



Solutions for ELECTRONIC DATA SECURITY



STERIS' Electronic Data Security Options allow users to configure a comprehensive, yet cost effective system to manage vital electronic data and comply with FDA 21 CFR Part 11 and European Annex 11 requirements.

Managing electronic data, complying with evolving regulatory requirements and reducing paper records can be a daunting task for pharmaceutical manufacturers. STERIS Corporation makes it easier with our suite of Electronic Data Security solutions, now standard options on most of our equipment. With STERIS, users can easily manage critical electronic data related to production batches, equipment status and user actions. Whether you need to pass electronic data to a centralized SCADA system or want to build a stand-alone Electronic Data management solution, STERIS has plan a for you.

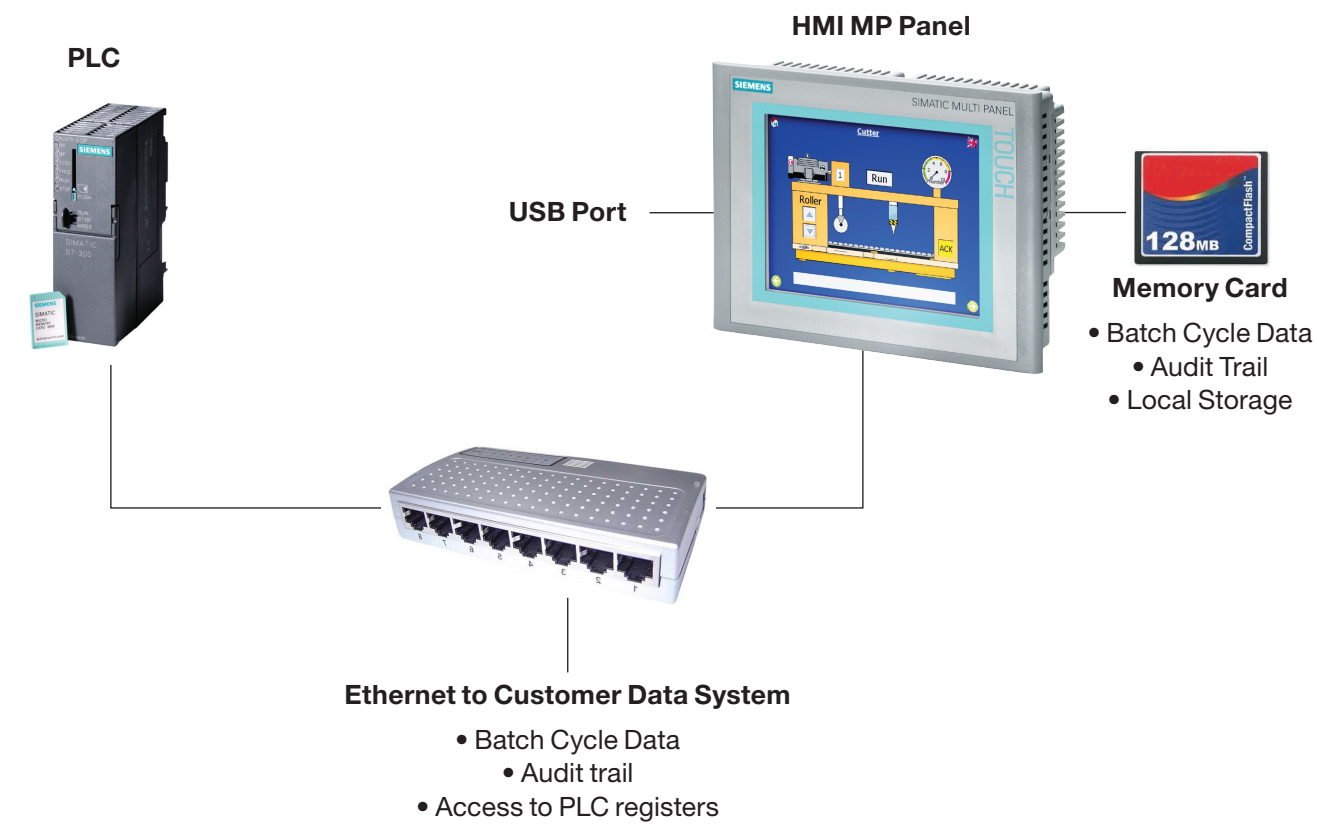
STERIS Electronic Data Security solutions have been developed, tested, and documented in accordance with GAMP 5 guidelines and provide the capability for complying with FDA (21 CFR Part 11) and European (Annex 11) regulations.

STERIS' complete Electronic Data Security suite:

- Audit Trail
- Password Security
- E-Signatures
- Data Archiving
- Batch Data Reporting

Option 1

STERIS Electronic Data Security - Siemens®



Upgraded Siemens® control package provides 21 CFR Part 11 and EU Annex 11 capability. Configured for users who have their own centralized data archiving and reporting capability.

The system includes:

Siemens PLC S7 315-2PN/DP with MP277 (8") Color Touch Panel.

