# Compliance to Pasteurized Milk Ordinance (PMO) Public Health Control with Eurotherm Standardized STLR/FRC Solutions

## Food and Beverage Knowledge Series

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Eurotherm®

## Executive Summary

According to the Grade “A” Pasteurized Milk Ordinance (PMO), high-temperature-short-time (HTST) and ultra-high-temperature (UHT) pasteurization processes must use a recognized compliant safety thermal limit recorder (STLR) and flow recorder/controller (FRC). These public health control recording devices help to prove that pasteurization temperatures have been maintained for the appropriate time, and that the product flow is diverted during low or high conditions.

This document details how Eurotherm™ standardized STLR/FRC solutions meet the public health control recording requirements of the PMO criteria.

# Introduction

Milk pasteurization can be defined as …

*The process of heating every particle of milk product to a specified pasteurization temperature and holding it continuously at or above that temperature for at least the specified holding time, in equipment that is properly designed and properly operated.*

The PMO specifies criteria for control and recording of pasteurization processes. For recording temperature, a recognized safety thermal limit recorder/controller (STLR) must be used to prove that pasteurization temperatures were maintained for the appropriate time, as per the design of the pasteurization equipment. A recognized flow recorder/controller (FRC) can also be used to prove that the flow was diverted accordingly during low/high flow conditions.

Eurotherm standardized STLR/FRC solutions for recording temperature limits and flow are available based on the nanodac™ recorder/controller and 6100A/6180A paperless graphic recorders. When supplied with Eurotherm standardized STLR and FRC configurations, these recording solutions are recognized for use as STLR and FRC public health controls in the FDA: INDEX OF MEMORANDA OF MILK ORDINANCE EQUIPMENT COMPLIANCE.

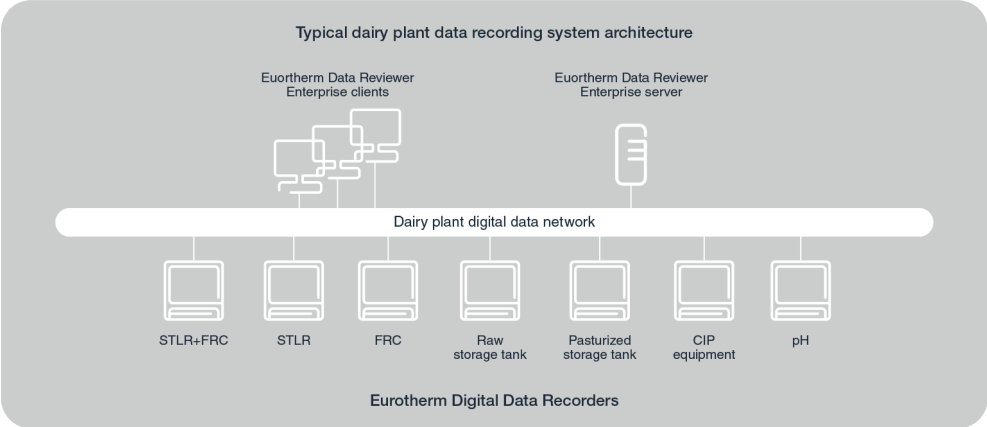
The Eurotherm nanodac, and 6100A/6180A standardized STLR/FRC solutions can perform STLR and FRC functions in single or separate instruments. These digital data recorders can further be used to track temperature data related to raw milk storage, pasteurized milk storage, clean in place systems (CIP), membrane filtration, reverse osmosis systems, and ultra-filtration systems, as well as pH data.

The nanodac, 6100A, and 6180A recorders can help to automatically collect not only process values but also contextual information related to changes in the pasteurization process (cut-in, cut-out, high flow, low flow, forward flow enabled, product flow diverted, etc.), and operator notes (STLR temperature compared to indicating thermometer temperature, indicating thermometer temperature at cut- out, indicating thermometer at cut-in, batch details, process changes, equipment notes, etc.).

Eurotherm digital data recorders support compliance to FDA 21 CFR Part 11, which provides guidance on the collection of secure electronic records and the importance of electronic signature management. As part of GxP (good practice) guidelines in the food and beverage industry, they also aid compliance to the data integrity principles of ALCOA+ which have already been introduced by the FDA in the pharmaceutical industry. Metadata collected by Eurotherm digital data recorders can be attributable to specific individuals, more legible than paper-based systems, time- stamped in the moment, and original through storage in a tamper-resistant file format. It can also be considered highly accurate through the digital representation of data and the accuracy of the instrumentation

**Figure 1**

*Eurotherm digital data recorder and reviewer network architecture*




A typical pasteurization data collection system uses a secured, isolated, and remote PC/server for archiving data related to thermal and flow limit devices. From this PC/server, the Eurotherm Data Reviewer software allows for inspection, audit, analysis, approval, exporting, and printing of data and metadata related to the milk pasteurization process.

Collecting milk pasteurization data in this manner provides dairy plants with an opportunity to increase data integrity levels, streamline operations around data collection (audits, equipment inspection, etc.), and save material and labor costs associated with replacing paper, pens, and the servicing of mechanical recording devices.

The following sections explain how Eurotherm standardized STLR/FRC solutions for STLR/FRC public health controls answer the data recording requirement criteria of the PMO.

The criteria are referenced from:

Grade “A” Pasteurized Milk Ordinance (PMO). VI. CRITERIA FOR THE EVALUATION OF COMPUTERIZED SYSTEMS FOR GRADE “A” PUBLIC HEALTH CONTROLS – 2019 Revision.

