Specialty Medical Gases—A Cinderella Story

A Special Report from The Linde Group

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At the mention of medical gases, the first products that usually come to mind are the oxygen used for breathing therapy and the nitrous oxide (laughing gas) used for conscious sedation. These vital gases are used extensively in healthcare. However, there is another group of gases supplied less frequently and in smaller quantities, but which are just as vital to patient welfare —"Cinderella" specialty medical gases.

"Just like Cinderella in the famous children's story, this group of gases is small, helpful, and largely unnoticed," says Steve Harrison, Head of Specialty Gases and Specialty Equipment for Linde Gases. "However, they are actually at the heart of specialty medical gas supplies."

In this article we review the Cinderella specialty medical gases that are used every day at hospitals and medical laboratories and by clinicians and others that service the healthcare industry—and for which quality is critical.

Test Gas Mixtures

Test gas mixtures are used to understand the status of patient health. The criteria used in their manufacture differ from that of therapeutic medical gases. While the same extremely rigorous quality standards apply, the content of specialty gases has to be accurately measured to ensure that all components are present and remain at precisely the right levels once they are produced.

These gases are used to test or calibrate some of the principal instruments used in hospitals today. The efficient calibration of medical equipment, used either directly or indirectly in the treatment of patients, is imperative. Harrison says the technology required to produce these specialized and often mixed calibration gases—whether to 100 or 1,000 parts per million—is extremely sophisticated. Maintaining the mixtures at the required levels is critical.

Among the most common tests carried out on patients are pulmonary or lung function tests. This group of tests uses sophisticated diagnostic instrumentation and mixes of Cinderella specialty medical gases that contain low levels of carbon monoxide. The amount of carbon monoxide in the patient's exhaled air is measured, which indicates lung functionality. Since patients' health and diagnoses often depend on the accuracy of these readings, highly specialized gas mixes are used to calibrate this equipment on a regular basis. The lung diffusion gases are often dispensed on prescription, whether used for inhalation or calibration of the analytical instrument, since the same gas cylinder is used for both purposes.

Blood gas analysis, also called arterial blood gas analysis, is a test that measures the amounts of oxygen and carbon dioxide in the blood, as well as the acidity (pH) of the blood. The equipment used to conduct this test requires frequent calibration to ensure accurate and reliable readings. Like lung diffusion gases, the calibration gases required for blood gas analysis are considered Cinderella gases.

Blood alcohol testing using breathalyzer equipment is another test gases category. These tests are commonly conducted in the gaseous phase by testing the level of alcohol in the driver's breath, but the test is also carried out using blood samples. Either way, the instrument used must be perfectly calibrated and tested regularly to ensure an accurate reading as results may be used as evidence in a prosecution. Accurate readings are so critical that national accreditation bodies, like the United Kingdom Accreditation Service (UKAS), have established ethanol-in-air calibration standards for evidential breath testing. In the US those standards must be certified by the gas supplier and the breathalyzer equipment certified by the National Highway Traffic Safety Administration. Calibration gases that have been accredited against these standards allow local traffic authorities to apply the breathalyzer test with confidence that the reading will be accurate and will hold up in a court of law.

Incubators

Specialty gases and mixtures are also essential for the proper functioning of incubators. These important medical chambers create controlled environmental conditions with elements such as temperature, humidity, and oxygen concentration, for the care of vulnerable infants.

Incubators are also used to maintain the integrity of body parts and tissue destined for transplants and for growing certain cultures to create an aerobic or anaerobic cell growth environment. This is particularly important when identifying the presence of Methicillin-resistant Staphylococcus aureus (MRSA), the bacterium responsible for several difficult-to-treat infections in humans.

"It is very important to have a controlled atmosphere that supports the intended process," says Harrison. "When growing aerobe organisms, the ambient atmosphere is based on oxygen or air, and when anaerobe organisms are cultivated the atmospheres are based on nitrogen or carbon dioxide. Both types usually have a carbon source for maximizing the growth. A different type of growth control occurs when sterilizing mixtures are used for the opposite purpose—to get rid of all organisms.

"While temperature control is not our business, the exceedingly precise nature of the incubator's gaseous environment is very much so," according to Harrison. "Each specific environment lends itself to the preferential preparation of cells that identify certain types of bacteria."

