

Pasteurization limit digital data recording solutions

Eurotherm™ provides a range of products, digital engineered solutions and services throughout the world. From design and build through to operations and maintenance, our solutions support process and thermal efficiency. Helping to improve market agility for OEMs and reduce the cost of ownership for end users.

Our pasteurization solutions support the United States Department of Health and Human Services, Public Health Service and Food and Drug Administration (FDA) Grade "A" Pasteurized Milk Ordinance (PMO), to help create a safer world.

Efficient and resilient

We empower our dairy industry customers to improve process efficiencies and reduce operational costs, while helping to maintain regulatory compliance to the PMO and similar standards.

High integrity data recording solutions and a risk-based cybersecurity approach help to safeguard operations, meet material property specifications, and minimize inspection, audit and other regulatory costs, while supporting a digital transformation path toward open IoT platforms that support the digital transformation to Industry 4.0.

Sustainable

We help our customers to meet energy targets and to reduce environmental impact by providing scalable, high efficiency, and high availability power control, automation, and data management solutions.

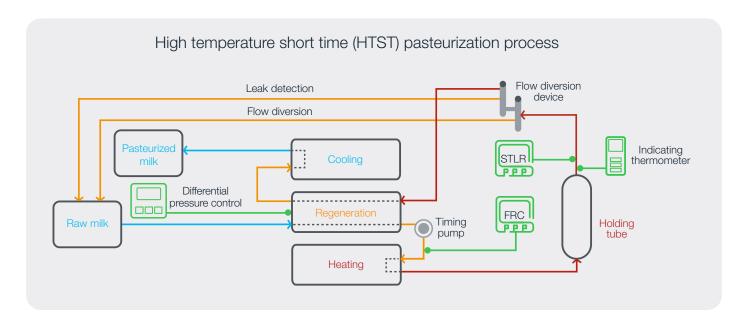
We have application expertise in:

- Precision process control
- Digital data recording based on the Data Integrity ALCOA+ principles
- Batch-based data management
- Visualization of contextual metadata
- Comprehensive audit trail
 - User management
 - Electronic signatures
 - High integrity data recording
- Dairy industry compliance
 - PMO criteria for electronic data collection
 - PMO criteria for Grade "A" public health controls
 - FDA 21 CFR part 11



Digital data recording in dairy production

Dairy producers have a growing need for data management and digitalization of their processes. According to the FDA dairy PMO, the pasteurization process has specific data requirements for safety thermal limit recorders (STLR), flow recorder/controllers (FRC), storage tanks, clean-in-place equipment, aseptic packaging, and other areas. Pasteurization of milk products is a heavily regulated process and is critical to public health and safety. Data recorders/controllers used for pasteurization play an important role in helping to manage that every particle of milk product is exposed to the appropriate temperature for the appropriate time. Moving from paper-based recording/storage methods to a high integrity digital data recording solution helps to improve operational efficiency for the data recording, archiving, approval, and retrieval process for audits, and offers trustable data that meets Data Integrity ALCOA+ principles and dairy PMO requirements.



A focus on HTST pasteurization

High temperature short time (HTST) pasteurization is one of the most common methods of pasteurizing milk products. HTST pasteurization allows a dairy producer to pasteurize large volumes of milk products continuously and efficiently. Key points of best practice control and monitoring are as follows:

- Every pasteurizer will feature an indicating thermometer responsible for presenting the reference temperature of the process
- The temperature of the milk product is controlled to a level that will ensure pasteurization
- A timing pump and holding tube allow the milk to travel through the pasteurizer at a flow rate that will ensure the product is pasteurized for the appropriate time
- The temperature is recorded independently by an STLR, which also has the responsibility of diverting product flow for reprocessing if the temperature falls below a safe pasteurization level also known as the cut-out temperature
- The flow rate can be recorded independently by an FRC, which also has the responsibility of diverting product flow if the flow rate is too high (preventing pasteurization) or too low (reducing product quality)

HTST pasteurizers use a heat exchanger to gain
efficiencies in raising the milk to a pasteurizing
temperature and cooling the milk afterwards. The
pressure on the pasteurized product side of the heat
exchanger must always be higher than the pressure on
the raw product side of the heat exchanger. A differential
pressure controller is used to indicate this difference in
pressure

The milk product pasteurization process is highly regulated. Guidance for compliance is provided by the Grade "A" Pasteurized Milk Ordinance (PMO) or similar regional regulations.

