*Review paper*
*UDC 637.141.3:006.83*

# HYGIENIC DESIGN ASPECTS OF PASTEURIZER TO ASSURE EFFECTIVE PASTEURIZATION OF MILK

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## Abstract

Design aspects of the pasteurizer shall be able to address effective pasteurization of each particle of milk as well as to prevent cross contamination of pasteurized milk.

This article reviews various international standards on milk pasteurization process design aspects to have effective pasteurization of each particle of milk. Key requirements like holding coil design, flow monitoring and control, valve design & placement, safe mode installation, process control & recording devices, temperature sensors response time and fail safe connection are detailed.

Effective pasteurization of each particle of milk shall able to ensure the safety throughout the shelf life of the milk & milk products as well as to facilitate compliance to the microbiological specifications both of hygienic indicators and pathogens, consistently.

***Key words****: Shelf-life, Microorganisms, Holding Coil, Effective Pasteurization, Safe mode installation.*

## 1. Introduction

In the last decade, various advances have happened in the design aspects of pasteurizer for effective pasteurization and to prevent cross contaminations. The design requirements are dynamic in the developed countries and various new requirements are incorporated time to time, to achieve food safety as well as optimum shelf life.

Temperature and time requirements for milk pasteurization are based on thermal death time studies for the key pathogenic microbes generally found in raw milk like: *Bacillus cereus, Listeria monocytogenes, Yersinia enterocolitica, Salmonella* spp.*, Escherichia coli O157:H7, Campylobacter jejuni* [1].

A heat exchanger used in pasteurization in dairy industry [2], is a piece of equipment that continually transfers heat from one medium to another. There are two main types of heat exchangers. First, direct heat exchanger, where both media are in direct contact with each other. It is taken for granted that the media are not mixed together (e.g. cooling tower) and second, indirect heat exchanger, where both media are separated by a wall through which heat is transferred (e.g. plate heat exchanger and tubular heat exchanger).

Pasteurization process [2] and [9], is a heat treatment process in which every particle of milk or liquid dairy product is heated to not less than the specified temperature and held at that temperature for not less than a specified time with the aim of avoiding public health hazards arising from pathogenic microorganisms associated with milk, and of reducing spoilage organisms.

## 2. Key requirements for effective milk pasteurization

### 2.1 Safe pasteurization of milk

To achieve safe pasteurization of milk/milk products, pasteurizer design must be robust to address the following:

- Hygienic design aspects to have effective pasteurization of each particle of milk.

- Hygienic design aspects to prevent cross contamination of pasteurized milk.

This review paper details the hygienic design aspects of pasteurizer to assure effective pasteurization of each milk particle.

Our earlier review paper published in the Journal of Hygienic Engineering and Deign - JHED [10], had detailed the "Hygienic design aspects of pasteurizer to prevent cross contamination of pasteurized milk".

Developing countries are yet to have standards for equipment design to achieve the above. In the absence of national standards each equipment supplier is supplying pasteurizers of their own design, which leads to partial compliance with the key hygienic design aspects.

**2.2 Pre-requisites to ensure effective pasteurization of each particle of milk**

To ensure effective pasteurization of each particle of milk the design shall address the following requirements, which are detailed in Figure 1.

- Holding coil design.
- Holding coil length.
- Flow monitoring and control.
- Flow diversion valve design.
- Flow diversion valve placement.
- FDV safe mode installation.
- Temperature sensor placement.
- Data recording.
- Temperature sensors response time.
- Fail safe measurements.
- Validation of pasteurization process.
- Verification of pasteurization process.

***2.2.1 Holding coil design***

The holding tube provides the means for ensuring that the product, in continuous flow is held at not less than the pasteurizing temperature for not less than the specified holding time [7].

To attain the minimum holding time it is critical that the design of the holding tube prohibits air from being incorporated into the system. Air in the system, if entrapped, will allow individual milk particles to move faster through the holding tubes, thereby reducing the holding time requirement, shared by respective regulations.

Important design requirement of holding coil is detailed in various regulations/international references. Holding coil is mandated to have continuous upward slope of minimum of 2.1 cm/m, to assure the desired holding time for each particle of milk.

The holding tube shall have a continuous upward slope in the direction of flow so as to avoid entrapment of air in the tube [7].

Must slope upwards 0.25 inch per foot, in direction of flow to eliminate air entrapment so nothing flows faster at air pocket restrictions [1] & [8].

The holding tube shall be designed to have a continuously upward slope, in the direction of flow, of not less than 20.8 mm per m. (1/4 inches per feet.) from its beginning to the connection at the inlet of the Flow Diversion Device (FDD) [6].

The holding tube must have a continuous slope of 2% (¼ inch per foot) upwards to the flow diversion device [4 and 5]. Any piping from the outlet of the heater to the flow diversion device that has less than the required slope shall not be considered part of the holding tube [5]. The slope is required to eliminate any air entrapment in the holding tube. To prevent variance in the slope, the holding tube shall be permanent fixed by mechanical supports [4].

Holding coils and with continuous upward slope are shown in Figure 2. T1 is temperatures sensor placed at holding coil inlet, T2 & T3 temperatures sensor are placed at Holding coil out prior to FDD.

