Innovative sealing concept for hygienic and aseptic filling

Valve designs in filling processes

IIn sterile and aseptic filling processes, the crucial criterion for the selection of the suitable valve designs is that the actuator unit and the working medium are hermetically separated from each other. Furthermore, the valve designs must withstand the existing operation, cleaning (CIP) and sterilization conditions (SIP). In addition to the various acid and alkaline cleaning agents, temperatures can reach 140 °C during sterilization.

To meet these requirements, diaphragm, globe or bellows valves are most commonly used today, featuring advantages and disadvantages depending on the place of use. The new and innovative PD valve design (plug diaphragm) combines the advantages of the previously used diaphragm and globe valve designs in a single valve.

Diaphragm valves

A variety of diaphragm valve types are currently used in ultra-clean and aseptic filling processes. This type of design is particularly suitable due to the safe separation of the medium from the actuator unit, the good cleanability and sterilization properties as well as the high number of possible switching cycles. Diaphragm valves are modular in design. They comprise an actuator with compressor, the seal (diaphragm) and the valve body (cf. figure 1). The appropriate seal is selected depending on the working medium. Diaphragms made of ethylene-propylene-dien-(monomer) rubber (EPDM) or polytetrafluorethylene (PTFE) are used. EPDM diaphragms are particularly suitable for abrasive media. They can also be used for many acidic and alkaline media, demineralized and deionized hot water as well as most industrial gases. PTFE diaphragms, on the other hand, are not only resistant to almost all chemicals, such as strong acids, alkalis and salts, but can also be used at high temperatures and in steam. Due to their inert property, they are also used for media containing alcohol, oil or grease, such as milk.

The application possibilities of diaphragm valves in filling processes are varied and are dependent on the process itself. If the media to be filled do not contain any gases and if the filling container is depressurized when filled, the valves are used as dosing and open jet valves. They are also often used for flow control. To this end, valve bodies with drilled holes in or recesses on the sealing weir or actuators with two positioning levels are used (cf. figure 2). For slow or fast filling processes, the valves are connected upstream of the actual dosing valve and flow sensor system (e.g. mass flowmeter or magnetically inductive flowmeter). A simple design of diaphragm valve can also be used as classic inlet and outlet valves in filling machines with piston and rotary piston pumps. The required filling volume is controlled by an adjustable valve stroke or the pump speed.

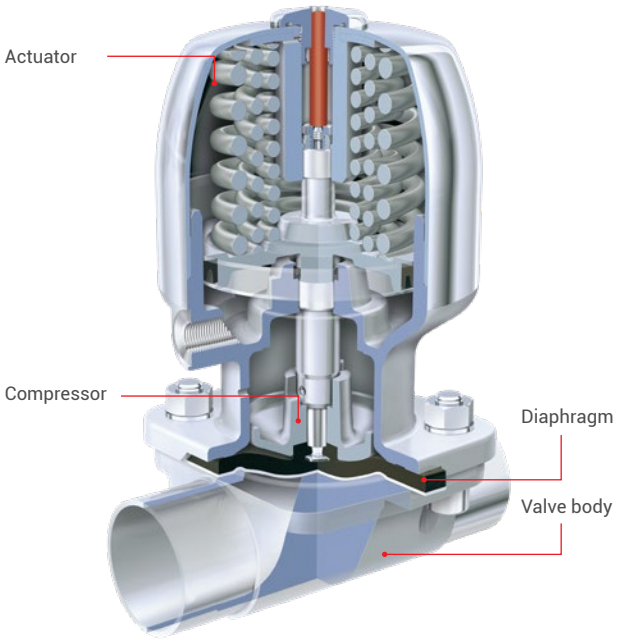


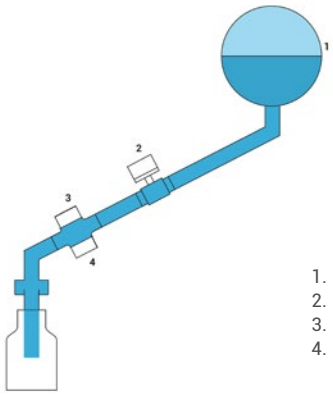
Figure 1: Design of a pneumatically operated diaphragm valve

GEMÜ 660
with stroke limiter and seal adjuster as standard

GEMÜ 688
with two-stage actuator as standard, with stroke limiter

Figure 2: Common diaphragm valves for use in filling machines

To protect the diaphragms, reduce the risk of failure and extend the maintenance intervals, it is advisable to equip the diaphragm valves with a seal adjuster for filling processes with high cycle duties. This adjusts how far the valve closes, therefore preventing the diaphragms from becoming overloaded. By contrast, a stroke limiter can be used for linear and rotary filling machines, in order to compensate for individual differences between the valve stems (line feeds and valves) or the different filling positions and, if necessary, to throttle the maximum filling speed.



