Helping India Breathe:
Ventilator Manufacturing During Covid-19

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Inspired by the Prime Minister’s call to fight the Covid-19 pandemic, Indian manufacturing rose admirably to the task and innovated and built a range of cost-effective ventilators. Joining hands with independent researchers and scientists, a range of top Indian companies built new models of ventilators, many of which have been deployed at the frontline of fighting the virus and helping patients.

In keeping with Prime Minister Modi’s vision of an Atma Nirbhar Bharat, the creation of this new domestic ventilator industry has shown the country’s manufacturing prowess despite all odds and shall provide encouragement and impetus to millions of entrepreneurs and engineers. This report tells the story of how this manufacturing miracle came into being and I congratulate Invest India for telling this story.

Dr Guruprasad Mohapatra

Secretary, Department for Promotion of Industry and Internal Trade, Ministry of Commerce and Industry
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Introduction

Indian companies responded efficiently to the Covid-19 pandemic by fast-tracking innovation, revamping assembly lines and expediting manufacturing of everything from N95 masks and Personal Protective Equipment (PPE) to diagnostic kits and ventilators in record time. Remarkably, from producing almost no ventilators domestically, India indigenously manufactured 60,000 ventilators in just three months.1

The third Empowered Group of Secretaries (EGoS) appointed by Prime Minister Narendra Modi was tasked with the responsibility of ensuring availability and production of essential medical equipments along with their procurement, import and distribution. At its inception in March 2020, the EGoS, chaired by Secretary, Department of Pharmaceuticals, Dr P. D. Vaghela, estimated that India would need 75,000 ventilators by June.2 The government, accordingly, gave tenders to two companies: Delhi-based Skanray Technologies and AgVa Healthcare in Noida to manufacture 30,000 ventilators in six weeks and 10,000 ventilators in a month, respectively, by the end of May.3

Since then, over a dozen entities have boosted the ventilator manufacturing capacity of India. These include large-scale automobile and Information Technology (IT) companies as well as universities and independent startups, and even National Aeronautics and Space Administration (NASA)-licensed firms replicating the Ventilator Interventation Technology Accessible Locally (VITAL) prototype developed by NASA’s Jet Propulsion Laboratory. These ventilators are mostly low-cost and affordable equipments that complement more expensive ventilators available in fewer numbers. Through a series of case studies, this report provides illustrative details of the exemplary way in which Indian manufacturing rose to the occasion to fulfil what the country needed urgently in the middle of a global health crisis. These handpicked case studies also provide an insight into the conception, development and production processes of India’s domestic ventilator manufacturers.

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Making in India

India has traditionally imported ventilators primarily from Europe and China to meet its requirements. In February, there were only eight ventilator manufacturers in the country and recognising the importance of ventilators in the near future, the Indian government banned the export of ventilators the day before the country entered a 21-day lockdown on 25 March 2020.

In March, the relevant EGoS and the Union Ministry of Health and Family Welfare (MoHFW) had indicated a projected demand of 75,000 ventilators by June 2020. Government hospitals had an estimated 8,432 ventilators in March and by May, India could boast of 19,398 ventilators countrywide. This was possible because domestic production of ventilators increased from 2,500 in February to 5,500-5,750 in March.

The EGoS had, in March, placed orders for 60,884 ventilators to HLL Lifecare Limited (HLL), a Public Sector Undertaking (PSU) under the aegis of the MoHFW, that has been the central procurement agency during the Covid-19 crisis. Of the total orders placed for ventilators, 59,884 have been given to domestic manufacturers whereas 1,000 ventilators will be imported. The projected demand and orders placed, account for the requirements of state governments too.

Under the Drugs and Cosmetics Act and Medical Device Rules, companies generally need a license to make items listed as Essential Medical Equipment. However, considering the medical urgency at hand, this rule was waived for manufacturers who had partnered with a licensed firm.
On 14 May 2020, HLL Lifecare Limited issued a Request for Proposal (RFP) for supply of ventilators to Government of India (GoI) institutes.  

Under this many major domestic players were given orders to manufacture ventilators - including Bharat Electronics Limited (in collaboration with Skanray Technologies) with whom an order for 30,000 ventilators was placed; AgVa Healthcare (in collaboration with Maruti Suzuki Limited) who were given an order for 10,000 ventilators; and the Andhra Pradesh MedTech Zone (AMTZ) with whom an order for 13,500 ventilators was placed. A number of domestic manufacturers have successfully begun deliveries of their orders, according to the stipulated time schedule and are currently at the stage of pre-dispatch inspection.

In order to better understand the process of ventilator manufacturing at a mass-scale, Invest India spoke to key industry stakeholders. Among the many manufacturers who have undertaken this essential task, case studies of a few are presented below.

