Diaphragm competence for hygienic applications

burkert Fullo CONTROL SYSTEMS

Bürkert Fluid Control Systems Christian-Bürkert-Strasse 13-17 74653 Ingelfingen

Phone: +49 7940 100 Fax: +49 7940 1091204

info@burkert.com www.burkert.com



Diaphragment competence From the development phase to implementation – Bürkert quality

The significance is already indicated by the name – it is the diaphragm that makes the difference with diaphragm valves. It is the critical component in this kind of valve. It ensures that the various process media do not mix, protects the process against external influences, and in some cases it does the opposite: protecting the environment from being influenced by the process.

All the more reason for making no compromises regarding quality as far as this essential item is concerned. With Bürkert's diaphragms and diaphragm valves you are on the safe side in every respect.

For instance, you benefit from the fact that all the materials used in making our diaphragms are traceable. This gives you the assurance that only the "best of ingredients" have been used for your diaphragm. In addition to this, you can choose from a wide variety of materials (and therefore diaphragm types), providing for maximum flexibility to suit your processing task. A number of diaphragms from our range are suitable for CIP (Cleaning in Place) and SIP (Sterilisation in Place), and it goes without saying that they are internationally certified for use in hygienic processing.

This brochure gives you an overview of the various diaphragm types and makes choosing one for your particular application simpler. The brochure is only intended to supplement personal support from our staff, not replace it. If you have any questions, please do not hesitate to contact us! We shall be glad to help and are looking forward to hearing from you.

Stored raw material



Product overview – The right diaphragm for all requirements

Our range of diaphragms covers the following five basic types, each with its own specific properties, each optimised to fulfil the requirements made in certain contexts.

EPDM diaphragms	Very flexible diaphragms made of ethylene propylene diene monomer rubber, mainly for use in hygienic processing.
FKM diaphragms	Diaphragms made of fluoroelastomer, which is especially suitable for use in water treatment.
PTFE diaphragms	These diaphragms are made of polytetrafluoroethylene, which is well suited for use in hygienic and chemical applications on account of its chemical inertness, i.e. the fact that it does not react readily with other substances.
Advanced PTFE diaphragms	These diaphragms are also made of polytetrafluoro- ethylene, in this case a second-generation version with better mechanical properties. This makes them specially suitable where particularly high temperature fluctuations are involved.
GYLON® diaphragms	GYLON is a PTFE that is manufactured using a special production technique. In comparison with conventional PTFE products, GYLON® is significantly less prone to so-called "cold flow"; in other words, it maintains its form even under stresses up to four times the flexural strength. This makes it very suitable for intensive hygienic applications.

Please note: Our diaphragms have been optimised and approved for use together with Bürkert diaphragm valves. The use of third-party diaphragms in Bürkert valves is not recommended and error-free functioning cannot be guaranteed in such cases.

Diaphragm after vulcanisation, prior to trimming.

EPDM diaphragms

Ethylene propylene diene monomer rubber is a synthetic rubber, i.e. elastomer, with a wide range of applications. The main reason for this is to be found in its excellent resistance to the influences of temperature and ozone, as well as its overall capacity to withstand the effects of weathering. Such diaphragms also display a good degree of resistance to polar substances and steam.

Properties

EPDM can cope very easily with both hot and cold water, alkaline media and weak acids. This means that diaphragms of this material are especially well suited for applications in the area of hygienic processing, where steam sterilisation and oxidising media are required.

We recommend not using these diaphragms in connection with media such as mineral and vegetable oils, vegetable and animal fats, aromatic or aliphatic carbohydrates, halogenated solvents or concentrated acids, because these substances damage the diaphragm structure and can lead to leakage. You will find further relevant information in our "Chemical Resistance Chart" brochure.

Temperature range

EPDM (AD):

-10 to +143 °C (steam sterilisation +150 °C for 60 min) for single-weir diaphragms +5 to +130 °C (steam sterilisation +140 °C for 60 min) for two-weir diaphragms for Robolux Multiport valves, type 2036

Diaphragm size

8 (standard: DN8, 1/4") to 100 (standard: DN100, 4")

Approvals

FDA: CFR21 Part 177.2600 EC Regulation 1935/2004 USP Class VI Chapters <87> and <88> at +121 °C 3-A Sanitary Standards 18-03





Two-weir diaphragm for type 2036 (Robolux)

FKM diaphragms

FKM refers to types of fluoroelastomer according to DIN ISO 1629 and ASTM D1418. All types of fluoroelastomer contain vinylidene (di)fluoride (VDF) as one of their monomers. Fluoroelastomers are of higher grade and therefore more expensive than neoprene rubber or nitrile rubber, amongst other factors because it provides greater resistance to heat and chemicals. The high degree of chemical resistance of fluoroelastomers makes for a broader range of applications for the FKM diaphragms in comparison with EPDM diaphragms.

