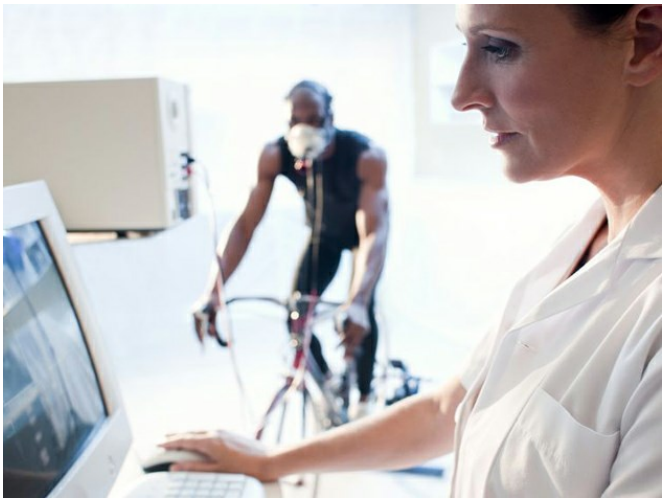
DATASHEET APPLICATION NOTE A094-ME09 - QUALITY CONTROL FOR RESPIRATORY PRODUCTS

APPLICATION NOTE A094-ME09

Quality control for respiratory products

There are many respiratory products used in the world, for example spirometry and ergospirometry devices. A spirometer will measure the volume of air movement into and out of the lungs where Ergospirometry is a diagnostic procedure to measure respiration and gas metabolism during an ergometer exercise, e.g. using a hometrainer.



In numerous medical fields you will find these products; cardiology, exercise physiology, sports medicine, etc. These are used for patients that have trouble breathing, e.g. someone suffering from chronic respiratory disease such as asthma or emphysema. In emergency care patients can profit from it suffering from heart attacks, stroke or shock. But even athletes use this technology testing their condition and endurance.

The big question is how to get the best performance of these devices? Validation is the magic word. For this Relitech designed a Metabolic Simulator.

Application requirements

In order to keep a high performance of respiratory products, such as lung function devices, and to meet the demands of legal regulations (ISO13485) as well, they need to be validated. The current situation in quality control regarding devices like these, is that it's limited due to the fact that each sensor (O_2, CO_2 and flow) is calibrated separately, disregarding the critical dynamic interaction between each sensor.

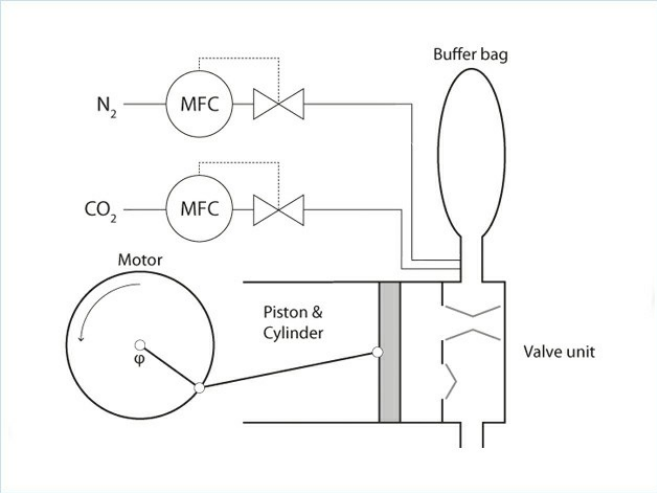
Important topics

- Linearity
- Reproducibility & accuracy
- Cross sensitivity, insensitive for other gases

Process solution

The Metabolic Simulator is a mobile device designed for on-site testing of respiratory products such as lung function machines. The simulator mixes pure nitrogen and carbon dioxide by using two Bronkhorst thermal mass flow meters (series EL-FLOW Select). Cross sensitivity is an issue here, it is important for the flow meters to be insensitive for other gases, as density is often an issue in these accurate measurements. Besides cross sensitivity and accuracy the reproducibility is crucial in these linear measurements.

The purpose of the mass flow controller is to generate a certain flow to calibrate the device. This flow has to contain a specified amount of oxygen and carbon dioxide. Carbon dioxide will be injected by 1-6 liter/min. However, to reduce the oxygen concentration in exhaled breath nitrogen is used to decrease the level of oxygen, with 1-20 liter/min.



Flow scheme

By mixing those two gases – nitrogen and carbon dioxide - breathing gas exchange patterns can be generated, real-time and extremely close to authentic human breathing patterns. The results are so-called capnographs – a monitor of the inhaled and exhaled concentration or partial pressure of carbon dioxide - that resemble the ones of for example, athletes. On the readout display of the Metabolic Simulator the capnograph values are visible. $V'CO_2$ represents the exhaled amount of carbon dioxide and $V'O_2$ is the amount of oxygen inhaled. BF is simply an abbreviation for breathing frequency.

Developing the metabolic simulator, Relitech was looking for compact and highly accurate mass flow meters and controllers as they crossed paths with Bronkhorst. The compactness of the thermal mass flow meters of the EL-FLOW Select series helped Relitech developing a more compact simulator.

Recommended Products



EL-FLOW SELECT F-201AV

- Min. flow 0,4…20 ln/min
  Max. flow 0,6…100 ln/min
- Pressure rating 64 bar
- Compact design
- High accuracy and repeatability

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