Respiratory Therapy

The Journal of Pulmonary Technique

St Luke's University Health Network One of the First in the World to Pilot Masimo SafetyNet

Masimo announced that St Luke's University Health Network (SLUHN) is one of the first institutions worldwide to use Masimo SafetyNet to monitor inhospital patients, as the network seeks innovative solutions to care for the surge of patients infected by COVID-19. Masimo SafetyNet is an innovative, economically scalable cloud-based patient management platform designed to help clinicians care for patients remotely in hospital settings and in nontraditional settings and circumstances. The telehealth solution uses a tetherless, wearable single-patient-use sensor to monitor patients with clinically proven Masimo SET pulse oximetry, and is designed to help manage the surge in COVID-19 patients while maintaining the safety of other patients and providers, allowing hospitals to expand patient remote monitoring into alternative care spaces, including overflow locations,

emergency recovery facilities, and home care settings. Aldo Carmona, MD, St Luke's Senior Vice President of Clinical Innovation and Chairman of the Department of Anesthesia and Critical Care, said, "This technology is game-changing in light of the crush of demand on our hospitals during this COVID-19 pandemic. With this wearable device, we can create temporary, popup respiratory monitoring units as needed to meet the changing patient volumes and track employees' health in their homes if they have been exposed to COVID-19, the flu, or any other serious illness." Designed to track the blood oxygen saturation and respiration rate of patients who are hospitalized or quarantined at home, Masimo SafetyNet combines tetherless SET pulse oximetry with a proprietary remote data capture and surveillance platform accessible from a patient's Android or iOS smartphone or smart device. Monitoring key physiological data can help provide clinicians with an accurate

snapshot of a patient's systemic health and facilitates awareness of the need for rapid execution of treatment decisions that can be life-saving. Patients are provided with a multi-day supply of single-patient-use sensors and access to the Masimo SafetyNet mobile app. With clinical feedback from St Luke's led by Dr Carmona and from University Hospitals led by Dr Peter Pronovost, Masimo SafetyNet has been designed for easy, intuitive use to provide customized, interactive CarePrograms that align with expert guidance on COVID-19. Monitoring data collected by the sensor is shared with the patient's smartphone using a secure Bluetooth connection. Twice daily, or as directed, the CareProgram can be configured to actively notify patients to answer questions such as, "are you having trouble breathing?" and "what is your temperature?", and pushes these responses along with the monitoring data to clinicians for evaluation. CarePrograms are fully customizable



Stay Safe. Stay Connected.

Remotely care for COVID-19 patients using a secure, proven telehealth platform.



Masimo SafetyNet[™] delivers continuous tetherless pulse oximetry and respiration rate monitoring alongside a secure patient surveillance and engagement platform— enabling providers to seamlessly extend care beyond the boundaries of the hospital.

Available for immediate deployment, Masimo SafetyNet is the only solution to deliver hospital-proven tetherless SET[®] pulse oximetry and surveillance monitoring to alternative care spaces.

Discover Masimo SafetyNet | www.masimo.com/masimo-safetynet

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician. See instructions for use for full prescribing information, including indications, contraindications, warnings, and precautions.



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©2020 by Goldstein & Associates, Inc. All rights reserved. Reproduction in whole or in part without written permission is strictly prohibited. to accommodate each institution's protocols, each patient's needs, and any changes in COVID-19 guidance—and can be updated through the cloud by providers even after being deployed, for maximum flexibility as situations evolve. In addition to COVID-19 CarePrograms, Masimo SafetyNet can be configured for more than 150 other CarePrograms for use with COPD, heart failure, oncology, and other patients.