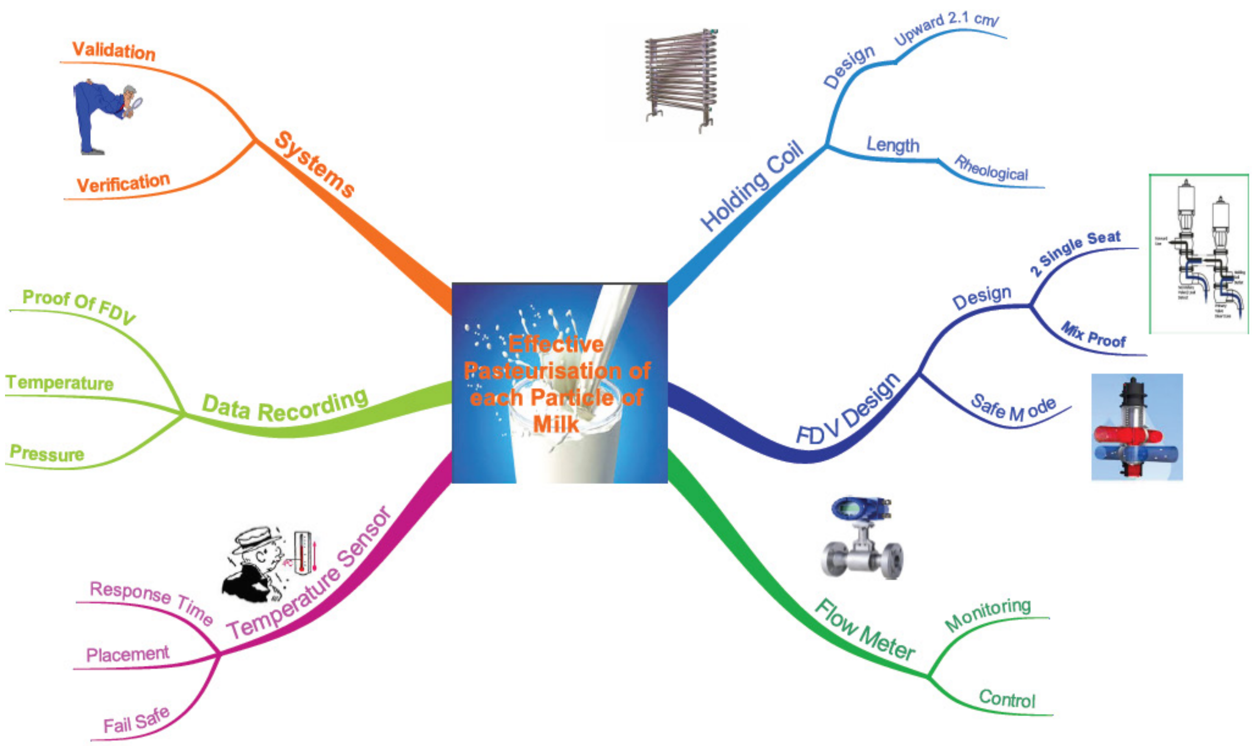


**Figure 1. Effective pasteurization of each particle of milk**

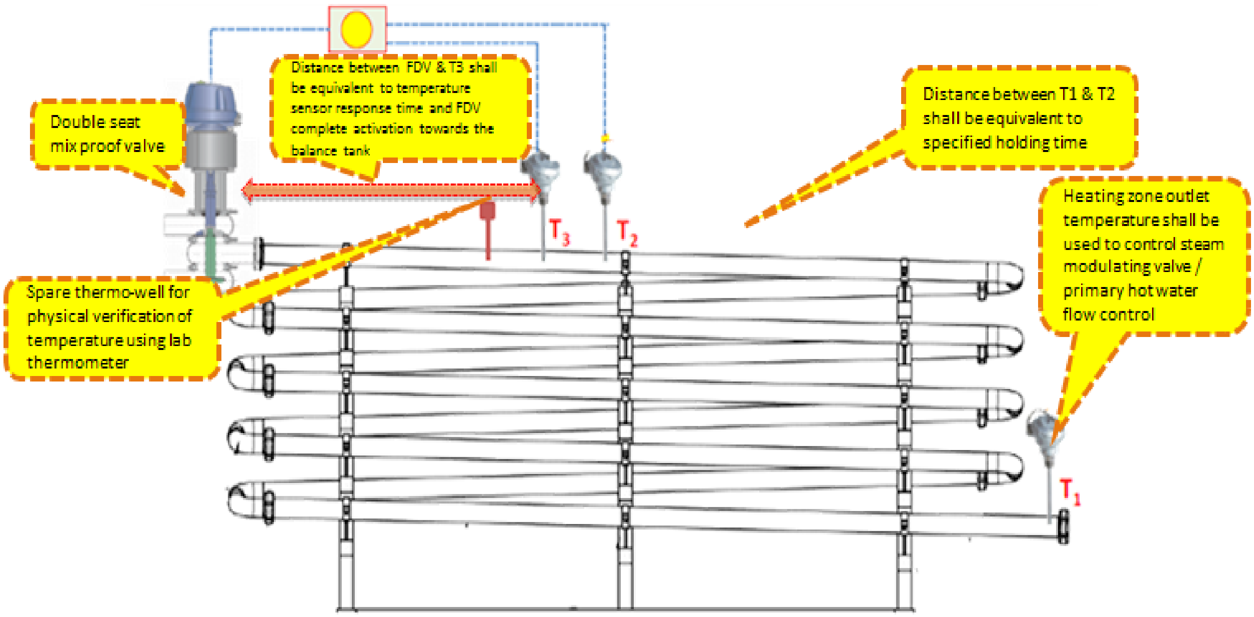


**Figure 2. Holding coil with continuous upward slope of 2.1 cm/m**

During the cleaning and sanitation of the pasteurizer, feed pump is used as cleaning in place - CIP supply pump for heat exchanger zones, connected pipelines, holding coil etc. Hence the holding coil diameter as well as connected pipeline diameter shall be able to meet the CIP turbulence of 1.5 m/second (5 feet/second) to assure proper cleaning and sanitation [6].

