

CRITICAL BAG MATERIAL CO₂TR SPECIFICATION IN MEDICAL PROCEDURES

Special attention is required regarding the carbon dioxide transmission rates (aka CO₂TR) of blood storage bags used for medical procedures. The CO₂TR of the bags must be completely understood, as this is often a matter life-and-death.

Challenge

Blood/IV bags and tubing are mostly made of polyvinyl chloride (PVC) or other polyolefins having high OTR and CO₂TR. This creates an environment to maintain fresh blood containing plenty of oxygen while preventing CO₂ build up. In some other applications, medical bags require a good CO₂ barrier (PVC with SiO_x coatings, etc.) to preserve the shelf life of critical medical solutions. Thus, there is a need to measure CO₂TR, ranging from very low to very high.

Application

For temporarily storing donated blood and/or medical saline solutions, plasticized PVC or other polyolefin bags are widely used due to their low cost, and disposability without worrying about cross contamination. Usually, PVC bags have high gas permeation values around 3000 cc/(m² · day) for CO₂TR. These high OTR and CO₂TR materials keep the blood in the bag fresh, facilitating oxygen ingress and excess CO₂ egress.

However, during some medical procedures such as dialysis, medical bags require very high gas barriers. As healthy human beings we use our lungs to inhale oxygen from the environment to keep us alive, and exhale metabolically produced CO₂ as waste gas, or use our kidneys to rid our bodies of toxins and



*Medical Bags are Used
in Various Medical
Procedures*



CO₂TR TEST IS CRITICAL IN MEDICAL APPLICATIONS

excess CO₂. For patients with lung or renal diseases, their blood needs to be cleaned regularly via dialysis, either by hemodialysis (cleaning blood by the filtration system inside a machine) or peritoneal dialysis. In a peritoneal dialysis, special solutions (with optimized PH levels) are fed into the patient's abdomen. The toxins are cleaned by using the inside membrane lining of the patient's abdomen (the peritoneum) as the filter, then waste liquid is drained out. It is critical for this medicated solution to maintain the drug's chemical stability, pH, and concentration during its expected shelf life. The PH level is very sensitive and potentially may be altered by only 400 ppm of atmospheric CO₂. The average CO₂TR requires $\leq 1.35 \text{ cc}/(\text{m}^2 \cdot \text{day})$ for bag materials.

Solution

Facing a potential life-or-death scenario, accurate test methods must be used to guarantee the quality of the packaging materials for medical bags. So, what is the method to test these materials for CO₂TR ranging from very low to very high? The solution is the MOCON PERMATRAN-C 4/30 Carbon Dioxide Permeation Analyzer. Compliant with ASTM standard F2476, while being equipped with a Modulated IR Sensor only sensitive to CO₂ molecules, it provides very accurate and repeatable test results within a wide measurable range from 0.5 to 8000 cc/(m² · day). This analyzer has the capability to test not only film samples, but also package samples such as medical pouches or other devices.

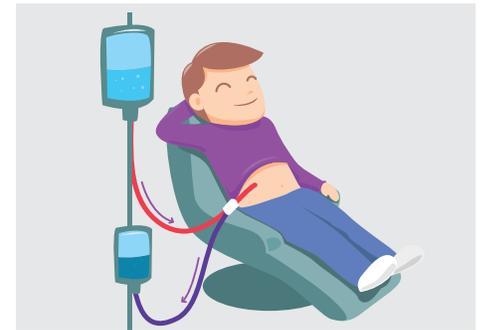
Benefits

- Modulated IR Sensor for short exam times, accurate and repeatable CO₂TR results.
- Removable cartridges for easy sample preparation and more consistent results.
- TruSeal feature to obtain more repeatable results.
- Automated gas flow and temperature control.
- Both film and package samples can be tested.
- Fully compliant with ASTM F2476.
- Software complies with FDA 21 CFR Part 11 that is important to healthcare industry.

*Hemodialysis dialysis
Procedures*



*Peritoneal dialysis
Procedures*



*PERMATRAN-C 4/30
Carbon Dioxide
Permeation Analyzer*



Conclusion

The PERMATRAN-C 4/30 is a very trusted CO₂TR analyzer for low-to-high-level barrier materials. Frequently used medical devices such as blood or IV bags, and medical tubing can be analyzed as films or whole packages. Ideal for both R&D and QA/QC processes. It is highly recommended to use the most accurate test methods available to characterize healthcare packaging materials where accuracy is crucial to saving lives.