

CASE STUDY | MEDICAL DEVICES

LITERALLY SAVING LIVES



Here's how Segue produced the life-saving ventilator in just 5 weeks by providing the Top-10 Global Medical OEM with a custom rapid-launch program and manufactured the first 36,000 units in record time.

SUMMARY

As the threat of overrun ICUs loomed amidst the pandemic, the R&D team at a Top-10 Global Medical OEM worked around the clock to launch their emergency-use ventilator to help fill the shortage. The company was poised to deploy its innovative respiratory technology in the fight against Covid-19, but faced an overwhelming supply and capacity shortage.

This Fortune 50 needed a contract manufacturing partner capable of building a supply chain and expediting product amidst allocation and price increases, and then manufacturing at speed and scale without sacrificing an iota of quality.

Rapid Results

✓
81%
FASTER

✓
14X
VOLUME

✓
0.002%
RMA%



How Segue’s ability to flex and scale rapidly delivered in record time to save lives

SITUATION

Global Crisis Demands Innovative Solutions

The Medical Top-10 had invested significant resources in design and development of its new portable ventilator. FDA approval finally came late in Q4, but by the New Year, the Covid pandemic had hit full force. Thousands of people around the globe were in urgent hospital care and massive ventilator shortages meant that doctors were having to make unthinkable choices about prioritizing treatment.

Designed by respiratory experts specifically for chaotic conditions and healthcare teams with varying skill sets, the innovative new ventilator was perfectly suited to change the course of the pandemic. Uniquely suited to overcome the challenges of the pandemic – scarcity of healthcare staff and equipment, massive influxes of patients – because of its portability and ease of use, the ventilator was urgently requested by governments in countries like France, Germany, Mexico, and the USA.

The company needed to launch and ramp at massive scale, in record time. Lives depended on it.

CHALLENGE

Ultimate Flexibility at Rapid Scale

The demands of medical device manufacturing are extensive. Because they directly impact patient safety, medical devices must meet the most stringent of quality and regulatory requirements. Medical Device OEMs and Tier I EMS providers must have the utmost confidence in their supply chains, from the power resistor manufacturer to the final system integrator. **If even the most simple of cable assemblies fails, the whole system fails.**

This Fortune 50 had relied on Segue Manufacturing Services for expert cable and harness design and production for over a decade. With our MedAccred accreditation and ISO 13485 certification we understood the importance of record-keeping and data collection across all manufacturing processes, and as evidenced by historical DPPM and RMA data, Segue had delivered unflagging high quality and reliability.

Therefore as a strategic supplier, Segue’s Xiamen team had already been part of this Top-10’s development team for three years during the new ventilator’s product design phase and FDA approval process. Segue’s cables were used in Design Validation and, following FDA approval, the companies were working to a 22-week timeline for NPI and product launch. Then the pandemic changed everything.

In this new environment, the materials and equipment that Segue had pipelined to produce 5,000 ventilators in the first year were suddenly dwarfed by the 36,000 per month that were urgently required.

The manufacturing processes developed to support a much lower run rate would require significant change.

And where would we find the expert people required to build 14 times the expected volumes?

SOLUTION

From Rapid Response to First Responders

» Lean Manufacturing Improves Throughput

Leaned Out End-to-End Process
Accelerated Video Audit & Transition Plan
Onboarded 250 People in 6 Weeks
Optimized Manufacturing Facility

» Supply Chain Leverage Mitigates Risk

Expedited Customs & Logistics
Established Continuity of Supply
Leveraged Strategic Global Relationships
Pivoted with Customer Requirements

» Vertical Integration Provides Ultimate Flexibility

SMT In-House for 'Smart' Cables
Responded Rapidly to ECOs
Leveraged In-House Overmolding Expertise
Optimized Flow for 17 Unique Assemblies

» Effective and Actionable Communication Amplifies Results

Provided 24/7 Global Response
Maximized Accountability with Daily Updates
Prioritized Open Communication & Urgency



Lean Manufacturing Improves Throughput

Segue's Lean Manufacturing and Six Sigma expertise was at the core of our solution.