Section 1. Definitions, (RR), and Section 5.1, Inspection of Dairy Farms and Milk Plants

https://ncims.org/wp-content/uploads/2020/07/2019-PMO.pdf

# Criteria 1

*"A computer or a PLC used for the public health control of a pasteurizer shall be dedicated only to the public health control of that individual pasteurizer. The public health computer shall have no other assignments involving the routine operation of the milk plant. Computer functions peripheral to the public health controls, such as CIP valve cycling, may be acceptable, provided it does not compromise the public health functionality of the public health computer or pasteurization system and all Ordinance requirements and safeguards are not compromised."*

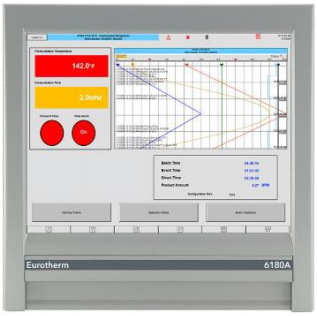
Source: U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration. Grade "A" Pasteurized Milk Ordinance (PMO), VI. CRITERIA FOR THE EVALUATION OF COMPUTERIZED SYSTEMS FOR GRADE "A" PUBLIC HEALTH CONTROLS. 2019 Revision.

## Compliance to Criteria 1

The Eurotherm nanodac, 6100A, and 6180A digital data recorders are microprocessor-based devices with non-volatile memory (data is stored internally even after power is removed). Therefore, they can be used as an instrument or computer for the public health control of pasteurization (e.g., STLR or FRC).

**Figure 2**

*STLR and FRC solutions using the nanodac recorder/controller and 6180A data recorder*


As with traditional circular paper recorders, Eurotherm STLR and FRC public health control solutions can be fitted with auxiliary functions related to the STLR and FRC pasteurization control application. These can include, but are not limited to:

- PID loop for controlling the heating of the product to a pasteurization temperature
- PID loop for controlling the cooling of the product after pasteurization
- PID loop for the control of a flow rate
- Secondary temperature input providing a 'watchdog' over the health of the primary temperature sensor
- Analog outputs for retransmission of process values
- Analog inputs for recording pasteurization related process values

None of these auxiliary functions negatively impact the Eurotherm instruments' ability to perform as a public health control for the STLR and FRC function.

# Criteria 2

*"The public health computer and its outputs shall not be under the command or control of any other computer system or Human Machine Interface. It shall not have an address that is addressable by any other computer system. A host computer cannot override its commands or place it on standby status. All addresses of the public health computer shall be ready to process data at any time."*

Source: U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration . Grade "A" Pasteurized Milk Ordinance (PMO), VI. CRITERIA FOR THE EVALUATION OF COMPUTERIZED SYSTEMS FOR GRADE "A" PUBLIC HEALTH CONTROLS. 2019 Revision.

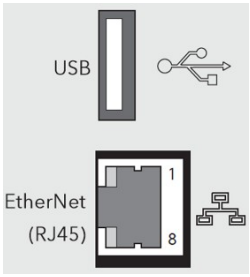
## Compliance to Criteria 2

The nanodac, 6100A, and 6180A standardized STLR/FRC solutions are self- contained instruments with their own HMIs. It is worth noting that Eurotherm digital data recorders feature USB ports and Ethernet ports, which in the STLR and FRC pasteurization applications are limited to the following uses.

The nanodac recorder/controller features one USB port at the rear of the instrument. The USB port can be used to receive communication from a USB barcode reader or keyboard. Operators can use these devices as an alternative to the instrument HMI keypad to enter operator notes, such as adding comparison data for indicating thermometer, indicating thermometer at cut-out, indicating thermometer at cut-in, etc. in an STLR application. A physical cover and a security seal can prevent physical access to this USB port.

**Figure 3**

*USB and Ethernet ports in the nanodac recorder/controller*

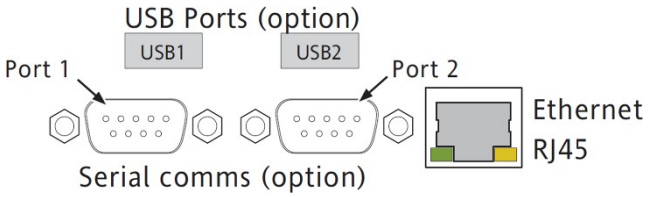



The nanodac recorder/controller also features one Ethernet port at the rear of the instrument. The Ethernet port has the specific function of passing digital data from the instrument to its archive location (PC/server). Typically, this Ethernet port has no other role. Access by devices connected to the Ethernet data archiving network can be limited through various techniques, such as network isolation, secure file transfer protocol (SFTP), virtual local area network (VLAN), managed Ethernet switches, corporate firewalls, password management, device access control (DAC), plant standard operating procedures (SOPs), etc. A physical cover and a security seal can prevent physical access to this Ethernet port.

The 6100A and the 6180A data recorders feature two USB ports at the rear of the instrument. The USB ports can be used to receive communication from a barcode reader or keyboard. Operators can use these devices as an alternative to the instrument HMI keypad to enter operator notes, such as adding comparison data for indicating thermometer, indicating thermometer at cut-out, indicating thermometer at cut-in, etc. in an STLR application. A physical cover and a security seal can prevent physical access to these USB ports.

**Figure 4**

*USB and Ethernet ports in the 6100A or 6180A data recorders*




The 6100A and the 6180A data recorders also feature one Ethernet port at the rear of the instrument. The Ethernet port has the specific function of passing digital data from the instrument to its archive location (PC/server). Typically, the Ethernet port has no other role. Access by devices connected to the Ethernet data archiving network can be limited through various techniques (network isolation, SFTP, VLAN, managed Ethernet switches, corporate firewalls, password management, DAC, plant SOPs, etc.). A physical cover and a security seal can prevent physical access to this Ethernet port.