14. COVID-19: Govt orders 60,884 ventilators, of which 59,884 to be made by domestic firms,” Deccan Herald, 1 May 2020.  
In response to industrialist Anand Mahindra’s announcement that Mahindra & Mahindra will undertake production of ventilators, requests poured in from many players, including startups. The company then explored a two-pronged approach. The first was an indigenous in-house development—essentially a mechanised Ambu bag with many safety features as an interim life saver. The second was a full-fledged mechanical ventilator for use in the Intensive Care Unit (ICU) for Covid-19 patients. To develop the latter, Mahindra & Mahindra approached Skanray, seeking their help in designing a simpler version of the ventilator.

Skanray’s research and development (R&D) team, led by Raghavendra H. S., explained the design and manufacturing process, technical specifications, functionality and risks of the ventilator to help Mahindra better understand the device and its complexities. The team was headed remotely by Apurbo Kirty, Head of Mobility and Connected Technologies, and every task and milestone was monitored by R. Velusamy, the Head of Global Product Development. Skanray’s team further guided the Mahindra team in taking next steps in designing the ventilator.
Mahindra has expertise in diverse sectors, from aerospace to state-of-the-art automobiles, but medical engineering was a new domain. Although Skanray openly shared the technology behind their most sophisticated ICU ventilators, both companies were examining the main challenge of scaling-up production to unprecedented levels.

The prime focus was on incorporating easily available components, and easy to use controls for paramedics with remote guidance from doctors. The scheme of the greenfield emergency ventilator was ready in two days. A team of 50 engineers including software engineers, electronics engineers, mechanical engineers, sourcing engineering and program managers was formed, working from home to detail the design, write the codes, prepare the bill of materials and identify vendors. To reduce imports and development time, automotive components used in Mahindra vehicles were selected.

The heart of the ventilator which controls all the functions was borrowed from Marazzo, Mahindra's compact multi-purpose vehicle. The control knobs of the ventilator were also taken from Marazzo's center console switch bank and AC switch bank. The Jawa motorcycle's classic round instrument cluster was used to display parameters like volume of ventilated gases, FiO2 percentage and mandatory error messages. Power backup battery was taken from Mahindra’s e-rickshaw, Treo.

The most challenging components were the pneumatic proportionating flow control valves which meter air and oxygen in the set ratio and the set volume. This is an essential component in most modern ventilators and were likely to be in high demand globally due to the pandemic. To mitigate this situation, Skanray worked parallelly with three suppliers: IMI Norgren, Parker and Emerson. This allowed to switch over to any supplier depending on availability. A task force was created to get the necessary permissions for more than 20 suppliers to open their factories and allow critical manpower to make the necessary parts. Mahindra Logistics did the mammoth task of arranging all the parts at the Mahindra Research Valley, Chennai. The first working prototype was made within seven days. Continuous software tuning and pre-certification tests were conducted with guidance and support from Skanray.

The ventilator is intended predominantly for invasive ventilation, suitable for both adults and pediatrics. It works in Assist/Control Mode Ventilators (ACMV) mode in which a patient, based on condition and need, is provided metered doses of air in addition to oxygen mixture as per the set volume, respiratory rate and FiO2. If patients try to breathe on their own, the ventilator switches automatically to assist mode thereby giving spontaneous breaths by synchronising with patients’ lung effort. The ventilator also has pressure support ventilation to help the patients wean out of ventilator support in a progressive manner. The ventilator’s simplicity allows it to be used even with minimal training. Plenty of monitoring parameters are available on Light Emitting Diode (LEDs) and gauges for users to
Whether or not they are used, I want to express my appreciation to Skanray, Dr Pawan Goenka, Velu and the joint team for their outstanding commitment and effort. You all made us proud.

**Anand Mahindra**
Executive Chairman, Mahindra & Mahindra

The new normal requires high degree of collaboration and this project is a successful example of how unrelated industries came together to work towards a common purpose. After several weeks of 24x7 work by our engineers and Skanray team, our ventilator especially designed for coronavirus is ready for production.

**Dr Pawan Goenka**
Managing Director and CEO, Mahindra & Mahindra

Skanray has been shipping these to the army and government hospitals through Infosys Foundation and Narayana Hospitals (NH) since mid-March. The engineers and management at Mahindra and Skanray wish the country will quickly brave through this pandemic so that scaling production of the ventilator will not be required.
In March 2020, Maruti Suzuki India Limited (MSIL) partnered with AgVa Healthcare to produce 10,000 ventilators in one month. On 30 March 2020, MSIL signed a Memorandum of Understanding (MoU) with AgVa Healthcare and within 10 days, on 11 April 2020, they had manufactured their first ventilator.\(^{15}\)

According to the Chairman of MSIL, R. C. Bhargava, Maruti Suzuki had been approached by the government to help in manufacturing ventilators in the fight against Covid-19. Since the company itself did not have the technology and know-how of manufacturing ventilators, they identified a two-year-old company, called AgVa Healthcare, which had a ventilator that was approved by the government. While AgVa was responsible for the technical knowledge and related matters, MSIL made use of its suppliers, experience and knowledge to help scale-up production.\(^{16}\)


