ResMed Products and Solutions in a COVID-19 World

Information on safely maintaining healthcare for all patients as well as applications for treatment of patients with COVID-19

The information contained in this document is current as of July 15, 2020, and is based on currently available information that will continue to change over time. The information in this guide with respect to treatment is believed to have a reasonable basis. ResMed assumes no obligation to update the information in this presentation, whether as a result of new information or future events. **The information contained herein should NOT be used as a substitute for the advice of an appropriately qualified and licensed physician or other health care provider. This general guidance is based on publicly available information. It is the responsibility of the user to check any applicable state or local requirements.**

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Executive Summary

As a medical technology manufacturer of respiratory devices, including ventilators, ResMed mobilized a global task force in response to the COVID-19 pandemic to support our guiding principle: the preservation of life throughout the world. As the first waves of the COVID-19 pandemic hit different countries – ResMed focused on mobilization of the supply chain to meet short term peak demands for medical equipment, especially ventilators.

As the pandemic passes its third month, it is clear that while some countries may have slowed their infection and death rate, there is no fast way to return to the way we did things before. Governments and healthcare organizations are focusing on two areas: managing COVID-19 infection risk at a population level to prepare for future waves of COVID-19 and re-establishing non-acute healthcare while maintaining the safety of patients and healthcare workers. Predictive modeling algorithms are being used to help identify which countries may be most at risk for ventilator shortage and to prepare governments, industry, and healthcare networks with adequate resources for the next wave of infections. As healthcare services have begun to rely heavily on telemedicine and remote management, ResMed products are well positioned to monitor and manage patients in an at-home setting through remote monitoring and patient engagement tools that can benefit the patient well beyond the current pandemic.

This document aims to inform governments, health officials, and clinicians in understanding the application of ResMed's devices in the current context of providing sleep and respiratory healthcare during the COVID-19 pandemic. It is based on current information, which is changing rapidly and can vary across regions – for specific regional guidance always refer to local published guidelines. **The purpose is not to direct clinical practice but to provide clear information on the available ResMed products and their application in response to the COVID-19 pandemic.**

Responding to the COVID-19 pandemic

Oxygen support and ventilation is important for critically ill patients

When making a treatment decision for a COVID-19 patient, clinicians must consider the wide range of symptoms and illness severities. Patients presenting with low oxygen saturation and increased respiratory rate will require oxygen supplementation, which can be delivered through a nasal cannula, mask or **non-invasive ventilation** (a form of mechanical ventilation)[1,2,3]. Those that fail to respond and subsequently develop hypoxemic respiratory failure or acute respiratory distress syndrome (ARDS) may require **invasive ventilation**, which delivers air through a tube inserted into the trachea either via intubation or tracheotomy.

Based on the experience of several countries, it appears that 5-6% of patients with COVID-19 require mechanical ventilation[4,5]. Of patients receiving treatment in the intensive care unit (ICU), 10-11%

received non-invasive ventilation[6,7] while a range of 29-97% received invasive ventilation[6-12,] due to ventilator availability and differing treatment strategy during the course of the pandemic across different regions.

Non-invasive ventilation provides oxygen support to the patient through two types of ventilation modes. Continuous positive airway pressure (**CPAP)** is a non-invasive ventilation mode which provides a constant steady pressure to keep the lungs expanded. Bi-level positive airway pressure (**bi-level PAP)** is a non-invasive ventilation mode that delivers two distinct pressures, one for inhalation and the second for exhalation; the change in pressures leads to flow of air in and out of the lungs. Most CPAP and bi-level PAP devices are compatible with supplementary oxygen, which can be entrained into the circuit or patient interface.