On March 30, patients at St Luke's University Health Network Bethlehem diagnosed with COVID-19 were outfitted with Masimo SafetyNet. Non-COVID-19 patients are also being monitored with this system in general medicalsurgical units. St Luke's plans to use the Masimo SafetyNet tetherless sensor and cloud-based surveillance system to monitor upwards of 2,000 hospitalized patients and lower acuity cases in the home. These may also include staff and patients who are quarantined at home with the virus. "Our patients at St Luke's have the most sophisticated and reliable respiratory monitoring available anywhere," Carmona says. "We know that continuous physiologic monitoring with Masimo's Patient SafetyNet improves outcomes and saves lives. The ability to extend that capability to patients in non-traditional settings and at home during this crisis with Masimo SafetyNet is transformative. Only through our relationship with Masimo could this have been possible."

Joe Kiani, Founder and CEO of Masimo, said, "Masimo is proud to be able to work with St. Luke's to help protect the health and safety of medical professionals and the patients they serve during this global pandemic."

Device Mitigates Risks to Workers

In today's unprecedented challenge to protect healthcare workers on the front lines as they battle the coronavirus pandemic, one Arizona company is providing a unique nebulizer system that is designed to optimize aerosol therapy and mitigate caregiver exposure to the contagion. Westmed, Inc, a leader in pulmonary medication delivery, introduced the original Circulaire Aerosol Drug Delivery System in 1997. In 2008, the company modified the Circulaire II with new features to create a quasi-closed device that significantly improved drug delivery performance, as well as the safety of the system. One enhancement included a unique Medication Reservoir, designed to retain the excess aerosol produced during nebulization which would subsequently be inhaled by the patient during inspiration, thus providing maximum output delivery of the nebulizer. As a result, only the Circulaire II System effectively doubles the dosage of medication with every breath. In addition to functioning as a holding chamber, conserving medication and enhancing aerosol delivery, the Reservoir also prevents room air dilution of medication to achieve the highest Fraction of Inhalable Aerosol in the industry. In fact, multiple studies





Masimo rainbow[®] Pulse CO-Oximetry

confirm, the Circulaire System delivers more drug mass in less time than any other conventional nebulizer. Plus, a One-Way Valve virtually eliminates the risk of the patient re-breathing into the nebulizer, to protect the nebulizer and the Reservoir from contamination by exhaled pathogens. Further, of particular importance today, while not a complete solution, an integral Exhalation Filter in the Circulaire II, with bacterial >99.99% and viral >99.98 efficiencies, mitigates exposure to exhaled patient droplets and medication during aerosol therapy. The Circulaire II is the only aerosol delivery system available that includes an integral Exhalation Filter as a standard feature. https://westmedinc.com/ circulaire-ii/

Help Offered to Fill Blood Shortages

Masimo announced that, in response to current worldwide blood shortages driven by the coronavirus pandemic, it is making rainbow[®] licenses available for no additional charge to hospitals where rainbow[®]-ready devices are already in use. The Masimo rainbow[®] platform allows for the noninvasive and continuous monitoring of 12 parameters, including hemoglobin (SpHb), oxyhemoglobin (SpO2), and methemoglobin (SpMet). Once rainbow[®] is enabled, hospitals can purchase RD rainbow[®] sensors at discounted prices during this pandemic. The program is available globally and is planned to continue until the pandemic subsides. SpHb provides real-time visibility to changes, or lack of changes, in hemoglobin between invasive blood samples-and has been shown to help clinicians improve patient blood management. In multiple outcome studies, SpHb has been shown to help clinicians reduce blood transfusions. SpHb is available on a variety of Masimo Pulse CO-Oximeters, including the Root Patient Monitoring and Connectivity Platform, Radical-7, and Rad-97, as well as patient monitors from 25 other patient monitoring manufacturers, including Dräger and Philips. "Our goal is to make the biggest difference we can during this challenging time. This is our third initiative in the past four days to help clinicians deal with COVID-19. Many hospitals have seen the value of rainbow[®], and we hope every hospital can now benefit from proven rainbow® noninvasive blood constituent monitoring technology," said Joe Kiani, Founder and CEO of Masimo. One of the many burdens COVID-19 is placing on health systems around the world is a shortage of blood products, as hospitals rush to treat an extraordinary surge of

