The Complete Guide to Choosing a Medical Sample Lines Vendor

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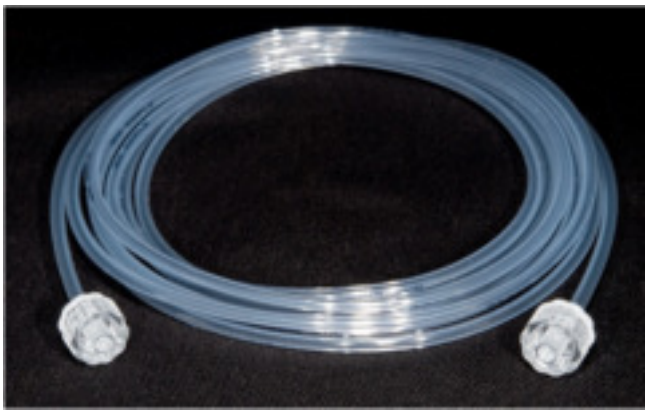

The Complete Guide to Choosing a Medical Sample Lines Vendor

Finding a qualified vendor for medical breath sample lines is not an easy task. On the surface, the product appears simple and easy to make. The application, however, reveals a number of technical challenges amplified by issues found in the day to day use of the products in the field. Plus, regulatory requirements necessitate choosing a company with the right quality approvals and registrations.

Perma Pure was the first to produce Breath Drying and Sample Lines for manufacturers of OEM Medical Equipment with Nafion® moisture reducing technology to make accurate analysis possible. Today, we are a major supplier of breath gas sampling lines to the global medical industry for capnography, anesthesia monitoring, PFT, and other types of patient monitoring.

Capnography provides information about CO2 production, pulmonary (lung) perfusion, alveolar ventilation, respiratory patterns, and elimination of CO2 from the anesthesia breathing circuit and ventilator. Capnographs usually work on the principle that CO2 absorbs infra-red radiation. A beam of infra-red light is passed across the gas sample to fall on a sensor. The presence of CO2 in the gas leads to a reduction in the amount of light falling on the sensor, which changes the voltage in a circuit. The analysis is rapid and accurate.

Water vapor interferes with the proper operation of analytical equipment in many ways. When designing your equipment it is important to understand the strengths and limitations of the different moisture removal methods available to you. This short guide was written to help you understand the problems inherent to breath sample lines and to make it easy for you to find the supplier that can be your long term partner.

To begin, we'll describe three areas where moisture removal is critical to obtaining accurate results and long term reliability of the analysis equipment:

- **Moisture Interference in Infrared Analysis used for CO_2 Monitoring & Measurement -** Water vapor appears on the scale in the same region as the CO_2 peak, making the results difficult to

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read and introducing inaccuracies based on the operators' interpretation of the results. Removal of the water, in vapor phase, preserves the CO_2 level while eliminating interference.

- **Moisture build-up in Sample Lines** - Condensation from the breath gas sample stream can collect in the sample lines, a problem normally found when the fully saturated sample at body temperature is brought into contact with the lines at standard room temperature.

- **Moisture Collection in the Sensor Cell -** Condensation in the sample will eventually reach the analyzer, and will cause irreparable harm to the sensor and render the equipment unusable – a problem commonly found when the fully saturated breath sample (at body temperature) is brought to the analyzer at a colder room temperature.

Conventional breath gas sample drying methods are fraught with difficulties and compromises, making it difficult or costly to get consistent and accurate results - and they may even increase infection risk.

Water Traps are inexpensive devices that are placed in line with the gas flow. They simply allow the water to condense out as the temperature of the gas cools to ambient. Unfortunately, they are very non-specific; not only do they remove whatever gases condense at the lower temperature, but also at least a portion of whatever gases dissolve in the condensate, potentially making your analysis inaccurate. Additionally, warm, moist air provides an ideal environment for the growth of micro-organisms such as bacteria and viruses which can collect and grow in the trap over time.

Desiccant dryers or Coalescing Filters function by binding water to an absorbent. The absorbent is typically a solid (such as silica gel) that binds water to its chemical structure as water-of-hydration. Desiccants are very simple to operate. Unfortunately, like water traps, they are very non-specific and remove many compounds other than water. Unlike water traps, water cannot be removed from desiccants by simply draining it away. While in operation, desiccants become progressively loaded with water and must periodically be regenerated by replacement of the desiccant or by driving off the water by heating in an oven. For most analyzer applications, this means a regular change-out of the desiccant which is time consuming and expensive over the life of the analyzer. Like with water traps, warm, moist air provides an ideal environment for the growth of micro-organisms such as bacteria and viruses which can collect and grow in the filter or desiccant over time.

Perma Pure's Unique Nafion®-based Breath Gas Sample Lines – The Best Performance Option

Breath Gas Sample Lines with Nafion® tubing take advantage of the unique moisture transfer properties of the material. Nafion® is highly selective - its unique chemical structure allows it to transport water vapor across the membrane without the loss of any other compounds. Depending on the relative water vapor pressure difference (concentration gradient) between the inside and the outside of the tube, moisture will rapidly move from one side of the membrane to the other. Perma Pure developed the ME

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Series of moisture exchangers with the Nafion® tubing exposed to atmosphere as a cost effective way to dry breath samples for analysis.

When Moisture is not a Problem

Some short-term monitoring equipment is less susceptible to moisture damage and for those applications we provide a wide range of conventional breath sampling lines. We offer materials such as PE, PVC, or coextruded PE/PVC and a wide variety of connection ends, filters and construction variations available to meet your specific requirements. Our in-house molding capabilities allow us to provide the connectors and exact tube length required to meet your design requirements.,

State of the Art Production Capabilities Support You

Suppliers to the medical industry need to understand the industry's requirements and speak its language. Perma Pure has become one of the industry's most trusted vendors, becoming a high volume OEM supplier to the world's prestigious medical device manufacturers with proven results in capnography, anesthesia monitoring, and metabolic testing. We provide:

- ISO 13485 certified and FDA Medical Device registered production facilities assure top quality and the cleanliness expected
- 100% leak and flow testing of every sample line to make sure each will work when needed
- Private Label and Custom packaging available eliminate the need for a third party for kitting

Design Strength and Experience

Perma Pure can help you design and develop the next generation of sample lines to meet your cost and performance targets. We offer you:

- ISO 9001 certified design and development capabilities
- Over 40 years of materials and applications experience to help you solve your technical problems
- A wide variety of common medical connectors available to interface with your existing or future equipment designs

Emphasis on Excellent Customer Service

Perma Pure is committed to providing the global medical industry with the high service level expected:

- Fast lead times, even for large quantity orders
- KANBAN just in time stocking programs available
- Interface with Ultriva and Nocturne Supply Chain Management Software

Additionally, Perma Pure LLC is a Halma company, and as a result has access to technology, investment, and manufacturing in support of a global business. Contact us today with your application requirements!