***2.2.2 Holding coil length***

The holding tube shall be designed to provide for the continuous holding of every particle of milk or milk product, for at least the minimum required holding time [6].

To achieve the holding of each every particle, the length of the tube to be designed to meet the required holding time of the fastest moving particle, based on the rheological properties of the milk or milk product.

Particle movement types, laminar flow and turbulent flow are detailed in Figure 3.

Calculation of type of flow is detailed in the article "Residence time distribution in aseptic processing of particulate foods" [19].

Radial velocity and temperature profile in tube are shown in the Figure 4 [19].

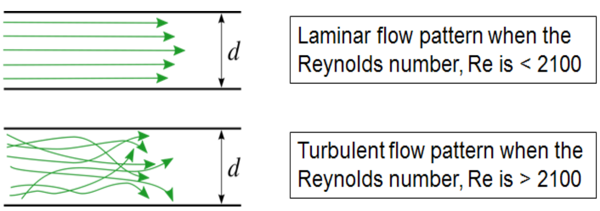


**Figure 3. Particle movement laminar flow turbulent flow [15]**

Velocity profiles are also influenced by the radial distance in the holding tube in addition to the rheological properties (specifically the flow behaviour index, n) as illustrated in Figure 5 [19].

Any piping from the outlet of the heater to the flow diversion device that has less than the required slope shall not be considered part of the holding tube [5].

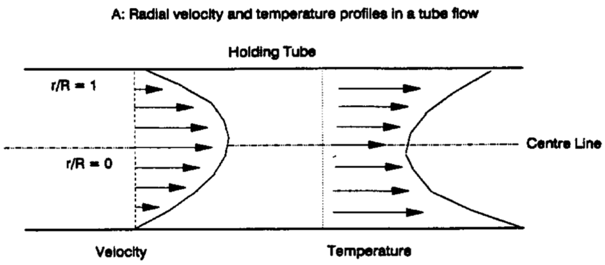


**Figure 4. Radial velocity and temperature profile in tube [19]**

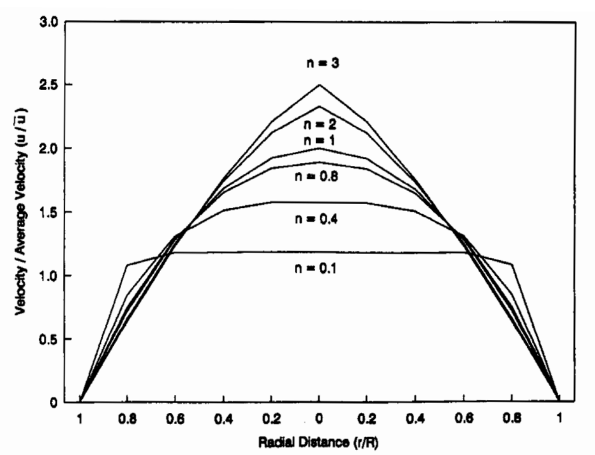


**Figure 5. Velocity and radial distance profile in tube [19]**

The length of the holding tube shall be the length of tube from the heating section outlet to the diversion temperature sensing device [7]. Hence holding coil length shall be the distance between T1 and T2 as per the Figure 2.

Holding Tube length for milk/ milk products shall be calculated, based the rheological properties of the product, as follows [11 and 19]:

**Step # 1:** Calculation of average velocity of product ($V_{average}$) in the holding tube:

$$V_{average} = \frac{\text{Flow rate in m}^3\text{/sec}}{\text{Surface area of the holding tube in m}^2}$$

**Step # 2:** Calculation of Reynolds Number (Re):

$$\text{Reynolds Number (Re)} = \frac{\text{Average velocity in m/s x Internal diameter of the holding tube in meter x Density in Kg/m}^3}{\text{Dynamic viscosity in Ns/m}^2}$$

Inference on nature of the flowing liquid with the use of Reynolds Number:

- Turbulent, if Re > 2100
- Laminar, if Re < 2100

**Step # 3:** Calculation of maximum velocity of product ($V_{max}$) in the holding tube:

- For the turbulent fluids: $V_{max} = V_{average}$ **x** 1.2
- For the laminar flow: $V_{max} = V_{average}$ **x** 2

**Step # 4:** Calculation of required length of holding tube in meter:

$$\text{Required length of holding tube (in meter)} = V_{max} \text{ x Minimum holding time (in sec)}$$

The holding time for Higher Heat Shorter Time (HHST) systems must be determined from the pumping rate rather than by the salt conductivity test, because of the short holding tube. The holding tube length must be such that the fastest flowing particle, of any milk or milk product, will not traverse the holding tube in less than the required holding time. Having in mind that because of laminar flow, the fastest flowing particle travels twice as fast as the average flowing particle, and it can occur in the holding tube during pasteurization of high-viscosity milk or milk products, the holding tube lengths have to be calculated as twice the length required to hold the average flow for the time standard [3].

Holding tube length in. for HTST pasteurizer systems [6] with a pumping rate of 3.78 litres (1 gallon) per min. can be seen in Table 1.

Heat treatment equivalent to pasteurization of common dairy foods milk with < 10% fat , > 10% fat and ice creams with particles < 1000 μm are detailed in the below Table 3 [16].

The holding tube shall be so designed that the simultaneous temperature difference between the hottest and coldest product in any cross-section of flow at any time during the holding period will not be greater than 0.5 $^0$C (1 $^0$F).

The average velocity through the holding tube shall not be less than 0.31 m per sec. (1.0 feet per sec.).