1. Product container
2. Flowmeter
3. Fast diaphragm valve
4. Slow diaphragm valve with bypass drilled hole

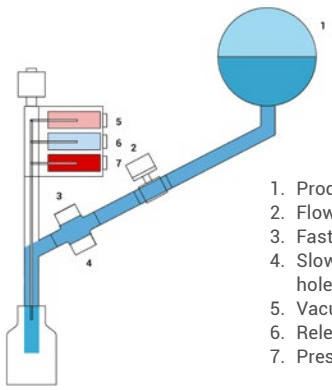
Figure 3: Example of a filling machine with two filling speeds and without dissolved gases

The relatively frequent maintenance of the diaphragms and the subsequent readjustment of the seal adjusters and stroke limiters is a disadvantage of the use of diaphragm valves in filling processes. It requires the maintenance staff to take great care and have expert knowledge.

In addition to the maintenance requirements, diaphragm valves also soon reach their limits in filling processes involving different filling speeds, filling of gaseous media or oxygen-free filling.

Combination of globe and diaphragm valves

Eine weitere Möglichkeit der sterilen und aseptischen Another option for sterile and aseptic filling is the combination of globe and diaphragm valves. Like diaphragm valves, these are also designed according to a modular design principle and comprise an actuator with seal and valve body. In comparison with diaphragm valves, globe valves have particularly good control characteristics and can withstand high cycle duties. Combinations of globe and diaphragm valves are used in filling processes in which filling is carried out at different speeds or with oxygen-sensitive and/or carbonated media. “Still” products (non-carbonated media) can also be filled with these valve types if nitrogen is used as the flushing and pressurization gas (cf. figure 4).



1. Product container
2. Flowmeter
3. Fast diaphragm valve
4. Slow diaphragm valve with bypass drilled hole
5. Vacuum channel with CIP return valve
6. Release channel
7. Pressurization channel

Figure 4: Example of a filling machine with two filling speeds and flowmeter for carbonated, oxygen-sensitive or still media

The different diaphragm valve designs used with this type of filling (cf. figure 4) serve the purpose of flow control.

The globe valves used are pressed onto the container to be filled such that they are gas tight and enable the filling process or end it after the required fill volume has been reached. Pneumatically operated auxiliary valves can be used to vacuum the container that has been press-fitted to the globe valves, flush it with CO2 or even relieve the pressure on it during filling of carbonated media. When filling oxygen-sensitive beverages, the containers are usually vacuumed two to three times and flushed or pressurized with CO2 or N2. Globe valves with a smaller design are also used as auxiliary valves. For use in ultra-clean and aseptic applications, please note that the actuator mechanism must be hermetically separated from the medium.

Since filling machine manufacturers develop their final filling valves individually with the corresponding auxiliary valves, the number of solution variants also multiplies according to the different filling containers (e.g. glass, PET, aluminium, tin sheet, plastic or stainless steel containers in the form of vials, bottles, cans, canisters, kegs, single-use kegs, etc.).

When using globe valves in filling processes, the relatively frequent maintenance and correct disassembly of the auxiliary valves are disadvantages. They must be cleaned, equipped with new parts and reassembled. Depending on the manufacturer of the final filling block, this can be complicated and time-consuming.

Combination of globe and bellows valves

Bellows valves can be used for sterile and aseptic filling, as an alternative to using a combination of globe and diaphragm valves. Bellows valves separate the medium from the actuator unit hermetically using PTFE or stainless steel bellows. Like the globe valves, they comprise an actuator with bellows as the seal and a valve body.

Bellows valves with drilled holes in the valve body or two-stage actuators are used for filling. Bellows valves are used for filling processes in which media are filled at different speeds or in which oxygen-sensitive and/or carbonated media are filled. “Still” products (non-carbonated media) can also be filled with these valve types if nitrogen is used as the flushing and pressurization gas. In this case, bellows valves are usually used as auxiliary valves.