Note that the 6100A and 6180A data recorder have a USB port and a removable memory media port behind a front door flap. In recorders provided as a standardized Eurotherm public health control solution (STLR and FRC), the door flap is configured as locked, and only instrument users with engineer-level access are authorized to unlock the flap.

To further aid security, when provided as a standardized Eurotherm STLR/FRC public health computer solution, the rear USB and Ethernet ports of the nanodac, 6100A, and 6180A recorders are configured to limit certain actions to users with an engineer-level password. For example:

- Installation and removal of instrument configurations via USB ports
- Data archiving via USB ports
- Instrument configuration via the Ethernet port

## Criteria 3

*"A separate public health computer shall be used on each HTST and HHST pasteurization system. Only the public health computer may provide control over the public health devices and functions of the HTST and HHST pasteurization system.*

a. Any other non-public health computer or human machine interface may request a function of a device (valve, pump, etc.) within the HTST or HHST pasteurization system; however, this request would be granted or denied by the logic in the public health computer depending on the current status of the public health computer program and the Ordinance's public health requirements.

b. The status of the inputs and outputs of the public health computer may be provided as inputs only to other computer systems.

c. Digital outputs from other computer systems may be connected to an input of the public health computer in order to request the operation of a device controlled by the public health computer.

d. The wiring connections shall be provided with isolation protection such as relays, diodes, or optical-coupling devices to prevent the public health outputs from being driven by other non-public health computer systems."

Source: U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration. Grade "A" Pasteurized Milk Ordinance (PMO), VI. CRITERIA FOR THE EVALUATION OF COMPUTERIZED SYSTEMS FOR GRADE "A" PUBLIC HEALTH CONTROLS. 2019 Revision.

## Compliance to Criteria 3

The number of inputs and outputs (I/O) available in a nanodac recorder/controller limits it from being a public health computer for multiple pasteurizers. Even though the 6100A and 6180A data recorders could be fitted with enough I/O, and configured to be a public health computer for multiple HTST or HHST processes, Eurotherm standardized public health computer solutions are only supplied configured for use on a single pasteurizer.

a. A non-public health computer or HMI would not have access to Eurotherm nanodac and 6100A/6180A standardized STLR/FRC public health computer solutions, except as allowed in (b.) below.

b. The relay outputs of a nanodac STLR or FRC public health control solution can be connected to other computer systems. The 6100A and 6180A public health control solutions could be fitted with additional relays or analog outputs to provide the status of the public health computer's digital or analog I/O to other computers. The nanodac, 6100A, and 6180A data recorders' Ethernet network can permit read-only access of information found in the public health computer.

c. Digital outputs from other computer systems would not be connected to a Eurotherm standardized control solution configured as an STLR or FRC.

d. Public health control (STLR or FRC) outputs would not be wired in a way that would allow other non-public health computers to have an influence. The Eurotherm standardized STLR/FRC solution configurations do not allow for public health outputs to be altered by non-public health computers. STLR and/or FRC functionality is self-contained within the public health control.

## Criteria 4

*"All public health outputs or devices within the HTST or HHST pasteurization system, such as solenoids, motor controls, and frequency drives, shall be controlled by dedicated hard-wiring or data network from the output terminal bus of the public health computer to the device. The dedicated hard-wired connection to the public health computer may be point-to-point to each device or multiple devices may be connected through a data network dedicated to the HTST or HHST pasteurization system.*

a. When a data network is used, any electronic switching equipment (switches, routers, hubs, etc.) associated with the data network shall be placed in an enclosure sealed by the Regulatory Agency.

b. Non-public health computers and/or devices that are not associated with the public health control functions of the individual pasteurization system shall not be connected to the data network.

c. In the case of devices that have the capability to be electronically reprogrammed to disable or modify regulatory limits, this functionality shall be disabled by a hardware switch that has been sealed by the Regulatory Agency.

d. All data network cables or ports enabling connectivity to the public health computer shall be sealed by the Regulatory Agency to prevent any other device connections."

Source: U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration. Grade "A" Pasteurized Milk Ordinance (PMO), VI. CRITERIA FOR THE EVALUATION OF COMPUTERIZED SYSTEMS FOR GRADE "A" PUBLIC HEALTH CONTROLS. 2019 Revision.

## Compliance to Criteria 4

With the Eurotherm nanodac and 6100A/6180A standardized STLR/FRC solutions, connections between instruments, a public health control PLC, and the control devices, are designed to be hard-wired.

a. There is a data network associated with the Eurotherm nanodac and 6100A/6180A standardized STLR/FRC solutions. This network is configured to be reserved for metadata transmission to an archiving PC/server. This PC/server and its cables are typically secured using instrument covers and security seals. The enclosure housing the Eurotherm public health control solution (STLR and FRC) can also be sealed to prevent access to the network.

b. Non-public health computers are not typically connected to the Eurotherm nanodac, 6100A, and 6180A data archiving network. Archived data would be reviewed using the appropriate Eurotherm software. Non-public health computers can be programmed for read- only access to the data available via the data archiving network, as described in Compliance to Criteria 3(b.) above.

c. The nanodac 6100A and 6180A digital data recorders do not use hardware switches to change an instrument from a “run” mode to a “programming” mode. Therefore, there is no regulatory seal for this purpose. Alternatively, Eurotherm instruments with the Auditor software option enabled provide for the use of unique User IDs and Passwords for change attributability and instrument access security. Reprogramming of the Eurotherm public health controls (STLR and FRC) can only be accomplished using an engineer-level password. Any reprogramming will be time-stamped and stored in the audit trail.

d. Data networks can be made secure with mechanical covers and security seals, or the enclosures housing the network instrumentation can be sealed by the regulatory agency.

