ICU

MANAGEMENT & PRACTICE

INTENSIVE CARE - EMERGENCY MEDICINE - ANAESTHESIOLOGY

VOLUME 20 - ISSUE 1 -2020

COVID-19 Challenges

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Precise Automated Resuscitation With RESPIRA

An innovative solution to ventilator shortages has been found in Spain – a relatively simple and cost-efficient alternative named RESPIRA.

One of the major problems for hospitals fighting the COVID-19 pandemic has been the lack of emergency ventilation devices. GPAINNOVA, a multinational company from Spain, has a simple and efficient solution to this – RESPIRA.

Novel Approach

RESPIRA is an ICU ventilator based on AMBU automation for assisted ventilation. It has been designed specifically for the needs of intensive care doctors involved in the COVID-19 treatment, and its performance is comparable to that of high-class ventilators from top brands.

RESPIRA automates manual resuscitation devices (BMV or AMBU) with sensors for remote real-time monitoring of parameters, such as frequency, tidal volume, flow, Ratio I:E and pressure of air supplied to the patient (maximum/PPI, minimum/PEEP and plateau). These parameters can also be fine-tuned thanks to an automatic system with PLC and an actuator – the two main components of RESPIRA that enable the precise piston movement and air insufflation. It also incorporates an FIO2 sensor with external display to monitor oxygen supply while a smart module allows for parameter adjustment based on pressure and tidal volume.

Such adjustability is achieved with advanced sophisticated software PLC developed in cooperation with top engineers of Siemens Digital Industries. This world-class partnership is what distinguishes RESPIRA from other projects, open-source and non-homologated for medical device data transmission. For the high-quality components, which ensure safety and reliability, the RESPIRA project has the technical support of SMC, TEG and MAM.

Major hospitals in Spain including Hospital Clínic of Barcelona, Sant Joan de Déu and the Institute for Health Science Research Germans Trias i Pujol have participated in developing RESPIRA and running validation tests.

Upholding Standards

In Spain RESPIRA has passed all technical examinations for both the machinery and documentation, including those from Agency of Medicines and Health Products for Spain (AEMPS). This means that the device standards are similar to those of professional ventilators.

The first phase of the clinical trial is now completed. At this point RESPIRA is approved for use in all hospitals in Catalonia, and 45 of those already have it onsite. The device is currently in the second phase of the clinical trials, which means it has been approved by AEMPS to be used in several patients affected by COVID-19.

For other hospitals in Spain and other countries, the device can be used during the COVID-19 emergency with an authorisation by the health authorities. An exemption from CE-marking requirements for medical devices in limited circumstances was approved by the European Parliament on 17 April, 2020, to cover shortages during the pandemic, with only local authorities' permission needed. GPAINNOVA has also applied for CE and FDA certification and is trying to fast-track the EU certification of RESPIRA as emergency medical equipment.

Work in Low-Resource Settings

GPAINNOVA is already in contact with several humanitarian organisations and plans to donate RESPIRA units to fight the COVID-19 pandemic in Africa. The device will be practical there, as it is very compact, light and portable. It can run on battery and has its own Wi-Fi, which allows to manage up to 16 units through one control station – a big advantage, considering the limited number of physicians in African countries. All this makes RESPIRA an attractive alternative to more complex ventilators, which hospitals there may not be equipped to install.

Manufacturing, Delivery and Support

RESPIRA is a locally manufactured product, with all the facilities located in Spain,

and can be quickly delivered globally. So far, GPAINNOVA has received orders for over 21,000 units. It is upscaling its production to 300 units per day and has the capacity to increase further if needed.

GPAINNOVA has branches in the U.S, China and Hong Kong, and distributing partners in every other country of the world. This ensures not only fast delivery but also efficient technical support and maintenance. There is a 24/7 hotline for any kind of technical enquiries from hosting hospitals.

For health professionals, GPAINNOVA has created comprehensive training videos like this one, which complement a very detailed manual. In addition, another 24/7 hotline is operated by Hospital Clínic of Barcelona to provide assistance to clinicians who work with RESPIRA across the world.

The device is relatively simple, assembled mostly from standard parts. It runs on dynamic and complex software and even though the technology is quite superior, RESPIRA's advanced features are still being offered at a very competitive price, even more so with large orders. It is portable and can be operated onsite or remotely, with an accessory incorporating Wi-Fi. This makes RESPIRA a cost-efficient alternative to standard ICU ventilators. Post-pandemic, in ambulances or emergency care the device can be used instead of manual resuscitation bags.

About GPAINNOVA

GPAINNOVA is a multinational company based in Barcelona, Spain. It specialises in surface metal finishing machinery and runs a water drones innovative project. With a turnover of €5.9 million in 2019, the company has received an EU Horizon 2020 grant under the SME Instrument Programme (phase 2 – innovation project). It has also been ranked 76th in the '1,000 fastest growing European companies in 2020' list compiled by the Financial Times. ■