EHEDG Guidelines

DOC 20

HYGIENIC DESIGN AND SAFE USE OF DOUBLE-SEAT MIXPROOF VALVES

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HYGIENIC DESIGN AND SAFE USE OF DOUBLE-SEAT MIXPROOF VALVES*

©EHEDG

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Introduction

Food process plants nowadays incorporate various multifunctional flow paths. Often one piping system is cleaned while another still contains product. This simultaneous cleaning can potentially result in the dangerous situation that product and cleaning liquid are separated by just one single valve seat. Any cleaning liquid that leaks across such a seat will contaminate the product. Therefore, two or three single seat valves in a "block-and-bleed" arrangement are applied (see figure 1). Other constructions like single-body double-seat butterfly valves are used (see figure 2), but these are not really mixproof. A better solution to prevent intermixing is the use of single-body double-seat mixproof valves. These valves have been used in brewing, beverage, food and milk plants in Europe for 20 years to ensure safe separation at intersection points in matrix piped systems. About 1 million double seat mixproof valves are in use.

Integration of several functions into each double-seat mixproof valve drastically reduces risks and costs associated with custom-built designs and on-site fabrication of single-seat valve assemblies. Dead spaces are minimised, reducing wastage of product, cleaning fluids and water. These advantages are amplified by the precision prefabrication of multi-valve manifolds. Simultaneous operation of multiple flow paths can also substantially increase effective plant capacity. As a result, installation, operation, validation and maintenance tend to be faster, cheaper and safer.

Different designs are offered by the various suppliers to fulfil the requirements in practical applications. Up to now there have not been any guidelines available to the equipment suppliers and food producers for the evaluation of the different constructions regarding the hygienic design and safe use of double-seat mixproof valves.

The purpose of the paper is to describe the basic hygienic design and the safe use of such valves. The valves should be easy to clean in-place, prevent intermixing during normal use, be easy to install and be reliable. In addition the accepted requirements on mixproof valves in Europe are summarised.
Figure 1: The use of two and three single seat valves in a "block-and-bleed" arrangement.
1 Hygienic design requirements

In Europe the design must meet all Machinery Directive (Council Directive 98/37/EC) and CEN EN 1672-2 requirements. Further the ISO 14159 hygiene requirements for the design of machinery must be followed. In addition the design must meet all requirements as set in the following EHEDG reports:

Doc. 8: Hygienic equipment design criteria
Doc. 9: Welding stainless steel to meet hygienic requirements
Doc. 10: Hygienic design of closed equipment for the processing of liquid food
Doc. 13: Hygienic design of equipment for open processing
Doc. 14: Hygienic design of valves for food processing
Doc. 16: Hygienic pipe couplings
2 Construction of double-seat mixproof valves

2.1 Typical valve construction

Double-seat mixproof valves vary in design, but most of them operate to the same principle. A typical design consists of a valve housing with two chambers (see figure 3). Each chamber has at least one port connected with a pipeline in the piping system. Between the two chambers the valve seat area is arranged with two seats, usually one atop the other with a separation cavity in between. The seats consist of an upper and lower closure device, typically a disc, which are connected to independent upper and lower shafts for opening, closing and individual seat lifting. The cavity between the two seats is open to atmosphere (vent). Leakage from this cavity is then used for leak detection of these seals.

In the US, because of current regulations required by FDA, the leakage vent must be equal to the largest pipeline feeding the valve. Relaxation of this requirement may be discussed with the local authorities.

![Figure 3: Typical Double-seat mixproof valve](image)

2.2 Safe design of double-seat mixproof valves

The double-seat mixproof valve has two seats in the seal area. The closed valve position must be detectable and provide an electronic alarm signal when not properly seated in the block position.