Due to the increasing demand of ventilators for the treatment of COVID-19 patients and potential ventilator shortages, government and health administrations around the world have issued guidance documents[1,13-21] to expand the possibility of treatment opportunities. In particular, guidance documents encourage facilities to provide non-invasive ventilation, including CPAP and bi-level PAP therapy devices, to enhance and expand critical care surge response capability[1- 3,17- 20, 22-25] and support patients in the sub-acute or out-of-hospital care environments[26]. Furthermore, to expand the availability of ventilators and other respiratory devices during the declared public health emergency, the U.S. Food and Drug Administration (FDA) has allowed for more flexibility for device modifications by manufacturers[27], such as use of ventilators outside their intended purpose or intended environment.

Applications, features, and device specifications of ResMed ventilators and bi-level devices

ResMed and Curative, a subsidiary of ResMed, manufacture a range of ventilators and bi-level devices. These devices are indicated for hospital and home use, and have the flexibility for use in various clinical scenarios to provide respiratory support to patients at various stages of dependency (see ***Figure 1***). It should be noted, however, that these are **not** the same as ventilator equipment typically used in high acuity situations in hospital ICUs. Curative devices are authorized for use in the United States pursuant to an Emergency Use Authorization from FDA. Regulatory approval will vary by geography and Curative devices may not be available in all regions pursuant to Regulatory approval in their respective jurisdiction.

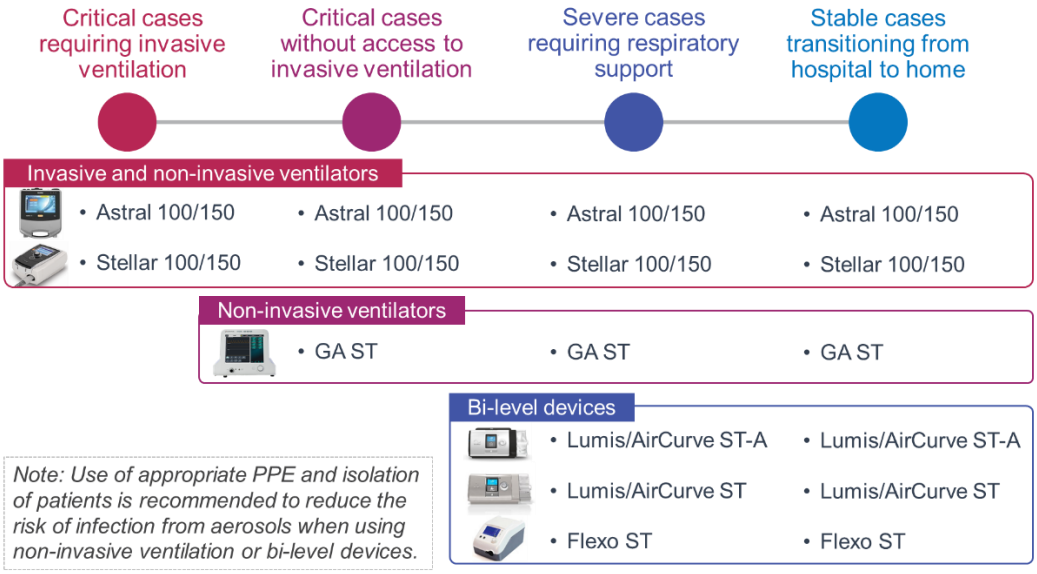

Figure 1. ResMed and Curative ventilators and bi-level devices in various clinical scenarios

Key specifications of ResMed ventilators and bi-level devices are provided in the table below (see ***Table 1***). **The method of ventilation is an important clinical decision to be made by the treatment team under rapidly evolving clinical guidelines for COVID-19 patients, availability of ventilation technology, clinical setting and availability of personal protective equipment for healthcare workers.** The following information about ResMed devices is designed to assist and inform these decisions by clarifying applications and features of different devices. ResMed also offers online tutorials of device setups, quick setup guides, suggested non-invasive ventilation settings and remote webinar trainings for users, all tools which largely allow for independent clinician setup of devices.

