PROPORTION-AIR

proportionair.com 877.331.1738 info@proportionair.com

ACCURATE PRESSURE CONTROL FOR MEDICAL BALLOON MANUFACTURING

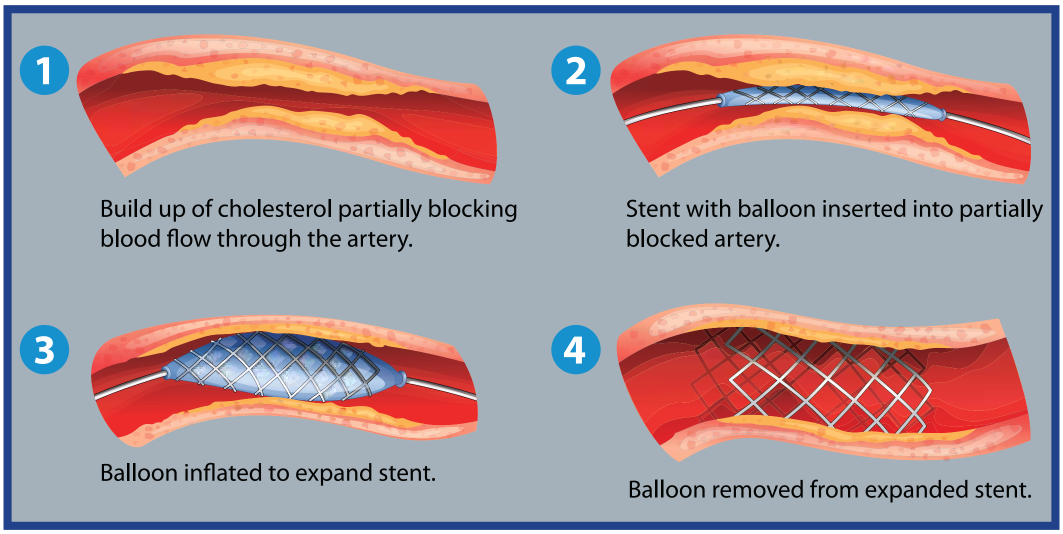


Fig. 1 *Stent with balloon angioplasty*

- *What are medical balloons and why their manufacture requires precise control*
- *How electro-pneumatic pressure regulators work and how they can used in medical manufacturing applications*
- *Common applications where pressure control is critical during the manufacture of medical balloons*

OVERVIEW

Production of vital medical equipment like angioplasty catheters and other medical balloons requires more than maintaining a single static pressure. This whitepaper will explain three applications where accurate and repeatable dynamic pressure control is imperative.

Every year in the United States nearly 1 million angioplasties (also known as percutaneous coronary interventions or PCIs) are performed. By 2026 the market share of the interventional cardiology devices is estimated to be valued at over $4.1 billion. Medical balloons are also used in many other procedures, such as dilation of arteries, stent placement, positioning other devices or instruments, occlusions, and as a localized delivery method for medication. Needless to say, competition in this segment is fierce and companies are constantly trying to innovate and improve their processes. Other data shows that device manufacturers spend approximately 7% of their annual revenue on research and development efforts. When lives are at stake, it is critical that end products meet strict quality control standards.

WHY IS PRESSURE CONTROL IMPORTANT?

Several steps in the manufacturing process require achieving and maintaining precise pressure control to produce high quality medical balloons. Accurate, repeatable pressure control ensures that inner and outer diameters are consistent with tubing and similar-shaped products, and that leak tests are performed with integrity. Closely regulating pressure can also reduce waste throughout the entire process. The majority of standard medical balloons in use today are made of plastic or plastic-derived materials such as polyvinyl chloride (PVC), polyethylene terephthalate (PET), or nylon. Ultimately the material selected depends on the end use of the catheter itself. Extra materials may be necessary for lubrication, anti-abrasion, or for drug delivery, but the basic manufacturing process for medical balloons remains the same.