Properties

Diaphragms made of FKM display a high degree of resistance to many solvents and other chemicals. For instance, they provide excellent resistance towards aliphatic hydrocarbons, aromatic and chlorinated chemicals and also withstand acids and alkalis with oxidation agents well. They are not suitable for use in connection with ether and bases. Therefore FKM diaphragms are predestined for use in water treatment on the one hand, but on the other hand we do not recommend them for steam sterilisation applications. You will find further relevant information in our "Chemical Resistance Chart" brochure.

Temperature range

FKM (FF) 0 to +130 °C (not recommended for steam)

Diaphragm size

8 (standard: DN8, 1/4") to 100 (standard: DN100, 4")

Single-weir diaphragm

PTFE diaphragms

Polytetrafluoroethylene is a synthetic fluoropolymer consisting of tetrafluoroethylene whose outstanding properties have led to its being used in a specially wide range of applications. As it consists of carbon and fluorine, two elements that bond to molecules with a high molecular weight, PTFE is a solid material. Due to the strong carbon-fluorine bonds it is especially inert, since other substances cannot break this bond. For this reason, PTFE is frequently used in tanks and pipelines for reactive and corrosive chemicals.

Properties

In view of their unusual chemical and thermal resistance and their good compatibility with hot and cold water as well as alkalis and concentrated acids, PTFE diaphragms are very well suited for use in hygienic applications. Thanks to its chemical inertness, PTFE cannot be cross-linked and therefore has no "memory" – in other words, unlike an elastomer it does not revert to its original shape following deformation. The material has a tendency towards flow distension, i.e. distortion under stress, otherwise known as "cold flow". A small degree of flow distension means that PTFE seals can fit better to a given mating surface than most other plastic seals. However, if the PTFE is excessively deformed due to temperatures above +130 °C or frequent temperature fluctuations (heating/cooling), the sealing bead might be damaged, resulting in possible leaks of the system.

PTFE diaphragms consist of two pieces: The PTFE shield is supported by an EPDM backing.

Temperature range

PTFE/EPDM (EA) -10 to +130 °C (steam sterilisation +140 °C for 60 min.)

Diaphragm size

8 (standard: DN8, 1/4") to 100 (standard: DN100, 4")

Approvals

FDA: CFR21 Part 177.1550 and CFR21 Part 177.2600 EC Regulations 1935/2004 and 10/2011 USP Class VI Sections <87> and <88> at +121°C



Diaphragms made of advanced PTFE

Polytetrafluoroethylene is a synthetic fluoropolymer consisting of tetrafluoroethylene whose outstanding properties have led to its being used in a specially wide range of applications. Just like conventional PTFE, advanced PTFE consists of carbon and fluorine. However, in addition to the properties of conventional PTFE it displays a number of additional and important properties. The higher-performance variant distorts considerably less even under higher stresses, and it responds less to the effects of high temperatures and temperature fluctuations than conventional PTFE. The denser polymer structure also improves process quality which reduces the degree of permeation through the diaphragm.

Properties

In view of their unusual chemical and thermal resistance and their capacity to cope with hot and cold water as well as alkalis and concentrated acids, advanced PTFE diaphragms are very well suited for use in hygienic applications, just like diaphragms of standard PTFE.

However, what sets diaphragms made of advanced PTFE apart from the conventional PTFE diaphragms is their behaviour regarding "cold flow". The effects of cold flow, which can be measured in terms of distortion under stress, are significantly less for advanced PTFE diaphragms. This definite difference regarding cold flow is most apparent at high temperatures and where stresses are repetitive. Therefore we can recommend the use of advanced PTFE diaphragms even where temperatures fluctuate and many sterilisation cycles are involved.

Advanced PTFE diaphragms are also supplied with a supporting EPDM backing. Reinforcing polyamide fabric distinctly improves the product's service life and stability.