The valve seats must be moved into the closed position and held there by a spring. This is to ensure correct control of the shafts and a fully blocked "safety" position of the valve in case of loss of air or power. If one seal is worn or breaks, the fluid must go out of the vent and must not build up pressure in the cavity area.
2.3 Hygienic and aseptic designs

Different valve constructions are used for hygienic and aseptic processes in the food production. For hygienic process lines the reciprocating shaft can be sealed by an elastomeric or polymer lip seal. This seal is easily cleanable, but will not prevent the ingress of micro-organisms. However, it prevents excessive microbial contamination of product.

In aseptic process lines where ingress of micro-organisms must be prevented, the shaft must be sealed by a continuous barrier, for example a membrane or bellows. Automatic control systems for bellows are available from suppliers. Figure 4 shows examples of double-seat mixproof valves for hygienic and aseptic process lines. Moreover, a steam or sterilant barrier may be applied in the atmospheric opening (vent) to prevent ingress of micro-organisms from the environment (see figure 5 for details).

![Mixproof valve with „lip-seal“ design for hygienic process lines.](image)

Figure 4a: Example of double-seat mixproof valves for hygienic process lines.
Figure 4b: Example of double-seat mixproof valves for aseptic process lines.

Figure 5: Control of vent on double-seat mixproof valve for aseptic lines.
2.4 Balanced types

As the distance between the two valve seats is only some millimetres, pressure shocks above the normal operating pressure may cause unexpected opening of the seats. Pressure shocks may occur in a pipeline system during operation and in particular during CIP. In order to assess the effect of pressure surges in mixproof valves the design aspects of "unbalanced" and "balanced" designs may be considered. Figure 6 shows unbalanced, single balanced and double balanced designs. Pressure shocks in pipelines may be caused by e.g.:

- quick closing of manually operated butterfly valves,
- emergency stop of a filling machine,
- seat valves, in which the closing movement of the stem is in the same direction as the flow,
- air supply discontinued, e.g. due to broken hose,
- evaporation of liquid in a pipe system.

Leakage free designs must be equipped with the relevant balancers as it is not possible for this type of valve to relieve pressure into the cavity area in the event of a pipeline pressure surge of sufficient magnitude to open the valve against the spring tension.

If the right design for the application is chosen, there is no opportunity for either valve seat to open unexpectedly.

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**Upper chamber**

Area $A_2$ is much bigger than the projected shaft area $A_1$. Due to the product pressure a differential force $F = p \times (A_2 - A_1)$ is acting onto the upper shaft.

If a pressure surge is much bigger than the design pressure it may overcome the closing spring force from the actuator and move the shaft downwards to open.

**Lower chamber**

A pressure surge in the lower chamber cannot make the bottom shaft move due to the metallic stop in the seat area.

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*Figure 6a: Mixproof valve with unbalanced shafts.*
Upper chamber
A pressure surge in the upper chamber cannot make the upper shaft move due to the metallic stop in the seat area.

Lower chamber
A pressure surge $p$ in the lower chamber cannot move the shaft in either direction because of equal areas $A_1 = A_2$.

Figure 6b: Mixproof valve with single balanced shaft.

Upper chamber
A pressure surge in the upper chamber cannot move the shaft in either direction because of equal areas $A_1 = A_2$.

Lower chamber
As upper shaft balanced.

Figure 6c: Mixproof valve with double balanced shaft.
2.5 Low leakage / Leakage free designs

During the valve operation "close" to "open" and "open" to "close" at process pressure most of the mixproof valves show an operational leakage in the intermediate position. The volume of the operational leakage depends on the seat design (see figure 7 for details), the transaction time to stroke the valve, the valve size and the process pressure in the pipe.

See figure 7a for a design with considerable operational leakage and 7b for operational leakage free design.

Figure 7a: Operational leakage on seat design with two axial seats.

Figure 7b: No operational leakage on seat design with radial seal.
2.6 Leak detection

Defined leakage paths designed to provide immediate detection must be in place for all process seals, such as housing seals, seat seals and shaft seals. These leakage paths must also ensure minimum effect on production operations, while providing an immediate indication of seal service requirements. The valve seal designs should also minimize any ingress of contaminants.