patients—at the same time that many blood drives have been cancelled. Therefore, hospitals are needing to manage blood supplies as efficiently and conservatively as possible. A growing body of evidence from around the world has shown that Masimo SpHb may help clinicians reduce unnecessary blood transfusions in both low- and highblood-loss surgeries: A randomized trial of 327 patients undergoing elective orthopedic surgery found that the use of continuous, noninvasive hemoglobin monitoring with SpHb reduced the rate of transfusions by 87% when compared to standard care without continuous, noninvasive hemoglobin monitoring. A prospective cohort study of 106 neurosurgical patients found that adding SpHb monitoring to standardof-care blood management resulted in decreased blood utilization in highblood-loss neurosurgery by 41%, while also decreasing time to transfusion when indicated by 41 minutes. A study of 100 patients undergoing abdominal cancer surgery found that SpHb monitoring decreased blood utilization by 39%, while facilitating earlier transfusions when indicated by 33 minutes. A study of 237 patients undergoing hip trauma surgery found that continuous SpHb monitoring during high-blood-loss surgery reduced the percentage of patients needing blood transfusions by 7% and number of transfused units per patient by 13%. In addition to SpHb, the rainbow[®] family of advanced noninvasive parameters includes SpMet, which helps clinicians noninvasively and continuously monitor methemoglobin levels in the blood. Elevated methemoglobin levels can be caused by inhaled nitric oxide (iNO) therapy, which is currently being

investigated as a potential treatment for lung complications associated with COVID-19. By allowing clinicians to monitor methemoglobin levels, SpMet may be an important monitoring tool during iNO therapy. SpHb and SpMet are not intended to replace laboratory blood testing. Clinical decisions regarding red blood cell transfusions should be based on the clinician's judgment considering, among other factors, patient condition and laboratory diagnostic tests using blood samples.

Getinge contributes to Ventilator Manufacturers Group to form Ventilator Training Alliance

Today several of the world's ventilator manufacturers announce a newly formed Ventilator Training Alliance (VTA) to support frontline medical providers to access a centralized repository of ventilator training. The content can be found in a mobile app managed by Allego. "Supporting our customers and facilitating ventilator training continues to be key to all stakeholders in this project", says Charles Merchant, Senior Director **Global Therapy Development Acute** Care Therapies at Getinge. "Dräger, GE Healthcare, Hamilton Medical, Medtronic, Philips, Vyaire Medical and Nihon Kohden, together with Getinge, have joined this humanitarian training coalition". The VTA app - powered by learning and readiness platform provider Allego - connects respiratory therapists, nurses and other medical professionals with ventilator training resources from alliance member companies, including instructional how-to videos, manuals, troubleshooting guides, and other ventilator-operation expertise critical to treating patients suffering from COVID-19-related respiratory distress. Ventilators play a critical role in the management of patients who require assistance because they cannot breathe effectively due to severe respiratory illness, such as COVID-19. Speed and ease of access to ventilator training has a direct impact on patients' health during the COVID-19 crisis. Content on the VTA app can be accessed on iOS and Android devices - even in environments with little to no Wi-Fi access - or from a web browser. The app provides healthcare professionals' multi-language closed captioning and mobile background audio when multitasking. The app is provided at no cost to medical professionals. To download the Ventilator Training Alliance knowledge hub application, visit the Apple App Store or Google Play store, or access the hub from any Web browser.

Study Looks at Integrated Clinical Surveillance Monitoring

Masimo announced the results of a recently published ten-year retrospective study in which researchers at Dartmouth-Hitchcock Medical Center investigated the impact of an integrated