	Astral 100/150	Stellar 100/150*	GA ST**	Lumis/AirCurve ST-A	Lumis/AirCurve ST***	Flexo ST*
Invasive Capability	Yes	Yes (with endotracheal tube[28]) †	No	Yes (with endotracheal tube[29]) †	Yes (with endotracheal tube[29]) †	No
Non-invasive Capability	Yes	Yes	Yes	Yes	Yes	Yes
Max Pressure (cmH_2O)	50	40	40 (high pressure, low pressure modes)	30	25	30
O_2 Entry Location	Inlet	Inlet	Inlet	Outlet	Outlet	N.A.
Max O_2 Flow Rate (L/min)	30	30	30	15	15	N.A.
FiO_2 Monitoring /Alerts	Yes	Yes	Yes	No (can use oximetry adapter)	No (can use oximetry adapter)	No
Humidification	External	Integrated or External	External	Integrated or External	Integrated or External	External
Alarms	Yes	Yes	Yes	Yes	No	Yes
Backup modes	Yes	Yes	Yes	Yes	Yes	Yes
Internal battery	Yes	Yes	Yes	No	No	No
External battery	Yes	Yes	No	Yes	Yes	No
Telemonitoring	Yes	Yes	No	Yes	Yes	No
Modes	CPAP, (S)T, P(A)C, (A)CV, P(A)CV, P-SIMV, V-SIMV, PS, iVAPS	CPAP, S, ST (optional iBR),T, PAC, iVAPS	CPAP, S, T, ST, APCV, CPAV, TVV-t, TVV-ST, TVV-APCV	CPAP, S, ST (optional iBR), T, PAC, iVAPS	*AirCurve*: CPAP, S, ST, T *Lumis*: CPAP, S, ST (optional iBR),T, PAC, iVAPS	CPAP, S, T, ST, APCV, TVV
Notes	Pre-set settings to simplify treatment choices; Astral 150 has double limb circuit capabilities	Requires use of leak valve with invasive therapy; used for patients recovering from acute lung injury (ARDS) or mild underlying lung disease; good option for step down units	Contains oxygen mixer	Most appropriate for ward environment	Most appropriate in home environment	

Table 1. Key specifications of ResMed and Curative ventilators and bi-level devices

* The Stellar 150 has been authorized for emergency use in healthcare settings in the U.S. to treat patients during the COVID-19 pandemic, subject to the conditions set forth in the FDA's Emergency Use Authorization (EUA)[30]. The EUA for Stellar includes expanded indications for use to include iVAPS with AutoEPAP, expanded warnings appropriate to critical care, including information on using Stellar 150 with an endotracheal tube. A list of ventilators authorized under the EUA can be found on the FDA website[31].

**GA ST and Flexo ST are devices offered by Curative, a subsidiary of ResMed. Curative devices are authorized for use in the United States pursuant to an Emergency Use Authorization from FDA. Regulatory approval will vary by geography and Curative devices may not be available in all regions pursuant to Regulatory approval in their respective jurisdiction.

*** AirCurve 10 ST-A and the European Lumis ST variant has been authorized for emergency use in healthcare settings in the U.S. to treat patients during the COVID-19 pandemic, subject to the conditions set forth in the FDA's EUA (ref above). The EUA for Lumis includes expanded warnings appropriate to critical care.

† Clinical bulletins regarding invasive use are authorized in the United States pursuant to an EUA from FDA. Regulatory approval for this use case will vary by geography and may not be authorized in all regions pursuant to Regulatory approval in their respective jurisdiction.

Addressing initial ventilator shortages with expanded device use

Invasive use of NIV devices

Given the potential shortage of mechanical ventilators in many countries, bi-level PAPs started being used in intubated patients on an emergency basis with limited and rudimentary evidence. A white paper by Syneos Health suggested that Volume Assured Pressure Support (VAPS), a mode available on newer bi-level devices, can work as a bridge of support to deliver ventilation via an endotracheal tube until a conventional ventilator becomes available[32]. Clinicians also published guidance on how to repurpose bi-level ventilators for use with intubated patients[33]. If a bi-level PAP device is to be used in intubated patients for invasive ventilation, at minimum, a rigorous external monitoring system, with all of the functionality and alarms that are required for monitoring critically ill and mechanically ventilated patients, needs to be in place[34].

