

CLEANROOM PRESSURE MONITORING



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Cleanrooms are an essential part of manufacturing, research and quality control in the pharmaceutical industry. They are isolated facilities specially designed to manufacture medications, containers, enclosures, and other medical devices required to remain sterile throughout the manufacturing line. The intervention of hazardous substances can penetrate highly critical medicines and compromise the safety of customers. The primary purpose of cleanroom is to prevent airborne particles that may carry harmful substances that can compromise the products' safety and quality. In doing so, the air supply, air distribution, air supply filtration, materials of construction and the operating procedures are regulated to control airborne particle concentrates to meet appropriate cleanliness levels.

Australian pharmaceutical manufacturers must demonstrate their compliance to TGA or PIC to hold a license in manufacturing products. The regulations set out specific classes of air cleanliness in terms of the number of air particles, which is generally expressed as the air volume concentration. They specify the amount of air particles that are required to be maintained in each of these classes. These regulations generally apply to different processes, including assessing raw materials to examining the premises and production machinery and evaluating staff training and hygiene procedures.

ISO classification number (N)	Maximum concentration limits (particles/m ³ of air) for particles equal to and larger than the considered sizes shown below (concentration limits are calculated in accordance with equation (1) in 3.2)					
	0,1 µm	0,2 µm	0,3 µm	0,5 µm	1 µm	5 µm
ISO Class 1	10	2				
ISO Class 2	100	24	10	4		
ISO Class 3	1 000	237	102	35	8	
ISO Class 4	10 000	2 370	1 020	352	83	
ISO Class 5	100 000	23 700	10 200	3 520	832	29
ISO Class 6	1 000 000	237 000	102 000	35 200	8 320	293
ISO Class 7				352 000	83 200	2 930
ISO Class 8				3 520 000	832 000	29 300
ISO Class 9				35 200 000	8 320 000	293 000

NOTE: Uncertainties related to the measurement process require that concentration data with no more than three significant figures be used in determining the classification level.

While designing a new cleanroom, many design factors need to be considered. It involves determining the level of cleanliness required to minimize the risk of product contamination while producing a facility which is both economical to design and run without adding restrictions to the product unit cost. One of the most critical considerations is maintaining the pressure differential in the circulation system to generate positive pressure in the cleanroom.

HVAC PRESSURE CONTROL IN CLEAN ENVIRONMENT

A pressure differential of 10-15 pascals must be maintained between the manufacturing area and its surroundings. The airflow is controlled so that high pressure is maintained in the aseptic areas. This procedure is done to ensure that the air flows from high pressure to low pressure zones i.e. from the aseptic to non-aseptic areas to prevent the air containing dust and any other contaminants from reaching the sterile environment.

Many cleanrooms are designed with a secondary space used for decontamination and pressurization when people are entering or leaving the space. Therefore, it is crucial to measure the air pressure in two separate areas of the cleanroom to indicate a difference in the readings.



Figure 1. Cleanroom environment

PRESSURE MEASUREMENT : INDUSTRIAL REQUIREMENT AND CHALLENGES

To accommodate for the challenging measurement in the cleanroom environment, the pressure measurement technology needs to be able to measure extremely low differential pressure. As mentioned above, positive pressure has to be maintained in the cleanroom at all times. Therefore, slight decrease in the pressure level may introduce contamination to the sterile environment. Cleanroom environment would require a sensor that can measure with unprecedented accuracy.

Differential pressure transmitters are generally installed in the cleanroom environment. The sensors can be mounted on ducts or walls. It can also be configured to alert the personnel when there is a variation in the air pressure. In addition, it is also important to zero-check the pressure transmitter in cleanroom pressure measurement to ensure that it is not deviating from its zero-reference value. This procedure is done to eliminate the errors caused by the stress of mounting the device on the measuring surface and any errors from manufacturing defects.

It is also crucial that the sensors can measure reliably in a long-term. Sensors, in general, will experience drift after a certain period and introduce measurement error. This means that the zero signal will be subject to a drift, which can often be as high as 1 to 2 Pascal per year, for example. Therefore, the end-user must be aware of this situation and send the sensors for re-calibration regularly.

A UNIQUE SENSING TECHNOLOGY

The Furness Control FCO432 differential pressure transmitter is capable of measuring ultra-low differential pressure and is suitable for clean room applications. Unlike other sensors technology that offers accuracy within the full-scale operation, this differential pressure transmitter provides up to 0.25% accuracy of measurement reading over the entire measuring range. Therefore, it is much more accurate than conventional pressure sensors technology.

The measurement data can be displayed in either the control room or in the sensor itself via the high brightness LCD or the optional OLED display. The FCO432 can also be configured with multiple functions such as setting up an alarm system to alert on-site staff if there is an abnormal fluctuation in the reading.

Another outstanding feature of the FCO432 is its auto-zero calibration system which is adjust the zero-reference value regularly. This ensures highly precise measurement which is crucial for clean environment. The output from this sensor can be scaled as linear for differential pressure reading or as a square-root function to facilitate the use of pitot tubes or other flow elements.

Bestech Australia supplies a wide range of pressure sensors and other sensors to measure physical parameters such as temperature, level, vibration, displacement, strain, and data acquisition systems for the mining industry. We provide full technical support of our products to assist with measurement challenges from design to delivery.

