PST
PROCESS SENSING
TECHNOLOGIES

Solutions for Oxygen Ventilator Medical Device Manufacturers

O_2 Sensors & Environmental Monitoring

MICHELL Instruments · Analytical Industries Inc · rotronic MEASUREMENT SOLUTIONS · LDetek · DYNAMENT INFRARED GAS SENSORS · NTRON Gas Measurement · SST

PST Product Range

PST can offer various solutions to oxygen ventilator manufacturers and a wide range of oxygen sensors for leak detection. Also a continuous monitoring system (RMS). A monitoring system helps assure product quality and will help the regulated medical device manufacturer to comply to various regulations, such as the FDA 21 CFR Part 820 and standards such as ISO 13485 and 14644.

PST also offer a range of services for GxP applications such as:

- Mapping
- Validation
- Calibration

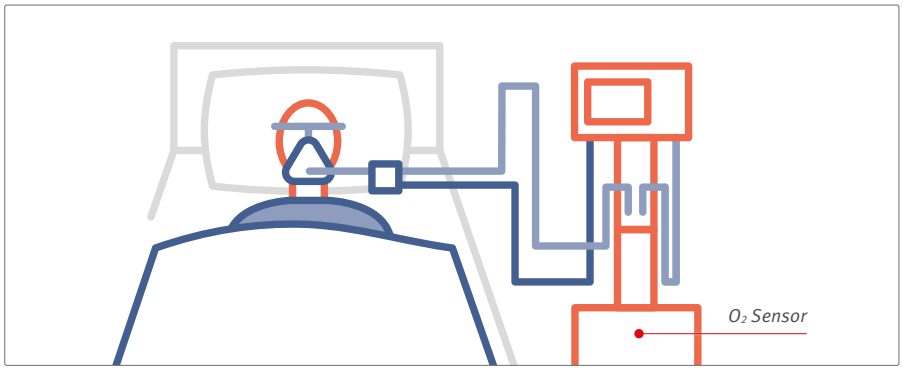
The Application

The main risk in oxygen ventilators is that if the oxygen supply was to leak it would create a potential fire hazard.

The solution is to install an oxygen sensor to monitor the environment. Anything above 20.7% will be detected by the oxygen sensor and trigger an alarm for the end-user.

Measure oxygen levels inside ventilators

The main goal of an oxygen ventilator is to deliver an oxygen mixture helping patients' breath. Oxygen ventilator manufacturers need to ensure that the medical device is safe for patients to use and warn the users in case of potential risks.



Patient Safety

Oxygen does not burn and is not flammable, however, it is an oxidizer and feeds fire. The fire triangle explains the rule that a fire need heat, fuel and oxygen to burn. If one of these 3 is removed, the fire will be put out.

A fire can be initiated by an activating energy, in most cases, it is heat. In the case of a medical device the heating of an electrical wire, or a spark (from any starting electrical device) with increased oxygen levels can easily ignite a fire.

Sensors for Oxygen Ventilators

Medical device manufacturers serving the non-invasive oxygen ventilator market need to comply to the IEC60601-1 for the safety and essential performance of medical electrical equipment. PST offer a range of sensors using various sensor technologies complying to the IEC60601-1 standard:

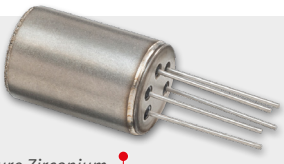
- Optical
- Zirconia
- Electrochemical

Our expertise can help define what technology is most suited to your oxygen ventilator based upon your requirements. Please find a small range of sensors that PST can supply for this application below:

Zirconia Oxygen Sensor

The Miniature Zirconium Dioxide Oxygen Sensors can be PCB mounted and are used when measuring ambient gas with the complete sensor immersed in the atmosphere which is to be measured.