## Criteria 5

*“Upon loss of power to the public health computer all public health controls shall assume the fail-safe position. Most computers can be placed in standby status by either a program instruction or manual switches. When the public health computer is in standby status, all public health controls shall assume the fail- safe position. Some computers have internal diagnostic checks that are performed automatically during start-up. During this time, the public health computer places all outputs in default mode. In this default mode, all public health controls shall be in the fail-safe position. The status of outputs or inputs of the public health computer may provide status to another computer for informational purposes. This shall only be accomplished through a hard-wired output (separate from any control output) from the public health computer to an input on another computer system. No other communication from the public health computer is allowed.”*

Source: U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration. Grade “A” Pasteurized Milk Ordinance (PMO), VI. CRITERIA FOR THE EVALUATION OF COMPUTERIZED SYSTEMS FOR GRADE “A” PUBLIC HEALTH CONTROLS. 2019 Revision.

### Compliance to Criteria 5

The Eurotherm nanodac and 6100A/6180A standardized STLR/FRC solutions have control outputs that are configured for Normally Open (NO) in alarm. This enables the divert valve to operate to its default condition during power loss situations.

The 6100A and 6180A public health control solutions (STLR and FRC) can be fitted with additional relay outputs, which can convey output status to a non- public health computer via hard wiring.

## Criteria 6

*"Some computers and/or PLCs have Input/Output terminals (buses) with "last state switches" that permit the designer to decide what state the output bus will take on power-up, after a shutdown, or loss of power. The choices are "on", "off", or "last state" occurring when the computer lost power. These "last state switches" shall be placed in the "fail-safe" or "off" position. Upon loss of power to the computer, all public health controls shall assume the fail- safe position. Most computers can be placed in standby status by either a program instruction or manual switches. The public health computer shall have its manual switch in the position that maintains all outputs in the "off" state during any operations except normal program execution."*

Source: U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration. Grade "A" Pasteurized Milk Ordinance (PMO), VI. CRITERIA FOR THE EVALUATION OF COMPUTERIZED SYSTEMS FOR GRADE "A" PUBLIC HEALTH CONTROLS. 2019 Revision.

### Compliance to Criteria 6

The Eurotherm nanodac and 6100A/6180A standardized STLR/FRC solutions do not use last state switches.

## Criteria 7

*"A computer performs its tasks sequentially, and for most of real time the computer outputs are locked in the "ON" or "OFF" position, while waiting for the computer to come back through the cycle. Consequently, the public health computer program shall be written so that it monitors all inputs and updates all outputs on a precise schedule, at least once every second. Most computers will be capable of performing this function many times in one (1) second. Program instructions may not exist within the public health computer program that are capable of altering the scan order of the logic or distract focus from this order. These would include "JUMP" or "GOTO" type instructions."*

Source: U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration. Grade "A" Pasteurized Milk Ordinance (PMO), VI. CRITERIA FOR THE EVALUATION OF COMPUTERIZED SYSTEMS FOR GRADE "A" PUBLIC HEALTH CONTROLS. 2019 Revision.

### Compliance to Criteria 7

The Eurotherm nanodac and 6100A/6180A standardized STLR/FRC solutions feature parallel processing techniques in which configured processes are executed in a structured and timely manner. Analog inputs are updated once every 125ms. The internal scan time for instrument operation is not adjustable.

## Criteria 8

*"The computer program used to control the required public health functions of HTST or HHST pasteurizers shall be stored in some form of ROM and be available when the public health computer is turned on. The use of tapes or disks are not acceptable."*

Source: U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration. Grade "A" Pasteurized Milk Ordinance (PMO), VI. CRITERIA FOR THE EVALUATION OF COMPUTERIZED SYSTEMS FOR GRADE "A" PUBLIC HEALTH CONTROLS. 2019 Revision.

### Compliance to Criteria 8

In Eurotherm nanodac and 6100A/6180A standardized STLR/FRC solutions, the configuration is stored in non-volatile flash memory for retention. External configuration storage devices are not necessary for STLR and FRC operation.

## Criteria 9

*"The public health computer program access shall be sealed. Any telephone modem accesses shall also be sealed. If the Input/Output terminals contain "last state switches", the Input/Output terminals shall be sealed. The vendor shall supply the Regulatory Agency with test procedures and instructions to verify that the program currently in use by the public health computer is the correct program. Typically, this is made available by providing a copy of the program that controls the public health computer of the HTST or HHST pasteurizer. The Regulatory Agency shall use this test procedure to confirm that the correct program is in use during a start-up, normal operation, and whenever the seal is broken. Challenging the system during normal operation could involve challenging the inter-wiring requirements through the CIP computer. One (1) method could include attempting access to the booster pump through the CIP computer. With the FDD mode selector in "PROCESS" or "PRODUCT" position, attempt to access the booster pump using the CIP computer. Public health controls in pasteurizers that may be compromised by such a challenge, shall be altered or re-programmed so this compromise is prevented and the access to this computer program shall be sealed by the Regulatory Agency. Similar challenges may be performed on other required public health functions that are computer controlled."*

Source: U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration. Grade "A" Pasteurized Milk Ordinance (PMO), VI. CRITERIA FOR THE EVALUATION OF COMPUTERIZED SYSTEMS FOR GRADE "A" PUBLIC HEALTH CONTROLS. 2019 Revision.