When using bellows valves for filling, the high maintenance requirements are a disadvantage, as is the increased dead space (in comparison with diaphragm or globe valves). In addition, bellows are sensitive to pressure surges, which can cause them to tear when closing, in particular when flow rates are high. This occurs in particular with gaseous media, such as carbonated beverages. In practice, it is difficult to clean bellows when the filling process involves highly concentrated fruit juice beverages that contain pulp. Depending on the design and functional principle, the inflow between the creases changes when the valve is open or closed, which is a disadvantage for the inflow and therefore for cleaning in CIP/SIP processes. This can cause enamelling or crusting of product residue that is not completely removed. Sooner or later, this results in microbiological deposits, which can cause contamination of the media (cf. figure 5).

Figure 5: Low-flow zones on valves with bellows are difficult to clean and also increase the valve's dead space

PD design is setting the course for the future

The increasing requirements of the filling industry mean the previous, common valve designs in filling machines are reaching their limits in relation to flexibility and productivity. Innovative filling concepts are becoming more and more important due to frequently small batch sizes, different fill volumes, short cycle times (only a few milliseconds) and media that is complex to fill. In addition, physiological and health-relevant ingredients in the medium to be filled are often very sensitive and require a process that protects them. Aseptic designs are essential both for ultra-pure or cold aseptic filling systems for foodstuffs as well as for pharmaceutical and biotechnological filling. Furthermore, the requirements for hygienic and operational safety in the pharmaceutical, biotechnology as well as the foodstuff and beverage industries are determined by ever stricter specifications. In order to fulfil legal requirements and comply with customer requirements, the aseptic PD design has been developed.

This design combines the advantages of diaphragm and globe valve design. It eliminates the disadvantages of the currently used diaphragm, globe and bellows valve combinations.

Advantages of the PD design:

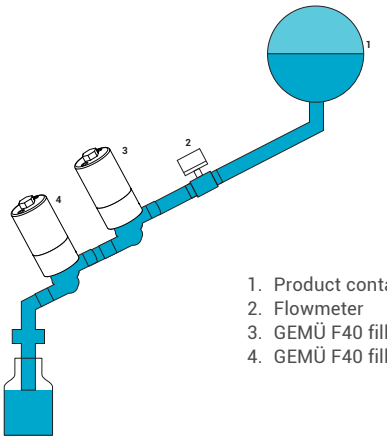
- High Kv values through innovative sealing geometry
- Simple and fast maintenance thanks to cartridge spare parts system
- Resistant sealing from modified PTFE, no retightening required
- High number of switching cycles (over 10 million) with freely programmable filling speed
- Hermetic separation of the actuator from the medium flow
- Long valve service life with more than 10 million cycle duties
- FDA and USP Class VI-approved seal material
- Regulating cone geometry can be adapted
- Minimal deadleg
- Optimal cleanability
- No “lift effect”
- Compact design according to 3A and EHEDG directives

The GEMÜ filling valve platform currently contains the GEMÜ F40 pneumatically operated filling valve and the GEMÜ F60 motorized filling valve

Pneumatically operated filling valve GEMÜ F40

The pneumatically operated filling valve GEMÜ F40 is designed for hygienic and aseptic filling processes as well as aseptic production plants. If two or more filling speeds are required, bypass types with 5–7 mm drilled holes can be used. Due to the pure PTFE sealing system, it can also be used without any problems with media containing oil or grease. It can also be used in filling machines for distributing all types of media (vacuum, liquid or gaseous) (cf. figure 6).

In order to regulate the valve opening, a positioner can be adapted on the pneumatic open/close valve. To automate the valve, it is also possible to attach electrical position indicators.



1. Product container
2. Flowmeter
3. GEMÜ F40 filling valve bypass drilled hole
4. GEMÜ F40 filling valve

Figure 6: Example of a filling machine with PD design for media without dissolved gases, implemented with two pneumatically operated filling valves and flowmeter for two filling speeds

The various legal requirements for hygienic and operational safety (e.g. German Medicinal Products Act (Arzneimittelgesetz, AMG), the German Food and Feed Code (Lebensmittel-, Bedarfsgegenstände- und Futtermittelgesetzbuch, LBFG), Food and Drug Administration (FDA), Regulation (EC) No. 1935/2004, 3A and European Hygienic Engineering and Design Group (EHEDG) Guidelines) in the pharmaceutical, biotechnology as well as the foodstuff and beverage industries were also taken into consideration in the development of the pneumatically operated filling valve.