Get in touch with us for more information on our capabilities and find out how we can work together to deliver a successful project.



Figure 2. Furness FCO432 ultra low differential pressure transmitter

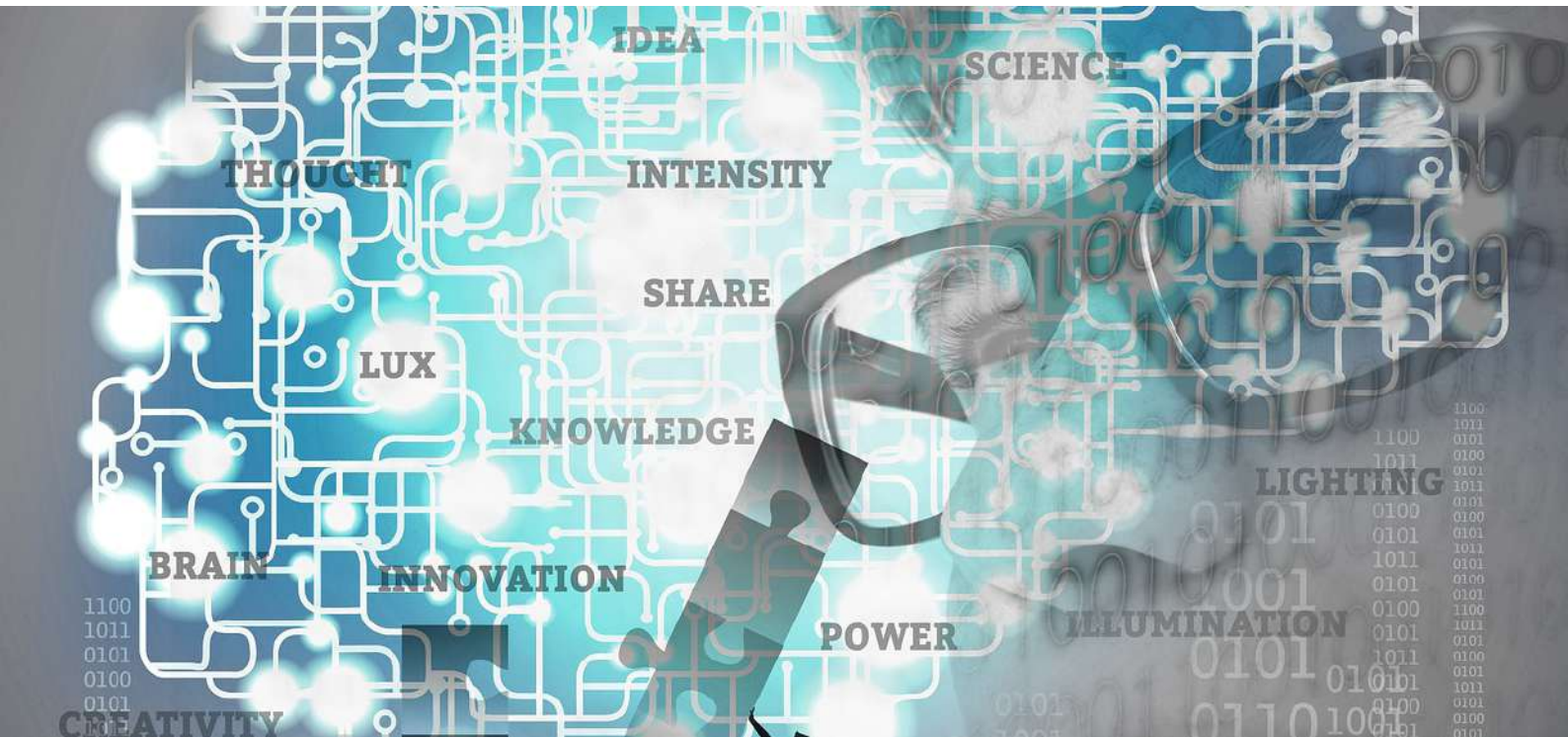
ABOUT US

Founded in 2002, **Bestech Australia** is an ISO9001 certified company. We specialize in supplying, designing and manufacturing sensors and instrumentation for measurement of physical parameters, data acquisition systems and technical teaching equipment for teaching and training of vocational and engineering education.

We are one of the fastest growing company in Oceania and we provide efficient solutions which could be an individual product or a complete turn-key system. We are constantly expanding our product portfolio to support the industry requirements for test and measurements as well as workforce upskilling. Our products are sourced from world leading suppliers and we complement this by own design and manufacturing capabilities backed by local technical support, service and calibration.

Our customers come from both industries and academia in the fields of engineering, mining, automotive, process & chemical, railway, food & beverages, aerospace, manufacturing, defence, energy and condition monitoring utilise our sensors and measuring instruments for monitoring processes, model validations, optimise products and gain insights from the measurement data as well as use our training equipment for developing and upgrading their on-site employee training program.

Our services include project consulting, sensors design, implementations, test and commissioning, specialists deployment, customer-specific design and development as well as system integration. Bestech consistently provide high-quality services to support your high-end test and measurement requirement.



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