### Compliance to Criteria 9

As stated in Compliance to Criteria 4, the configuration for the Eurotherm nanodac and 6100A/6180A standardized STLR/FRC solutions is protected via unique User IDs and Passwords. Configuration can only be changed by an individual with an engineer-level access. Any changes to the configuration are attributed to the unique User ID and are recorded within the tamper resistant data file. Furthermore, any changes to the configuration will increment a configuration number.

It is recommended that unique User IDs and Passwords for the engineer-level access be allocated to the most senior milk plant personnel.

For the nanodac recorder/controller, instrument configuration files are archived as *.uic files and can be reviewed using Eurotherm iTools Engineering Studio software.

www.eurotherm.com/itools

For the 6100A, and 6180A data recorders, instrument configuration files are archived as *.uhz files and can be reviewed using Eurotherm C-Edit software.

www.eurotherm.com/6000

Eurotherm test procedures are available for the nanodac and 6100A/6180A standardized STLR/FRC solutions.

## Criteria 10

*"If the public health computer contains FORCE-ON, FORCE-OFF functions, the public health computer shall provide indicator lights showing the status of the FORCE-ON, FORCE-OFF function. The vendor's instructions shall remind the Regulatory Agency that all FORCE- ON, FORCE-OFF functions shall be cleared before the public health computer is sealed by the Regulatory Agency."*

Source: U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration. Grade "A" Pasteurized Milk Ordinance (PMO), VI. CRITERIA FOR THE EVALUATION OF COMPUTERIZED SYSTEMS FOR GRADE "A" PUBLIC HEALTH CONTROLS. 2019 Revision.

## Compliance to Criteria 10

Within the Eurotherm nanodac and 6100A/6180A standardized STLR/FRC solutions, "alarm panel" display technology with red/amber/green backgrounding is used for improved visibility compared to traditional indicator lamps.

In Eurotherm STLR and FRC public health control solutions, measured values are presented for STLR Temperature, Cut-Out Temp, Forward Flow (1 or "On" = forward flow and 0 or "Off" = diverted flow), FRC Flow, and Flow Alarm (1 or "On" = high or low flow alarm and 0 or "Off" = no flow alarm). When the pasteurization process is in forward flow, all display backgrounds of measured values will be green. When a temperature Cut-Out and/or a flow Cut-Out condition has occurred, the display background of the measured values will be red. In a low flow condition, the displayed FRC Flow background color is changed to amber.

The nanodac STLR and FRC public health control solutions achieve this operation using the standard panel alarm display within the nanodac instrument. For the 6100A and 6180A recorder based STLR and FRC solutions, a custom user screen has been designed and documented.

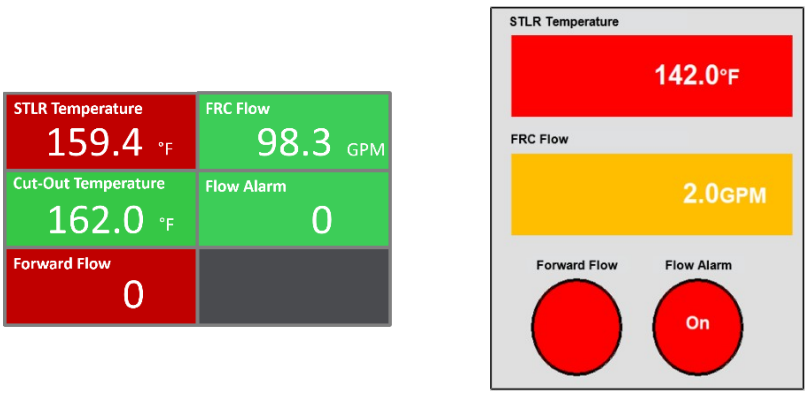



**Figure 5**

*nanodac recorder and 6100A/6180A recorder STLR and FRC solution alarm panel examples*

## Criteria 11

*"The Input/Output terminals of the public health computer shall contain no operator override switches that are accessible without compromising a regulatory seal."*

Source: U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration. Grade "A" Pasteurized Milk Ordinance (PMO), VI. CRITERIA FOR THE EVALUATION OF COMPUTERIZED SYSTEMS FOR GRADE "A" PUBLIC HEALTH CONTROLS. 2019 Revision.

### Compliance to Criteria 11

The Eurotherm nanodac and 6100A/6180A standardized STLR/FRC solutions do not have any override switches connected to I/O terminals.

## Criteria 12

*"Computerized systems that provide for printing the pasteurizer recording chart by the public health computer shall ensure that the required calibration is maintained. During chart printing, the public health computer shall not be diverted from its tasks for more than one (1) second. Upon returning to public health control tasks, the public health computer shall complete at least one (1) full cycle of its public health tasks before returning to chart printing."*

Source: U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration. Grade "A" Pasteurized Milk Ordinance (PMO), VI. CRITERIA FOR THE EVALUATION OF COMPUTERIZED SYSTEMS FOR GRADE "A" PUBLIC HEALTH CONTROLS. 2019 Revision.

### Compliance to Criteria 12

The Eurotherm nanodac and 6100A/6180A standardized STLR/FRC solutions are modern digital data recorders capable of high accuracy measurement. To help maintain high accuracy and precision, Eurotherm recommends that instrument calibration be checked at regular intervals using National Institute of Standards and Technology (NIST) traceable equipment and PMO standard tests.

