

Impact Resistant Acrylic Boosts Performance for Innovative Resuscitator

Incorporating an impact resistant acrylic polymer has helped improve the performance of a unique disposable resuscitator. Nellcor, part of Tyco Healthcare, a leading manufacturer and distributor of medical devices worldwide, recently introduced its line of INdGO™ Disposable Manual Resuscitators. Unlike previous generations of resuscitators, the new device provides a built-in INdCAP™ colorimetric carbon dioxide (CO₂) detector, enabling emergency personnel to quickly and easily monitor breath-to-breath CO₂ exhalation.

In choosing materials to design the INdGO device, Nellcor engineers tested a number of high performance plastics. However, when they failed cold temperature impact tests, the engineers turned to acrylic for a solution. Thanks to CYROLITE® G-20 HIFLO® acrylic-based multipolymer compound, the new device has proven to be compatible with the litmus paper used to detect CO₂ levels, while providing the impact resistance necessary to survive cold climate conditions.

The INdGO manual resuscitator enables the detection of CO₂ in exhaled air, which ensures that an endotracheal tube is properly inserted into a patient's trachea and not the esophagus (food pipe). "Our INdGO manual resuscitator with integrated INdCAP CO₂ detection provides caregivers with breath-to-breath confirmation that the patient is intubated properly," says Patrick Martin, Senior Project Manager, Nellcor.

Litmus paper in the INdCAP detector used to detect the CO₂ in the exhaled gas was found to be sensitive to outgassing

from certain polymers, forcing engineers to narrow their choice of available plastics to manufacture the device. Most often used for emergency response situations, impact resistance, and durability of the materials were critical factors.

"Several materials were tested for the device," comments Dan Dwyer, Senior Project Engineer. "We had used CYROLITE G-20 HIFLO compound in the past, and it proved to provide the compatibility, impact strength, and clarity we wanted for the device."

INdGO disposable resuscitators are designed with a number of features that allow first responders to quickly and properly intubate a patient during emergencies. The entire unit is latex-free to avoid complications with hypersensitive patients. A Monprene® bag material enhances refill response rates for timed and consistent air delivery, and a dual-swivel elbow with a 100 degree angle enables a wider range of motion and reduces airway torque. In addition, INdGO manual resuscitators deliver exceptionally high



levels of Fraction of Inspired Oxygen (FiO_2), critical to patients who are oxygenating poorly.

Visual Color Detection

The defining feature of the INdGO manual resuscitators is the color changing INdCAP CO_2 detector. The detector visually indicates CO_2 content of the air by changing color with every breath. This breath-to-breath detection of CO_2 content in the air lets emergency response personnel quickly verify that the endotracheal tube is correctly placed in the trachea—and not the esophagus—during intubation. The litmus paper contained in the INdCAP CO_2 detector distinctly changes from purple to yellow with each breath for up to two hours. If the INdCAP detector remains purple, indicating only air, this means the endotracheal tube is blocked or not properly in place, preventing airflow into the lungs. The presence of CO_2 in exhaled breath (end-tidal carbon dioxide, or ETCO_2) helps ensure that air is reaching the lungs and being absorbed by the patient.

In an effort to reduce the risk of esophageal intubation, many clinical organizations now recommend ETCO_2 detection for verifying proper endotracheal tube placement. The combination of the resuscitator bag and the CO_2 detector provide a convenient, cost-effective way for clinicians and first responders to meet current clinical guidelines set by the American Heart Association (AHA), American Association for Respiratory Care, the American College of Emergency Physicians (ACEP), and both the American

Society of Anesthesiologists and the European Society of Anesthesiologists (ESA), requiring the use of CO_2 detection during intubation.

The materials used for the resuscitator must not compromise the performance and accuracy of the INdCAP, and therefore polymer outgassing could not be tolerated. In tests, acrylic polymers were found to have minimal outgassing when compared to other medical grade plastics and proved ideal for this application.

Cold Weather Resistance and Hoop Stress

Because the INdGO resuscitators are used for emergency situations, Nellcor needed to ensure they could perform in a battery of conditions. The NRV (non-rebreathing valve) connector at the end of the resuscitator bag holds the INdCAP CO_2 detector and connects the rotating elbow that feeds the endotracheal tube. This connection is the mechanism that directs exhaled air into the INdCAP with every breath.

The insertion of the elbow into the connector pushes outward on the female connector ring in the housing; this outward force on the female connector is referred to as "hoop stress." Over time at varying temperatures, it was found that hoop stress caused the female end to crack and craze with certain polymers.

A commonly used Styrene-Butadiene Copolymer originally slated for the housing was found to perform poorly in low temperatures because it became too rigid. Nellcor therefore began to look into other polymers to use in place of the copolymer. Nellcor began testing

different polymers for 1,000 hours in various conditions, looking for cracking and crazing. Plastics will settle and adjust to stress by 1,000 hours and will typically exhibit any damage that could occur during that time.

Compatible Polymers

The INdCAP housing itself had already incorporated a compatible polymer, CYROLITE G-20 HIFLO compound, manufactured by CYRO Industries, which had minimal outgassing and provided excellent clarity to view the litmus paper. The litmus paper used in the CO_2 detection was reactive to certain polymers, limiting the choices that could be used for the device. Due to CYROLITE G-20 HIFLO compound's compatibility with the litmus paper, Nellcor tested it for the housing and found it could handle hoop stress even in low temperature situations. With a tensile strength of 7,000 psi, CYROLITE G-20 HIFLO compound was able to withstand the rigors of emergency response situations. The material's impact properties proved stronger than previously used materials and provided 89 percent light transmission for improved optical clarity, with only three percent haze. The material's specific gravity of 1.11 also provided Nellcor with excellent yields.

CYRO Industries
PO Box 5055
Rockaway, NJ 07866
800-225-0172
www.cyro.com