

Let them breathe: The Beginnings of New Breath with **Biorespira**



“Learn from Italy,” says **Dr. Corrado Ghidini**, **Managing Director of Italian Biomedical Devices srl (IBD)**, and **Biorespira** creator. Italy, with the unfortunate distinction of being the first democracy hit by the coronavirus, SARS-CoV-2, was devastated early in the COVID-19 pandemic. Especially in the northern region of the country, patients with COVID-19 flooded the hospitals in March 2020, overwhelming healthcare providers and facilities.

In Italy, patients came to the hospital fighting to breathe, and doctors turned to the treatment and equipment available at the time. Intensive care units filled instantly, and mechanical ventilators that require intubation were the standard of care. All over Italy, people who were not sick were urgently searching for ways to help.

Dr. Ghidini went to his friend, **Dr. Nicola Petrucci**, **Chief of Intensive Care Unit at Hospital of Desenzano del Garda** to donate N95 masks as the hospital had quickly depleted its supply of personal protective equipment for doctors and nurses. “What else do you need?” Dr. Ghidini asked his friend. “What else can I do?”

“**The patients cannot breathe. We do not have enough ventilators or ICU beds for patients who are suffering from respiratory distress caused by COVID-19,**” said Dr. Petrucci. “More than mechanical ventilators, we need high flux ventilators to prevent the abnormally high use of intubation that we are seeing.”

At the beginning of the project, Dr. Ghidini started a GoFundMe campaign to raise capital for the development, surpassing the 20,000 Euro target quickly with hundreds of donors joining in to fund **Biorespira** development. The strong response shows the willingness of people in the community to help in any way, and was the first use of the rallying hashtag, #letthembreathe.

With the cry for help from front-line healthcare providers, Dr. Ghidini had the IBD engineers pivot their focus and critical design thinking to noninvasive ventilation equipment. Just like the well-funded and fully staffed team of Ferrari engineers working with the brightest minds at the Italian Institute of Technology, the **IBD innovation team went from concept to working prototype for the Biorespira Pulmonary Ventilator in just 5 weeks.**

IBD Expertise

Since its founding in 2014, Dr. Ghidini, MD, DDS and MBA, has led IBD in following a product concept and development philosophy of **reverse innovation**. He and his team of engineers specialize in evaluating existing healthcare equipment designed for in-hospital use by trained operators for long-term patients with chronic conditions. From this starting point, **their goal is to design smaller, portable, easy to use equipment that can be used in facilities and for at-home care by technicians and individuals**, using technologies IBD has patented. Their first success using reverse innovation is dialysis equipment targeted to patients with kidney disease in emerging country markets.

The versatile **Biorespira** Pulmonary Ventilator is designed to have the following capabilities:

- Operation by a nurse, home healthcare provider or family member without medical training
- Able to use oxygen from a canister or in-facility wall connector

- Delivery of oxygen through helmet or mask, in a closed system that is safer for everyone near the patient, including other people in the same environment, whether healthcare provider or in-home care and family
- Works in general treatment room (vs. ICU), shared nursing home room, or private home; no special environment requirements such as negative pressure
- Allows efficient use of oxygen supply and greatest distribution of breathing capabilities to multiple patients
- Offers oxygen saturation from 20% to 100%, depending on the patient's needs
- Delivers high-flux flow from 20mL to 120mL, with common level of 60mL
- Indications include pre-intubation and post-extubation, for acute patient treatment such as COVID-19 patients may require
- Power supply from 100V to 240V for use around the world

Design concepts IBD biomedical engineers apply in reverse innovation include the following elements:

- Miniaturization, reducing the size of large-scale equipment down to a portable, lightweight form factor
- Simplicity in use with touchscreen, easy to understand messages and prompts for operation by nurse or in-home caregiver
- Economical, using far less oxygen and bringing capabilities of expensive ventilators at a reduced cost so they are accessible to more people and facilities

Beyond Prototype

IBD is the innovation engine behind the **Biorespira** Pulmonary Ventilator, and Dr Ghidini knew he needed a company with market reach to take the next steps of mass production and distribution around the world. SECO S.p.A., a long-time partner of IBD, was the logical choice for this partnership.

SECO's resources, including high-quality production, marketing, sales and support infrastructure, will bring the intended benefits of **Biorespira** to COVID-19 patients around the globe. **Massimo Mauri, CEO of SECO**, explained, "Partnering with IBD to bring **Biorespira** beyond early development and into production and worldwide distribution was an easy decision for SECO. **The combination of SECO expertise with IBD innovation yields a powerful and vital solution to a worldwide crisis.**"

"COVID-19 is not only an Italy problem and **Biorespira** is not only an Italy solution. With **Biorespira**, many people have a better chance at breathing again," explains Dr. Ghidini.

IBD and SECO are working to achieve an Emergency Use Authorization from the Food and Drug Administration in the United States, with a Pre-EUA application submitted. The team will begin selling **Biorespira** when the authorization is granted. In expectation of that time, production of **Biorespira** units is underway, with first units expected to be available from mid-July 2020.

Donation units

"Doctors around the world currently agree that assisted lung ventilation is the only effective therapy for patients with COVID-19 pneumonia with ventilatory impairment," explained Dr. Ghidini. "In an effort to share these capabilities widely, **we start with 30 units to donate, with the first units going to Hospital of Desenzano del Garda and additional units to donate to hospitals and care facilities around the world.**"

Those interested in applying for a trial unit should contact IBD at: corrado.ghidini@ibdbiomed.com

"COVID-19 has had a shocking and terrible impact on the world in early 2020. I'm encouraged to see the support for **Biorespira** first through crowdfunding and now in our partnership with SECO," said Dr. Ghidini.

Mauri, agreed, saying, "We hope that certification by the FDA in the US and in other regions will happen quickly so healthcare systems and other facilities like nursing homes and assisted living complexes have **Biorespira** as a weapon to fight COVID-19's horrible effects."

At the time of this writing, the number of cases of COVID-19 is approaching 8 million and deaths from the disease tops 425 thousand. Infectious disease doctors continue to warn of potential spikes in cases until a safe and effective vaccine is developed, which is still many months away. **The need for accessible noninvasive pulmonary ventilators remains high for the foreseeable future. Biorespira is designed to meet that need.**

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