To address a shortage of dedicated ICU ventilators during the COVID-19 pandemic, ResMed released two clinical bulletins describing factors to consider when adapting the Stellar 100/150[28] and other bi-level devices[29,35] with oxygen input for invasive use with an endotracheal tube as opposed to a tracheotomy tube. Clinical bulletins regarding invasive use with an endotracheal tube are authorized in the United States pursuant to an Emergency Use Authorization from FDA. Regulatory approval for this use case will vary by geography and may not be authorized in all regions pursuant to Regulatory approval in their respective jurisdiction. When using Stellar 100/150 with an endotracheal tube, an appropriate external monitoring system should be in place and should only be performed in hospital settings.

Low-dispersion circuits

In addition to published guidance on standard cleaning and disinfection procedures[36,37,38] (see cleaning guides to ResMed devices[39]), some concerns have emerged regarding the risk of dispersion of aerosolized virus when utilizing ventilation procedures. However, evidence suggests that non-invasive ventilation procedures are more likely to produce large droplets (>10 µm) rather than aerosols, and that these are largely confined to within one meter due to their large mass[36]. In addition, a good mask interface fit can diminish widespread dispersion of exhaled air[40,41] and aerosols[42] and create minimum room air contamination[40,43].

Nonetheless, the risk of aerosol dispersion needs to be mitigated with appropriate isolation of patients and the use of Personal Protective Equipment (PPE) for healthcare workers, such as gloves, disposable shirts, goggles, N95 masks/respirators and eye protection[14,42,44,45], which are now considered standard protective equipment in a COVID-19 ICU[42,36]. The use of compatible expiratory valve filters for single-limb non-invasive ventilators and the use and replacement of the air inlet filter and main flow bacteria filter between patients and at regular intervals may also help to reduce the risk of patient or ventilator contamination[46].

Given the potential ventilator shortage and the concern of infection risk to healthcare workers during the COVID-19 pandemic, an alternative low-dispersion circuit design with non-vented masks has been

explored as a therapy option due to its ability to limit droplet dispersion during non-invasive ventilation therapy[47]. As low dispersion circuits are not the intended use for ResMed's devices, ResMed published a clinical bulletin describing the use and cautions of a low dispersion circuit with Stellar[48] (see Figure 2) and in conjunction with supplemental oxygen with Lumis, AirCurve, AirSense, and S9 platforms[49] (see Figure 3). Regulatory approval for this use case will vary by geography and may not be authorized in all regions pursuant to Regulatory approval in their respective jurisdiction. Patient and device instructions for these devices should continue to be followed in addition to the information provided within these bulletins.