In vitro fertilization (IVF) eggs and embryos are also stored in IVF incubators. These incubators must have a very clean and constant environment. The IVF mixtures are typically either five percent carbon dioxide in air, or five percent carbon dioxide, five percent oxygen in nitrogen.

"A steady and rigidly controlled stream of gases flows through an incubator's chamber continuously, so the quality of the gas mixture must be of the highest order and must be repeatable in order not to compromise the incubator's function," says Harrison. "Linde is able to provide our medical customers with certificates that guarantee the composition of these mixes and are able to prove accuracy of a given mixing tolerance. Our HiQ® specialty gases range has many products that support this field, embracing high purity gases, accurate gas mixtures, precision engineered gas supply systems, and high quality support services."

In the biopharmaceutical arena, plants and trees are harnessed to grow and synthesize the chemicals used in pharmaceutical preparations. Incubators are used to grow many of the plants that are precursors to pharmaceutical ingredients as temperature, humidity, and gas mixtures are outcome-critical.

Anesthetics

Anesthetic delivery devices also rely heavily on the Cinderella specialty medical gases. During operations carried out under gaseous anesthesia it is critical to achieve and sustain the right gas mixture that the patient inhales. Although pure oxygen is generally used, this is often coupled with nitrous oxide for its pain-relieving properties. Nitrous oxide also lowers the amount of actual anesthetic used. Other widely used gases in general anesthesia are desflurane, sevoflurane, and isoflurane.

Anesthesiologists depend on the integrity of these highly sophisticated anesthetic delivery devices. To ensure accuracy, these devices require testing and calibration with accurate calibration gas mixtures.

"The most sensitive medical devices are found in the heart of the hospital—the operating theater," says Harrison. "These devices are tested and calibrated using specialty gases which are supplied in small quantities, in small cylinders, much like aerosol cans. Most people rarely see them or hear of them, yet they are completely critical for the safe conduct of the sophisticated surgery carried out these days."

Pure Gases

Pure gases, as opposed to gas mixtures, also play a significant role in the healthcare industry where they are used in diagnostic work. Clinical laboratories conduct sophisticated tests on patient blood and urine samples for hospitals and doctors. High-tech instrumentation such as liquid chromatography-mass spectrometry (LC-MS) and high-performance liquid chromatography (HPLC) are often used for in this testing.

LC-MS is a powerful analytical technique used in industries requiring very low detection limits of sometimes unknown samples. In some LC-MS procedures, high purity nitrogen is used to remove solvent from samples before introducing the sample in to a mass spectrometer. Pure helium is also used for degassing in liquid chromatography.

HPLC is a form of column chromatography. It has the ability to separate and identify compounds that are present in any sample that can be dissolved in a liquid. This equipment needs high purity gases such as nitrogen or helium to operate accurately.

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Sample Storage

In the liquid phase, nitrogen is used by the health care sector for its properties of extreme cold. Liquid nitrogen (LIN), for example, can be used to store biological samples indefinitely, without risk of degradation, at temperatures as low as -196 degrees C. This capability also has important implications in the realm of human fertility, where semen and eggs are stored for future use.

"Storing medical samples with LIN allows them to stay healthy indefinitely," says Harrison. LIN also makes it possible to freeze samples rapidly, so the potential damage associated with slower freezing processes, where the water crystals freeze in a different way and cause tissue damage, is avoided.

LIN samples also are now being use in litigation procedures involving medical treatments that have gone wrong.

