



MICROBIAL SOLUTIONS

EndoScan-V™

EndoScan-V™ v6 Features

- Validated on Microsoft® Windows® 7 and 10 operating systems
- Utilizes database function with PostGres database
- Sample and accessory databases
- Enhanced user management
- Intuitive drag and drop functionality for easy template setup
- Facilitates 21 CFR Part 11 and data integrity compliance
- Fully searchable audit trail
- Enhanced tracking and trending integration via [Charles River Cortex™](#)
- Validation, installation, operation, and performance qualification packages available
- Available in English, French, German, Spanish, Italian, and Brazilian Portuguese

Data-driven decisions are the only way to confidently confirm product quality and ensure patient safety. With over 70 million LAL tests being performed every year, it is now a requirement to ensure that electronic data generation is secure and reliable. Your endotoxin detection platform requires software that generates accurate raw data analysis for reporting, tracking, and trending. Accurate and timely results are critical to ensuring your laboratory and manufacturing processes stay in a state of constant control.

[EndoScan-V™](#) is a validated endotoxin detection and measuring software used to generate and report quantitative LAL test data. The program performs the requisite calculations and creates batch reports for product release. For added protection, it generates secure data and audit trails on all actions. The program was designed with flexible capabilities and performance options for gaining operational efficiencies. All aspects of the software form the pillars of data integrity compliance: fully searchable audit trail, flexible user control and management, and reliable data generation and backup.

How confident are you in the accuracy and security of your release testing data?

Fundamental Elements for Data Integrity Compliance

User Management: All settings and actions in the software are attributed to a privilege. Privilege groups can be established so flexibility within user access to any part of the software can be as restrictive or open as needed. Controlling user access to how data is generated and stored is critical for confirming data integrity. For additional security each user requires a username and password. EndoScan-V™ includes an automatic lock function when no activity occurs for a specified time while the test continues to run in the background.

EVERY STEP OF THE WAY

Searchable Audit Trail: Allows the user to search using open keyword or pre-defined searches for critical actions. The ability to switch on comments for Post Assay changes, Global Settings changes, and Digital Signature changes allows the company to capture the Why to the Who, What, and When of an audit trail. This enables a reconstruction of all events if necessary. Audit trail searches can be printed and manually signed. The ability to reconstruct critical elements of data generation gives firms more insight into the investigative process during unexpected events and ultimately ensures compliance with data integrity standards.

Regulatory Compliance: Fully aligned with 21 CFR Part 11 regulations for electronic records, the software allows users to implement, integrate, and comply with data integrity guidelines globally.

Database Structure: All data and global settings are stored within a PostGres database where a regularly scheduled backup can be set to ensure retrieval of all data and settings if needed. This ensures easy data recovery in the event of a disaster or other unexpected event occurs, eliminating the risk for unacceptable data loss.

Tracking and Trending: With its foundation of data collection and report generation, EndoScan-V™'s ability to expand allows the add-on of other Charles River programs that enhance the overall user experience and ability to keep a state of control in a manufacturing environment. Data from EndoScan-V™ can be visualized in our Charles River Cortex™ software to allow for in-depth tracking and trending of data, which can support laboratory investigations.

Multi-Instrument Control and Support: All legacy and current Endosafe® cartridge instruments, and multiple BioTek ELx808IU instruments can be operated from the same software installation.

Navigational Ease of Use: Newly designed iconography provides the user with an intuitive menu to allow users to seamlessly navigate the software with a simplified workflow.

EndoScan-V™ Client Manager Software (M1261): A modified package is available to allow managers to change global settings, review and sign data, review audit trails, and control user management from the office without having to enter the laboratory.

Secure Export Functionality: Through supported instrumentation, EndoScan-V™ has automatic export capability so data can be exported to centralized databases (e.g., LIMS/Cortex™ via secure XML and CSV).

Digital Signature: The integrated digital signature option permits document review and sign-off.

PC System Requirements

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PC which meets all minimum requirements for the Windows 7 operating system or Windows 10 system.