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clinical surveillance monitoring system, using Masimo SET and Patient SafetyNet technologies, on mortality related to the use of prescribed opioids in the general ward. Over the ten years studied, of 111,488 patients in units with surveillance available, there were zero patient deaths and no patients were harmed by opioid-induced respiratory depression while continuous monitoring was in use. In contrast, among patients in units without surveillance available, there were three deaths. The surveillance monitoring system provided continuous monitoring using Masimo SET Measure-through Motion and Low Perfusion pulse oximetry, and was comprised of Masimo Radical-7 and Rad-87 Pulse CO-Oximeters, Root Patient Monitoring and Connectivity Hubs, and Masimo Patient SafetyNet, which provided supplemental remote monitoring at central view stations and alarm and alarm escalation notifications to clinicians' pagers. Monitored parameters included oxygen saturation (SpO2) and pulse rate (PR). The researchers reviewed ten years of data collected from 2007 to 2017, over which time there were 126,697 general care unit discharges. Dr Sue McGrath and colleagues at Dartmouth-Hitchcock Medical Center found that, over the 10 years, of the 111,488 patients in units with surveillance monitoring available, "none died or were harmed by opioidinduced respiratory depression when surveillance monitoring was in use."



Of the 15,209 patients in unmonitored units, three patients died from opioid overdose. The reduced death rate when surveillance was available, compared to when it was not available, was statistically "significant" (p=0.03). A fourth patient died in a unit where surveillance monitoring was available but Masimo technology was not being used at the time of the adverse event. The researchers noted, "The fact that one patient with known risk for opioid sensitivity died while in a unit where monitoring was available but not in use highlights the importance of system adoption and adherence to standards of care." The researchers concluded, "For a 10-year period, the rescue system with continuous surveillance monitoring had a profound effect on death from sedative/analgesic administration in the general care setting. This approach to patient safety can help address the risk of sedative/analgesic-related respiratory arrests in hospitals." Regarding the cost of deploying such a system, the researchers noted, "Although cost is often raised as a barrier to implementation, a previously performed financial analysis demonstrated cost-effectiveness of surveillance monitoring due primarily to intensive care unit patient days avoided when early detection of patient deterioration occurs." They continued, "This study confirms that surveillance monitoring for pharmacologically induced respiratory arrest in hospitalized patients can virtually eliminate deaths due to this serious but treatable complication. In other high-risk,

safety-focused industries, the level of evidence that currently exists for continuous surveillance monitoring to mitigate the risk of accidental sedative/analgesic overdose would likely prompt immediate calls for widespread implementation of safety interventions." Joe Kiani, Founder and CEO of Masimo, commented, "We are incredibly grateful to Dr McGrath, her colleagues, and everyone at Dartmouth-Hitchcock Medical Center for demonstrating the value of continuous monitoring of post-surgical patients over a ten-year period. Hundreds of other hospitals have adopted our technology and have reported similar results. We hope that this new study will inspire every other institution to implement Masimo SET on their general floor to eliminate preventable deaths due to opioid overdose, especially at this time when illnesses that impact the respiratory system, such as COVID-19, are so prevalent." In previously published studies at Dartmouth-Hitchcock Medical Center, researchers found that after deploying the continuous monitoring system in the original 36-bed unit, there was a 65% reduction in rapid response team activations and a 48% reduction in transfers back to the ICU. After five years of use, they reported zero preventable deaths or brain damage due to opioids, as well as cost savings of \$7 million, and after ten years, they reported maintaining a 50% reduction in unplanned transfers and a 60% reduction in rescue events, despite increases in patient acuity and occupancy.



Patient SafetyNet Supplemental Remote Monitoring and Clinician Notification System