\(^{16}\) “Maruti joins hands with AgVA Healthcare to supply 10,000 ventilators by May-end,” LiveMint, 24 April 2020.
Additionally, state-owned Bharat Heavy Electricals Limited also supported AgVa Healthcare by providing them with electronic chips for the ventilators.17

The companies in collaboration steadily ramped up their daily production rate and had already produced 1,250 ventilators by the end of April.18

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Almost every national and international flight was stalled. All our vendors were under lockdown and nothing was moving. Ramping up ventilator production at that moment felt like a far-fetched dream. However, in these difficult times Invest India stepped in. With a strong leadership and an able team, we were able to circumnavigate through the problems by getting access to our raw materials. Invest India helped in getting all the permissions to us and to our vendors. Not only this, they went to great lengths to get the raw materials air lifted by charter flights. This entire journey of producing such a large number of ventilator would have been impossible without the help of Invest India.

Diwakar Vaish
CEO and Co-Founder, AgVa Healthcare

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18. “Maruti joins hands with AgVA Healthcare to supply 10,000 ventilators by May-end,” LiveMint, 24 April 2020.
HP partnered with Redington 3D in India, to successfully produce 120,000 ventilator parts for AgVa Healthcare. As part of this initiative, 12 categories of parts have been 3D printed, to manufacture 10,000 ventilators that are now being deployed across India to treat Covid-19 patients. The parts include inhale and exhale connectors, valve holders, oxygen nozzles and solenoid mounts among others. As these components have complex designs and fine tolerance, it would have taken four to five months to manufacture these quantities using the conventional process. With HP 3D printing technology, these parts were printed in just 24 days.

AgVa Healthcare’s ventilator is an ICU ventilator with volume, pressure and flow control. The entire system can be controlled by a capacitive multi-touch interface without the need of compressed medical air. It is extremely portable and can be used in ICU transport or homecare. This partnership is part of HP’s global commitment in the battle against Covid-19. Till date, HP and partners have produced more than 2.3 million 3D printed parts. As part of this initiative, HP has ramped up its 3D printing team and global Digital Manufacturing Partner Network to design, validate and produce essential parts for medical responders and hospitals.

On 2 June 2020, HP Inc. announced another milestone in enabling the frontline workers and communities to respond to the challenges of Covid-19 through 3D printing.
In these unprecedented and difficult times, HP remains committed to serve the community and those impacted by the ongoing health emergency. The successful execution of the AgVa healthcare project is a testament of the capabilities of HP’s 3D printing technology and how it can remove the limitations of designing by producing complex products in short time.

Rajat Mehta
Country Manager, 3D Printing and Digital Manufacturing, HP India Market

Source: HP’s 3DP technology helps manufacture ventilators to support Covid-19 treatment in India, HP Inc. Press Release, 3 June 2020, New Delhi
The sudden onset of Covid-19 has created an unprecedented situation that strained the healthcare system beyond its capacity, and ventilators needed to treat critical patients were in short supply. In response to the government’s call for ‘Make in India’, Hyundai Motor India (HMI) connected with Air Liquide Medical Systems (ALMS), a leading French global ventilator manufacturer based in Chennai to explore collaboration opportunities. ALMS, with over 40 years of industry experience, holds a unique position as one of the very few global companies with a manufacturing facility for ventilators in India. HMI has been making in India for the global market since 1999 and has a sophisticated manufacturing set-up equipped to produce multiple models with multiple variants on a single line. The technical expertise of ALMS and large-scale manufacturing ability of HMI brought forth a natural synergy between the two companies. They entered into an agreement to ramp up production volumes of ALMS with an aim to produce 1000 ventilators, in a phased manner, to be handed-over to the Government of Tamil Nadu. During this time, HMI had also worked on an in-house design of a mechanised Ambu bag with many safety features as an interim life saver.
ALMS has multiple ventilators that fall under various categories such as ICU, emergency and home care in its product range. Orion-G, one of their flagship models, was developed in India and is CE (Conformité Européenne) marked, which certifies adherence to global health and safety standards. The easy-to-operate model designed specifically keeping in mind the needs of clinicians in India, comes with extensive ventilation modes, built-in nebulisation and displays all necessary loops and curves with a host of monitored parameters. The PSV (Pressure Support Ventilation with PEEP\textsuperscript{19}) and PSV-NIV\textsuperscript{20} modes available in Orion-G will be pivotal during clinical management of Covid-19 patients. This combined with the additional focus to source raw materials and spare parts within the country, the company decided that Orion-G was the perfect choice.

At the outset, HMI posted an expert team at ALMS facility to identify the hold-ups restricting production capacity. First, to de-bottleneck the supply chain HMI identified alternate vendors capable of meeting volume and timeline requirements, evaluated the constraints faced by existing vendors to help them ramp up production and ensured timely placement of domestic and overseas orders. These measures ensured the uninterrupted supply required to ramp up production capacity.

