)

Additional Features in Lovo Software 4.0

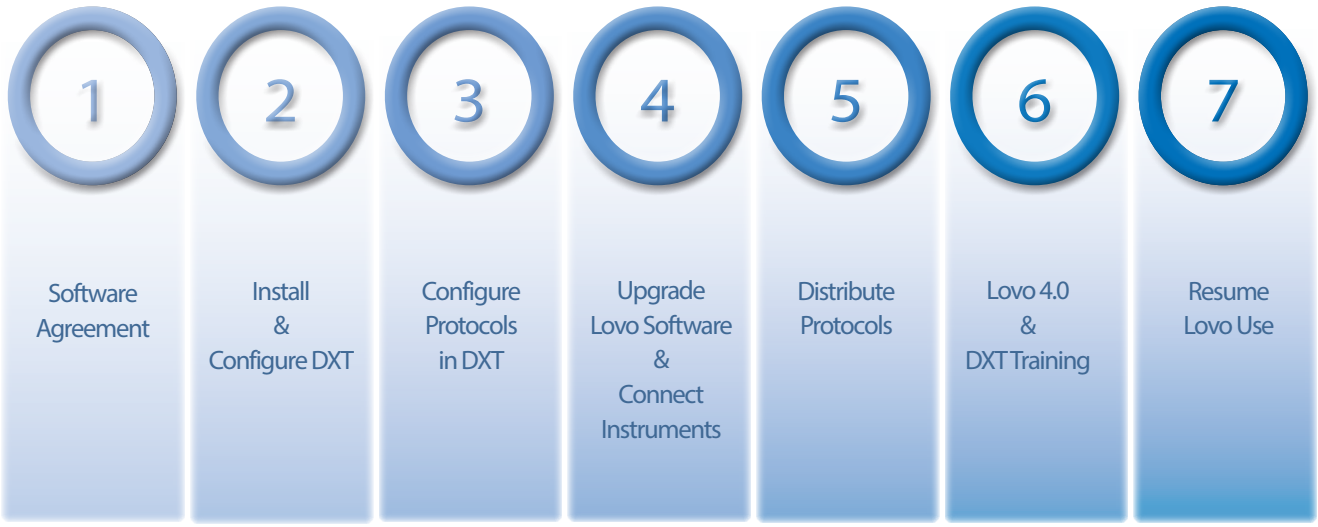
- Larger source processing via 1–wash cycle or batched processing
- Target final concentration
- Configurable automated mid–cycle pauses
- Mid–procedure sampling and re–estimations
- Back–to–back incubations
- Save more protocols on Lovo
- Achieve lower final product volumes via final air rinse
- Target minimum IP dilution and incubation volume per cycle

User Enhancements

- Alert resolution improvement
- Step–by–step kit installation instructions and installation check improvements
- Service IQ/OQ procedure improvements
- View real–time status of procedures (synchronizes every 30 seconds)
- DXT protocol management and estimator
- DXT site overview
- DXT compatibility with customer SSL certificate



Purchase & Implementation Process



Technical Support and Troubleshooting is provided by the Fresenius Kabi team of experts throughout the various implementation stages.

Technical Specifications

DXT System Requirements		
Operating	Windows 11 Pro	Windows Server 2022
Database Management System (DBMS)	SQL Server 2019 Express	SQL Server 2022 Express
Processor	4 Cores @ 2.3 GHz	4 Cores @ 2.3 GHz
Memory	16 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.

[1]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.

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 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.

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