The Eurotherm nanodac and 6100A/6180A standardized STLR/FRC solutions are digital data recorders. There is no facility for printing from the instrument. Data is sent to a data archiving PC/server. Public health control tasks and data archiving/reviewing functions are separate activities. All chart printing or data exporting is managed using Eurotherm Data Reviewer software.

www.eurotherm.com/data-reviewer


**Figure 6**

*Eurotherm Data Reviewer software*

## Criteria 13

*"When printing a chart, some systems may provide status reports on the chart paper of selected Input/Output conditions. This is usually done by interrupting the printing of the chart and printing the Input/Output conditions. Such interruptions for status printing are permitted only when a continuous record is recorded on the chart. When an interruption is initiated the time of the start of the interruption shall be printed on the chart, at the beginning of the interruption and at the end of the interruption. The time interval during which the public health computer is diverted from its public health tasks for status printing shall not exceed one (1) second. Upon returning to public health tasks, the public health computer shall complete at least one (1) full cycle of its public health tasks before returning to status printing."*

Source: U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration. Grade "A" Pasteurized Milk Ordinance (PMO), VI. CRITERIA FOR THE EVALUATION OF COMPUTERIZED SYSTEMS FOR GRADE "A" PUBLIC HEALTH CONTROLS. 2019 Revision.

### Compliance to Criteria 13

The Eurotherm nanodac and 6100A/6180A standardized STLR/FRC solutions have a built-in HMI that visualizes a simulated printed chart. The vertical trend in Figure 7 includes graphical representations of changes in I/O status. The vertical trend traces the textual representation of I/O, and the public health tasks are executed in parallel. Operations are refreshed at intervals of 125ms minimum.

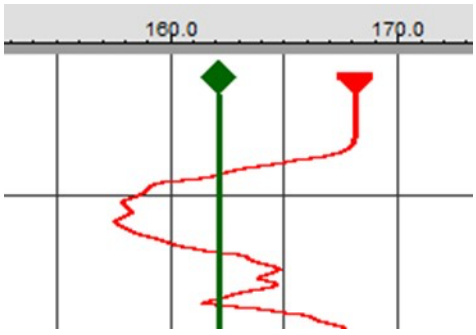



**Figure 7**

*Graphical and contextual data*

These instruments are digital, so there is no risk of a mechanical printing process interrputing the instrument's operation.

## Criteria 14

*"When the public health computer prints the holding tube temperature trace at specific intervals, rather than a continuously changing line, temperature readings shall be printed not less than once every five (5) seconds. In addition, during the recorder/controller thermometric response test, the temperature shall be printed or indicated at a time rate sufficient to allow the Regulatory Agency to measure the 7ºC (12ºF) rise in temperature as described in Appendix I, TEST 8. Temperature Recorder/Controller Thermometers-Thermometric Response of this Ordinance."*

Source: U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration. Grade "A" Pasteurized Milk Ordinance (PMO), VI. CRITERIA FOR THE EVALUATION OF COMPUTERIZED SYSTEMS FOR GRADE "A" PUBLIC HEALTH CONTROLS. 2019 Revision.

## Compliance to Criteria 14

For the Eurotherm nanodac and 6100A/6180A standardized STLR/FRC solutions, numerical measured values are updated once every 125ms. Graphical trend traces are configured to be updated once every 1 second. Historical data is configured to be recorded once every 1 second.

# Criteria 15

*"When the public health computer prints the event pen position, the position of the FDD, either forward or divert at specific intervals, rather than continuously, all changes of position shall be recognized by the public health computer and printed on the chart. In addition, the event pen position and temperature in the holding tube shall be printed on the chart in a manner that the temperature in the holding tube can be determined at the moment of a change in position of the FDD."*

Source: U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration. Grade "A" Pasteurized Milk Ordinance (PMO), VI. CRITERIA FOR THE EVALUATION OF COMPUTERIZED SYSTEMS FOR GRADE "A" PUBLIC HEALTH CONTROLS. 2019 Revision.

## Compliance to Criteria 15

The Eurotherm nanodac and 6100A/6180A standardized STLR/FRC solutions indicate Flow Diversion Device (FDD) status in two ways. First, on the vertical trend chart the STLR forward flow event trace (black) will show the binary conditions of forward flow (On or 1) or diverted flow (Off or 0). The FRC flow alarm event trace (cyan) will indicate the binary conditions of flow alarm ( On or 1), or no flow alarm (Off or 0).

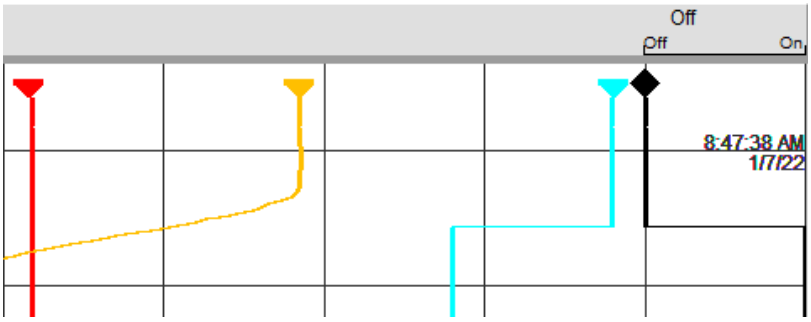



**Figure 8**

*Event trace examples*

Second, time-stamped textual messages that indicate the change in the FDD state will be displayed and recorded. For example:

- "Forward Flow Enabled" will be displayed with a date and time stamp when Cut-In has occurred.
- "Process Cut-In at xxx.x°F" or "Process Cut-In at xxx.xGPM" will be displayed with a date and time stamp when Cut-In has occurrred
- "Product Flow Diverted" will be displayed with a date and time stamp when Cut-Out has occurred
- "Process Cut-Out at xxx.x°F" or "Process Cut-Out at xxx.xGPM" will be displayed with a date and time stampl when Cut-Out has occurred.