MEDICAL TUBE EXTRUSION

Many medical devices made from plastic start off as tubing. Medical balloons are no exception. The granulated raw materials are poured into an extrusion machine, which heats and mixes the material. Liquified material is then forced through a rotating nozzle or screw, creating the tube form. A winder pulls the tubing downstream of the extruder. The more precise dimension of the outer and inner diameters are formed through a combination of both vacuum and positive pressure in the cooling and sizing chamber. It is critical that exact pressure be maintained throughout the entire sizing process to ensure uniformity. Vacuum breaker assemblies piloted by electro-pneumatic pressure regulators provide positive pressure to overcome the pull of the vacuum sources. During the sizing process, the tubing is also cooled and hardened to solidify the shape. The finished tubing is wound on a reel at the end of the production line.

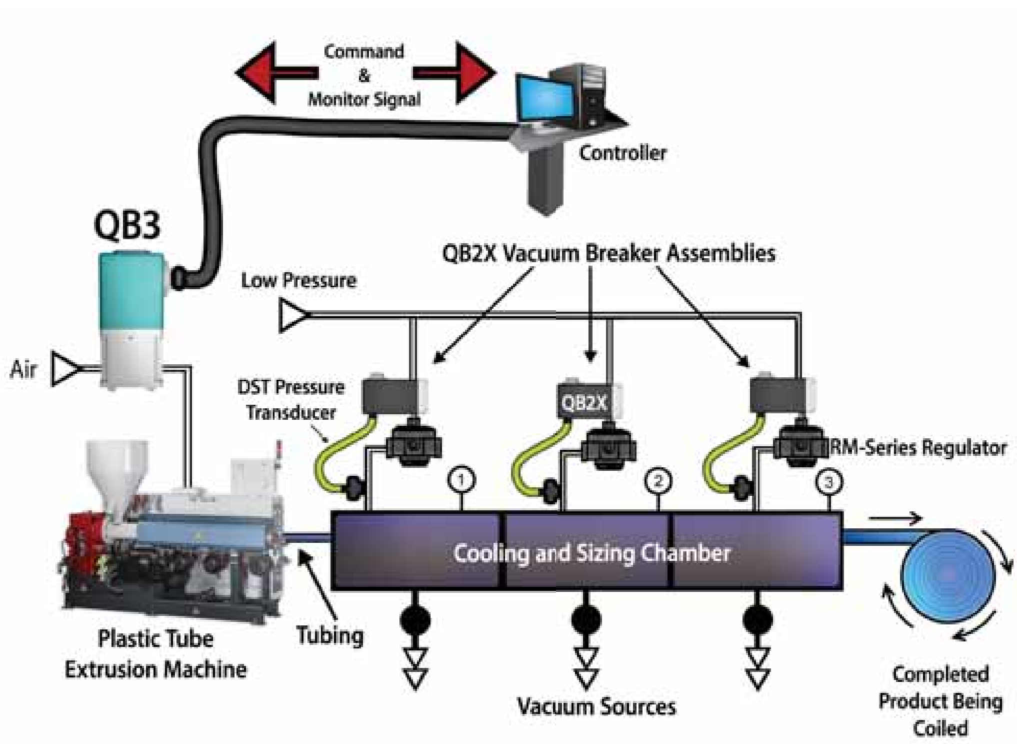


Fig. 2 *A QB3 electro-pneumatic pressure regulator is used for low pressure and constant and stable flow control for the initial tubing formation. The cooling and sizing process uses QB2X vacuum breaker assemblies to break the vacuum created in the chamber. The assemblies use 2nd loop feedback collected from integrated transducers downstream to adjust their pressure output.*

MEDICAL BALLOON MOLDING

The adoption of scientific molding principles over traditional injection molding has long been common place in the medical device manufacturing industry, and precision is a key motivator. Digital design, software monitoring, and data collection have allowed for major advancements in efficiency, preventing defective parts, and overall material waste. The most important variables in the actual device production are flow rate, pressure, temperature, and cooling time/rate. Using devices that allow proper control of these variables is absolutely necessary to achieve consistent and repeatable results.