Next, HMI’s manufacturing engineering members closely assessed the production system, layouts and employee capabilities with an objective to increase the production volume substantially to meet the current requirement. The team made 3D layouts of ALMS manufacturing facility and redefined the process of engineering for a continuous output. Based on this assessment, the ALMS team reorganised the existing equipment to set up a high-process assembly line, outsourced select non-critical tasks and enlisted additional manpower.

The final review of the production plan resulted in a multi-layered strategy including suggestions to invest in specialised tools, jigs and fixtures and measures to implement strategic process change and material management. A critical quality test (burn test) that mandated continuous operation for 72 hours demanded a large area of space to accommodate the ventilators. Using HMI’s advanced 3D imaging, the teams understood that they could utilise the existing space by stacking the ventilators vertically. This idea increased the test capacity up to six times without having to expand the work space. The teams also monitored, assessed, reviewed and made tweaks wherever required.

ALMS created a cross-functional team, proactively streamlined the manufacturing and quality processes and monitored the work done with daily production management systems to ensure they meet the set targets. These interventions simplified the operations and increased output by five times, suitable to service

\textsuperscript{19} PEEP: Positive End-Expiratory Pressure  
\textsuperscript{20} PSV-NIV: Pressure Support Ventilation-Noninvasive Ventilation
the current market requirement. The personal commitment and dedication of every member working on this project has greatly helped overcome the challenges faced and brought forth a seamless collaboration between the teams.

The pandemic situation has not just provided a unique opportunity for two otherwise unusual allies to work together for a greater cause, but it has undoubtedly enriched the team’s personal and professional experience in the process.

Air Liquide Medical Systems is employing all the resources available to manufacture innovative, easy-to-use and high-performing ventilators and is confident that this collaboration with Hyundai will bring about a positive shift in the fight against Covid-19. As a company, ALMS India will continue to spearhead the Make in India initiative.

Anil Kumar
MD, Air Liquide Medical Systems Pvt Ltd
In the effort to save precious lives, Hyundai and Air Liquide Medical Systems are working together with the Government of India to battle Covid-19 on a war footing and we are morally committed to serve society by ensuring the delivery of a steady supply of quality critical care respiratory devices such as ventilators.

S.S. Kim
MD & CEO,
Hyundai Motor India Limited
The mission of Dynamatic Technologies was to develop a low-cost and scalable solution that could run directly from an oxygen tank, much like what is used by mountain climbers, divers and fighter pilots. The company’s best engineers along with doctors and scientists worked long hours through the lockdown on developing the concept.

The product, PranaVent, took shape from the drawing board to 3D printed prototypes in no time. After extensive testing, Dynamatic Technologies developed tooling for mass production with an entire supply-chain ecosystem within a few kilometres from their facility. Scalability has been their focus, in case of a sudden surge in demand.

All parts are made from medical-grade material, and the processes are fully compliant with ISO 13485 standards. PranaVent does not need electricity to run. Instead, it works directly off the pressure from an oxygen cylinder. Endurance testing compliant with ISO 10651 has been successfully completed with zero defect. The product is extremely versatile, capable of supporting patients with different pressure, flow and breathing rates, as well as a variable gas percentage mix. This product is the result of
a confluence of engineering, medical science and entrepreneurship at Dynamatic Technologies Limited. From concept to design, prototyping and qualification, the company is fully ready to mass produce up to 42,000 mechanical ventilators per month.

Our objective was to develop a scalable and low-cost emergency field ventilator/resuscitator in the shortest possible time. With the PranaVent, we have met our target. Since it uses no electricity, it can be deployed in rural areas. And it is 100 per cent made in India!

Udayant Malhoutra
CEO and Managing Director, Dynamatic Technologies Ltd
In addition to major companies such as the ones discussed above, India’s startup ecosystem also came forward to respond to the need of the hour during Covid-19.

Under revamped guidelines, that came into effect after 31 March 2020, all medical equipment fell under the Central Drugs Standard Control Organisation (CDSCO).\(^\text{21}\) The drug regulatory body has, however, allowed all companies to manufacture ventilators without requiring any licensing. Thus, Indian startups took on the mantle to produce ventilators with unique features.

This step was crucial in motivating many Indian startups to take on the mantle of producing ventilators with unique features. Young companies dedicated to using technology towards improving healthcare, who would otherwise have to depend on funding for various clearances, were presented with a chance to make a difference during the crisis. The following section presents case studies of a few startups, among many, that worked towards the development of ventilators.

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With Amaya, a simple ventilator splitter, Ethereal Machines is preparing India to fight the Covid-19 pandemic. Previously, Ethereal Machines has addressed challenges for clients in the medical field, dealing with creating implants, prosthetics and similar medical devices. However, as Covid-19 reached India, the team began speaking to senior doctors to understand key areas of concerns. The overwhelming response they received highlighted the shortage of ventilators.