Disposable CPAP Devices Donated

Mercury Medical, a healthcare manufacturer focused on introducing new critical care medical device technologies, announces the donation of 2,500 Flow-Safe II Disposable CPAP devices to the state of New York for treating COVID-19 patients. The FDA recently issued guidelines indicating that BiPAP and CPAP devices can be used to effectively help treat COVID-19 patients in Respiratory Distress. CPAP therapy has been shown to be very efficacious in preventing these patients from deteriorating to the point where they require mechanical ventilation. With the current shortage of mechanical ICU ventilators, these CPAP devices can play an important role in meeting New York's surge capacity to treat the influx of COVID-19 patients. Currently, the New York City Fire Department (FDNY) has been using Mercury Medical's Flow-Safe II EZ disposable CPAP device for patients exhibiting symptoms of Respiratory Distress for the last few years. The Flow-Safe II family of products are disposable ventilatory support devices that deliver CPAP and/or Bilevel CPAP therapies. They do not require a mechanical machine or electrical power; simply connect to an oxygen source within the hospital to deliver adjustable CPAP pressures; can be disposed of after use to eliminate cross contamination; are simple to use and are very cost effective. John Gargaro, MD, Mercury Medical president and CEO, states, "We have been following daily updates regarding the growing spread of COVID-19 and the resulting health impact on the State of New York, especially in New York City and surrounding areas. We are donating 2,500 each of our Flow-Safe II product to help New York's efforts in saving lives during this COVID-19 crisis. We believe that this product can be used effectively on coronavirus patients with the goal of minimizing the need for mechanical ventilators, thus freeing them up to be used on more critical cases."

FDA Clears Blood Gas Analyzer Used for Critically III Patients in Acute Care Settings

Siemens Healthineers announced that its latest critical care testing solution, the RAPIDPoint 500e Blood Gas Analyzer, has received clearance from the US Food and Drug Administration. The analyzer generates

blood gas, electrolyte, metabolite, CO-oximetry, and neonatal bilirubin results, which are used to diagnose and monitor critically ill patients in the intensive care unit, operating room, or emergency room. Already available in countries requiring the CE mark, the RAPIDPoint 500e Blood Gas Analyzer is now available for critical care testing in the United States. "Pointof-care teams monitoring respiratory conditions in critical care settings need a blood gas testing solution that delivers fast, accurate results and increases workflow efficiencies. A safe operating environment amid growing concerns about cybersecurity threats in healthcare is also important," said Christoph Pedain, PhD, Head of Point of Care Diagnostics, Siemens Healthineers. "The RAPIDPoint 500e Blood Gas Analyzer has become a trusted instrument in Europe's endeavor to combat COVID-19 and to help address an unprecedented demand for blood gas testing in affected respiratory patients." The RAPIDPoint 500e Blood Gas Analyzer is an essential instrument supporting COVID-19 response efforts, where blood gas testing plays a critical role in managing infected patients and monitoring their respiratory distress. Routine blood gas testing is also performed when patients require mechanical ventilation. Arterial blood gas tests provide the status of a patient's oxygenation levels and enable healthcare providers to determine whether adjustments to ventilator settings or other treatments are required. The analyzer elevates confidence in patient results with Integri-sense Technology, a comprehensive series of automated functional checks designed to deliver accurate test results at the point-ofcare. "As an ICU physician, I know that the values I am handed during an emergency allow me to confidently make life-saving decisions. The RAPIDPoint system is easy to use and allows me to not worry about the machine and focus my attention on my patients," said Dr Daniel Martin, Royal Free Hospital, London. Additionally, the RAPIDPoint 500e Blood Gas Analyzer integrates seamlessly into hospital networks with the Siemens Healthineers Point of Care Ecosystem, which offers convenient, remote management of operators and devices located across multiple sites. For more information



about the RAPIDPoint 500e Blood Gas Analyzer, visit https://www.siemenshealthineers.com/rapidpoint500e.

Company Ramps Up Production

Getinge, the world market leader in advanced ventilators for intensive care units, announced another rampup in production capacity, to 26,000 ventilators in 2020. The increase equals a growth of 160% compared to 2019, when 10,000 ventilators were produced. The demand for advanced ventilators for the intensive care units in hospitals continue to increase globally as a result of the COVID-19 pandemic outbreak. Getinge is ramping up the production capacity stepwise at its production facility in Solna, Sweden, and is now increasing production capacity to 26,000 in 2020, compared to the previous planned 16,000 unit level that was communicated on March 17. The ramp up will start immediately and progress in close collaboration with Getinge's suppliers. "We continue to ramp up to be able to respond to the increasing demand from our customers", says Elin Frostehav, Vice President Critical Care at Getinge. "We work closely with our sub-contractors and the ramp up is of course pending availability of supply parts". In 2019, Getinge produced 10,000 ventilators at the production facility in Solna.