We finely examined the product transfer, NPI and manufacturing processes and highlighted all areas we could reduce process cycle time while still eliminating the chance of defect generation. From there, we identified actions we could take to coordinate and streamline the transfer process and product launch to increase efficiency while driving rapid production. The teams executed an accelerated video audit with scant prep time across multiple time zones.

The Xiamen leadership team recruited and onboarded over 250 people in 6 weeks, including ISO 13485 and IPC training. Commanding third spot on China's Most Livable Cities list, Xiamen has a talent pool of professionals unequaled elsewhere in China, and Segue's team is expert.

We expedited tooling, increased production capacity and built new test fixtures in order to achieve high run rates and reduce programming and functional test cycle time while maintaining exceptional quality. We reorganized our production floor and manufacturing cells to optimize materials and product flow, employ new visual management tools and reduce travel time.



Supply Chain Leverage Mitigates Risk

Segue's location in Xiamen, the fourth largest Chinese port and container hub, allows for very efficient Customs processing and rapid transit around the globe.

Segue was able to build new supply pipelines and expedite all components by leveraging 30 years of supply chain relationships and procurement expertise, particularly in Asia where the ventilator cable assemblies were being built.

Amid the pandemic, global conditions, and our customer's strategy to overcome constraints, were continually changing. In this chaotic environment, Segue's optimal port-city location in China and our flexible business model were key to optimizing our customer's logistics strategy. For example, their procurement group was able to change carriers mid-stream, and Segue also assumed direct shipments to multiple sites.

Vertical Integration Provides Ultimate Flexibility

Segue's vertical integration was directly responsible for overcoming many material constraints. With 17 unique cable assemblies in the ventilator, from the very simple to a half dozen very complex, Segue's high-mix, low-volume, fully integrated model was critical.

Rare for a cable and wire harness assembly manufacturer, Segue's Xiamen facility has an SMT line which means that we were able to produce 'smart' cables – those with a simple PCBA/controller – in-house.

Not only did this shave off days of lead time, it also meant that the ECOs common in a new product launch could be processed rapidly, providing ultimate flexibility.

Overmolding is crucial in the manufacturing of many medical devices to protect electrical components and cable cores during sterilization and other medical processes, and to improve patient comfort. [Segue has both injection molding and low-pressure overmolding machines in-house, meaning we were able to control the lead time as well as the quality of overmolded cables in the ventilator, and provided our customer's design engineering team with flexibility to create custom cable assemblies without having to qualify and manage an additional supplier.](#)



“When our customer’s team has the visibility they need, and trust in their partner, it’s amazing what can be accomplished.”

Christine Joyner
Director of
Program Management
Segue Manufacturing



Effective and Actionable Communication Amplifies Results

We examined all transactional processes to optimize organizational communication as well as inter-company communication between the companies’ teams in North America, China and Europe.

Time zones became irrelevant. Drawing on an experienced working relationship, the Segue China leadership team spearheaded by General Manager Stephanie Lin and our customer’s global commodity management team worked tirelessly to stay abreast of daily developments and challenges. Segue’s operations executive in Boston who was point on the program was routinely texting, emailing and talking on the phone at all hours. The teams at both companies were engaged 24/7.

For six weeks, the Executive teams at both companies were often in communication daily, and convened a weekly standing call to remove any barriers and enable rapid response at all program levels. And Segue’s operations team worked non-stop to keep all key stakeholders informed, sharing milestone updates, shipment tracking and materials status daily with the customer teams that were counting on us.

“Our joint focus was on eliminating as much time as possible between decisions and results,” said Christine Joyner, Director of Program Management at Segue. “During this period, it was not at all unusual for me or my counterparts to be on the phone at 11pm! The Segue teams in China and North America worked very hard to ensure we communicated effectively across time zones and around the clock to make critical information accessible whenever it was needed. When our customer’s team has the visibility they need, and trust in their partner, it’s amazing what can be accomplished.”

