



THEMA4

STERILIZERS PROCESS CONTROLLER

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After fifty years in the business, Fedegari still holds an unquestionable technological supremacy among sterilizer manufacturers worldwide.

This achievement stems exclusively from its continuing commitment to control every aspect of its machines and of the process.

Fedegari is in fact the only manufacturer that still produces in-house all the critical components of its sterilizers.

This has allowed Fedegari to acquire, over the years, a deep knowledge and understanding of everything that directly or indirectly affects the overall performance of the machine in terms of both process and maintenance.

These two aspects are not always considered adequately by buyers who lack hands-on experience with production machines and are often easy prey for commercial arguments that deal only with certain aspects of the management of the machine - such as component standardization - neglecting the real reason why a sterilizer is bought.

It is easy to think that all sterilizers are capable of the same performance, especially if they use the same components, but it is certainly more difficult to find and measure their actual differences.

All this has a significant financial impact on the buyer: high performance leads to higher productivity and streamlined maintenance leads to shorter downtimes and reduced personnel training times.

Nowadays, the process controllers of a sterilizer are a highly critical element both in terms of performance and in terms of safety and assurance that the processes carried out cannot be tampered with.

The new THEMA4 controller's main differences with respect to the previous generations are:

- Open hardware architecture based on PC/PLC (Siemens and Allen-Bradley)
- Process control based on a real-time operating system (Wind River VxWorks)
- Windows-like software interface
- Design compliant with GAMP4
- System compliant with FDA 21 CFR, part 11.

This project was in fact launched in order to meet the requirements of those users who, performance aside, prefer to work with commercial hardware components and with



an interface that more closely resembles the programs they use every day, while meeting the requirements of the strictest reference standards and regulations.

However, the new controller retains from its previous generations the software architecture based on a library of fundamental process phases that was introduced toward the end of the 1980s and ensures still unrivalled flexibility and safety.

THEMA4 has been designed on an open client-server architecture with a standard Ethernet/TCP-IP communication protocol, with the server and the first client installed in a panel-PC located on the loading side of the sterilizer. Additional remote clients can therefore be connected to the server over an Ethernet network in order to meet any requirement of the user. Likewise, it can be safely integrated with SCADA by means of standard communications protocols, serial line or Ethernet TCP/IP.

The panel-PC is a high-performance industrial PC with 12.1" touch-screen (TFT color LCD) installed as standard on the front fascia of the machine.

Additional PCs (MS-Windows) already connected to the company Ethernet LAN can also be used as remote clients. The same graphical user interface (GUI) must be installed on these PCs. The process can therefore be printed on any network printer.

All process data, in addition to the requirements of FDA 21 CFR, part 11, are retained securely and in a tamper-proof manner on the panel-PC, which acts as a server, and can therefore be transferred from the panel-PC to the company LAN for paperless management of the documentation related to every batch produced with the sterilizer.

