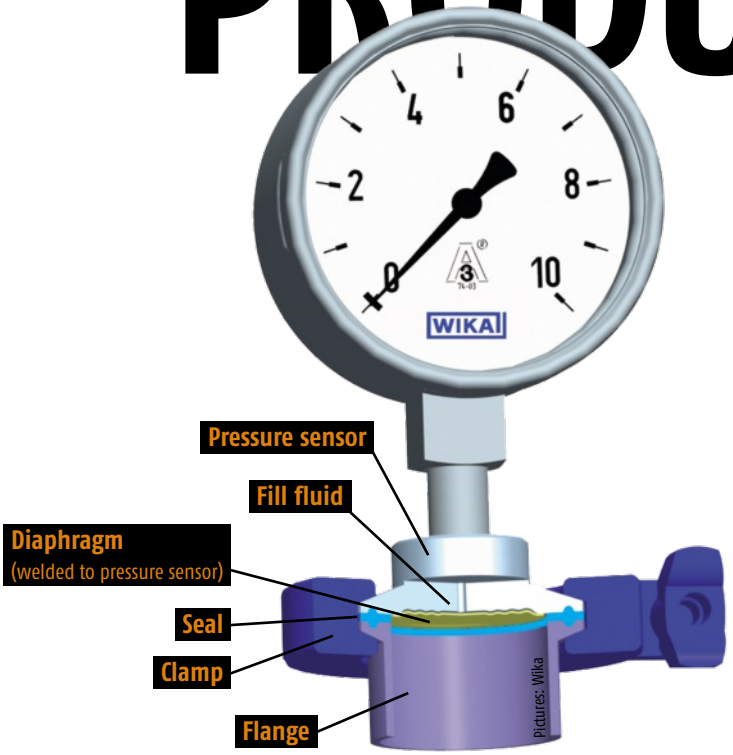
A SAFETY–NET FOR PHARMA–PRODUCTION



Setup of a diaphragm seal system

How double–diaphragm and diaphragm break monitoring technology provides safety for pharmaceutical production plants — By using diaphragm seals, pressure measuring instruments can be adapted to even the harshest of process conditions. Here, a diaphragm separates the measuring instrument from the process medium and transmits the pressure hydraulically. A double-diaphragm design offers a solution for pharmaceutical applications, where the process must remain sealed under all circumstances and the hazard risk for people and the environment must be minimised.

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One of the main goals of the European Union is consumer protection and the welfare of its citizens. To further this goal, the community has set up extensive rules for the producers of consumer goods. Among them are the GMP (Good Manufacturing Practice) guidelines that apply, in particular, for pharmaceutical production. Good Manufacturing Practice essentially means that all foreseen measures, which guarantee that the drug has the required quality for the intended use, are taken. Preventing contamination is therefor a major aspect of pharmaceutical production: This applies both to the ingredients as well as the equipment with which the drugs are manufactured. The plant equipment includes the measurement instrumentation, which for many production steps delivers important data on the production quality — for example system pressure.

Many processes in the pharmaceutical industry use critical media. To guarantee that the measuring instruments are easy to clean and provide a precise reading, many manufacturers use diaphragm seal systems: With these systems, an elastic, corrosion-resistant metal diaphragm shields the instrument from the medium. The space between diaphragm and instrument is completely filled with a fluid, for example glycerine or paraffin oil, depending on the measuring task at hand. The diaphragm takes the process pressure

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PROCESS-Tip

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Double sure: Diaphragm break monitoring and double-diaphragm on the diaphragm seal system.

and hydraulically transmits it to the instrument, such as a pressure gauge, transmitter or switch. Diaphragm seals are either mounted directly to the instrument or connected via a flexible capillary, providing reliable measurement even in harshest conditions.

Seals for Sensitive Products

However, one risk remains: Unforeseen process disturbances can damage or even destroy the sensitive diaphragm, so that the fill fluid finds its way into the process. As a result, extra care must be taken when specifying the fluid for sanitary applications to ensure it is suitable for contact with the particular medium. This can be documented through conformity with the provisions of the American Food and Drug Administration (FDA). For compliance with the GMP guidelines, further documents are required, for example a listing in the country-specific pharmacopoeia. These tolerances are, however, not unlimited: In some cases, contamination must be prevented under all circumstances and in any direction. Thus, no fill fluid must be allowed to soil the product or escape into the environment. This is the case, for example, when producing vaccines with live viruses or of genetically modified organisms — The consequences would be dramatic in each case.

For anyone who must exclude all eventualities, a more advanced seal is available from Wika, with a double diaphragm and diaphragm break monitoring. Using this patented system, the space between the two diaphragms is evacuated and the vacuum is monitored. The type of monitoring can be specified individually, depending on the sensitivity of the process: With regular on-site inspection, a pressure gauge with green-red display will be sufficient, in other cases a visual or audible alarm in the control room may be required. When using media with a high risk potential, the operator can use a pressure switch which will immediately halt the process in the event of any leakage. Should the wetted diaphragm become damaged, the second forms a reliable seal to the process and maintains the pressure monitoring until the damage has been rectified. Since a break within the system is detected immediately, no microbes can get past the diaphragm without notice.

For pharmaceutical applications, comprehensive process safety is the most important feature of double diaphragm seals. Furthermore, these units give plant operators a significant time advantage: When utilising instruments with "simple" diaphragm seals they must, often after each batch, remove all measuring instruments from the process and check the diaphragms for possible damage. Only then can the product batch be released for further processing. This operation and the waiting time are dispensed with when measuring assemblies with integrated diaphragm break monitoring are used.

Investing in the safety of pharmaceutical processes is an inevitable task, especially with regard to the possibly consequences. In terms of protection of product and environment, the diaphragm seal systems offer considerable advantages. Matching them to the individual process environments does involve additional planning. However, in the long run the economic aspects of this measurement technology — the simplified process control, reduced waiting and downtime and minimised failure risk — will make up for this, paying back with reduced costs and optimised running operation.