3 Application and use of double-seat mixproof valves

The double-seat mixproof valve allows simultaneous transfer of product and cleaning liquids across the valve ports. Typical applications are valve manifolds in multifunctional flow systems, CIP connections to process lines, storage tanks and fillers; one line including the connected valve chamber can then be cleaned while the others still handle product.

Another application is that after filling a tank, the connecting fill lines can be cleaned directly and change over to other tanks and fillers is easily possible (see figure 8).

If there is an alarm indicating improper valve seating in the block position, the system should stop the flow of CIP solution. No manual overrides are allowed. Controls must be secured to prevent unauthorized changes.

If there is a product safety risk, an additional flush with hot water or steam for the whole piping system, depending on the type of product in the pipelines is required.

![Figure 8a: Typical mixproof valve installation in a tank matrix.](image)
4 Cleaning in place

During normal operation of a mixproof valve the following areas are soiled with product residues (see figure 9):

— The upper chamber of the valve housing by the product being conducted through the pipeline.

— The seat area between the two chambers when the valve is in the "open" position. The cavity with the drain pipe in the bottom shaft due to operational leakage and leakage due to worn seat seals.

— The lower chamber of the valve housing by the product being conducted through the pipeline.
Figure 9: Areas in a mixproof valve to be cleaned by CIP process.

Area I:
Surface in the top chamber including ports, globe shaft and seat disc down to the seat seal.

Area II:
Surface in the leakage chamber including seat ring up to the seat seals, bottom side of top shaft, inner side of the bottom shaft (drain pipe).

Area III:
Surface in bottom chamber like in top chamber.

Typical methods to clean the surfaces concerned are:

— Pipeline CIP for independent cleaning of the housing chambers limited by the shaft seal on the one side and the seat seal on the other side.

— Seat (plug) lifting to flush the seat seal c/w metallic stop, the cavity and the drain pipe (see figure 10).

— Cavity spray cleaning to reach the leakage chamber up to the seat seals and the drain pipe (see figure 11).

— Shaft cleaning to reach the shaft surface and the area behind the shaft seals (see figure 12).
Figure 10: Seat lift cleaning

Seat lifting required to clean away product residues between seat seal contact line and metallic stop. During this process also the leakage cavity (vent) is cleaned.

Figure 11: Cavity spray cleaning

Top seat disc raised

Bottom seat kept closed

Top seat disc

Bottom shaft

Vent
Seat lift cleaning and cavity spray cleaning are carried out at virtually zero static pressure in the vent area to ensure safe separation. Virtually zero static pressure must be ensured, because in this operating mode there is only one seat seal between the product in the pipeline and the CIP liquid in the leakage area.

It is in the responsibility of the valve supplier to provide the necessary information on how to operate and, especially, how to clean the valve in place in a safe way without pressure build-up in the neutral area.

In the US, because of current regulations required by FDA, the cavity must not be cleaned until product has been removed or isolated. Variations may be individually evaluated.

## 5 Summary of requirements

- Basic hygienic requirements are described in the Standards and EHEDG guidelines (see chapter 2).
- Valve seats must be moved into the closed position and held there by a spring, also in case of loss of air.
- Failure of the independent valve seat to close must be detected and alarmed.
- The valve disc seals must be individually pressed into their closed positions.
- The design must ensure that unintended movement of one disc cannot be transferred to the other.
- The neutral area must be drainable by gravity.
- The neutral area must be at virtually atmospheric pressure during every operating condition, such as:
  - product run in both pipelines with valve open or closed
  - CIP in one pipeline with seat cleaning of the related seat
  - cleaning of the cavity in the closed position of the valve.

Note:
If shaft flushing causes a pressure build-up in the cleaning chamber, it must only be carried out, when no product is in the related housing chamber.
The valve must retain its closed position also during vacuum in the connecting upper or lower pipelines.

Care must be taken of pressure surges, for instance by using valves with balanced shafts or designing the installation to prevent the valve seats from opening.