The PMO guidance requires that dairy plants train their operators to manage the pasteurization process correctly.

Attention must be given to the following:

- A pasteurization run (or batch) must document the plant code, pasteurizer, product type, and product amount
- Operators must record the cut-in temperature (the temperature at which pasteurized milk is diverted forward to the heat exchanger for cooling), using an

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- Operators must record the cut-out temperature (the temperature at which the milk is diverted for reprocessing if the pasteurization temperature is not met), using an indicating thermometer
- Operators must record the temperature provided by the STLR, compared to the temperature provided by the indicating thermometer

Process data combined with the contextual data listed above, provide the pasteurization metadata that supports public health. Generally, metadata records are required to be kept for the life of the dairy product.

Eurotherm solution

- Small/medium distributed control systems
- Precision control strategies
- Batch/recipe management
- Digital data management
- Power control for electric heaters
- Local HMIs to full SCADA solutions
- High availability architecture (redundant solutions and 'Store and Forward' feature)
- Data analysis
- Historian server
- Reporting

PMO and other regulations

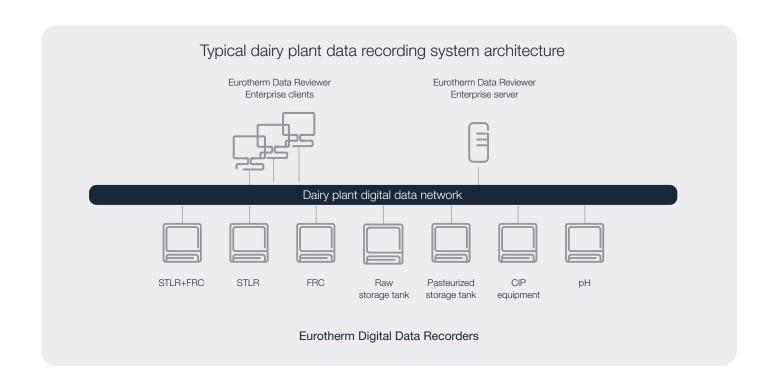
Dairy producers must follow regulatory requirements, such as the PMO. Eurotherm digital data recorders are compliant with the PMO criteria for electronic data collection (see M-b 355). Our STLR and FRC digital data recorder solutions aid compliance to the PMO criteria for Grade "A" public health controls.

Paper-based versus digital data

For many dairy producers, paper remains the primary means for recording data. A move to digital data recording can lead to a data management system that offers operational efficiencies and cost reductions. Trust in data can be the final result, with the added benefit of a high return on investment.

Data Integrity ALCOA+ guidelines

Key regulatory bodies (FDA, EMA, WHO) and some advisory bodies (PIC/S, ISPE) have agreed on the Data Integrity related ALCOA+ principles. ALCOA defines that data should be Attributable, Legible, Contemporaneous, Original and Accurate. In addition to ALCOA, guidance has gone further with ALCOA+ to help ensure data is Complete, Consistent, Enduring, and Available. As an experienced automation supplier, well established in life science processes, Eurotherm is a main supporter of that vision and contributed to the definition and the revision of



Industry 4.0 ready technology

Eurotherm control and data recording solutions are IoT ready, providing a data integrity layer within open IoT platform system architectures and aiding the digital transformation to Industry 4.0 technology.

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Eurotherm

Faraday Close, Worthing, West Sussex, BN13 3PL United Kingdom

Phone: + 44 (0)1903 268500

www.eurotherm.com



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