Minimum CIP velocity through the holding tube and other pipelines shall be minimum 1.5 m /sec. (5.0 feet per sec.).

Minimum velocities during CIP and product in holding tubes are captured in Table 3 [6].

The holding tube shall be so designed that no portion between the inlet and the FDV temperature sensor is heated. Optionally, it may be shielded, covered or enclosed to reduce heat loss as long as the holding tube is accessible for inspection [6],

### ***2.2.3 Flow monitoring and control***

Flow monitoring and control devices have to be installed at suitable location to monitor and control the milk and liquid milk product flow in the holding coil, during the pasteurization process.

Flow meter have to be interlocked with the flow diversion valve which divert the milk/liquid milk product. If the flow goes more than the design specification, than effective pasteurization of each particle of milk/liquid milk product will be affected. During such diversion the holding coil will get contaminated by the inadequately pasteurized milk/milk product. Adequate time delay (15 seconds) for FDV activation to be provided, so that the hot milk destroy all relevant microorganisms, prior to entering downstream regeneration.

Flow meters shall conform to the hygienic design standards as per EHEDG and/or 3A standards of flow meters for milk and liquid milk products.

Flow meter diameter shall be designed the same diameter of the pipeline in the pasteurizer interconnecting pipelines, so as to comply the flow requirements during production as well as cleaning and sanitation.

Meter based timing system - MBTS shall be a flow regulating system consisting of a primary flow-promoting (timing) pump, a control valve or check valve and a magnetic flow meter which uses an electrical signal to control the flow rate of the product through the holding tube of the high temperature short time (HTST) pasteurizer [6].

### ***2.2.4 Flow diversion valve design***

Most of the international standards, details the flow diversion valve - FDV design. Bacteria-tight FDV design shall be either be mix proof valve or two single seat valves in series.

**Table 1. Holding tube length for HTST pasteurizer systems [6]**

| **Time (sec.)** | **Sanitary Tubing Size- Outside Diameter (in.)** | | | | | |
|---|---|---|---|---|---|---|
| | 1.0 | 1.5 | 2.0 | 2.5 | 3.0 | 4.0 |
| 15.0 | 110.83 | 44.34 | 23.85 | 14.87 | 10.15 | 5.71 |
| 25.0 | 184.73 | 73.88 | 39.75 | 24.77 | 16.91 | 8.51 |

**Table 2. Heat treatment equivalent to pasteurization of common dairy foods [16]**

| | All dairy produce (excluding ice cream) with | | | | | | Ice Cream mixes with particles <1000 µm |
|---|---|---|---|---|---|---|---|
| | Milks with <10% fat and no added sweeteners and particles | | | Dairy produce with ≥ 10% fat and/or added sweeteners and concentrated dairy produce with > 15% total solids and particles | | | |
| Particle Diameter | <200 µm Ø | 200 to <500 µm Ø | 500 to <1000 µm Ø | <200 µm Ø | 200 to <500 µm Ø | 500 to <1000 µm Ø | |
| Minimum holding time (seconds) | Minimum Temperature ($^{0}$C) | | | | | | |
| 1.0 | 81.6 | - | - | 84.4 | - | - | - |
| 2.0 | 79.0 | 81.6 | - | 81.8 | 84.4 | - | - |
| 3.0 | 77.6 | 79.0 | - | 80.4 | 81.8 | - | - |
| 4.0 | 76.5 | 77.6 | 81.6 | 79.3 | 80.4 | 84.4 | - |
| 5.0 | 75.7 | 76.5 | 79.0 | 78.5 | 79.3 | 81.8 | - |
| 6.0 | 75.1 | 75.7 | 77.6 | 77.9 | 78.5 | 80.4 | - |
| 7.0 | 74.6 | 75.1 | 76.5 | 77.4 | 77.9 | 79.3 | - |
| 8.0 | 74.1 | 74.6 | 75.7 | 76.9 | 77.4 | 78.5 | - |
| 9.0 | 73.7 | 74.1 | 75.1 | 76.5 | 76.9 | 77.9 | - |
| 10.0 | 73.3 | 73.7 | 74.6 | 76.1 | 76.5 | 77.4 | 85.5 |
| 11.0 | 73.0 | 73.3 | 74.1 | 75.8 | 76.1 | 76.9 | - |
| 12.0 | 72.7 | 73.0 | 73.7 | 75.5 | 75.8 | 76.5 | - |
| 13.0 | 72.4 | 72.7 | 73.3 | 75.2 | 75.5 | 76.1 | - |
| 14.0 | 72.1 | 72.4 | 73.0 | 74.9 | 75.2 | 75.8 | - |
| 15.0 | 72.0 | 72.1 | 72.7 | 74.8 | 74.9 | 75.5 | 79.5 |
| 30.0 | 70.7 | 70.8 | 70.9 | 73.5 | 73.6 | 73.7 | - |
| 60.0 | 69.4 | 69.4 | 69.5 | 72.2 | 72.2 | 72.3 | - |
| Minimum holding time (minutes) | Minimum Temperature ($^{0}$C) | | | | | | |
| 1 | 69.4 | 69.4 | 69.5 | 72.2 | 72.2 | 72.3 | - |
| 2 | 68.1 | 68.1 | 68.1 | 70.9 | 70.9 | 70.9 | - |
| 5 | 66.4 | 66.4 | 66.4 | 69.2 | 69.2 | 69.2 | - |
| 10 | 65.1 | 65.1 | 65.1 | 67.9 | 67.9 | 67.9 | 74.0 |
| 15 | 64.3 | 64.3 | 64.3 | 67.1 | 67.1 | 67.1 | - |
| 20 | 63.8 | 64.8 | 64.8 | 66.6 | 66.6 | 66.6 | 69.0 |
| 25 | 63.3 | 63.3 | 63.3 | 66.1 | 66.1 | 66.1 | - |
| 30 | 63.0 | 63.0 | 63.0 | 65.8 | 65.8 | 65.8 | - |

**Notes:**
1. Ø = particle diameter.
2. Minimum holding time. The minimum holding time is set at 1 second to give an adequate safety margin. Shorter holding times will require validation to demonstrate the effectiveness of the time temperature combination in controlling the hazard(s).
3. Lowest allowable temperature. The pasteurizing temperature given for a 30 minute holding time is the lowest allowable temperature for pasteurizing the specified product types.