Both seats must be in the closed position before the pipeline CIP or cavity spray process can be activated. Only on tank applications it is necessary to open the valve to drain the tank via the CIP-return-line.

In the US, because of current regulations required by FDA, mixproof valves shall not be used to separate raw products from pasteurized milk or milk products.
6 Comparison of different methods for safe operation

<table>
<thead>
<tr>
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<th>Three on/off valves or one on/off and one change-over valve</th>
<th>Swing bend panels</th>
<th>Mixproof valves</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Process safety</strong></td>
<td>Ensured by two seals and full port drain.</td>
<td>Ensured by physical break.</td>
<td>Ensured by two serial seat seals and neutral area inbetween.</td>
</tr>
<tr>
<td></td>
<td>Ambient air sluice due to large volume in pipe connection.</td>
<td>Ambient air sluice due to large air volume in swing bend.</td>
<td>Isolation chamber sealed during product flow – no risk of contamination.</td>
</tr>
<tr>
<td></td>
<td>Product flow path through isolation chamber (piping) means high risk of contamination.</td>
<td>Product flow path through isolation chamber (piping) means high risk of contamination.</td>
<td></td>
</tr>
<tr>
<td><strong>Suitability for multifunctional plant operation</strong></td>
<td>Not recommended</td>
<td>Not recommended</td>
<td>Independent CIP cleaning of the cavity possible in the closed valve position by seat lifting or cavity spray cleaning.</td>
</tr>
<tr>
<td><strong>Space requirements</strong></td>
<td>Footprint of installation same as other methods, more elevation required for drainage.</td>
<td>Panels become very large.</td>
<td>Compact valve manifolds possible. Minimal elevation requirement.</td>
</tr>
<tr>
<td><strong>Installation</strong></td>
<td>Greater risk of faulty installation such as bad weldings, insufficient supports, incorrect orientation of valve bodies and lines, bad drainage. Manifolds become very complex and expensive. Two plc control panels for the two valve actuators required.</td>
<td>More on site fabrication and validation required which has implications to quality and time.</td>
<td>Controlled fabrication under factory conditions possible. Pre-fabrication of large valve manifolds done routinely.</td>
</tr>
<tr>
<td><strong>Maintenance</strong></td>
<td>Difficult to service individual valves. More clamps / flanges required for disassembly or removal of complete valves.</td>
<td>Medium. Handling may involve abuse.</td>
<td>Low number of parts and seals. Only one actuator. Easy to service due to top pullout of mixproof inserts.</td>
</tr>
<tr>
<td><strong>Operating costs</strong></td>
<td>Considerable product losses during switching. More pressure drop as flow goes up and down through valves.</td>
<td>Considerable product losses when a swing bend is dismantled. Minimal pressure drop as swing bend panels are normally full line size. Manual operation required.</td>
<td>Comparatively low. Minimal product losses on low leakage operation valves.</td>
</tr>
<tr>
<td><strong>Process flexibility</strong></td>
<td>Difficult / impossible to create a large manifold.</td>
<td>Piping system becomes long and complex, expensive and difficult to incorporate modifications.</td>
<td>Easy to create manifolds, fully automated lines possible. Easy to realize future modifications.</td>
</tr>
<tr>
<td><strong>Continuous flow</strong></td>
<td>Continuous flow management possible.</td>
<td>Continuous flow management is not possible.</td>
<td>Continuous flow management possible.</td>
</tr>
<tr>
<td><strong>Water/chemical product loss</strong></td>
<td>High, due to large drainage area, difficult to clean.</td>
<td>High, as content of bend and connected pipes is lost during manual handling.</td>
<td>Minimal</td>
</tr>
<tr>
<td><strong>Human error</strong></td>
<td>Difficult to understand piping arrangements.</td>
<td>Risk that an operator connects a dirty bend to a disinfected line or makes an incorrect connection. Safety issues with leaking caps or caps not installed properly during CIP.</td>
<td>Easy to fully automate. No safety issues as CIP fluid losses are minimal through isolation cavity.</td>
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