Since the start of 2020, Getinge has increased its production capacity with 160%, compared to 2019. The estimated increase in demand and production capacity of ventilators is expected to be accretive to Getinge's result. Learn more about Getinge's products at www. getinge.com.

Should CPAP Therapy be used with COVID-19 Patients?

Some clinicians are currently inquiring if CPAP therapy can be used with COVID-19 patients. According to the many experts, the response is an overwhelming YES! Josh Farkas MD, associate professor of Pulmonary and Critical Care Medicine at the University of Vermont states, "COVID patients really need positive pressure more than anything else. For example, their work of breathing is often tolerable-so they may not need much mechanical support for the work of breathing (indeed, mechanical support could lead to injuriously large tidal volumes)." The best modality to provide lots of positive pressure is simply Continuous Positive Airway Pressure (CPAP). CPAP may not seem dramatic, but this modality actually provides the greatest amount of positive pressure to allow for the most powerful recruitment." Importantly, recently communicated new findings from the Intensive Care Society, (ICS),

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state, "CPAP may be of benefit to patients, (COVID-19), earlier on in the disease process than first thought and may prevent deterioration of some patients to the extent of them not going on to need invasive ventilation." Mercury Medical markets technology that can provide both CPAP and Bilevel therapies using low cost Flow-Safe CPAP and Bilevel CPAP disposable devices. Current research supports the use of Flow-Safe Disposable CPAP devices. In addition, The American Journal of Emergency Medicine concludes that a disposable CPAP device, (Flow-Safe II Mercury Medical), is just as effective as a mechanical portable ventilator (Philips Respironics Trilogy 202). A continuum of care protocol can be established by placing COVID-19 patients on a disposal CPAP/ Bilevel device upon entry to the EMS vehicle / ER Department; maintaining the same device during the hospital stay until an intensive care ventilator is indicated. The Flow-Safe disposable CPAP/Bilevel devices are packaged with non-vented full face deluxe masks. When used with an expiratory filter, they may reduce the incidence of cross contamination, are simple to use,

require little training and run on medical grade air/oxygen systems currently available in hospitals today.

Company Expands Array of Devices

CAIRE Inc.'s strong portfolio of oxygen therapy solutions in China has expanded yet again with the recent release of the award-winning FreeStyle Comfort portable oxygen concentrator. Credited with pioneering the first portable oxygen concentrator, CAIRE engineers have designed this latest product with an innovative ergonomic, curved shell, and delivery features to ensure oxygen is provided with each breath. "CAIRE oxygen therapy brands—specifically the FreeStyle series-have long been relied upon to aid individuals suffering from Chronic Obstructive Pulmonary Disease. The FreeStyle Comfort is an innovative update to a proven brand with clinical enhancements and smart O2 delivery features that will further improve the delivery of oxygen to patients, also benefitting clinicians and caregivers who support their healthcare needs," said Earl Lawson, President and CEO of CAIRE Inc. The release of the FreeStyle Comfort in China, available

and distributed through the company's Chengdu facility, meets a critical need of providing oxygen therapy, one of several treatment options, to those individuals suffering from COPD, or other longterm respiratory conditions. In April of 2018, ScienceDaily published an article regarding Tulane University's study of the largest group of COPD across age groups in China. Research found that almost 100 million adults have COPD in China with many not aware they have the chronic lung disease. "The release of the FreeStyle Comfort in China marks an important step in serving this population of people who want to breathe better and enjoy the latest innovation and technologies in a lightweight package," Lawson added. This is the third major release of the new portable oxygen concentrator since its official US debut in 2018, which drew top honors from industry peers and publications, and its European release in 2019. Weighing only 5 lbs, the FreeStyle Comfort offers on-demand oxygen flow and features a uniquely-designed ergonomic shape that rests comfortably against the curves of the body. Enhanced proprietary smart oxygen delivery features including CAIRE's