WinCC Flex® software with audit trail capability

- Audit trail includes user identification, time and date for initiation of cycle, cycle abort, cycle parameter changes, alarm acknowledgements, unsuccessful login/access attempts, etc. Audit trail is viewable from the HMI.

Local memory card

- Local memory card for temporary data storage of audit trail and batch cycle data.

Ethernet port

- Batch data and Audit trail can be exported to a Customer supplied control system in a transportable format. Audit trail is transferred in CSV format. Data registers can also be read from the PLC via Ethernet.

Password Protection

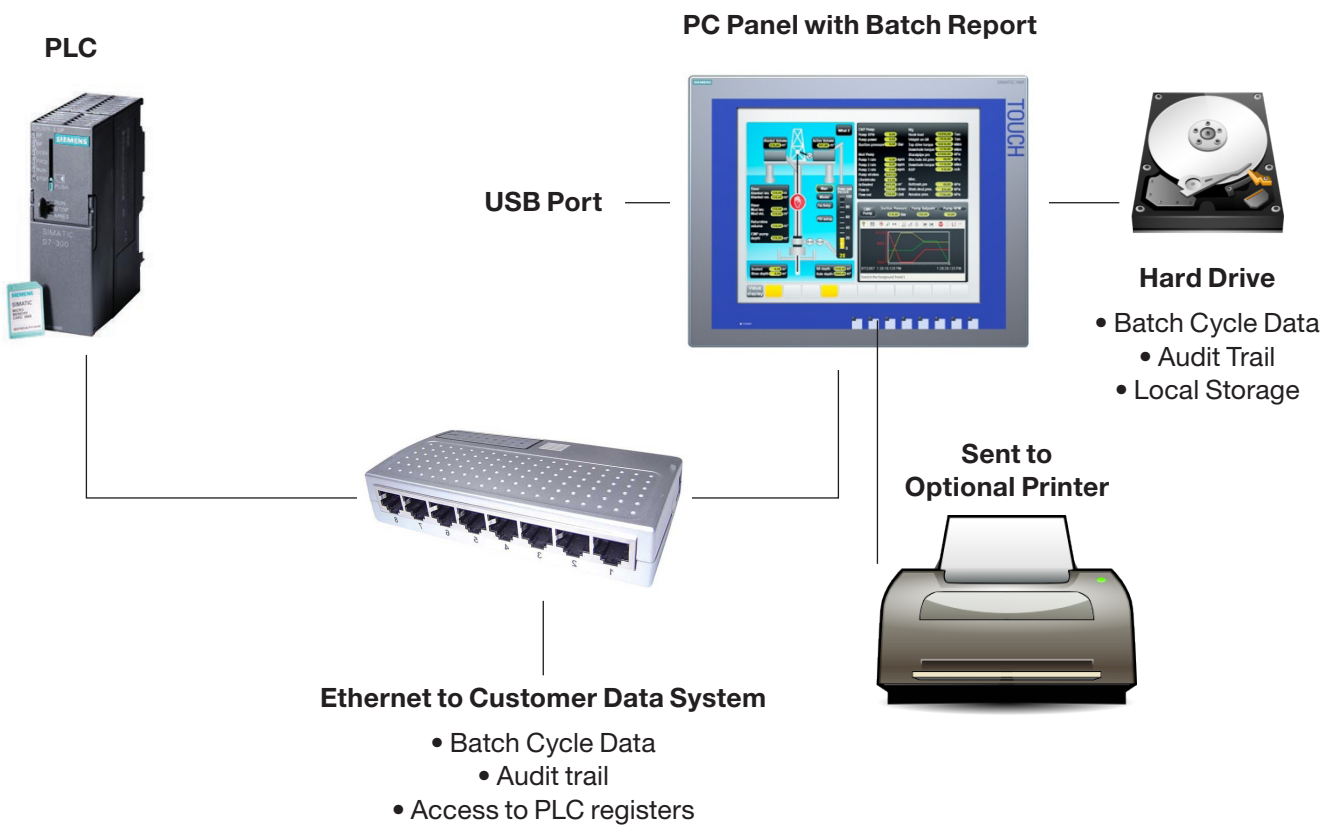
- Password protection features including unique access levels, aging, alpha numeric requirements, automatic log-out, etc.

E-signature

- E-signature for final batch verification/acceptance is available.

Option 2

STERIS Electronic Data Security with Data Archiving and Enhanced Batch Reporting - Siemens®



Upgraded Siemens® control package provides 21 CFR Part 11 and EU Annex 11 capability with data archiving and enhanced batch reporting.

The system includes:

Siemens PLC S7 315-2PN/DP with SIMATIC Panel PC Touch Panel.

WinCC Flex® software with audit trail capability

- Audit trail includes user identification, time and date for initiation of cycle, cycle abort, cycle parameter changes, alarm acknowledgements, unsuccessful login/access attempts, etc. Audit trail and data is viewable from the PC.

Local Data Storage

- Local hard drive for storage of audit trail and batch cycle data.

Batch Reporting

- Predefined Batch Report in PDF format. Batch report may be exported or printed using optional printer.

Ethernet port

- Audit trail can be exported to a Customer supplied control system in CSV format. Batch data can be exported in PDF format. Data registers can also be read from the PLC via Ethernet.