**Table 3. Minimum velocities during CIP and product in holding tubes [6]**

| Outer diameter tube size (inches) | Length equivalence of a standard 90° tube bend (inches) - *NOTE | Minimum recommended CIP Flow Rate (1.5 m/sec) (in gallons per minute - GPM) | Area of tube internal diameter (I.D). (Sq. in.) | Minimum average velocity at 0.31 m/sec (in gallons per minute - GPM) |
|---|---|---|---|---|
| 1 | 3.48 | 10 | 0.594 | 2.0 |
| 1 ½ | 4.94 | 24 | 1.485 | 4.8 |
| 2 | 6.83 | 43 | 2.761 | 8.6 |
| 2 ½ | 8.65 | 70 | 6.491 | 20.4 |
| 3 | 10.48 | 102 | 6.491 | 20.4 |
| 4 | 13.68 | 180 | 11.545 | 36.0 |

*NOTE: The length equivalence of a standard 90° tube bend can be deducted from the linear length calculation based on the number of 90° tube bends incorporated into a single or multi-loop holding tube design [6].

To prevent reinfection of pasteurized product passing through the divert valve, it must be bacteria-tight [2].

Valid valve designs are comprised from [7 & [8]:

(a) Primary valve.

(b) Secondary valve.

(c) Combination of valve.

(d) Mix proof valve.

(a) Primary valve

A primary valve shall be provided that, when activated, diverts product back to the raw product balance tank.

(b) Secondary valve (leak escape)

The diversion device shall also incorporate a secondary valve, to divert in a separate diversion line back to the raw-product balance tank any product that leaks across the primary valve seat. The secondary valve when switching from the 'forward-flow' position to the 'divert' position shall operate simultaneously with the primary valve. However, on return from the 'divert' position to the 'forward-flow' position, there shall be a delay of not less than 5 s after the primary valve returns to forward-flow before the secondary valve returns.

(c) Combination of valve (Primary & Secondary Valves)

A combination of valves shall achieve leak path protection between diverted unpasteurized product and pasteurized product. In general, this action can be achieved by the utilization of two changeover valves, a primary valve and a secondary valve.

Operation and controls of the primary and secondary FDVs are detailed in various standards.

As per 3A [6], leak escape shall be provided on the forward-flow side of the valve seat. However, when back pressure is exerted on the forward-flow side of the valve seat, while the product flow is being diverted, the leak escape shall lie between two valve seats or between two portions of the same seat, one upstream and the other downstream from the leak escape.

The leak escape port of a single stem valve shall be designed and the valve so installed as to drain all leakage to the outside. The leak escape shall be designed with one or more openings, with a total effective open area equivalent to at least 3.99 mm (5/32 in.) diameter [6].

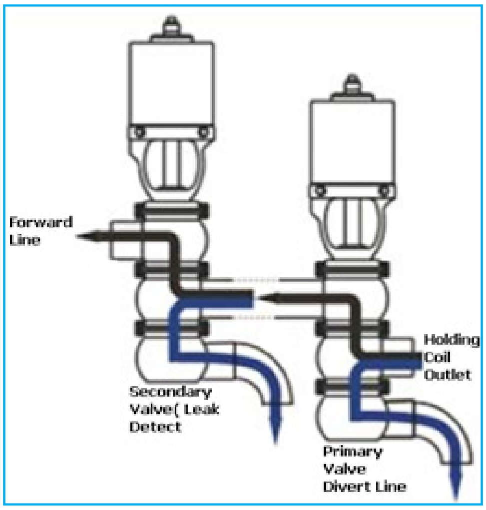


**Figure 6. Combination of Primary & Secondary Valves**

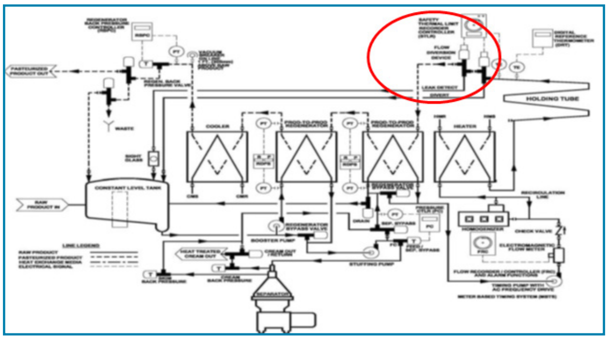

**Figure 7. HTST pasteurizer schematic [3] with divert & leak detect valves**

The leak escape port of a dual stem FDD shall be equal to or greater than the size of the inlet and shall conform to the requirements [6].