Diaphragms made of Advanced PTFE

Temperature range

Advanced PTFE/EPDM (EU) -5 to +143 °C (steam sterilisation +150 °C for 60 min) Advanced PTFE/EPDM laminated (EK) +5 to +90 °C for two-weir diaphragms for Robolux Multiport valves, type 2036

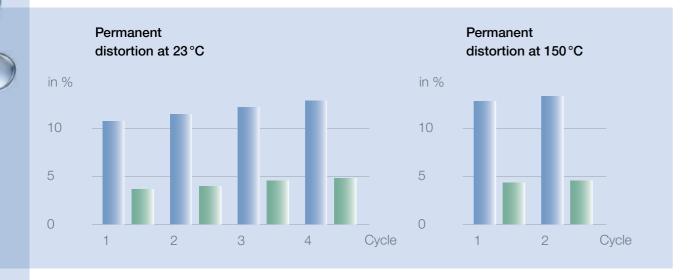
Diaphragm size

Standard PTFE

8 (standard: DN8, 1/4") to 100 (standard: DN100, 4")

Approvals

FDA: CFR21 Part 177.1550 and Part 177.2600 EC Regulations 1935/2004 and 10/2011 USP Class VI Chapters <87> and <88> at +121 °C



The Advanced PTFE diaphragm material (green) always displays significantly less distortion compared with standard PTFE (blue).

Advanced PTFE



GYLON® diaphragms

GYLON® is a new type of diaphragm material that is regarded as representing the third polytetrafluoroethylene (PTFE) generation. Thanks to its excellent properties, GYLON® currently covers the widest range of applications.

PTFE and filler materials are restructured in the special GYLON® manufacturing process. This reduces the permeability of the diaphragm, while the positive PTFE properties remain (e.g. resistance to various chemicals). In addition, GYLON® distorts much less even under high stress. In comparison with conventional PTFE, this material is less affected by high temperatures and temperature fluctuations. This produces a diaphragm with an extremely long service life.

Properties

Especially in the pharmaceutical, food and beverage industries, downtimes can be seriously inconvenient. Therefore diaphragms used in sterilisation cycles must be able to withstand high concentrations of chemicals, temperatures, flow rates and pressures. In comparison with conventional PTFE products, GYLON® is significantly less prone to so-called "cold flow" in hygienic applications; in other words, it maintains its form even under stresses up to four times the flexural strength. The diaphragm's lower void content also lowers the risk of cross-contamination and increases its service life, resulting in lower operating costs. In addition, GYLON® is very resistant to temperatures and chemicals and therefore ideal for use in processes such as CIP (Cleaning in Place) and SIP (Sterilisation in Place).

Temperature range

GYLON®/EPDM laminated (ER)

- -5 to +130 °C (steam sterilisation +140 °C for 60 min.)
- +15 to +130 °C (+5 °C for min. pressure >= 1 bar; steam sterilization +140 °C for 60 min) for Robolux Multiport valves, type 2036

Diaphragm size

8 (standard: DN8, 1/4") to 80 (standard: DN80, 3")

Approvals

FDA: CFR21 Part 177.1550 and Part 177.2600 EC Regulations 1935/2004 and 10/2011 USP Class VI Chapters <87> and <88> at +121 °C 3-A Sanitary Standards 18-03 and 20-22



Practical tests confirm the simulation results

In order to optimise the service life and leak-tightness of the diaphragms, simulations are used at an early stage of the development process. The results of the compression and flow model tests, at first purely theoretical, could be confirmed by experiment.

Longer diaphragm service life

Thanks to a comprehensive redesign of the valve body, the closing force of the valve is distributed uniformly over the diaphragm. In addition, the compressor contour for EPDM and PTFE was optimised. This component is essential, because it is what presses the diaphragm onto the weir and ensures a tight seal.

The figure below demonstrates the smooth, form-locking load transfer: The diaphragm lies uniformly flat on the metal housing.

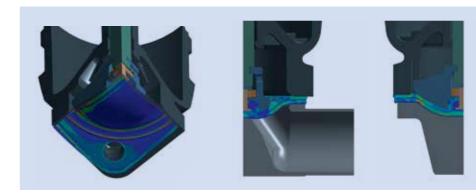
The service life of the diaphragm can be increased even more through the use of a valve actuator with reduced actuator force (while maintaining the same diaphragm size).

High degree of leak-tightness

To avoid the possibility of media or other foreign particles entering from outside, the leak-tightness is very important. This is achieved through the sophisticated design of the diaphragm sealing lip: It increases the specific compression at the critical point.