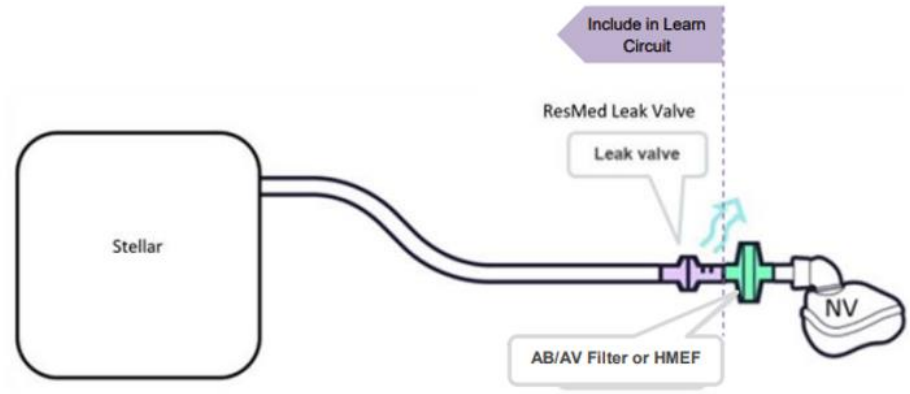

Figure 2. Low dispersion circuit setup with Stellar

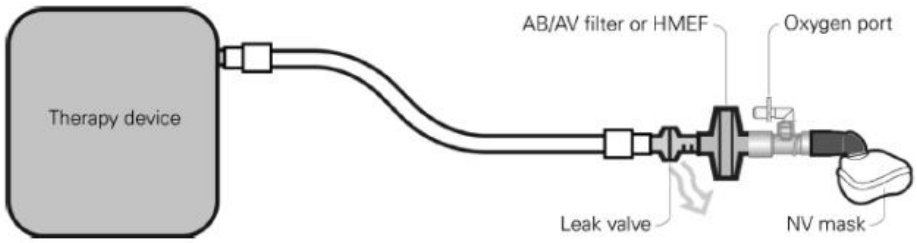

Figure 3. Low dispersion circuit setup with supplemental oxygen port

The limiting component of the low dispersion circuit design is the ResMed Leak Valve due to concurrent high demand with invasive ventilation systems. A clinical bulletin[50] was released to provide guidance to clinicians when using the ResMed Leak Port, as an alternative to the ResMed Leak Valve in low dispersion circuit setups to support COVID-19 care demand needs (see Figure 4). Regulatory approval for this use case will vary by geography and may not be authorized in all regions pursuant to Regulatory approval in their respective jurisdiction.

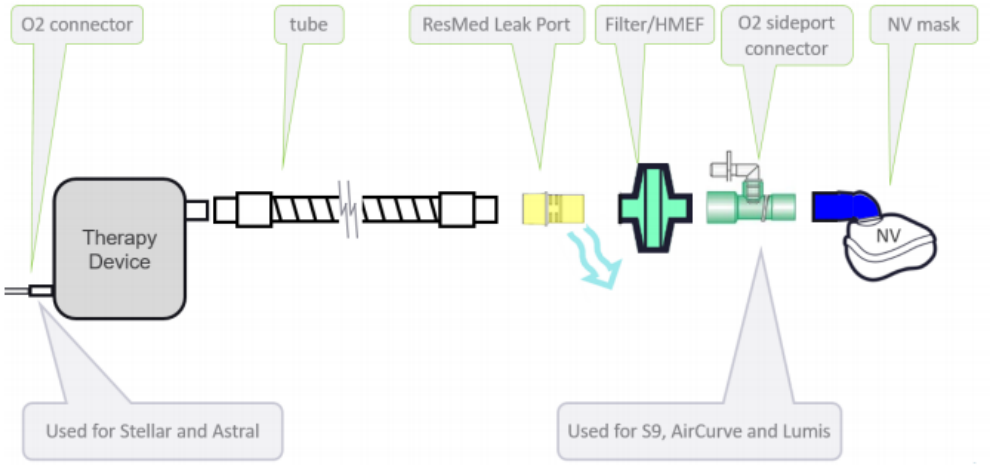

Figure 4. Low dispersion circuit setup with ResMed Leak Port

The ResMed Leak Port has been evaluated and deemed acceptable for use as an alternative to the ResMed Leak Valve, given supply limitations in the COVID-19 pandemic. However, the ResMed Leak Port does not have an anti-asphyxia which mitigates rebreathing in case of device malfunction. It is important that the use of the ResMed Leak Port be used in circuits with alarmed ResMed devices only (e.g. S9/Lumis/AirCurve ST-A, Stellar, Astral) so that alarms can alert clinicians on device malfunction or if inadequate therapy is being provided to the patient and mitigate against CO_2 re-breathing.

Preparedness for second wave of COVID-19 infections

Epidemiological findings show that implementation of non-pharmaceutical, behavioral interventions such as social distancing has limited transmission of COVID-19 to date[51]. However, the lifting of these interventions creates a risk for a second wave of infection in the fall season[52-54]. Insights from modeling studies suggest that infection rates during the second wave may peak below the first infection wave due to awareness, monitoring, contact tracing, more extensive testing, mask wearing, and rapid reinstatement of social distancing[53,55-57]. These predictions can help governments, industry, and healthcare networks to prepare resources for the next wave of infections.