- Long operating life
- Easy single point calibration
- Option of two response times and a temperature range of -100 to 250 °C



Miniature Zirconium Dioxide Oxygen Sensors

PSR-11-917-M2

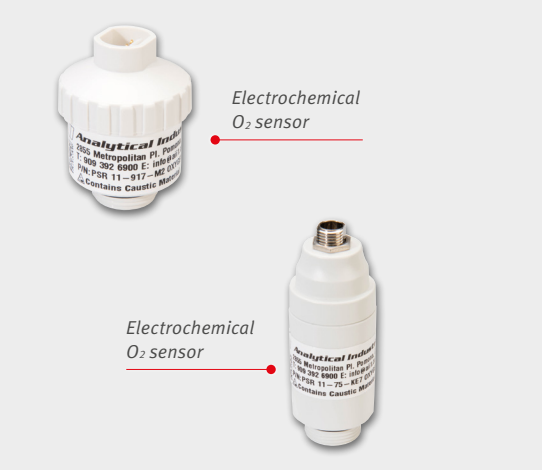
Advanced galvanic type % oxygen sensor with excellent stability and accuracy under stringent applications.

- 0...100% measuring range
- 0...45°C operating temperature
- 60 months expected life

PSSR-11-75-KE7

Advanced galvanic type % oxygen sensor with excellent stability and accuracy under stringent applications.

- 0...100% measuring range
- 0...45°C operating temperature
- 60 months expected life



Environmental Monitoring Regulations for GMP Applications

The US Food & Drug Administration (FDA) is an agency within the Department of Health and Human Services, a government agency that establishes and publishes regulations that govern the sale of various products to protect and promote public health. Medical devices are one of the products regulated by the FDA.

The FDA requires that manufacturers establish and maintain quality systems to ensure that their products meet the usability and safety needs of their customers. Quality systems for products that are governed by the FDA are based on Good Manufacturing Practices or GMP's. The GMP compliance requirements for medical devices are outlined in the Code of Federal Regulations (CFR):

- 21 CFR Part 808
- 21 CFR Part 812
- 21 CFR Part 820, this is the main interest in terms of environmental monitoring

The PST product range can help comply to the FDA 21 CFR Part 820 Quality System Regulation, Subparts G and M.

Subpart G – Production and Process Controls

The Rotronic Monitoring System (RMS) is a real time environmental monitoring system designed for GxP applications that can help monitor critical process parameters and other parameters to ensure product quality. The PST teams worldwide can offer support in terms of service, calibration, for control and monitoring equipment, and calibration procedures as well as system validation based upon the GAMP®5 recommendations.

Subpart M – Records

RMS is a FDA 21 CFR Part 11 conform software solution that offers full data integrity for record purposes. As the environmental monitoring is part of the device history and quality system it is crucial that these records are maintained during a minimum of 2 years from the date of release for commercial distribution by the manufacturer.