The design prototype is premised on creating a device that could help administer breathing to two patients simultaneously. Ethereal Machines succeeded with the help of a strong team of doctors with whom they worked hand-in-hand. Working on the ground, Dr Sonal Asthana and her team at Aster CMI hospital, Bengaluru were able to foresee immediate needs, providing crucial insights to Ethereal.

Amaya was influenced by a response to the need for ventilators in Italy. In Bergamo, where the pandemic hit hardest, a simple ventilator splitter was used on the frontlines to help provide oxygen to two patients, instead of one. The splitter would supply in a 50:50 ratio, but this may not be ideal because patients generally require differential ventilation. Depending on individual recovery rates, the ratio is either 30:70 or 40:60. Cross-contamination between two patients using
the same ventilator posed an additional problem.

Ethereal Machines believes that in the current situation of a global upheaval of logistics and supply chain, a solution that can be quickly created locally could help innumerable local communities. Equipping hospitals across the country with Amaya will take long, therefore, the team wants to ensure that communities can be self-reliant. To that end, they have made all their designs open source so that anyone can replicate the designs and build their own version of Amaya. Going forward, this could play a big role in healthcare as communities attempt to become self-reliant. People, instead of inventing something from scratch, can simply replicate, and improvise, a readily available and successful design.

Invest India team helped us in securing permits to move around Bengaluru and to open our factories.

Kaushik Mudda
CEO and Co-Founder,
Ethereal Machines
Nocca Robotics was founded by two IIT-Kanpur graduates in 2017. The startup is involved in designing and manufacturing robots for waterless cleaning of solar panels. It is incubated at Startup Incubation and Innovation Centre, IIT Kanpur (SIIC-IITK). The company was running pilot installation trials with six clients when the Covid-19 lockdown was announced. This abrupt halt gave the team time to explore other opportunities.

Under the leadership of Professor Amitabha Bandyopadhyay, and Dr Nikhil Aggarwal, CEO, SIIC-IITK circulated a list of Covid-19 related problem statements across all 63 incubated startups of SIIC-IITK. Based on their product designing and engineering skills, Nocca Robotics team chose to design and develop a fully functional invasive ventilator.

The expertise of Nocca Robotics in product designing and the excellent med-tech innovation ecosystem provided by SIIC-IITK became major factors that contributed to the rapid development of this high-end ventilator. SIIC-IITK complemented Nocca’s technology efforts by mobilising a team of experienced clinical intensivists, med-tech industry leaders and other corporate leaders to come together as an advisory task force to help the team achieve this objective.
The task force brought a structure to the team that helped in developing a ventilator that conforms to the government’s stringent guidelines. Each task force member, along with the Nocca Robotics team and SIIC incubator team, took care of different segments of the product development. For instance, one group was responsible for tech development, the other group for supply chain while a third focused on bringing manufacturers on board. Another group was tasked with ensuring that product development is in compliance with statutory government guidelines. Usually the development of any Category ‘C’ medical device takes a minimum of three years time.

The strong team of engineers, doctors and global business leaders attracted early traction from some of the global giants in the manufacturing and distribution space. Experienced leaders were able to catalyse rapid interactions, swift decisions and seamless connections with service providers, while reaching out for help whenever required.

The team not only achieved the development of a sophisticated and reliable product but also ensured that it is manufactured in a rapid and decentralised manner and the end-user gets a product which is reliable and offered with impeccable service. The development of NOCCA V310 ICU Ventilator is a new paradigm for Indian product development and manufacturing wherein a tech-savvy group of young entrepreneurs worked together with seasoned corporate leaders, clinicians, experienced biomedical engineers and leading med-tech industry executives to realise the journey from conceiving a product to manufacturing it, at a dizzying speed.
IIT Kanpur and Nocca Robotics have signed an MoU with the defence public sector company Bharat Dynamics for manufacturing the ventilators on a not-for-profit basis for India initially which is expected to be available for about INR 3.5 lakh (USD 4,635) per unit. Whereas the price of imported ventilators with similar specifications start from INR 12 lakh (USD 15,894) and goes up to as high as INR 25 lakh (USD 33,113) a unit.