For example, prior to the pandemic, the United States was estimated to have access to about 160,000-200,000 ventilators[58,59], but many of these ventilators only had partial functionality. As a result, states such as New York and New Jersey found themselves with anticipated ventilator shortages[60]. Devices delivered from the Strategic National Stockpile lagged behind in technology and functionality[60], which created a greater need for modern, full-featured ventilators.

Using varying country-specific rates of infection, current ventilator availability, frequency of ventilator use, and duration of ventilator use, predictive modeling[61] can identify which countries may be most at risk for ventilator shortage during subsequent waves of virus infections[62]. While the shortages have eased in

some countries, different assumptions of future waves and governmental responses create a range of predictions[63].

Successful ventilation also depends on sufficient number of suitably trained staff, availability of supplies and PPE, and timely ability to match access to ventilators with critically ill cases[64]. In addition, it is still unknown how many post-acute COVID-19 patients with an unknown post-acute pathophysiology will require longitudinal care including supplemental oxygen and pulmonary rehabilitation[65].

ResMed has dramatically increased production of both ventilators and accessories[66,67] and continues to monitor ventilator availability in countries around the world in order to supply ventilators to countries with the highest need for ResMed's devices and solutions that are well positioned in a COVID-19 world.

Growing emphasis on telemedicine and remote management

94% of hospitalized COVID-19 patients are discharged directly home[68]. Routine follow-ups are suggested in order to continue to monitor a patient's lung function, exercise capacity, muscle function, balance, and patient reported outcomes[69-74]. Due to continued infection risk and the recommendation for self-isolation with positive COVID-19 test results[69,71,75,76], many recovering patients are using telemedicine services instead of in-person health services to reduce spreading their infection to others. In addition, non-COVID-related health services have also seen an expanded use of telemedicine services instead of in-person services to reduce patient infection risk.

Clearly, the use of telehealth and remote care services have been critical to the safe management of both COVID-19 patients and non-COVID-19 patients during the current pandemic. ResMed's CPAP and respiratory care devices already offer telemedicine and telemonitoring capabilities which has allowed patients to still receive health services remotely during this pandemic.

Following declaration of a U.S. national public health emergency and calls for more flexible health services during the COVID-19 pandemic, U.S. federal regulations were relaxed and payment policies were expanded, resulting in broader access to telehealth services. On March 17, 2020, the United States Health and Human Services (HHS) announced historic waivers[77,78] to expand telehealth access, including out-of-state licensure flexibilities and federal enforcement of HIPAA-approved telehealth communication tools. On April 2, 2020, the Federal Communication Commission also adopted a $200 million telehealth program[79] as part of the Coronavirus Aid, Relief, and Economic Security (CARES) Act to provide technology tools to support the growing demand for remote care.

Historically, the Centers for Medicare & Medicaid Services (CMS), the single largest payer for healthcare in the United States, has only allowed telehealth services for a limited patient population with strict requirements and limited services. Effective March 1, 2020, rapid expansion of CMS' telehealth coverage[80] eliminated rural, originating site, and geographic requirements. Eventually, congress would also grant CMS the authority to waive modality and practitioner requirements. State-specific telehealth policies have also been modified to offer new flexibilities and expanded coverage services for both COVID-19 and non-COVID-19 cases.

These changes are only intended to remain in place until the end of the public health emergency. However, due to the explosion in use of telehealth, increasing demand, and overwhelming preference by patients, providers, and payers, advocates are pushing for permanent changes following the pandemic.