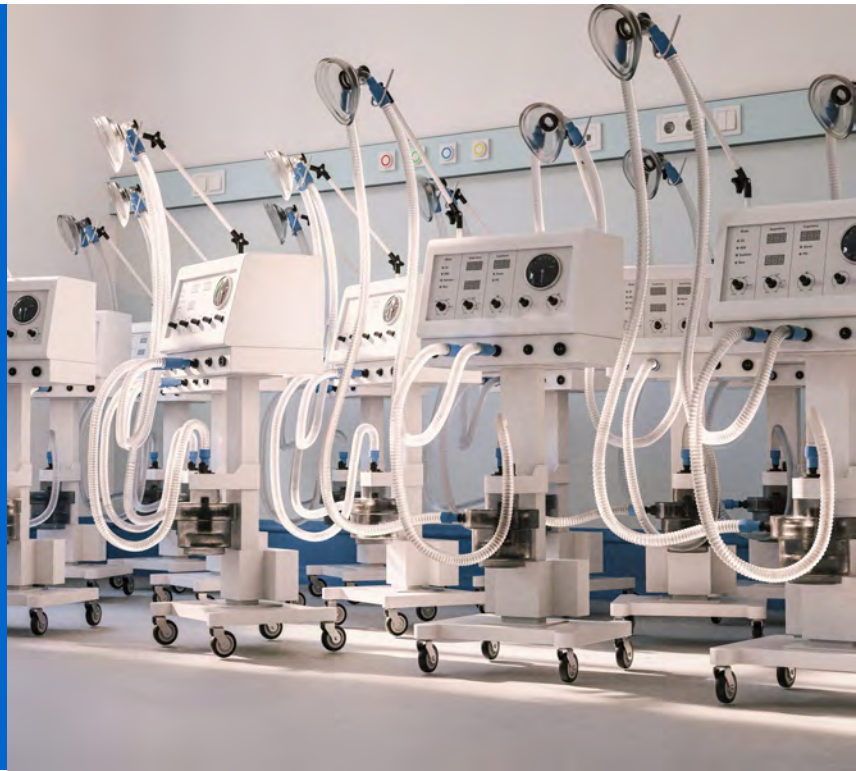


RESULTS

Seamless Transitions Produce Maximum Impact

In partnership with teams across this Medical Top-10's sophisticated organization, Segue Manufacturing Services ensured the healthcare leader was able to get its innovative, life-saving ventilator to market at scale, in record time, with exceptional reliability, amidst a global pandemic.

Segue provided the ultimate flexibility and reliability for the high-mix, mid-volume requirements, shifting seamlessly with changing demand in extraordinary circumstances.



✓
81%
FASTER

81% Faster than Expected Delivery

RECORD TIME

For this incredibly critical ramp, Segue's Engineering, Supply Chain, Operations and Executive teams compressed a 22-week lead time and delivered the first units in just 5 weeks with full-scale ramp just one month later.

✓
14X
VOLUME

14X Increase in Production Volumes

RAPID SCALE

The original production schedule planned for 5,000 units/month of each of the 17 cable assemblies in the ventilator. To combat the global pandemic, the Segue team scaled this to 36,000 units/month of each of the 17 assemblies, all within 5 weeks.

✓
0.002%
RMA%

0.002% RMA Percentage

EXCEPTIONAL QUALITY

In the hundreds of thousands of cables produced in the first three months alone, Segue received just one single RMA for 30 pieces of just one of the 17 cable assemblies, the result of an ECO.



ABOUT SEGUE MANUFACTURING SERVICES



Segue Manufacturing Services is a global contract manufacturer specializing in complex electro-mechanical integration, cable & harness assembly and engineering services with rapid Made-in-the-USA solutions and seamless transitions to our facility in China and 3PL in Mexico. Our highly skilled Engineering, Test and Manufacturing teams are expert in quick-turn NPI and launch, low-volume production, full-scale manufacturing and worldwide distribution.

www.segue-mfg.com