



cortex™
from charles river



Charles River Cortex™

Features and User Benefits

- Real-time data tracking and trending
- Simplified investigations
- Operational management of instrumentation
- Rules-based email alerts (For Endosafe® nexgen-PTS™ instruments)
- Searchable audit log
- Customizable graphs
- EndoScan-V™ integration (5.5.5 SP1 and higher)
- Available in six languages (English, German, Italian, French, Spanish, and Portuguese)
- Electronic signatures for all Endosafe® cartridge instruments
- Enhanced user management profiles
- Enhanced data integrity status
- Increased visibility into key performance indicators
- Elevated compliance position
- More efficient LAL testing operations



Creating centralized control for a decentralized approach.

Maintaining the long-term health and stability of a manufacturing environment while also confirming product quality and safety are a microbial quality control manager's top priority. The need to investigate out-of-specification (OOS) results continues to be one of the most commonly observed cGMP issues during quality control laboratory inspections, so having access to accurate, relevant, and reliable data is essential to support confident decisions on product quality. Moreover, current regulatory authorities' warning letters and new global guidance documents communicate the increasing requirements on data integrity, making many organizations aware of existing deficiencies in their data and reporting. Charles River Cortex™ enables users to effortlessly improve their compliance status.

With the growing volume of quantitative LAL tests being performed today, electronic data generation is now an expectation, rather than the exception. It can be challenging to securely manage data and maintain oversight of multiple systems distributed throughout a facility, but advances in technology have made it possible to do just that.

[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.

How are you currently managing, tracking, and trending your endotoxin data?

During an audit, one of the first things an auditor will ask to see are an organization's deviations or investigation reports. Regulatory authorities expect that organizations track and trend data and that they take action based on unexpected or undesirable observations along with out-of-specification results. Because investigations are so critical to get right the first time, most organizations do this with well-defined quality management systems and quality management lifecycles. With the ability to continuously monitor endotoxin results, users can analyze trends in real time to maintain a complete state of control throughout their manufacturing facility. The Cortex™ database provides a way to investigate OOS endotoxin results in an organized way that drives to root cause based on facts, evidence, or collected data and records a firm's decision-making process for defending their actions to regulators. It allows users to gain an understanding of their data and address inconsistencies, helping

them to further streamline lab investigations and make critical process changes that lead to reduced process variability. The platform has a flexible reporting framework, which enables users to build customized trending graphs at any level of summarization. With the ability to filter and refine through preset views and columns, generate occurrence reports, determine action and alert limits, and track and trend on any field and set of data from all data generating platforms, users have complete flexibility on what they want to see from any data set, including statistical analytics, operator statistics, and product information.

For systems that require [EndoScan-V™](#) software as the data driver, Cortex™ can easily be configured to automatically import the exported data from version 5.5.5 SP1 and higher. Raw data files will remain with EndoScan-V™, as will the audit trails for the data generated in EndoScan-V™. Electronic signatures for data generated in EndoScan-V™ must be applied to the reports within the software.



Do you have a process in place for tracking which analysts are using which instruments during an assay?

With three levels of user management profiles (i.e., administrator, manager, and user), a user can be established to grant appropriate access to operators. Administrative rights allow access to the entire platform, including setup and setting changes. Managers can access the product database and configure operators. Users are able to view and print reports. Password protection adds an extra level of security, prompting for login credentials before accessing and performing functions. With Cortex™ all data is in one database; rather than needing to search through multiple result files, it is simple to filter and search for specific data, key elements for data integrity compliance, audit trail, backup and restore of the database (server side), and Manager and Administrator user management levels. With Cortex™ the data is automatically sent from

[EndoScan-V™](#) or nexgen systems, making it immediately available for analysis and removing the potential for human transcription errors. User Management with digital signatures allows for data to be directly imported from a device and permits restoration of databases for regulatory and data integrity compliance. With the ability to instantly alert users on any developing issues, Charles River Cortex™ is the data integration solution that delivers peace of mind by breaking down data silos and addressing today's data problems before it's too late to correct them. Additionally, a field to add comments to all [Endosafe® cartridge instruments](#) test records allows end users to maintain data integrity.



Do you have a way to track analyst and product data from your instruments over time?

It's becoming increasingly necessary for organizations to track and have accountability for all instrumentation used in the laboratory and on the manufacturing floor. This means tracking key details about an instrument such as calibration date, calibration due date, what assays the instrument has the ability to perform, and who is trained and qualified to use that instrument. It's also key to have controls in place whether the instrument is portable or stationary, to ensure that the instrument is being properly utilized by trained or qualified personnel.

Having an efficient and meaningful way to analyze data can not only assist in investigations, but allow users to, over time, recognize trends such as CV issues, endotoxin results, and consistent analyst errors. With the [Endosafe® nexgen-PTS™](#), users can manage their fleet of systems by creating a sample database, developing device users, scheduling calibration dates, and disabling devices that have passed calibration dates. The platform provides email notification functionality for deviation of set rules and ranges (e.g., invalid test criteria or test failures) for the Endosafe® nexgen-PTS™ systems, supporting real-time data generation of critical in-process testing.



How do you know if your process is experiencing a deviation that could result in an OOS?

Enabling real-time monitoring of a process to observe trends before they become out of specification allows organizations to take action to course correct before an out-of-specification occurs. Being proactive allows a firm to control their process and not let their process control them. This information can be powerful in aiding in investigations, unearthing root causes earlier, and utilizing data or facts as support. Investigations can cost thousands in downtime and supplies, and can be a QC/QA nightmare. If sample values for a product (or sampling point) are slowly increasing, while still within the acceptable endotoxin limit but exceeding a client defined rule in Cortex™, it will generate an email notification

(with [nexgen-PTS™ instruments](#)) to QC personnel/management to prompt further analysis. With this proactive approach, the user could investigate and quickly determine root cause, and remediate it before a full-scale contamination event occurs. With Cortex™, users can continuously monitor endotoxin results, allowing them to pull data from all of their instruments and query and trend according to any and all inputs for each test. Analyzing trends in real time can help maintain a complete state of control and gain an understanding of root cause to address potential inconsistencies to further streamline lab investigations.



Endotoxin Testing Instrumentation and Software

Product Line	Product	Code
Charles River Cortex™	Charles River Cortex™ software	M1600
	Charles River Cortex™ license/device authorization per Endosafe®-PTS™ (PTS100K) instrument	M1601
	Charles River Cortex™ license/device authorization per Endosafe® nexgen-PTS™ (PTS150K) instrument	M1602
	Charles River Cortex™ license/device authorization per Endosafe® MCS™ (MCS100K)	M1603
	Charles River Cortex™ license/device authorization per Endosafe® nexgen-MCS™ (MCS150K)	M1604
	Charles River Cortex™ license/device authorization for Plate Reader/Tube Reader	M1605
Charles River Cortex™ Service and Support	IQ/OQ service	AMC502S





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