Amitabha Bandyopadhyaya
Co-Founder,
Nocca Robotics

As told to Invest India by Professor Amitabha Bandyopadhyaya, IIT Kanpur
In response to the Covid-19 crisis, the Indian Railways developed a low-cost ventilator at its Kapurthala Rail Coach Factory. The device, called Jeevan, comes at a time when health services across the country are struggling with a shortage of medical equipment. As of late April, the product prototype was awaiting clearance from the Indian Council for Medical Research (ICMR) before going into mass production.²²

In the fight against coronavirus, engineers at the Kapurthala Rail Coach Factory have developed a prototype of a ventilator named ‘Jeevan’, which is extremely inexpensive. This ventilator made with indigenous technology will be a great relief for our comrades fighting the corona epidemic.²³

Piyush Goyal
Union Minister for Railways

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²³ Piyush Goyal Twitter, 6 April 2020. https://twitter.com/PiyushGoyal/status/124707388996838336
Amidst rising numbers of Covid-19 cases in March 2020, the faculty at IIT Roorkee tried to identify ways in which they could contribute to the fight against the virus. Thus, the Prana-Vayu ventilator was created. The team behind this low-cost, portable ventilator includes Professors Akshay Dvivedi and Arup Kumar Das along with their PhD students from IIT Roorkee and Dr Debendra Tripathi from AIIMS, Rishikesh. Prana-Vayu does not require compressed air and is suitable for Covid-19 specific respiratory support.

The R&D for the ventilator began during the lockdown when there was no market access. However, local administration provided requisite travel permissions for access to the local market. The prototype of the first version of the Prana-Vayu ventilator was revealed in a webinar organised by Confederation of Indian Industry (CII) on 2 April 2020 where the Prana-Vayu generated considerable interest. The ventilators’ first version worked on the controlled operation of the prime mover to deliver the required amount of air to the patient and had automated the process to control pressure and flow rates in the inhalation and exhalation lines. The ventilator also had feedback that could control tidal volume and breath per minute. The team then designed and fabricated the ventilator at the Tinkering Lab, IIT Roorkee, with indigenous components.
More ventilator modes, safety features, user interface were developed and incorporated in subsequent versions of Prana-Vayu, transforming it from an emergency ventilator into a full-fledged one. Further, a test lung was used to check the efficacy of Prana-Vayu. These tests were repeated many times and necessary refinements were incorporated based on the analysis. The latest version of the Prana-Vayu successfully tested for compliance with the Human Patient Simulator (HPS) at AIIMS, Rishikesh where an independent team of doctors performed tests on the individual modes for its functionality in different settings and lung conditions. Different modes of the Prana-Vayu ventilator were also tested on a SARS-COVID lung model. At present Prana-Vayu has real-time respiratory monitoring with the wired or remote interface and boasts 13 advanced mechanical ventilation modes. It can be used for invasive as well as non-invasive ventilation. It can be further developed as an industrial product for complete life support, which can compete with most advanced versions available in market.

As told to Invest India by Dr Akshay Dvivedi, Associate Professor, IIT-Roorkee
Biodesign Innovation Labs is contributing to India’s ventilator capacity through the RespirAID, an emergency and transport ventilator that can be crucial in saving lives. It is an automated respiratory assisting and invasive device that provides intermittent positive pressure ventilation to patients with respiratory illnesses, and to those who need immediate stabilisation with sedation and intubation. It is affordable, portable, easy to use and delivers all the essential features such as breath rate, tidal volume, inspiratory expiratory ratio, peak pressure and PEEP in addition to alarms.

In March 2020, Biodesign Innovation Labs collaborated with Remidio Innovative Solutions, a medical equipment manufacturer, to mass produce RespirAID. Remidio was given a non-exclusive license to provide supply chain and engineering support in the manufacturing of RespirAID ventilators. Apart from Remidio, agreements were also signed with KRAS and Cyient allowing them to manufacture RespirAID on a contractual basis. This helped scale production from an initial target of 1000-5000 devices to 50,000 devices for the Indian market and global markets, by the end of the year. To ensure safety and performance, all Biodesign’s equipment are Technical Inspection Association (TUV) laboratory tested.
Invest India, Startup India, the Government of India and the Government of Karnataka provided Biodesign with support on logistical and supply chain related issues. The Centre for Cellular and Molecular Platforms (CCAMP) and IKP Knowledge Park, a science and technology promoting biotechnology, pharma, medical devices and energy, also helped Biodesign through their outreach activities.

**Gautham Pasupalethi**
Co-Founder and Chairman, Biodesign Innovation Labs
The project head Zulqarnain, a first-year student of Industrial Design Centre at IIT Bombay, was visiting his hometown in Kashmir when the lockdown was announced, and the institute closed. As the number of cases surged across the world, Zulqarnain learned that there were only 97 ventilators in the Kashmir Valley. He sensed an urgent need for more ventilators that would also help in easing people’s worries.

Zulqarnain then teamed with his friends from Islamic University for Science and Technology (IUST), and NIT Srinagar. With assistance from Design Innovation Centre (DIC) at IUST in Pulwama, the team successfully designed a low-cost ventilator using locally available materials. While their initial aim was to replicate a tried and tested design, they soon developed their own design of the ventilator as work on the ventilator progressed.

Zulqarnain proudly remarks, “The prototype costed the team around INR 10,000 and when we go for mass production, the cost will be much lower. While high-end ventilators used in hospitals cost lakhs of rupees, Ruhdaar provides necessary functionalities which can provide adequate breathing support necessary to save the life of a critically-ill Covid-19 patient.”