To achieve high visibility of an FDD state change, the Eurotherm nanodac and 6100A/6180A standardized STLR/FRC solutions are configured with a chart speed of 36 inches (91.4 cm) per hour. This allows for accurate determination of pasteurization temperature or pasteurization flow against an FDD event change caused by temperature or flow. Furthermore, event traces are scaled to appear on the far right of the vertical trend view so that they are not visually in conflict with pasteurization temperature or pasteurization flow measurements.

## Criteria 16

*"The vendor shall provide a built-in program for test procedures or a protocol shall be provided so that all applicable public health tests, contained within Appendix I. of this Ordinance, can be performed by the Regulatory Agency for each instrument, i.e.:*

a. Recording Thermometers: Temperature accuracy; time accuracy; check against indicating thermometer and thermometric response.
b. FDD: Valve seat leakage; operation of valve stem(s); device assembly; manual diversion; response time and time delay intervals if used.
c. Booster Pumps: Proper wiring and proper pressure control settings.
d. Flow-Promoting Devices Capable of Generating Flow Through the Holding Tube: Are installed with proper wiring interlocks."

Source: U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration. Grade "A" Pasteurized Milk Ordinance (PMO), VI. CRITERIA FOR THE EVALUATION OF COMPUTERIZED SYSTEMS FOR GRADE "A" PUBLIC HEALTH CONTROLS. 2019 Revision.

### Compliance to Criteria 16

The Eurotherm nanodac and 6100A/6180A standardized STLR/FRC solutions can be thoroughly tested against the applicable PMO Appendix I test procedures.

Applicable test procedures can be found in the following Eurotherm documents.

- Standardized 6180A STLR+FRC Solution, Pasteurization Safety Thermal Limit Recorder and Flow Recorder/Controller, Application Guide, HA033668ENG Issue 1
- Standardized nanodac STLR+FRC Solution, Pasteurization Safety Thermal Limit Recorder and Flow Recorder/Controller, Application Guide, HA033669ENG Issue 1

## Criteria 17

*"Computers require high quality; clean, well-regulated power supplies to operate reliably and safely. Spurious voltage spikes can cause unwanted changes in public health computer RAM. To assure the public health computer will execute its functions error free the following items parameters shall be considered:*

a. A "clean" power source that is relatively free of spikes, interference and other irregularities shall be supplied to the public health computer.
b. The correct program should be confirmed at the time of sealing. (Refer to the criteria cited within #9 of this Section.)
c. The output bus "last state" switch should be in the "off" or "fail-safe" position which shall stop all functions of the HTST or HHST pasteurizer in case of a spurious program error.
d. All public health computer outputs shall not have any operator override switches and shall be wired in a manner that only allows the public health PLC complete control.

*It is necessary that the installer or designer for the public health PLC ensure that the proper program is in the public health computer memory before the Regulatory Agency seals the computer. It is also necessary that any program changes be written to the public health computer's back-up chip if one exists."*

Source: U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration. Grade "A" Pasteurized Milk Ordinance (PMO), VI. CRITERIA FOR THE EVALUATION OF COMPUTERIZED SYSTEMS FOR GRADE "A" PUBLIC HEALTH CONTROLS. 2019 Revision.

## Compliance to Criteria 17

The Eurotherm nanodac and 6100A/6180A standardized STLR/FRC solutions feature switch-mode power supplies that can accept 85V-264V ac for instrument power.

a. The provision of a clean power source is typically the responsibility of the milk plant. However, the use of switch-mode power supplies in Eurotherm public health control solutions helps to eliminate a problem associated with an inconsistent power supply.
b. The Eurotherm nanodac and 6100A/6180A standardized STLR/FRC solutions are pre-configured to perform public health control operations for HTST, HHST, or UHT processes. Tests can be carried out before sealing to provide further evidence that the instruments are configured as appropriate. Furthermore, Eurotherm public health control solutions feature a configuration number that is incremented when changes are made.
c. The Eurotherm nanodac and 6100A/6180A standardized STLR/FRC solutions feature normally open (NO) de-energized in alarm outputs.
d. The Eurotherm nanodac and 6100A/6180A standardized STLR/FRC solutions do not have any override switches connected to I/O terminals.

# Criteria 18

*"Computer programs used for public health controls on pasteurizers shall conform to the attached logic diagrams. Minor modifications to these diagrams are permissible to accommodate or delete items that are unique to a specific HTST or HHST pasteurization system. For example, on meter-based timing systems when the FDD selector switch is placed in the CIP position:*

a. A minimum ten (10) minute time delay is required for the FDD to remain in diverted flow; and
b. During this time delay the booster pump shall shut down and remain off for ten (10) minutes and then the Programmed CIP Operation is allowed to fully perform all the cleaning functions for the HTST or HHST pasteurization system, including allowing the timing pump, the separator, and the booster/stuffer pump to run during cleaning operations and the FDD to pulse or cycle."

Source: U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration. Grade "A" Pasteurized Milk Ordinance (PMO), VI. CRITERIA FOR THE EVALUATION OF COMPUTERIZED SYSTEMS FOR GRADE "A" PUBLIC HEALTH CONTROLS. 2019 Revision.

## Compliance to Criteria 18

The configuration within the Eurotherm nanodac and 6100A/6180 standardized STLR/FRC solutions complies with the logic functions outlined in the PMO. However, in some cases, separate instrumentation such as a public health control PLC for CIP and booster pump operation can be responsible for some of these logic functions.

