

ENDOSCAN-V

EndoScan-V

EndoScan-V is a software program used to collect and report quantitative Limulus Amebocyte Lysate (LAL) test data. The program has been verified and validated to be consistent with FDA requirements and performs the requisite calculations and batch reports for product release. For added protection, it generates secure data files and audit trails on all actions involving files and test data. The program was designed with flexible configuration capabilities and performance options for gaining operational efficiencies. It is fully compliant with 21 CFR Part 11 regulations for electronic records.

The foundation of EndoScan-V is data collection and report generation, but its capability for expandability allows the add-on of other Charles River programs that enhance the overall potential of the program. Additional programs available include electronic signature software that permits document review and sign-off with access to a server and data trending software that can analyze results from multiple kinetic systems.

Software Functionality

EndoScan-V has a broad range of features that make it an optimal choice for endotoxin measuring software. It has been structured to work with any size laboratory with capabilities for linking into a network or for functioning as a stand-alone workstation. It is compatible with the ELx808, the Sunrise incubating microplate reader, and the ATi tube reader. The system can also be run with a fully automated robotics system.

There are many opportunities for customization of the program to meet specific product and user requirements such as the user definable product database with an auto spiking feature, reporting of endotoxin values per mg, ml, and device, optional separate reports by product, and bar coding and automatic export functions, if desired.

For proper security, EndoScan-V has a password protection feature and automatic logout which signs off a user when no activity occurs without stopping the test itself.

Features of EndoScan-V

- Click and drag functions for easy template set-up
- User-defined database for selection of validated test parameters
- MVD/MVC calculator available
- Help section with regulatory information, user manual and a list of published endotoxin limits
- Flexible exporting function from any kinetic reader to trending software, Excel, LIMS and centralized databases
- Enhanced security features for added protection
- Installational Qualification (IQ), Operational Qualification (OQ), and Performance Qualification (PQ) packages available
- Available in English, French and German