Sree Chitra Tirunal Institute for Medical Sciences and Technology (SCTIMST) is an institute of national importance under the Department of Science and Technology. It tied up with Wipro 3D in Bengaluru to jointly build a prototype of an emergency ventilator system based on Artificial Manual Breathing Unit (AMBU).

The ventilators can help meet urgent requirements arising from Covid-19. Ambu bag or a Bag Valve Mask (BVM) is a hand-held device used to provide positive pressure ventilation to a patient who is either not breathing or is breathing inadequately. However, the use of a regular AMBU needs an aid for its operations. Since that would make the aid highly susceptible to the virus, it is not advisable. Sree Chitra’s Automated AMBU Ventilator, developed with inputs from clinical faculty, will assist critical patients, who do not have access to ICU ventilators, in breathing.

This device is portable and lightweight and enables positive pressure ventilation with a controlled rate of expiration, inspiratory to expiratory ratio, tidal volume, and among others. A PEEP valve can also be added as an extra component to maintain pressure on the lower airways at the end of the breathing cycle, preventing the alveoli from collapsing during expiration. The compressed gas source can also be attached to the system. The automatic device will minimize the need of support personnel in the isolation room, thereby enabling a safe and effective lung-protective operation for Covid-19 patients.25

Council of Scientific and Industrial Research (CSIR) and its constituent lab National Aerospace Laboratories (NAL) in Bengaluru have, in a record time of 36 days, developed a non-invasive Bilevel Positive Airway Pressure (BiPAP) ventilator to treat Covid-19 patients. The ventilator, called SwasthVayu, is a microcontroller-based precise closed-loop adaptive control system with a built-in biocompatible ‘3D printed manifold & coupler’. It also has a Highly Efficient Particulate Air (HEPA) filter that reduce risks of the virus spreading. The ventilator boasts features like spontaneous, Continuous Positive Airway Pressure (CPAP); timed and auto BiPAP modes with provision to connect an oxygen concentrator or enrichment unit externally. The system has been certified for safety and performance by National Accreditation Board for Testing and Calibration Laboratories (NABL) accredited agencies. It has also undergone stringent biomedical tests and beta clinical trials at the NAL Health Centre.

This machine’s advantage is its simplicity. It can be used without any specialised nursing, is cost effective, compact and configured primarily with indigenous components. It is ideal for treating Covid-19 patients in wards, make-shift hospitals, dispensaries and homes too. CSIR-NAL are in the process of taking the ventilator forward with the regulatory authorities for approval, which is expected shortly. Dialogues with major public and private industries as potential partners in mass production have already been initiated.26

Partnering with the Best in the World

NASA’s Jet Propulsion Laboratory (JLP) in Southern California developed a ventilator specifically for coronavirus patients. The JPL engineers designed the special ventilator, named Ventilator Intervention Technology Accessible Locally (VITAL), in a little over a month and received emergency use authorisation from the Food and Drug Administration (FDA) on 30 April 2020.27

VITAL uses one-seventh as many parts as a traditional ventilator, relying on components already available in supply chains. This high-pressure ventilator is a simple and affordable option for treating critical Covid-19 patients that allows traditional ventilators to be used for those with the most severe symptoms. The ventilator’s flexible design allows it to be modified for use in field hospitals.

Three Indian companies were selected and licenced to manufacture NASA’s coronavirus ventilators. These are Alpha Design Technologies Pvt Ltd, Bharat Forge Ltd and Medha Servo Drives Pvt Ltd.

INTERVIEW

Colonel H. S. Shankar

Chairman & Managing Director, Alpha Design Technologies Pvt Ltd

1. Congratulations on being licensed by NASA to manufacture their Covid-19 specific ventilator VITAL. Could you please walk us through your proposal and the process of being granted the license?

It is a proud moment for Alpha Design, a subsidiary company of Adani Defence Systems & Technologies Ltd. (ADTL) in India, to be acknowledged by NASA for Covid-19 specific ventilator. We can assure you that Alpha Design will not leave any stone unturned to live up to the expectations of the licensing authority, NASA, to deliver the product with the necessary approvals from Food and Drug Administration (FDA) of the USA and by the ICMR in India.

The license was granted to Alpha Design after a diligent process facilitated by NASA for selecting capable industrial partners in the prevailing unprecedented times. The process for the grant of the license is as follows –

- There were two models of the ventilator product (Pneumatic Ventilator and Compressor Ventilator) which were jointly developed by JPL under NASA and Caltech University.
• Interested industrial partners were required to register with NASA for the ventilator program and to submit the proposal.

• Alpha Design and its experts had engagement session(s) with NASA to walk them through the company’s capabilities including its technical and operational expertise.

• ADTL’s capabilities coupled with its entrepreneurship approach helped JPL and Caltech to select ADTL for both the models of the ventilator including Ventilator - Pneumatic model and Ventilator - Compressor model.