High pressure operating range is a must for angioplasty catheter blow molding. In Fig. 3 below, a Proportion-Air GX pressure regulator controls the pressure of nitrogen used to form a medical balloon inside a heated mold. The command signal is sent to the device via controller/PLC and then analog output is returned for data acquisition. Adjustments can be made at the controller/PLC in real time to alter any variables under control by the GX unit.

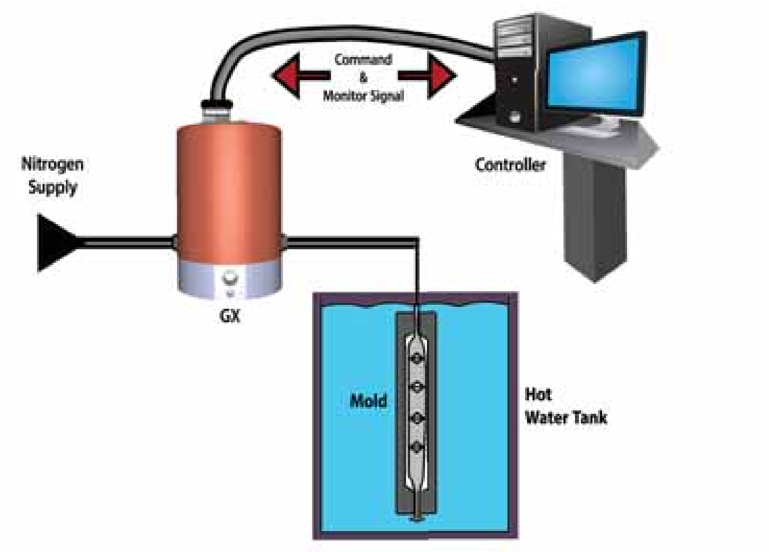


Fig. 3 *A GX pressure regulator can control the amount of pressure applied to a shape a catheter in a blow molding application. The GX can operate up to 1000 PSI with ±0.25% accuracy at full scale.*

MEDICAL BALLOON TESTING

Medical balloons go through a series of rigorous testing before use in actual surgical operations. New material developments continue to drive the production of increasingly thinner-walled balloons. The most important characteristic is the strength of the structural integrity of the balloon itself. A balloon is considered compliant, semi-compliant, or non-compliant based on the working pressure range and final inflation shape it forms. Regardless of categorization, assuming and maintaining shape without any leakage under pressure is essential. Confirmation that the new balloons meet or exceed the test criteria will ultimately determine if a new design is eligible to submit for FDA approval.

LEAK TESTING

Leak testing is integral to balloon design. Even a minute rupture that allows leakage of gas or fluid can result in serious complications, such as embolisms. In Fig. 4 below, a Proportion-Air QB3 pressure regulator is controlling the supplying and voiding of nitrogen or helium at different pressure levels to check for leakage. First the QB3 applies positive pressure to fill the balloon to a specified level. The supply is stopped and the pressure level is monitored for a specific amount of time, dependent on the level of testing. This is also known as a pressure decay test. If the loss of pressure is smaller than the accuracy window of the QB3 (±0.5%), the product is considered leak-free. The gas is then voided by the QB3 applying vacuum pressure. The gas is then voided by the QB3 applying vacuum pressure.