UltraSense technology, which ensures that oxygen is delivered in conjunction with the patient's breath rate, and autoDOSE, which ensures delivery of oxygen even if no breath is detected, help ensure the clinical efficacy of the product. Portable oxygen concentrators, operational via battery or electrical power, take ambient air, filter it and then deliver up to 95 percent purified oxygen to the user. This convenience of being able to plug-in and recharge anywhere has contributed to portable oxygen concentrators increasing in popularity as compared with other oxygen modalities like cylinder tanks and liquid oxygen portables which rely on being refilled by a gas supplier. The device meets FAA guidelines for use on commercial air flights and offers wireless connectivity to CAIRE's telehealth solution, CAIREview.

Protecting Healthcare Workers from Patients with COVID-19

COVID-19 is a highly contagious virus, with an infectivity rate even higher than SARS. Patients progress from simple upper respiratory symptoms to requiring supplemental oxygen to intubation and mechanical ventilation. During the period of requiring supplemental oxygen and particularly during the periods where they may require aerosol therapy,

healthcare workers at their bedside are exposed to aerosolized particles exiting their oxygen delivery devices. In most cases, when just using an oxygen mask, the aerosolized particles exiting laterally from holes in the mask for exhalation, bath the healthcare worker in particles that may not be visible to the naked eye. During the SARS epidemic the design team from 12th Man Technologies developed the Hi-Ox oxygen mask, that has no holes in the mask and all inspired and exhaled gas is delivered to the patient through one-way valves. Not only is it able to deliver higher FiO2s than a NRBM, all exhaled air flows down the front of the patient's body and not towards the healthcare workers standing at their side. Some centers have added a filter to the expiratory limb to capture the exhaled contaminants. The Ontario Ministry of Health has recommended the Hi-Ox as the mask to use for oxygen delivery during respiratory pandemic outbreaks. Tri-Anim Healthcare is a distributor of the Hi-Ox.

Mallinckrodt and Novoteris Receive Clearance from Health Canada

Mallinckrodt plc, a global biopharmaceutical company, and Novoteris, LLC, a clinical stage medical



device and pharmaceutical developer focused on innovative nitric oxide gas applications, announced that the Therapeutic Products Directorate of Health Canada has cleared the companies' joint pilot clinical trial, entitled "Inhaled Gaseous Nitric Oxide (gNO) Antimicrobial Treatment of Difficult Bacterial and Viral Lung (COVID-19) Infections" application to investigate the use of Thiolanox, a high-dose inhaled nitric oxide therapy for the treatment of patients infected with novel coronavirus (SARS-CoV-2) at Vancouver Coastal Health Authority facilities. The investigative therapy employs Novoteris' Inhaled Nitric Oxide Delivery Device (INODD) and Mallinckrodt's high-concentration, 5000 PPM nitric oxide gas for inhalation canisters. The study will investigate the therapy's safety and effectiveness in treating COVID-19 and its associated lung complications. The companies expect to begin recruiting patients in the coming days. "Inhaled nitric oxide may have an antiviral effect, as well as improve oxygenation and pulmonary arterial pressure in patients suffering from COVID-19," said Steven Romano, MD, Executive Vice President and Chief Scientific Officer at Mallinckrodt. "We're proud to be partnering with Novoteris on this pilot trial and are committed to increasing understanding of this potentially important therapeutic option for healthcare providers on the front lines of this unprecedented health emergency." COVID-19 is a contagious respiratory illness caused by a novel coronavirus. Patients with COVID-19 have mild to severe respiratory illness that can include symptoms such as