Benefits of telemedicine

Telemedicine has emerged as a key tool to allow for physicians and clinicians to provide more efficient care to non-COVID patients during this time of limited resources. In clinical populations prior to the COVID-19 pandemic, use of telemedicine through telehealth or telemonitoring services resulted in higher patient satisfaction[80-86], improved health outcomes[85,87-89], and increased quality of life measurements compared to those that received typical care[85,87,90-92]. Clinicians also found that patient adherence and compliance to therapy was improved when patients were offered telemedicine services[93-95]. Likely due to this increased compliance, patients that used telemedicine services also demonstrated decreased healthcare utilization[85,88,89,90,92,96-102] with shorter and less frequent hospitalization and lower healthcare costs.

Telemedicine/telemonitoring capabilities of ResMed devices

Patient setup through home sleep tests, home delivery, and virtual setups

During the months of April and May, some sleep physicians in some parts of the U.S. saw a reduction in new patient referrals. As sleep labs begin reopening in June and July with limited bed capacity in some states, new patients seeking treatment may experience a delay in appointment availability. Home sleep tests allow for sleep labs to expand their patient capacity by offering sleep testing services in the patient's home. Following diagnosis, devices can be provided to the patient through home delivery. In addition, virtual set up processes allow patients to connect with home medical equipment distributors on a 1:1 basis through a video call. To date, compliance remains high with patients, confirming that this testing and setup method is sufficient to meet the needs of patients post-COVID-19 by remaining competitive in the area, helping setup and support patients faster, offering cross-functional regional support, and adapting to patients' schedules.

In the wake of COVID-19, ResMed released MaskSelector, a digital tool for remote CPAP mask fittings that creates personalized recommendations to the home medical equipment provider based on a patient's sleep attributes and facial measurements. This online service will help clinicians who need better remote capabilities to fit and select masks for patients during the current environment of social distancing and beyond. The preliminary success of MaskSelector highlights the ongoing need and value of more digital patient experiences.

Remote patient monitoring through AirView

ResMed offers AirView, a secure, cloud-based remote patient monitoring tool to treat the entire care continuum of obstructive sleep apnea or respiratory conditions. These tools allow physicians to work

remotely and provide better care to patients through quick access to patient data, ability to share clinical insights remotely with other health professionals, and a reduction in in-patient follow-ups.

In response to the current COVID-19 pandemic, ResMed recently accelerated the launch of AirView for ventilation in Europe to help clinicians and care providers maintain their quality of care for patients suffering from respiratory conditions. With a large number of respiratory care patients requiring regular check-ups and support from hospitals, physicians, and homecare providers, AirView helps protect patients and medical staff as well as increasing the capacity of the health system. European clinicians and care providers can remotely monitor key indicators of their patient's condition, such as respiratory rate and blood oxygen saturation, via their computer or smart device. Clinicians can also access detailed respiratory information from ResMed's Astral and Stellar ventilators and Lumis bi-level devices.

Patient engagement through myAir

myAir is a user-friendly tool that allows patients with ResMed's Air10 sleep therapy devices to track their nightly sleep data and offers interactive coaching that empowers patients to stay engaged and compliant with their therapy. By providing the patient an opportunity to manage their own therapy through educational tools, it can also ease demands and increase efficiencies on the physician and sleep laboratories. A clinical study[104] demonstrated that patient engagement through myAir resulted in more patients achieving adherence criteria and increased therapy usage, even for those patient with historically low adherence.

Conclusion

At ResMed, we have supported our customers, clinicians, and patients by increasing our production of both invasive and non-invasive ventilators and publishing clinical bulletins that expand treatment options for patients suffering from COVID-19 and keep healthcare workers safe.

ResMed's mission to expand healthcare access to patients in home and post-acute settings aligns with the current need of the COVID-19 pandemic to broaden healthcare opportunities and limit infection risk to both patients and clinicians. As governments create a growing emphasis on telemedicine and telemonitoring opportunities, ResMed's devices are well positioned with active telemonitoring systems and patient engagement applications to support patients suffering from respiratory diseases and sleep disordered breathing. Throughout the COVID-19 pandemic and beyond, ResMed will continue to support our patients, clinicians, and customers through our focus on patient-centered care and leadership in digital health.

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