As per [3], if the area between the divert and leak-detect valve seats is not self-draining when the FDV is in the diverted position, a delay of at least one (1) second and not more than five (5) seconds is required between the movement of the divert and leak-detect valves when the FDV assumes the forward-flow position.
Except that, the delay may be longer than five (5) seconds if: the timing system is a magnetic flow meter based timing system; or if the holding time in diverted-flow through an unrestricted divert valve line is longer than the required pasteurization time as specified and except that, no time delay is required in pasteurization systems in which the FDV is located downstream from the pasteurized regenerator and in which all forward-flow product-contact surfaces of the FDV are sanitized, or sterilized during the normal start-up process.

<u>(d) Mix proof valve [7]:</u>

Alternatively to the primary and secondary valves a single mix proof valve (Figure 8) that provides two independent valve seats and a leak path between forward flow and diverted product may be utilized provided that:

(a) Mix proof valve has a pressure balanced seat when on forward flow and diverted flow.

(b) Mix proof valve has a leak path which in the event of a seal failure will not result in the pressurizing of the leak chamber, greater than 15 $mm^2$.

(c) Leak path and all of the valve seats of the mix proof valve can be cleaned in place.

(d) Leak path is in clear view; and

(e) The valve is spillage free at change.

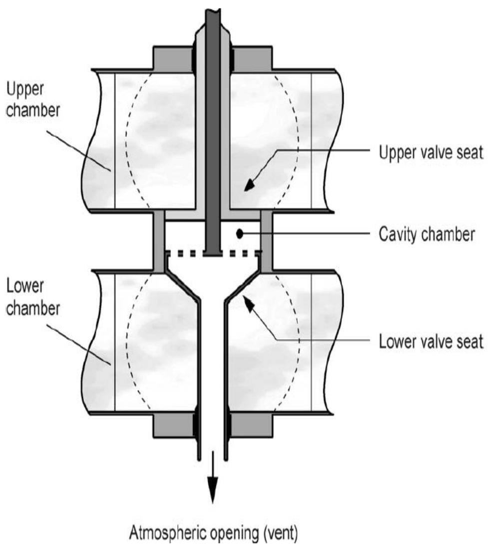


**Figure 8. Mix proof valve [14]**

For appropriate functioning and to prevent cross contaminations, FDV ports have to be connected as follows:

- Middle port: Holding coil outlet to get connected with the FDV middle port.
- Top port: Towards downstream regeneration.
- Bottom port: Towards the balance tank.

Figure 5 HTST pasteurizer schematic [3], captures the FDV ports connections.

***<u>2.2.5 Flow diversion valve placement</u>***

<u>Option # 1:</u>

To control the heating temperature FDV have to be located at the holding coil outlet controlled by the temperature sensor located at the holding coil outlet, prior to FDV.

To control the cooling temperature FDV have to be placed at the cooling zone outlet.

Placement of FDV at cooling zone outlet, back pressure valve and vacuum breaker are to be sequenced as per Figure 9.

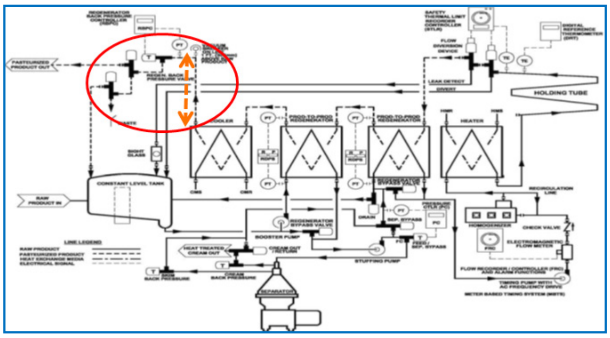

**Figure 9. HTST pasteurizer schematic [3] with FDV location at cooling zone outlet**

Vacuum breaker to be placed at least 30.5 centimeters (12 inches) level above the raw milk or milk product in the pasteurizer system.

Figure 9 HTST pasteurizer schematic [3], captures the FDV connections at cooling zone outlet.

FDV must not have "manual forward" option/ "simulation" option during the pasteurization process. If equipped with such option, inadequately pasteurized milk will enter the downstream regeneration and cooling zones, which is leading to contamination.

During the FDV installation and pipeline fabrications, it is recommended to minimize the return line length as low as possible, so as to optimize the CIP time through pulse setting FDV upper port to be connected towards the downstream regeneration and down port towards the balance tank.

FDV return lines from holding coil outlet, leak detects lines and cooling zone outlet shall be connected to the balance tank, by self-drain in nature.

Option # 2: (FDV located at regenerator and / or cooler section)

As per [3], the FDV may be located downstream from the regenerator and/or cooler section, provided, that when the FDV is located downstream from the regenerator and/or cooler section, the FDV shall be automatically prevented from assuming the forward-flow position until all product-contact surfaces between the holding tube and FDV have been held at or above the required pasteurization temperature continuously and simultaneously for at least the required pasteurization time as defined.

However, time taken to achieve desired pasteurization temperatures at holding coil outlet and cooling zone outlet, is more than the option 1.

### 2.2.6 FDV safe mode installation

FDV works based on is pneumatic principle. Hence, FDV have to be connected normally open (NO) towards the balance tank i.e., FDV port get opened towards the balance tank during inadequate/nil air pressure/power failures, irrespective of milk temperature at holding coil outlet.

If the FDV is not in connected in safe mode, in the absence of air /inadequate air pressure, FDV shall fail to divert the inadequately pasteurized milk to balance tank. This shall lead to a failure of critical control point.

If the air actuator assembly in the FDV is reversible, actuator assembly to be reversed to get the same corrected to safe mode.

If the air actuator assembly in the FDV is not reversible, supplier to be contacted for correction.

### 2.2.7 Temperature sensor placement

While installing the Temperature sensor in the pipeline, tip to be placed against the flow direction, to have accurate measure. Figure 10 details the same.