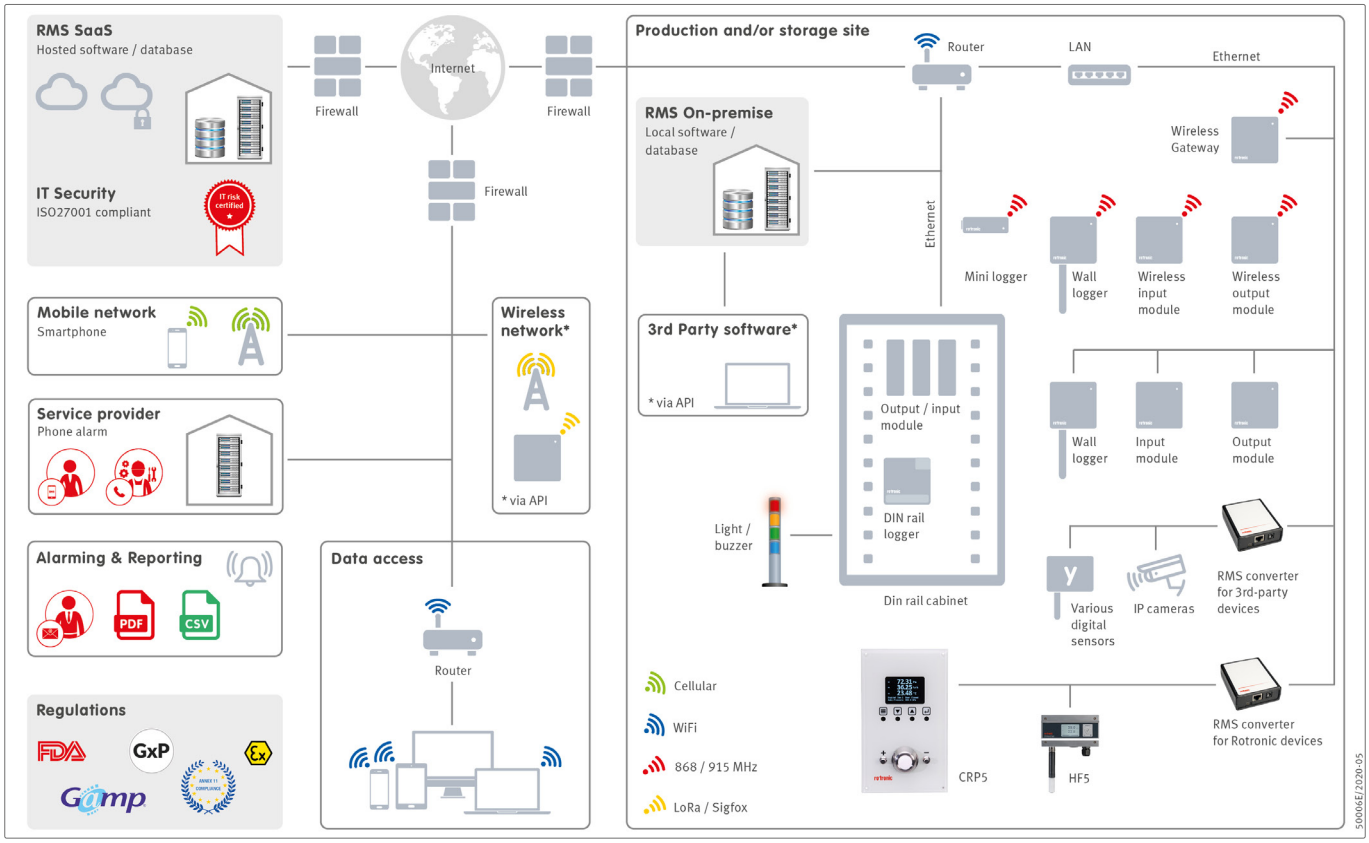
The ISO 13485 Quality Management for medical devices is an internationally agreed standard that sets out the requirements for a quality management system specific to the medical devices industry and aligns with the FDA 21 CFR Part 820. However, an ISO is only a guideline and not a regulation and as of such is not mandatory but does offer various benefits such as demonstrating compliance with regulatory and legal requirements and ensuring the establishment of QMS practices that consistently yield safe and effective medical devices.

RMS helps fulfil the following ISO 13485 requirements:

- 6.3 Infrastructure
- 6.4 Work Environment and Contamination Control
- 7.5.1 Control of Production and Service Provision
- 7.5.6 Validation of Processes for Production and Service Provision

PST can also offer monitoring solutions to comply to the ISO 14644 standards for cleanrooms and associated controlled environments.

RMS Architecture Possibilities



Process Sensing Technologies

The PST Group consists of a group of manufacturers who together provide an unmatched suite of instruments, analyzers and sensors for precision measurements in industrial process control, environmental monitoring, natural gas and petrochemical processing as well as applications in food and medicine.

Using our products, customers save millions of dollars each year through increased energy efficiency in their processes and reduced process disruptions. The quality of food, medicines, semi-conductors and thousands of manufactured goods depends on reliable measurements of critical parameters such as humidity, oxygen, CO, N_2, H_2, hydrocarbons, pressure or CO_2 during production, storage and transport. Our products directly improve the profitability of our customers and help them to stay compliant with stringent industry regulations.

We own and manufacture the sensing technologies used in the majority of our products. This allows us to remain in a strong leadership position and pass on the benefits of our innovation to our customers.

PST Leading Brands

Analytical Industries – Pomona, CA, USA
Michell Instruments – Ely, UK
Rotronic – Bassersdorf, CH
LDetek – Quebec, CA
Dynament – Mansfield, UK
Ntron – Navan, IE
SST Sensing – Coatbridge, UK

Market Leader

In oxygen sensors and gas analysis instrumentation, humidity and trace moisture instrumentation, impurities in gases analysis and flammable gas sensors.

Group Facts

- OEM for leading AM technology manufacturers
- 22 service and sales subsidiaries
- Global support network with 50+ authorized distributors
- 8 global manufacturing locations

Humidity *Temperature* *Dew Point* *Water Activity* *Differential Pressure* *Oxygen* *Flow* *CO_2* *Impurities* *Flammable Gases*

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