Explanation of the figures - simulation results

The figures show simulation results from the diaphragm valve optimisation project. This involved a typical quarter-model and the application of the finite element method (FEM). The normal parameter for investigating the compression of plastics is the degree of elastic distension. Locations where a high degree of compression is required to ensure a tight seal for the valve are shown in red. The compression is lower at the locations coloured green and yellow. The colour blue indicates locations where the forces are distributed uniformly. A closed valve with a DN40 GYLON® diaphragm at 5 bar medium pressure is shown here.



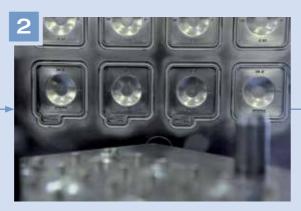
Production – From raw rubber to a precisely shaped high-tech diaphragm

Quality is central to our diaphragm production – for as explained at the beginning, the diaphragm is the "heart" of the diaphragm valve. More than any other component, it determines process performance. Minor faults can easily have major effects.

An overview of the production process



The raw material is stored in an air-conditioned warehouse and protected against light.



Several diaphragms can be manufactured at once with the aid of a vulcanisation tool.



tion as well.

EPDM raw material prepared for vulcanisation

– there is a textile layer between the two EPDM plates.



In addition to the experience gained in handling the various materials, exact manufactur-

ing processes according to the specifications of Bürkert's engineers play a decisive role

as well, of course. Therefore we only cooperate with audited and qualified production

partners who are able to fulfil our high demands in terms of quality in their own produc-

The vulcanisation tool on the press – the EPDM blanks are laid into the moulds.



A finished high-tech diaphragm.



When the vulcanisation process is completed, the finished diaphragms can be removed from the tool.



The production-specific parameters such as time, temperature, pressure etc. are monitored during the vulcanisation process.

14

Design – Form follows function

The choice of material is an important factor when it comes to developing a new diaphragm. The material has to fulfil a range of specifications regarding ingredients and composition (FDA, USP etc.), while also being as easy to handle as possible (e.g. for vulcanisation).

The functional design is oriented towards the anticipated range of implementation for the diaphragm. The engineer is constrained in terms of the material properties and the requirements that the diaphragm has to meet in later use.

Samples of each diaphragm are produced for testing in respect to chemical resistance and service life. The prototypes are tested on special equipment that subjects them to various challenges (pressure, temperature, steam etc.) before being supplied to the customer. Where the test results are positive, the new diaphragm is integrated into the customer's system and then adopted into the product portfolio after a successful period of use.



2-piece PTFE/EPDM diaphragm

The diaphragm is a composite of PTFE and EPDM. The EPDM supports the PTFE or Advanced PTFE diaphragm in contact with the medium, increasing the service life.



EPDM diaphragm for type 2036 two-weir Robolux version

The two-weir diaphragm valve solution is unique: It is based on a diaphragm with two connections, enabling the sealing of two parallel seats.

Connection types

Button



Elastomer button for connecting to the actuator (manual or pneumatic).

Thread



Pin with thread – the pin is screwed into the actuator.

Bayonet



Radial arm pin: The pin is fixed in the pressure piece of the actuator via a quarter-turn – significantly easier, error-free assembly.

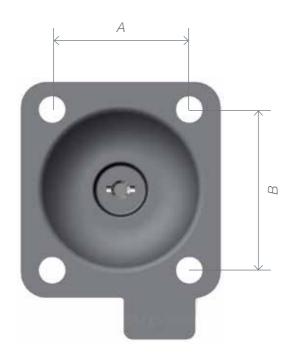
Robolux



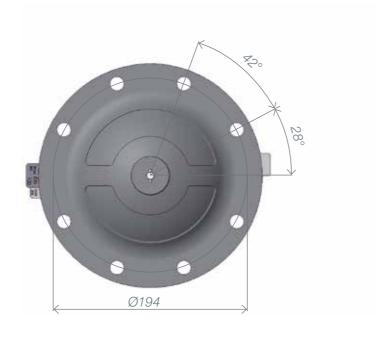
Two-weir diaphragm valve solution, two connections.

Dimensions -It all depends on having the right size

The diaphragm sizes given are to help you find the diaphragm size that exactly serves your needs.