Password Protection

- Password protection features including unique access levels, aging, alpha numeric requirements, automatic log-out, etc.

E-signature

- E-signature for final batch verification/acceptance is available.

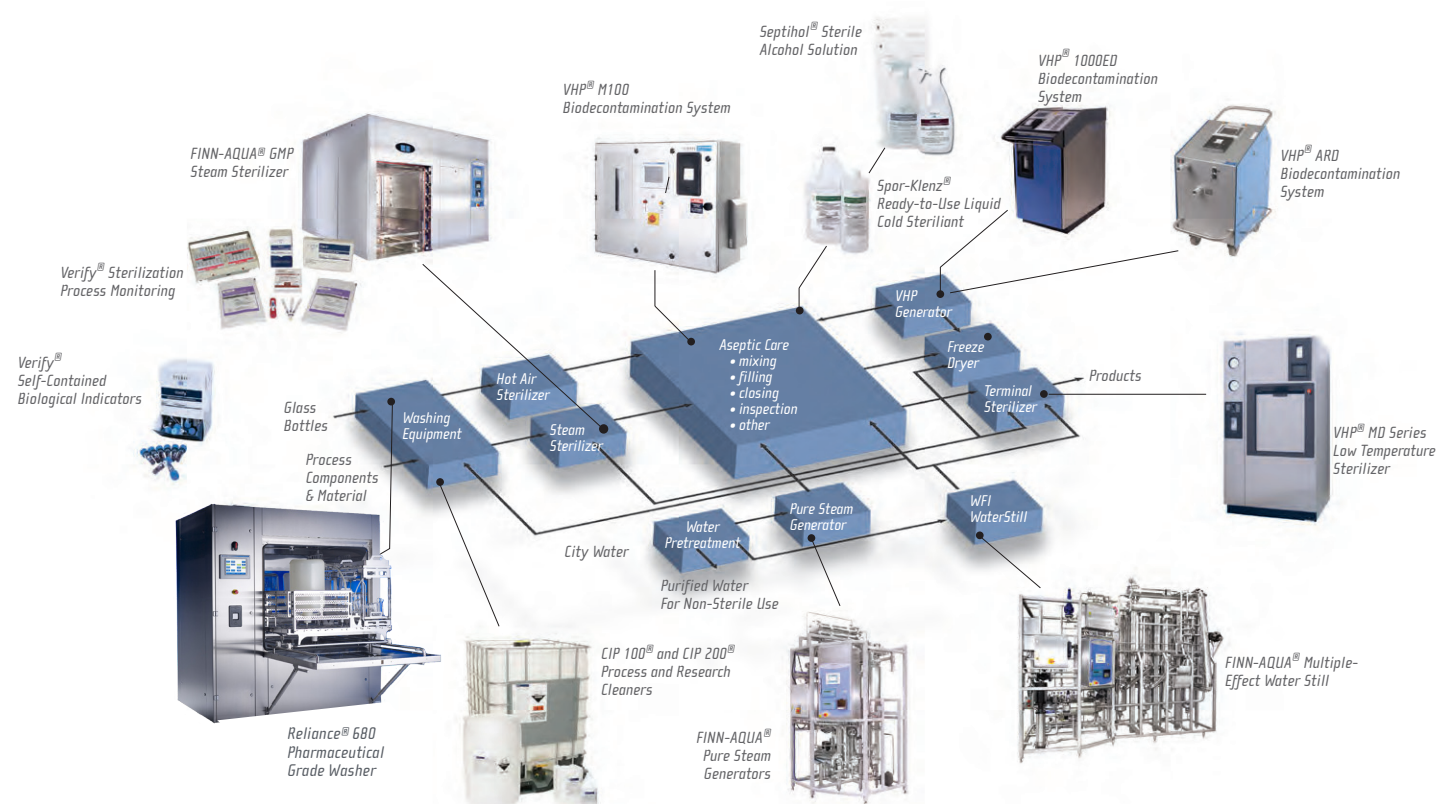
The STERIS Difference

STERIS's Life Sciences division provides solutions to help prevent contamination at virtually every critical point in your manufacturing process. Our systems are specially designed to answer the contamination challenges associated with regulated pharmaceutical environments, including research laboratories, aseptic processing, and bulk biopharmaceutical manufacturing.

Our expert resources offer integrated solutions to help you achieve faster process validation, more efficient operations, and greater cost control. We also provide onsite training, educational seminars, and technical support to keep your employees current with regulatory

compliance issues, product safety and new technologies and protocols. Our support is available when and where you need it through our worldwide manufacturing presence and broad distribution channels.

STERIS Corporation is a leading provider of infection prevention, contamination prevention, microbial reduction, and surgical support systems, products, services, and technologies to healthcare, life sciences, research, food, and industrial customers throughout the world.



STERIS has a comprehensive offering of detergents, disinfectants, skin care products and sterility assurance products that support your needs. We also have world class technical support to design the most effective cleaning program for your facility. Contact your local sales representative or refer to our website at www.sterislifesciences.com



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