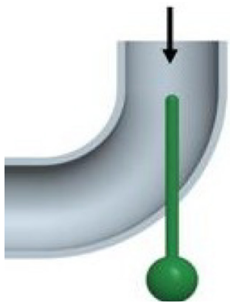

**Figure 10. Temperature sensor tip are to be placed against the flow direction [12]**

### 2.2.8 Data recording [7]

General

A data recording system with a circular or strip chart, or an electronic data recording system, shall be installed to provide a continuous and permanent record of all essential information. Electronic data recorders shall provide data updates at an interval of less than 2 seconds.

Data to be recorded

The following data shall be permanently recorded during plant operation and cleaning:

(a) Date and time of day.

(b) The pasteurization temperature requirement (specific to the milk/milk product).

(c) The mode of the diversion device, (from feedback on diversion valve) during pasteurization.

(d) The temperature of the outgoing product after processing.

(e) The temperature and duration of the cleaning and sanitizing cycles.

(f) Differential pressure records

(g) Flow rate.

Chart recorders

Chart recorders used to record pasteurizing temperature shall comply with the following requirements:

(a) The chart range shall be not less than 20 $^0$C, including 5 $^0$C above and below the diversion temperature.

(b) Chart graduations shall be not more than 1 $^0$C represented by spacing of not less than 2 mm.

(c) Chart recorders shall be accurate to within 0.5 $^0$C over the range 3 $^0$C above and below diversion temperature.

(d) Time intervals shall be represented by lines with spacing that represents not more than 15 min. separated by not less than 6 mm at the diversion temperature.

(e) Be capable of recording at all times the mode of the diversion device i.e. forward flow.

Chart type recorder and electronic recorder with the above requirements, especially proof of FDV operation, is shown in Figure 8 and Figure 9.

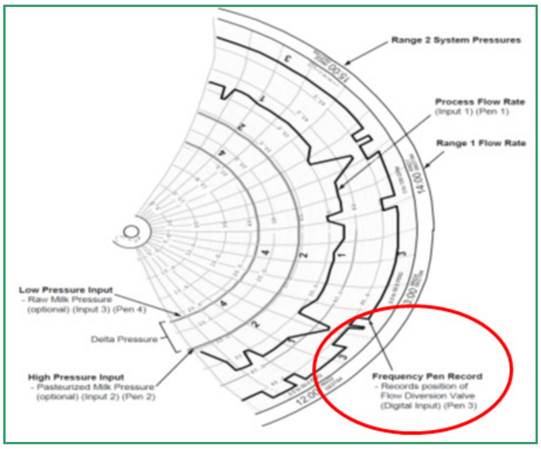


**Figure 11. Chart Recorder with proof of FDV Operation and other features [18]**

| DATE | TIME | PAST-1 TRANSFER JOB | HEAT. TEMP | FLOW | CHIL. TEMP | Proff of FDV Operation: FDV at Holding Coil outlet | | FDV at Cooling Zone outlet | | STATUS |
|---|---|---|---|---|---|---|---|---|---|---|
| 4/6/2014 | 0:00:43 | RMST_3_PMST_3_PAST_1 | 79.53 | 19721.69 | 3.46 | AUTO | FRWD | AUTO | FRWD | PRD |
| 4/6/2014 | 0:01:43 | RMST_3_PMST_3_PAST_1 | 79.53 | 19704.33 | 3.46 | AUTO | FRWD | AUTO | FRWD | PRD |
| 4/6/2014 | 0:02:43 | RMST_3_PMST_3_PAST_1 | 79.49 | 19730.37 | 3.46 | AUTO | FRWD | AUTO | FRWD | PRD |
| 4/6/2014 | 0:03:43 | RMST_3_PMST_3_PAST_1 | 79.53 | 19713.01 | 3.52 | AUTO | FRWD | AUTO | FRWD | PRD |
| 4/6/2014 | 0:04:43 | RMST_3_PMST_3_PAST_1 | 79.53 | 19773.77 | 3.52 | AUTO | FRWD | AUTO | FRWD | PRD |
| 4/6/2014 | 0:05:43 | RMST_3_PMST_3_PAST_1 | 79.49 | 19739.05 | 3.52 | AUTO | FRWD | AUTO | FRWD | PRD |
| 4/6/2014 | 0:06:43 | RMST_3_PMST_3_PAST_1 | 79.49 | 19747.73 | 3.52 | AUTO | FRWD | AUTO | FRWD | PRD |
| 4/6/2014 | 0:07:43 | RMST_3_PMST_3_PAST_1 | 79.53 | 19765.09 | 3.52 | AUTO | FRWD | AUTO | FRWD | PRD |
| 4/6/2014 | 0:08:43 | RMST_3_PMST_3_PAST_1 | 79.53 | 19799.81 | 3.46 | AUTO | FRWD | AUTO | FRWD | PRD |
| 4/6/2014 | 0:09:43 | RMST_3_PMST_3_PAST_1 | 79.53 | 19756.41 | 3.46 | AUTO | FRWD | AUTO | FRWD | PRD |
| 4/6/2014 | 0:10:43 | RMST_3_PMST_3_PAST_1 | 79.53 | 19773.77 | 3.35 | AUTO | FRWD | AUTO | FRWD | PRD |
| 4/6/2014 | 0:11:43 | RMST_3_PMST_3_PAST_1 | 79.49 | 19713.01 | 3.29 | AUTO | FRWD | AUTO | FRWD | PRD |

**Figure 12. Electronic Recorder with proof of FDV Operation and other features**

### *2.2.9 Temperature sensors response time*

To address the "Response time" of the temperature sensor to facilitate complete FDV activation, adequate distance have to be provided between the temperature sensor and FDV. Same is detailed in Figure 10.

