

A Call to Arms – How the Automotive Supply Base can help address the Ventilator shortage

Our New Reality

As the coronavirus continues to dominate human behavior and headlines globally, the ramifications continue to be widespread and numerous. During the past weeks, the shortage of medical ventilation units has become a primary concern for hospitals and the healthcare industry. The looming shortage of ventilators and other critical healthcare products such as gloves, gowns, and masks has the federal government scrambling for additional supply as the number of infected patients grows. On Wednesday, President Trump announced he would enact the Defense Production Act to fight the shortage of critical products.

The world now faces a shortage of ventilators due to limits in production capacity and the fact that China, Italy, and the UK have bought much of the global supply during the past two months. Governments and the global medical industry now face the prospects of fighting respiratory failure in a product market normally guarded by intellectual property protection and far lower demand. Now is the time for some much-needed innovation. Most of the major automotive manufacturers worldwide are jumping in to figure out how they can help alleviate the shortage of the lifesaving ventilators. Late Friday, GM announced that they are collaborating with Ventec Life Systems to increase their production of its respiratory care products.

In the ultracompetitive automotive space, products are designed and manufactured with a delicate balance of safety and cost. While pundits in the medical field have expressed their skepticism about the gearheads jumping into a precision medical product market, the two critical questions are whether something is feasible and how quickly it can happen. It would seem the time is ripe when the Department of Defense is seeking submissions for approval for non-FDA ventilators used by the military. This theme is similar to the World War II “call to arms” effort with the automotive industry joining the cause, not to build tanks and airplanes, but instead to support the manufacturing and supply of ventilators and other key medical products. However, the ability to go from ground zero to mass production represents a substantial challenge even in an industry like automotive, which is laden with advanced technology.

Potential Solution Paths

A number of possible channels exist and are in play given the crisis. The first priority given the immediate timeline is to help the existing ventilator manufacturers increase their output of existing designs. Industry capacity clearly is unable to provide sufficient supply, therefore driving a need for non-traditional approaches. Automotive companies, as highlighted by GM's partnership with Ventec, are working closely with ventilator manufacturers to figure out how to increase capacity, ranging from technical and manpower assistance to converting automotive manufacturing facilities over to produce these units. The potential production of complete ventilation units would most likely be under a license from an OEM with IP rights and validated designs. Government and regulatory bodies will need to be fully on-board to quickly validate and approve the changes in production plants, processes and procedures. Questions still exist if a shortfall of key resources such as assembly expertise and product testing capacity will be sufficient and can be ramped up quick enough to fill the void.

The second priority is the supply chain constraints that are limiting capacity. While the shortage of manufacturing capacity and capability of ventilators is obvious, the supply chain constraint for components is still being assessed. Once supply chain bottlenecks are clearly identified, whether it be critical parts, logistics or simply purchasing power, the automotive community stands poised to help. GM's letter to its supply base indicates that they are quickly assessing what is needed to increase ventilator production at Ventec and will reach out to individual suppliers as appropriate. To date, several automotive suppliers have been contacted and have initiated efforts to produce critical parts.

In the case of the supply chain, it would appear critical ventilator subsystem providers with specific requirements are scarce. In some cases, the expertise required is beyond producing a simple component made of metal or plastic, but rather an understanding of the critical performance specifications for the overall ventilation system. In other words, design and test capabilities may not be required for single component providers, but will certainly be welcome to improve the chances of filling supply chain shortages or shortening a successful new product launch.

In parallel to efforts to increase ventilator production, government and health care resources are scouring inventory stores and other sources for older, perhaps obsolete ventilation units that can quickly be refurbished, remanufactured, or repurposed for near term use. It has been reported that an estimated 100,000 units have been identified that may fit the bill. Automotive suppliers with remanufacturing, 3D additive manufacturing, or rapid prototyping capabilities may be called upon to help in the efforts to get these units operational and back into the medical community's hands.

Another path to increasing the commercial ventilation supply is manufacturing a simpler, more basic mechanical ventilator design that can be rapidly secured or manufactured. Currently, the

military possesses these types of ventilators that can be available if needed and can be manufactured much quicker than more complex versions. Although the supply shortage is focused on commercial applications, circumstances may lead to the substitution of these military applications during these times of crisis. Additionally, available technical data for military models may also assist companies looking to supply the commercial applications by short-cutting the development cycle and better understanding key engineering performance criteria.

There clearly has been a “call to arms” of all industries to develop simple, functional mechanical ventilators that can be mass produced in short order. Companies where similar applications exist are found in firefighting, scuba and aerospace equipment. Each requires comparable pressurized breathing systems, components and testing capabilities that are applicable to the ventilator market. While these options are in play, even with optimal fast-tracking of regulatory approvals, viable ventilator production is months away. As such, alternative ventilator products will represent the “2nd wave” of supply.

How the Automotive Industry Can Help

During times of emergency needs and unplanned innovation, matchmaking between customers and suppliers is even more time sensitive. Manufacturers with some combination of valve, electronic, sensor, tube, clean room and 3D printing capabilities should be especially poised to help during this time of crisis.

This is a rapidly evolving effort involving top executives within healthcare, industry and government. Everybody in our automotive supply base is anxious to help. While the problems are being understood and the solutions are developed, the supply base can undertake several activities to maximize readiness. First, assess your equipment and capacity to supply product at medical-level specifications. Understand if you can gain access to clean room environments. Also, experience and capacity with 3D printing may very well play a critical role and serve as a key differentiator.

Assess your core competences and product ranges as they relate to ventilators. Clearly a risk assessment is still required during times of crisis and the sourcing of component providers. Having relevant experience with product sizes, material grades and quality standards relative to ventilator applications reduces risk in the form of quality and timing. From a manufacturing process standpoint, pumps and valves, electronics, circuit boards, and sensors and tubing are the core components of most ventilator units. Again, understanding how your manufacturing processes align with ventilator component applications is a basic first step.

Human capital should be another consideration. Companies whose staffs have strong expertise in product engineering, manufacturing engineering and supply chain, will be better served for a quick transition.

Lastly, reaching out to your customer base may help you understand the key constraints and how you can play a supporting role. In the Ventec case, key suppliers will be contacted by GM Purchasing once the needs are identified.

Conway MacKenzie, in collaboration with OESA, is staying close to this rapidly evolving situation in an effort to keep the automotive supplier community informed and provide whatever assistance we can. We are in contact with automotive, medical device and health care leadership as the issues are being studied and solutions are being developed. Our intent is not to circumvent the direct communications between the OEMs and supply base rather to keep our community informed and most certainly help devise solutions, if called upon, as the problems become clearer. OESA and Conway MacKenzie have the networks to assist the automotive OEMs and Tier 1's to go deeper and broader into the supply community If required. And most importantly, any successful contribution from our industry could mean saving someone's life.

Please contact us at OESA or Conway MacKenzie if you have any questions or input.