In addition to the advantages listed above, the operator can also benefit from the enormous improvements in the efficiency of the filling machine. Due to the diaphragm's exceptional service life as well as its ease of maintenance, downtimes can be clearly reduced.

Via an innovative cartridge spare parts system, not only the media seal, but also all wearing parts are replaced in the actuator. Maintenance can last a few seconds (cf. figure 7).

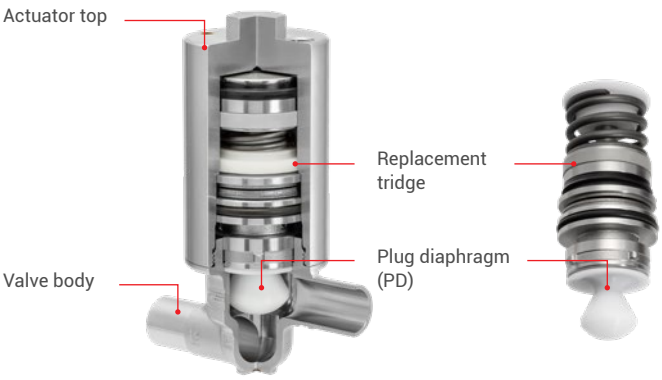


Figure 7: The spare cartridge incl. the PD diaphragm are fully replaced – a torque wrench is suitable for this

Motorized filling valve F60

The motorized filling valve GEMÜ F60 iis particularly suited for the use of fast and highly precise control and regulating applications. Due to the positioning accuracy of up to +/- 10 µm and a traverse speed of up to 300 mm/s, in addition to batch quantities of 1.7 litres per second, batch quantities of a few microlitres per second are also possible (cf. figure 9).

The use of high-quality stainless steel for the actuator and body as well as cable seals with electrical protection class IP 69K permit the cleaning and disinfection of the exterior surfaces with all common cleaning products and sanitisers with all common spray and blasting processes. Due to the protection class, the motorized PD valve is particularly appropriate for use in cleanrooms and insulators. The risk of contamination by compressed air lines as a result of gauge pressure, as is the case with pneumatic actuators, is therefore avoided. Due to the omission of the compressed air line, possible spray shadows are also minimised.

The closing force of the actuator is programmable via its current consumption. Therefore it can be adapted to fit the operating conditions on a case-by-case basis and the service life of the actuator and seal (PD) system can be substantially increased. Similar to the pneumatically operated filling valve, maintenance for this unit is also simple and fast to perform due to the cartridge spare parts system. By controlling the actuator temperature and the current consumption, it is possible in theory to plan valve maintenance in advance. The monitoring of the valve stroke allows a conclusion to be drawn with regard to the status of the seal (cf. figure 8).

An overview of the features of the motorized filling valve:

- Long expected service life of the valve
- Various possible actuator speeds (up to 300 mm/s)
- Extremely high positioning accuracy (up to +/- 10 µm)
- Very high filling accuracy
- Freely programmable filling speeds over the filling time for adaptation to various media, container geometries, etc.
- Extremely short filling cycles with optional programmable fill curves
- Reproducible filling cycles of less than 300 ms in real-time
- Suitable for all control functions
- Can be operated in almost any bus system
- Protection class IP 69K
- Motor design and adaptors according to 3A and EHEDG directives

Figure 8: Motorized filling valve GEMÜ F60

The GEMÜ F60 motorized filling valve makes it possible, with the corresponding sensors (magnetically inductive flowmeter (MID), mass flowmeters (MDM), weigh cells or capacitance probes) to communicate via highly efficient controllers, bus systems and control units, in order to map not only position control, but also process control if necessary. Actuator communication takes place via various bus systems.