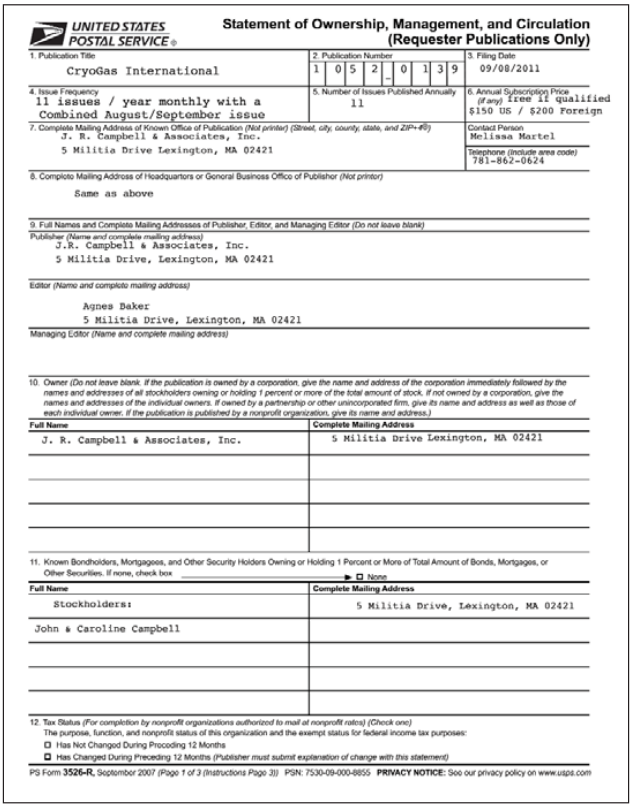
As Harrison explains, "For example, was a particular biopsy sample analyzed correctly? In cases like this, the presence of a duplicate sample that has been preserved using LIN and stored for this very purpose, means the tissue can be tested again—even years later—to verify the original result. These days, medical groups in a number of countries take duplicate samples to protect themselves in the case of litigation. The critical factor here is maintaining the integrity of the sample in the long term."

In the UK and the Netherlands, Linde now operates "cryopreservation" facilities. Linde's BOC Cryobank in the UK is a state-of-the-art facility dedicated to cryogenic bio-storage of irreplaceable samples. The concept of storing back-up or additional samples at an off-site location is intended as an additional security feature, should an unforeseen incident affect the primary facility. Linde Gas Cryoservices in the Netherlands also specializes in the field of low temperature technology, offering extensive services in temperature controlled freezing, cryogenic storage, and logistic management of biomedical and pharmaceutical material.

"Liquid nitrogen can be a hazardous substance to handle, so it makes sense to hand over this requirement to a gas company whose personnel have the correct training and who has the appropriate equipment to manage this complex technological process," according to Harrison. "The hazards associated with working with LIN include the risk of asphyxiation when used or stored in poorly ventilated areas, cryogenic burns and frostbite when unprotected flesh is exposed to it, and hypothermia associated with the low air temperatures arising from proximity to the liquefied gas.

"Although we've been supplying LIN to customers for the past 50 years and supporting customers with training in safe practices, protective clothing, and gas detection equipment to identify breathable or unsafe atmospheres, the establishment of proprietary cryobanks is a sign of a definitive shift in the medical industry. It is part of a global outsourcing trend that is seeing businesses opting to focus on their core competencies and outsourcing other requirements to appropriate service providers." ■

For more information on Linde's Cinderella specialty medical gases and equipment visit http://hiq.linde-gas.com or contact press@linde-gas.com.



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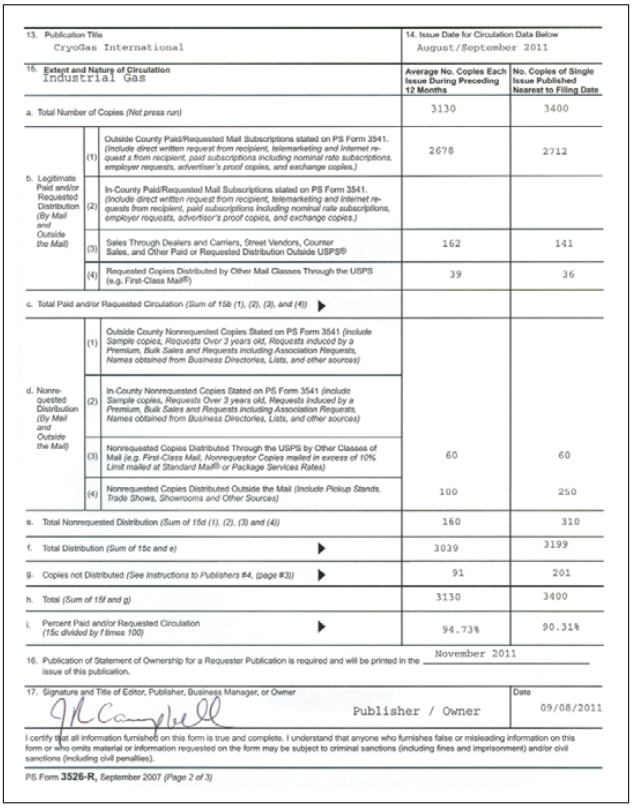

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