Response time of the sensor have to be verified by the supplier certifications as well as periodic onsite verification should be performed.

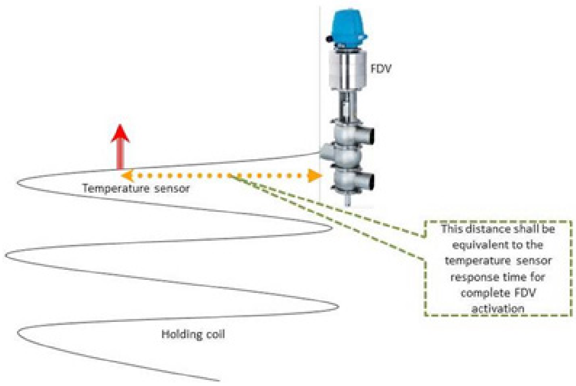


**Figure 13. Location of temperature sensor and FDD to address the response time**

### *2.2.10 Fail safe measurements*

To overcome the food safety risks due to the temperature sensor failure, FDV shall be controlled by more than 1 sensors.

Simulation possibility of FDV in fully automated pasteurizer shall not be programmed.

Manual forward switch of FDV in semi-auto pasteurizers shall be removed. In case fully automatic pasteurizers like programmable logic controller (PLC) or Human–machine interface (HMI) control, , FDV forward option must be prohibited.

### *2.2.11 Validation of pasteurization process*

Validation and verification of heat treatment equipment and processes is shared in detail by ANZDAC Guidelines for Food Safety [16].

Also as per ISO 22000:2005 [17], clause No. 8.3, when used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application shall be confirmed. This shall be undertaken prior to initial use and shall be reconfirmed as necessary.

Hence if the pasteurizer is operated in PLC software, suitable validation is necessary to demonstrate the above requirement.

### *2.2.12 Verification of pasteurization process*

Periodic verification of the key controls is essential to assure the effective pasteurization of the milk/milk products.

Indicating Thermometer(s)

Indicating thermometer(s) at holding coil outlet - One thermometer shall be installed in the fitting at the outlet of the holding tube, so as verify periodically the QA personnel, as per verification frequency (preferably every 8 hours).

Indicating Thermometer(s) in general? - One thermometer shall be installed at cooling zone outlet, so as verify periodically, as per defined verification frequency (preferably at every 8 hours and during internal audits).

Fail Safe verification

FDV fail safe checks should be verified by disconnecting the compressed air supply. Irrespective the holding tube outlet temperature, the FDV shall divert the product back to the balance tank. Verification frequency should be conducted preferably after FDV maintenance, new FDV installations, during internal audits and also at every 7 days.

Above verification method is applicable for the cooling zone outlet FDV also.

Positive pressure fail safe checks should be verified by disconnecting the compressed air supply to the back pressure valve/adjusting the manual backpressure valve.

When the product pressure drops less than the raw/cooling media's, FDV shall divert the product back to the balance tank. Verification frequency should be conducted preferably after back pressure valve maintenance, new back pressure valve installations, internal audits and also at every 7 days. AS 3993-2003 [5] detailed the pperiodic verifications of the pasteurizer, Table 4.

**Table 4. Pasteurizer checking and testing frequencies [5]**

| Check | At commissioning | Daily | On 6 months | Annually | On 5 years | Comments |
|---|---|---|---|---|---|---|
| **All pasteurizers** | | | | | | |
| Compare indicating thermometer reading & recorded temperatures (A4.1.1) | ✓ | ✓ | | | | |
| Operation of diversion & alarms (A4.1.2) | ✓ | ✓ | | | | |
| Recording system operational (A4.3b) | ✓ | ✓ | | ✓ | | |
| Check thermometer calibration and recalibrate as necessary (A4.1.1) | ✓ | | ✓ | | | |
| Testing of heat transfer surfaces (e.g. plates) for failure-such as pressure testing (A4.3c) | | | | ✓ | | |
| Heat exchanger gaskets (A4.3d) | | | | ✓ | | |
| Verification of holding tube by direct measurement (salt conductivity test) (A4.4.1) | ✓ | | | | ✓ | Required at any time when modifications to the pasteurizer may result in a variation to flow rate or volume of holding section. |
| Response time (A4.3a) | | | | ✓ | | |
| **Secure heat exchanger** – such as double skinned plates | | | | | | |
| Check leak paths (A4.1.3) | ✓ | ✓ | | | | Corrective action must be taken within 24 hours of a leak being identified. |
| Inspect the integrity of leak cavity visually (A4.4.2) | | | | | ✓ | |
| **Secure differential pressures** | | | | | | |
| Operation of pressure differential diversion (A4.1.2) | ✓ | ✓ | | | | |
| Calibrate pressure gauges (A4.3f) | ✓ | | | ✓ | | |
| Positive pressure difference controlling systems (A4.3e) | | | | ✓ | | |
| **Secure medium** | | | | | | |
| Check medium integrity (visual or conductivity) (A4.1.4) | | ✓ | | | | |

## 3. Conclusions

Incorporation of all the design aspects in the equipment specification have to be able to ensure effective pasteurization of milk/milk products, which shall help to achieve desired food safety as well as optimum shelf life.

- Apart from the requirements shared in this paper, 2.2.1 to 2.2.12, surface roughness, dead-ends, plate heat exchanger specifications [13], rubber/gasket specifications, and online filter design also have to be suitably addressed.

- For the benefit of the global consumers, harmonization of the various international standards on milk pasteurization and sterilization process will be useful.

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