



bürkert
FLUID CONTROL SYSTEMS

SUCCESS STORY

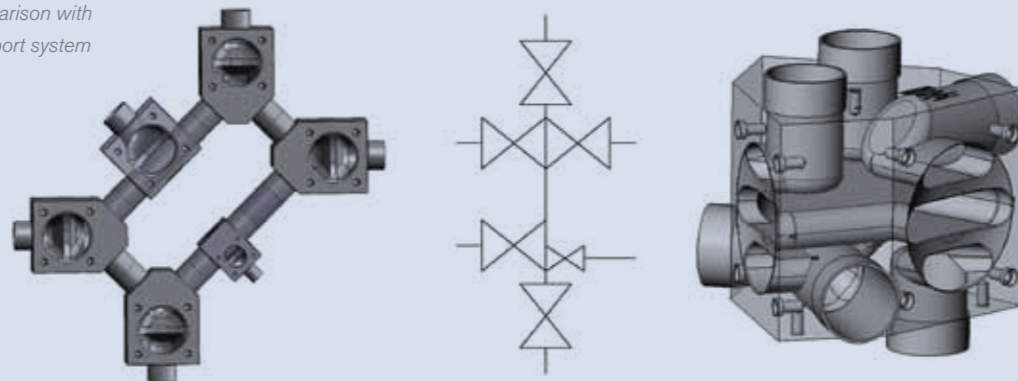
Bürkert < > **B | BRAUN**

Innovative valve interfaces ensure customized productivity in B. Braun LIFE Nutrition plant.

Compact design and optimal fluidics: One of the complex Robolux 10-port valve interfaces in the cleanroom installation at B. Braun



Conventional ring system in comparison with fluidically identical Robolux multi-port system



Maximum capacity with minimum space

B. Braun Melsungen AG is one of the leading companies in the international pharmaceutical and medication sector. With an investment of 164 million Euros the company is currently building the LIFE Nutrition plant, one of the world's most modern production sites for innovative nutrition solutions, at the company headquarters in the North Hessian city of Melsungen. Solutions for clinical nutrition such as amino acid solutions, carbohydrate solutions and fat emulsions are manufactured and packaged in two production lines at the new manufacturing facility with an integrated lab. After more than five years of planning and construction and an extensive test phase, the plant is scheduled to start full-time production in the spring of 2012.

The new factory was built in the direct vicinity of the LIFE plant, Europe's most modern infusion solution factory, which started production in the year 2005. The planning team in the new plant included the in-house engineers and specialists from the planning and consulting company Chemengineering commissioned by B. Braun with the project as well as the operators of the LIFE plant from the very beginning. They contributed their experience from daily operations and were able to point out problems and weak points already during the conception phase.

The special challenges in the planning of LIFE Nutrition included the requirement of B. Braun for construction of the new plant in a building that is architecturally identical to that of the older LIFE plant. Despite equal spatial conditions, the new production facilities needed to be significantly more efficient and flexible. During the search for innovative, space-saving solutions for the complex valve interfaces required for the production technology, Chemengineering contacted the fluid technology specialist Bürkert, among others, in the spring of 2008. With the multi-port valve Robolux Bürkert has a patented solution in its portfolio for achieving very complex and compact valve interfaces with a low internal volume. Within a few weeks and based on the specifications, Bürkert developed models for the first, especially complex valve interfaces, which were professionally visualized and presented with the help of modern 3D PDF files. "The advantages of a Robolux multi-port system in comparison with conventional single-layer valve interfaces and ring systems were literally evident at first glance", says Alexander Equit, National Key Account Manager for Pharma, Biotech and Fine Chemistry at Bürkert.



6-port valve interface with controllable opening and closing characteristics for steam

Valve configuration in the B. Braun plant

The compact design as well as the possibility to connect Robolux with standard systems has resulted in valve interfaces which meet the technical and practical needs such as maintenance and cleaning as well as flexibility in different operation modes. These system solutions are unparalleled, prompting optimizations which standard solutions can only offer with difficulty or to a limited extent.

S. Reinhardt, C. Dostal (Plant operators LIFE and LIFE Nutriton)



Setup of the Robolux double actuator system

One membrane, two valves, many advantages

The special feature of the patented Robolux valve design is that two independent process switching functions can be achieved with one membrane. This reduces installation requirements, eliminates T-adapters and minimizes the overall number of valves and membranes needed. The multi-port membrane valves were designed for high-purity installations and make it possible to design complex systems that are considerably more compact. "Due to this technology, even a 10-port valve interface requires very little installation space, has a minimal internal volume and practically no dead flow zone", Equit explains. The lower inner volume offers several advantages: In addition to improved flow and evacuation properties, both cleaning and changeover of the interfaces for the manufacture of other products is easier and faster.