Installation size for diaphragm size 8 to 80



Installation size for diaphragm size 100

Diaphragm size	Α	В	
08	24.75	24.75	
15	33	37	
20	40	44	
25	46	54	
32	60	67	
40	65	70	
50	78	83	
65	95	102	
80	114	127	
100	Ø 194		

Traceability -Transparency for more security

In a pharmaceutical plant, traceability is essential in order to ensure that all materials have the corresponding certificate, and in order to fulfil the documentation and quality assurance requirements regarding production times and production methods. Traceability is required both by the GMP (Good Manufacturing Practices) guidelines as well as by the ASME BPE guidelines.

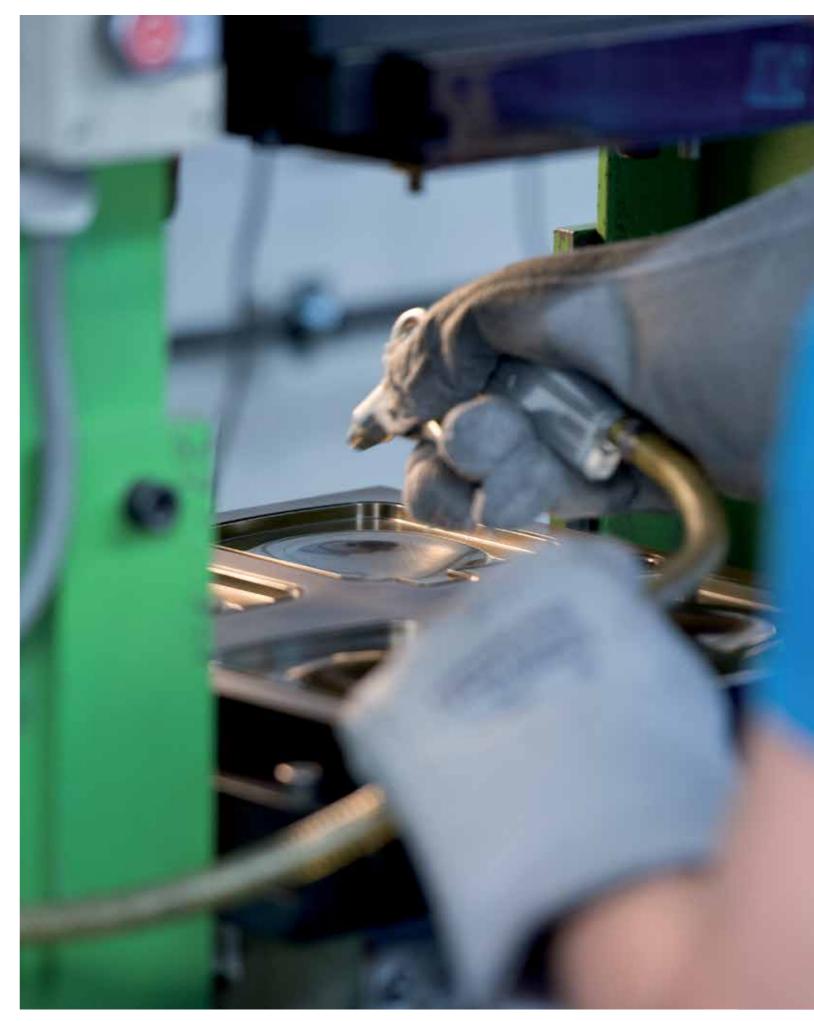
The visible production date provides for transparency, for the diaphragms have differing service lives depending on where and how intensively they are used. If the diaphragm needs to be replaced, Bürkert will be glad to put its experience, competence and service at your disposal. We look forward to providing specific personal consultation.



Certificates – The precondition for successful process validation

Process validation is an essential part of quality assurance regarding process safety. Its purpose is to ensure that a process or a system can repeatedly fulfil the specifications, also in the long term. To ensure that your process yields the desired results in a reproducible manner, it is vital to use reliable and high-quality components. You can be quite sure of this with diaphragms and diaphragm valves from Bürkert, because our products are comprehensively tested and certified. External testing institutes have tested and certified our membranes according to ASME BPE 2016 Appendix J.





Bürkert diaphragms – Selecting the right components

By way of providing support when you are deciding which diaphragm to choose to meet the requirements of your process in the best possible way, we have collated our broad range of products into the following table, with the details and clarity you need. If you would like more help in choosing the right components, please call us. We shall be glad to provide specific personal consultation.