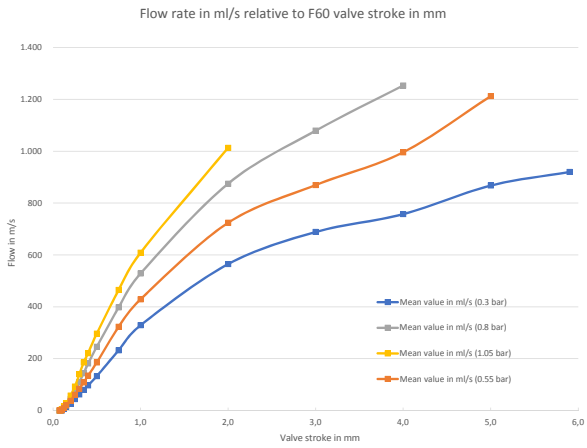


Figure 9: Characteristics of the motorized filling valve GEMÜ F60 with various filling pressures (test medium water 25 °C, flow rates determined for balancing out)

The motorized filling valve makes it possible to implement customized batch quantities and filling curves. It permits product and container shape-dependent programming of the filling speed and batch quantity. This leads to optimal filling results for all containers (cf. figures 10 and 11).

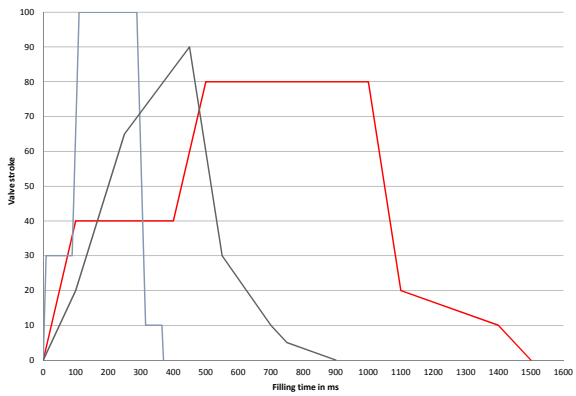


Figure 10: Examples of fill curves that are possible with the motorized filling valve – fill curves of below 300 ms are possible

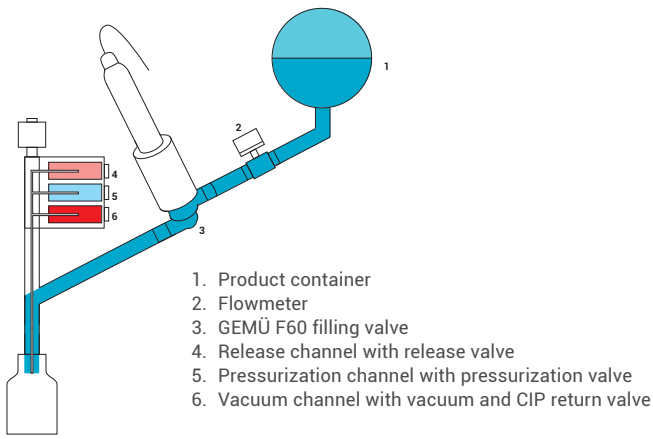


Figure 11: Example of a filling machine with the motorized filling valve for implementation of any fill curves with flowmeters for media with and without dissolved gases

Conclusion

To be able to use valves in sterile and aseptic filling processes, they must fulfil stringent requirements. A hermetic separation of the mechanical actuator components from the media flow as well as the ability to effectively clean and sterilise the media wetted areas are essential aspects. To date, diaphragm, globe and bellows valves have been used for filling in the pharmaceutical, biotechnology as well as the foodstuff and beverage industries. These offer many advantages, however they have the potential to be optimized for filling processes. The new and trailblazing valve design undertakes to eliminate the shortcomings of the existing filling valve variations and therefore meet the growing requirements of the filling industry.

Until today, diaphragm, bellows or globe valves as well as combinations thereof were the only option available for complying with the stringent requirements of ultra-clean or aseptic filling. State-of-the-art research & development in the area of filling valves represents a new and innovative filling valve platform.

This filling valve design makes it possible for virtually all processes in the pharmaceutical, biotechnology as well as foodstuff and beverage industries to implement hygienic and aseptic filling applications.

Both the pneumatic as well as the motorized filling valve variations set new standards as regards

- Speed,
- Precision,
- Flexibility,
- Ease of maintenance

and are therefore guaranteed to improve the quality and productivity of filling processes.

GEMÜ Gebr. Müller Apparatebau GmbH & Co. KG
Fritz-Müller-Straße 6-8 · D-74653 Ingelfingen-Criesbach
Phone +49 (0)7940 123-0 · info@gemue.de