2. Alpha Design Technology’s manufacturing expertise leans more toward defence and related equipment. How did you prepare to begin manufacturing ventilators of such specificity?

The primary design of these ventilators leverages electro-mechanical modules in the form of Printed Circuit Board (PCB) assemblies, display units, controllers and signal processing, with built-in firmware including solenoids, valves etc. The entire architecture is enclosed in a robust mechanical structure and all connectivity is through electronically activated circuits. Hence, this is aligned to the expertise that ADTL has built-up over the last two decades in manufacturing military grade electronic equipment for the armed forces.

The existing infrastructure at Alpha Design for manufacturing defence electronic equipment can be seamlessly deployed for manufacturing ventilators of given specifications. The manpower skills, technological capabilities and quality management systems which are part of defence electronic equipment have a lot of semblance to the ventilators.

It should be noted that Bharat Electronics Ltd (BEL), which is a major defence electronics manufacturing organisation in India under Ministry of Defence, was chosen by Defence Research and Development Organisation (DRDO) to manufacture ventilators as well due to synergies with their system and electronics capabilities. The same applies to Alpha Design which has the capabilities to manufacture world class ventilators.
3. Does the shift to manufacturing ventilators challenge your existing supply chains? How do you intend to overcome these challenges?

As discussed above, there is a high degree of alignment between the current portfolio of products and equipment of Alpha Design which is required for the suggested ventilators. The bill of material for the ventilators overlaps with our supply chain since most of the subsystems are built with PCB assemblies using both active and passive electronic components which are available worldwide through authorised distributors of the Original Equipment Manufacturers (OEMs).

In addition, VITAL also supports us by suggesting the authorised suppliers based on their Quality Product List (QPL) and thereby commonality exists between electronic assemblies used in ventilators of VITAL design versus electronic assemblies of defence electronic equipment.

4. What production targets does Alpha Design Technology foresee for manufacturing VITAL and what is the prospective timeline?

Alpha Design is in the process of manufacturing of 10 sets of both the models of ventilators as prototypes. Five sets will be delivered to FDA, USA and five sets to ICMR for qualification and approval. Depending upon the results of this exercise and any improvements as required, it will be taken for industrial production. Alpha will also use the expertise of medical professionals to get the units tested and evaluated even before they are offered to FDA and ICMR. Post final approval, ADTL plans to start initially by manufacturing 500 sets per month and scale up to reach 2000 sets a month within six months.

5. How crucial, in your opinion, will VITAL be in meeting the challenges imposed by the Covid-19 pandemic?

The design of VITAL supports patients who are in the early stages of being infected by Covid-19 with symptoms such as breathing difficulties, and those who can be treated without being admitted into an ICU. It will help in reducing the intensity of the disease and reducing the pressure on intensive care in the hospitals which is required for more critical patients with more advanced ventilators.

This opportunity opens up additional avenues in related technologies in the medical and para-medical fields as it helps in gaining knowledge of qualification requirements of a typical medical equipment to be approved through stringent procedures adopted by organisations such as FDA, ICMR etc.

6. Why do you think this is a major achievement for India?

ADTL is grateful to JPL and Caltech for recognising and entrusting us with this critical product to be industrialised in a short time frame. It is critical to highlight that this initiative by NASA is a giant leap towards humanity by providing the entire technology free of cost.

It is now in our hands to use this technology effectively and build in efficiency and quality in the supply chain that could be useful for the wider population. While the business opportunity is huge with the imminent export order of ventilators back to the US and other countries, it is more fulfilling to play our role in helping the world through an unprecedented time through this corona crisis. Further, Alpha Design, a subsidiary of Adani Defence and System Technologies, foresees its engagement with NASA and associated bodies as a starting point to industrialise state of the art technologies into valuable products to serve the humanity at large.
Conclusion

The story of how Indian industry – both startups and big manufacturers – collaborated swiftly and joined hands with engineering and technological institutes from across the country to boost production is an indication of the country’s manufacturing strength.

The increased production allowed India to manufacture 60,000 ventilators indigenously, despite a 21-day lockdown and a ban on the import of ventilators. The machines built were not only lifesaving but also priced very competitively to ensure that the largest number of people could benefit from them.

The dynamism depicted in the case studies presented in this report not only represents India’s entrepreneurial zeal but also sets the path to the country becoming a global exporter of ventilators. As long as the ventilators are designed and manufactured in consultation with senior healthcare providers and in keeping with the guidelines of India’s DRDO and ICMR, they could find acceptance not only in India but also around the world.

The Covid-19 crisis has triggered a wave of design, manufacturing, and innovation in India. In ventilators, for instance, almost a whole new domestic industry has been created in these times of turmoil, showing the power of Make in India, and ensuring that Prime Minister Narendra Modi’s dream of an Atma Nirbhar Bharat or self-reliant India is fulfilled.