Material	Bürkert Code	Diaphragm size	Temperature		Approvals				Vacuum	
	Code	SIZE	min.	max.	Steam sterilisation	FDA	EC 1935/ 2004	3A (compl. valve)	USP Class VI	
EPDM	AD	8 to 100	-10°C	+143°C	+150°C for 60 min	yes	yes	yes	yes	yes
FKM	FF	8 to 100	0°C	+130°C	-	-	-	-	-	yes
PTFE/ EPDM 2-pieces	EA	8 to 100	-10°C	+130°C	+140 °C for 60 min	yes	yes	-	yes	yes
Advanced PTFE/ EPDM 2-pieces	EU	8 to 100	-5°C	+143°C	+150°C for 60 min	yes	yes	-	yes	yes
GYLON®/ EPDM laminated	ER	8 to 80	-5°C	+130°C	+140 °C for 60 min	yes	yes	yes	yes	yes
Robolux – EPDM	AD	RV50 to 110	+5°C	+130°C	+140°C for 60 min	yes	yes	-	yes	yes
Robolux – Advanced PTFE/ EPDM laminated	EK	RV50 to 110	+5°C	+90°C	-	yes	yes	-	yes	yes
Robolux – GYLON® EPDM laminated	ER	RV50 to 110	+15°C (+5 °C for min. pressure >= 1 bar)	+130°C	+140°C for 60 min.	yes	yes	-	yes	yes

Service and Maintenance – Optimising diaphragm service life

Our staff will be pleased to help if you have any questions regarding the diaphragms themselves and service provision such as diaphragm replacement, maintenance and start-up.

The service life of a diaphragm depends on the following factors:

- the material of which it is made
- the medium with which it comes into contact
- the pressure acting on the diaphragm
- the medium temperature
- the actuators force needed to achieve the required leak-tightness
- the control pressure for double-acting actuators and normally opened actuators

Ways of beneficially influencing the diaphragm service life:

For NC valves (normally closed), match the actuator size (actuator force) with the medium pressure in order to initiate the process. For smaller medium pressures, select the actuator with reduced spring force (EC04 option).

For NO (normally open) and double-action valves, select the control pressure to be no more than is necessary to seal the medium pressure.

When maintenance is required, follow the procedure given in the operating instructions. Please also pay attention to the torque for the bolt as specified in the operating instructions. Using the wrong torque can lead to the valve leaking or the diaphragm service life being shortened. This will help you to optimise your process.

Our staff will be pleased to help if you have any questions about service provision regarding diaphragm replacement.

Notes on storage:

As a guideline, the maximum shelf life is 7 years and the maximum service life is 3 years.

Further recommendations can be found in the document "Storing elastomer components". Elastomer components can lose the characteristics that give their name in the course of time. These changes come about on account of a range of influencing factors such as light, heat, ozone, humidity, distortion, oxygen or oils and solvents. International standards specify basic requirements for the correct storage of elastomers, e.g. DIN 7716 and ISO 2230.

Spare parts with ID number

To provide optimal support with regard to the maintenance and servicing of your diaphragm valves, we have a broad range of spare parts as presented on the following pages. Your diaphragms are supplied to you packed individually and dust-proof.

		EPDM spare parts Code AD	GYLON® spare parts Code ER
Diaphragm size	Connector	ID number	ID number
08		688421	693175
15	Button	688422	-
20		688423	-
15	Bayonet	693163	693176
20		693166	693177
25	Thread	688424	693178
32		688425	693179
40		688426	693180
50		688427	693181
65		688428	586616
80		688429	586617
100		688430	-

		PTFE spare parts Code EA	Advanced PTFE spare parts Code EU
Diaphragm size	Connector	ID number	ID number
08	Button	677674	679540
15	Bayonet	677675	679541
20		677676	679542
25		677677	679543
32		677678	679544
40		584378	584379
50		584386	584387
65		677681	679743
80		677682	679744
100		677683	679745

The table features standard one-weir diaphragms. For two-weir, please refer to the manual or contact us.



Practical testing – the multi-medium testing facility

When the simulations using compression and flow models (see also page 13) have been completed, the diaphragms and valves have to go through extremely severe practical testing.

The conditions required are generated in Bürkert's multi-medium testing facility (see figure below). It can subject a number of valves to alternating cold and hot water, steam, vacuum and air stresses. The tests cover a very large number of switching cycles and are fully automated. This makes it possible to mirror important processes such as CIP (Cleaning in Place) and SIP (Sterilisation in Place) just as they are carried out in the field. It is also possible to set up customer-specific, individual testing for special requirements.



Bürkert - Close to You