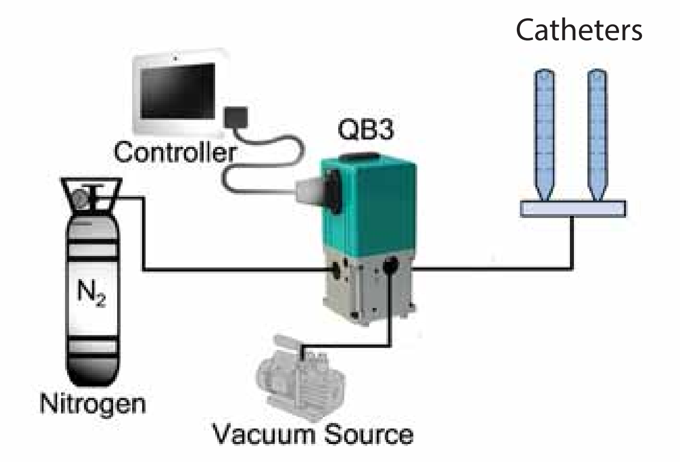
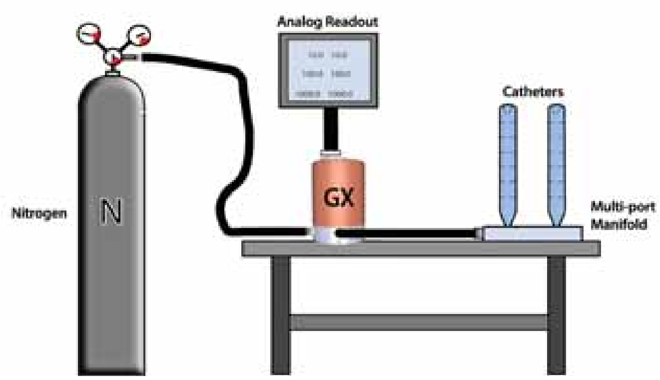


Fig. 4 *A QB3 electro-pneumatic pressure regulator is used to fill catheters with nitrogen for leak testing. Once no leaks are confirmed, it can also void the nitrogen to prepare them for use.*

BURST TESTING

Inflatable medical balloons are also subjected to a destructive test to determine the rated burst pressure (RBP). The FDA defines RBP as "the pressure at which 99.9% of balloons can survive with 95% confidence." At the pressure when the balloons begin to show signs of a loss of pressure the data is recorded and the process is repeated for catheters of different sizes and lengths to determine the final RBP for a particular line of designs. Fig. 5 shows a Proportion-Air GX high pressure regulator device supplying nitrogen to balloons on a manifold test stand. In a laboratory setting burst test with such a small part under test, precise and accurate high pressure control is a must. The standard test method is what is also known as a "step test." The supply pressure begins at an initial pressure and is then stepped up gradually through different pressure ranges with appropriate holding periods between pressure increments. When the balloon bursts, the data is recorded and analyzed for determining the RBP.

Fig. 5 *A GX Series electro-pneumatic pressure regulator can be used to control pressure in a catheter burst test. The GX supplies steady levels nitrogen in gradually higher intervals until a part under test bursts. The pressure level at the point of bursting is recorded and sent to the analog readout or controller for data acquistion.*



THE FUTURE OF MEDICAL DEVICE MANUFACTURING

Medical device manufacturers continue to develop new and innovative ways to use medical balloons to minimize the need for invasive surgical procedures. Even though these new devices continue to shrink in size, they also manage to incorporate more technology, greater connectivity, and other features. Testing this new equipment and ensuring the safe design of future products will continue to play a major role in what will influence the healthcare of tomorrow. Medical devices that require inflation or the transfer and/or storage of fluids must be free from manufacturing defects, and precision pressure control is vital to ensure a safe, quality product is produced. Pneumatics is still a top choice for medical device manufacturing given its low start-up cost, clean and reliable operation. In the past, pneumatic equipment had a reputation of being vague in its general movement and operation. Modern electro-pneumatic control equipment, including pressure regulators, has alleviated these concerns. Precision pneumatic equipment is a great choice to guarantee devices meet the demanding criteria for medical instruments.

FOR MORE INFORMATION

Looking for more info on electro-pneumatic pressure regulators or other pneumatic control devices? Please visit our website or contact our applications team at 317.335.2602 or **info@proportionair.com**.

PROPORTION-AIR