The valve interface concept presented jointly by Bürkert and Chemengineering convinced B. Braun. On the basis of the Robolux valve interface, a new fluidics scheme was developed and modern multi-port Robolux systems were included in the plans. The Robolux interfaces can be cleaned optimally and very effectively due to directional flow. This systematically prevents the typical disadvantages of ring systems – an especially large inner volume and undefined flow, which complicates cleaning. In steam sterilization, a Robolux valve interface reaches the required sterilization temperature in about half the time. However, the final decision for the use of Robolux valve technology was not yet made. "The requirements and standards for use in Life Science systems are extremely high not only at B. Braun, and are continuously reviewed through audits", Equit explains.

Clean is not pure: Competence for electropolishing of complex forms

Therefore, Bürkert had to demonstrate that the complex valve interfaces can be delivered in the surface quality defined by Basler Standard BN94. For this purpose, the Bürkert group company, BBS-Systems AG in Wil, Switzerland developed a solution for reliable electro polishing of the Robolux systems, in which 30 µm of metal is removed from the media contact surface with a special electrolyte under the effect of DC current. The material is removed without mechanical, thermal and chemical influences. The surface becomes smooth and shiny in the micro range – possibly damaged outer layers are removed and the properties of the pure stainless steel can be utilized. For reliable electropolishing of the complex interior of a 10-port system in all areas, the standard process had to be modified somewhat and adapted to the special requirements of these solutions.

The audits were carried out to validate not only the electro polishing but also the black white separation in Bürkert's production plants of products which are intended for the Bio-tech sector. All components manufactured from stainless steel may come into contact only with stainless steel, to avoid contamination and rust film. The bodies of the fittings are produced on special production lines, where only stainless steel is used. From goods receipt to goods issue the components manufactured from stainless steel are kept apart from the other products through separate storage systems.

During production, the production quality and compliance with the defined standards is checked in unannounced Factory Acceptance Tests (FAT).



Positioner 8696 in combination with Robolux RV110 for steam control



Visualization of the fluorescent effect of riboflavin under UV light in a valve interface

Reliable partners are crucial for the project success. And this is where Bürkert convinced us through their innovative energy at the start of the project and because of their timely, fair and above all flexible handling in combination with a high quality product.

Stephan Reuter (Project Manager Chemengineering)



Fittings installation in the cleanroom of the new LIFE Nutrition plant at B. Braun in Melsungen

Theory meets practice: Riboflavin test confirms properties of the valve interfaces

As a significant part of these tests, Bürkert developed and constructed a special test rig for complex valve interfaces within the framework of the project. With the help of a riboflavin procedure this test rig can be used to confirm that a finalised valve interface actually complies with the defined and required properties. The riboflavin procedure is normally used in tank construction, to check whether a tank can be cleaned completely and without residue. In the testing of fluidic systems, typically only 3D flow simulations are used; despite the complex programming requirements, however, these simulations do not achieve 100 % reliable results concerning the flow properties.

As part of the FATs, Bürkert conducted additional riboflavin tests on the most complex of the Robolux valve interfaces, using Bürkert's own test rig. In compliance with the VDMA directive, the inside of the valve interfaces is fully soaked using an atomizer with a test solution containing riboflavin that fluoresces when exposed to UV light. Afterwards, the part being tested is put into operation and flushed with water. After the part has been flushed with WFI (water for injection) or deionized water for the specified time, the valve interface is dismantled and exposed to UV light. If all flow areas were sufficiently exposed to water during the timed flush, no fluorescence can be detected in a visual inspection with a UV lamp in a dark environment. With the help of these tests, the flow properties and cleanability of fluidic systems and valve interfaces can be determined with one hundred percent reliability.

Furthermore, riboflavin tests on complex valve interfaces create added value. The results of the tests can likewise be used for optimizing cleaning processes with respect to the cleaning cycles, the required cleaning time and the quantity of cleaning agents needed. Also, the design of complex valve interfaces in a test phase can be evaluated and optimized by the use of riboflavin tests. Bürkert is currently the only manufacturer of fittings and valve interfaces in the world that owns and operates a riboflavin test rig.

Fluidics from one source

After the Robolux valve interfaces convinced the decision-makers, Bürkert was granted the contract in September 2009 to deliver not only the valve interfaces, but all process fittings for the LIFE Nutrition plant. Among others, Bürkert valve types 2031, 2032, 2033 and 2034 are used. "B. Braun therefore receives the entire fluidics technology for the new production facilities from one source", Alexander Equit explains. "The project is very demanding in terms of fluidics, since the entire plant operates only with pressure and gradients, without pumps."

In addition to the engineering, production and delivery of the valve interfaces and fittings, Bürkert also will support B. Braun with the evaluation of all fittings during the commissioning and passivation of the entire plant and will conduct on-site training with the use of a show truck to familiarize the operating personnel with the new valve technology.

Bürkert Fluid Control Systems

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