Minimum hardware configuration:

- Intel Core i3 - 2.5 gigahertz (GHz) or faster
- 64-bit architecture
- 4 gigabyte (GB) RAM

Recommended hardware configuration:

- Intel Core i5 2.0 (GHz) or faster
- 64-bit architecture
- 8 gigabyte (GB) RAM

Hard drive minimum requirements:

- Minimum hard drive space for EndoScan-V™ Client installation – 200 MB
- Minimum hard drive space for EndoScan-V™ Services installation – 50 MB Minimum hard drive space for Microbial Solutions Database installation – 200 MB

Windows Server System Requirements:

We support Server 2012, Server 2016, and Server 2019 (Server) using the GUI mode only.

Please note – Server Core is not supported.

Minimum hardware configuration:

- 1.4 GHz 64-bit processor
- Compatible with x64 instruction set
- 512 MB RAM
- 32 GB free of space for Server OS and 4 GB for Installation

Recommended hardware configuration:

- 2.0 GHz 64-bit processor
- Compatible with x 64 instruction set
- 8 GB RAM
- 60 GB free space for Server OS and 4 GB for Installation

Screen resolution requirements:

- Recommended resolution scaling is 100% for all supported resolutions.
- Resolution scaling set to 125% is only supported for the resolution of 1920 x 1080

Supported Languages:

The software supports English, French, German, Spanish, Italian, and Brazilian Portuguese.

- The installed OS language must be one of the 6 languages we support (English, French, German, Spanish, Italian and Brazilian Portuguese).
- The Display language can be the language of choice but if a Sino-Tibetan language (Korean/Japanese/Chinese) is chosen, the user must use English in the Windows Format (Region and Language-> Format) settings.
- The Windows Format (Region and Language -> Format) must be one of the 6 languages we support (English, French, German, Spanish, Italian, and Brazilian Portuguese).

EndoScan-V™ Product Codes

Product	Code
EndoScan-V™ 6.0	M1260
EndoScan-V™ 6.0 Client Manager	M1261
Software Validation	TS600

Charles River's Bacterial Endotoxin Testing Software Portfolio

Charles River's bacterial endotoxin detection and measuring software is designed specifically to help reduce variability and increase operational efficiencies by achieving quantitative results and incorporating flexible configuration capabilities. While EndoScan-V™ will provide you with real-time, secure, and reliable endotoxin test data, Charles River Cortex™ can provide an integrated solution to securely consolidate, query, and analyze that data for necessary internal QA and FDA trending reports.

Charles River Cortex™

Charles River Cortex™ is an all-encompassing endotoxin software platform for data and instrument management, investigation analysis, and process monitoring. It provides an integrated solution to securely consolidate, query, and analyze all real-time endotoxin data, for necessary internal QA and regulatory authorities' trending reports, to effortlessly elevate compliance status. The decentralized, multi-client solution provides complete QA/QC control over instrumentation, allowing a number of client machines (i.e., PCs with the Cortex™ client software installed) to access the same database and server. Customers can compile and manage data from any of the Endosafe® rapid testing platforms, microplate readers, and tube readers into a unified data infrastructure to gain complete insight over their laboratory and manufacturing processes, while making informed, confident decisions. Cortex™ allows users to proactively manage and monitor the operational integrity of the entire facility's equipment fleet including component effectiveness, calibration schedules, and system readiness within a single, end-to-end risk management environment.

Charles River Cortex™ Product Codes

Product Line	Product	Code
Charles River Cortex™	Charles River Cortex™ software	M1600
	Charles River Cortex™ license/device authorization per Endosafe®-PTS™ (PTS100) instrument	M1601
	Charles River Cortex™ license/device authorization per Endosafe® nexgen-PTS™ (PTS150) instrument	M1602
	Charles River Cortex™ license/device authorization per Endosafe® MCS™ (MCS100)	M1603
	Charles River Cortex™ license/device authorization per Endosafe® nexgen-MCS™ (MCS150)	M1604
	Charles River Cortex™ license/device authorization for Plate Reader/Tube Reader	M1605
Charles River Cortex™ Service and Support	IQ/OQ service	AMC502S
	Annual maintenance	AMC1600