# Criteria 19

*"The ladder logic diagrams for the FDD and the booster pump show a programmed CIP cleaning cycle operation as part of the computerized system. Some milk plant operators may wish to use another computer for CIP cleaning operations, so that milk plant personnel, may change CIP cleaning programs. When using this method, the connections between the FDD, booster pump, and milk plant computer, shall be provided with solenoid relays or similar devices for the FDD and booster pump outputs. This prevents them from being operated by the milk plant computer, except when the mode switch of the FDD is in the "CIP" position and all applicable requirements have been satisfied."*

Source: U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration. Grade "A" Pasteurized Milk Ordinance (PMO), VI. CRITERIA FOR THE EVALUATION OF COMPUTERIZED SYSTEMS FOR GRADE "A" PUBLIC HEALTH CONTROLS. 2019 Revision.

## Compliance to Criteria 19

This is typically a function of the public health control PLC associated with the pasteurization process, not the STLR or FRC.

# Criteria 20

*"The vendor shall provide to the Regulatory Agency a protocol and documentation as follows:*

a. The computer ladder logic printout and/or storage device (programmed ROM chip, etc.) identical to the public health computer that controls the pasteurizer. This is usually in the form of ladder line logic for each component of the pasteurization system(s) and may include programming for CIP and other functions.
b. A user manual including testing procedures and instructions as required in Criteria #9 of this Section."

Source: U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration. Grade "A" Pasteurized Milk Ordinance (PMO), VI. CRITERIA FOR THE EVALUATION OF COMPUTERIZED SYSTEMS FOR GRADE "A" PUBLIC HEALTH CONTROLS. 2019 Revision.

## Compliance to Criteria 20

A function block diagram method is used to configure the Eurotherm nanodac standardized STLR/FRC solution. This can be provided as a printout. However, this configuration information can also be provided in a file (.uic) that can be reviewed using Eurotherm iTools Engineering Studio software. A free version of iTools software can be downloaded at www.eurotherm.com/itools.

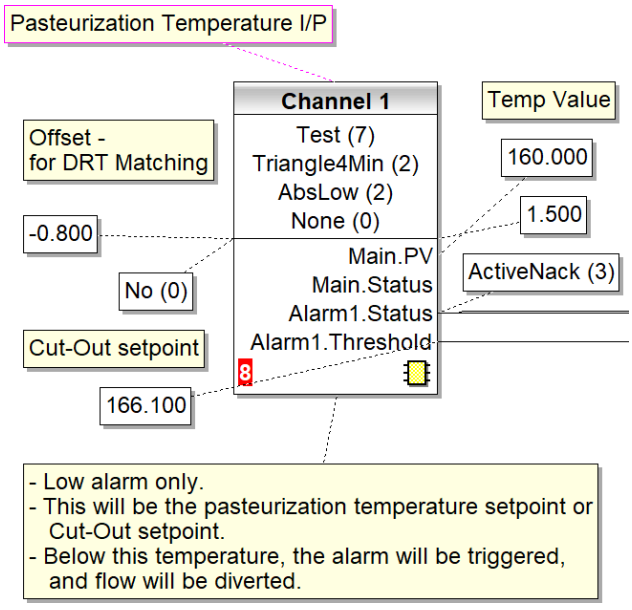



**Figure 9**

*The iTools programming environment uses function blocks and graphical wiring*

For the Eurotherm standardized 6100A and 6180A STLR and FRC public health control solutions a table-based configuration is used. Although this can be provided as a printout, configuration information is more easily reviewed using Eurotherm C-Edit software. C-Edit software can be downloaded for free as part of the 6000 Series Tools software package www.eurotherm.com/6000.

# Conclusion

Around the world, dairy plants are looking to digitally transform their business operations. An opportunity to move from paper-based technologies for process measurement and business operations is available. Return on investment is appropriate and easily calculated. Benefits include higher efficiencies, increased sustainability, and a higher trust in the data collected.

The Eurotherm standardized STLR and FRC pasteurization limit solutions based on the 6100A/6180A data recorder and nanodac recorder/controller answer the recording requirements of the the Grade “A” Pasteurized Milk Ordinance (PMO), VI. CRTERIA FOR THE EVALUATION OF COMPUTERIZED SYSTEMS FOR GRADE “A” PUBLIC HEALTH CONTROLS, 2019.

## About Eurotherm

With a long history in precision process control, automation, and high integrity data management, Eurotherm by Schneider Electric has a broad range of knowledge and expertise in regulated industries, including food and beverage, helping customers to comply with data integrity related standards and guidelines, such as::

- Pasteurized Milk Ordinance
- National Dairy Code (Canada)
- U.S. FDA 21 CFR Part 11


- Pasteurized Milk Ordinance
- National Dairy Code (Canada)
- U.S. FDA 21 CFR Part 11


As well as providing a range of control and data acquisition products, and engineered systems, Eurotherm provides a wealth of expertise in food and beverage applications, offering comprehensive engineering support and services, including data management, energy management, and cybersecurity services. For more information on solutions that help meet the PMO and similar standards, visit www.eurotherm.com.

## About the authors


**Rick Jarrell** has over 35 years’ experience within process automation, Rick Jarrell is now a leading specialist within the Life Sciences and Food & Beverage sectors of the Americas. Rick has regularly presented on Pharma 4.0 topics such as managing processes aligned with the ALCOA+ data integrity concept. Rick’s expertise has helped customers achieve precision process control and process monitoring, allowing them to reach high levels of regulatory compliance and data integrity by design.

**Amber Watkin** has over 25 years’ experience in the Eurotherm portfolio, covering Glass, Heat Treatment, Semiconductor, Life Science, and Food and Beverage industries. She has been responsible for promoting Eurotherm energy saving, efficiency enhancing solutions and services, designed for energy intensive, high performance, specialized and regulated thermal processing applications.

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