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cough, fever and shortness of breath. In severe cases, COVID-19 can cause acute respiratory distress syndrome (ARDS)—a disorder in which fluid leaks into the lungs, making breathing difficult or impossible—and can lead to multi-organ failure and sometimes death. **"Our collaboration with Mallinckrodt to study high-dose inhaled nitric oxide to treat patients with COVID-19 and associated lung complications is an exciting step in both**

companies' commitment to helping the world battle this global pandemic," said Alex Stenzler, Founder and President at Novoteris. Inhaled nitric oxide (iNO) has been evaluated in randomized controlled trials, both in pediatric and adult patients with ARDS, and demonstrated partially dose-dependent improvement in blood oxygenation and decreased pulmonary artery pressure and, in one trial, improvements in the composite measure of days alive or free of ventilator support at day 28 of the trial (the last day evaluated). There have been other trials evaluating iNO in the context of ARDS, which have demonstrated mixed results. In an in vitro study, inhaled nitric oxide has demonstrated an inhibitory effect on the replication cycle of severe acute respiratory syndrome-related coronavirus (SARS-CoV). Furthermore, a small clinical trial in SARS-CoV patients demonstrated improvements in blood oxygenation, a reduction in supplemental oxygen and a reduction in the amount of ventilator support. "This is an important day for patients and healthcare providers," said Chris Miller, PhD, Assistant Professor, Faculty of Medicine at University of British Columbia and Founder and Scientific Advisor at Novoteris. Dr Miller, team

lead for the study at Vancouver Coastal Health Research Institute, and an expert in nitric oxide therapies, with a research career spanning more than 25 years studying the antimicrobial effect of high-dose nitric oxide to treat lung infections, said, "I am very pleased to be working with Mallinckrodt and Novoteris on this study using high-dose inhaled nitric oxide for patients with COVID-19." Mallinckrodt is currently working with the US Food and Drug Administration on the possibility of making the company's INOmax (nitric oxide) gas, for inhalation product available to US patients with pulmonary complications of COVID-19 as quickly as possible through the appropriate regulatory mechanism. INOmax has been on the market in the US since 2000, and is indicated for the treatment of term and near-term neonates with hypoxic respiratory failure associated with pulmonary hypertension. Please see Important Safety Information below. The safety and efficacy of INOmax and iNO for pulmonary complications associated with COVID-19 have not been established. For more information, visit clinicaltrials.gov.

Fighting COVID-19 is Our Mission

The mission of IngMar Medical is to decrease patient suffering and improve outcomes is fueled by the actions you are taking right now, and we want to help you win this fight. We hope this knowledge base will help you enable others to act in this crisis. Thank you for your unwavering courage and dedication to healthcare. Watch and share our recorded presentations to learn essential information on mastering the art of mechanical ventilation, particularly for patients diagnosed with COVID-19. These presentations provide e-learning content as well as hands-on demonstration of training scenarios. Download complimentary scenario simulations that you can run on your ASL 5000 Breathing Simulator. These simulations will enable you to provide hands-on training and develop your staff's competency in treating a patient diagnosed with COVID-19, supported by mechanical ventilation. Browse the resources we used to inform our COVID-19 scenario simulations as well as basic training tools and videos meant to help clinicians understand the proper use of most major ventilators. Visit https://www.ingmarmed.com/ covid19/ for more details.

Cuff Pressure Management While Keeping a Safe Distance

Safety with HVLP cuffs. The TRACOE smart cuff manager can be used with tracheostomy tubes as well as endotracheal tubes. This innovative product allows a visual control at a safe distance. Being a single patient product, the risk of cross infection is reduced to a minimum. The main function of this product is to keep the cuff pressure at a stable range between 20 and 30 cm H2O. This helps minimize the risk of silent aspiration and improper sealing which can cause damage to the respiratory system. Additionally, it reduces the risk of aerosol formation due to insufficient cuff pressure. Find more information at https://www.tracoe.com/en/products/ technic/article/article/ref-730-5-tracoetechnic-smart-cuff-manager/

Best Practices for COVID-19

For the prevention of COVID-19 spread, the focus has been correctly placed on the issue of community transmission.



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This includes clinical settings like hospitals or health practices where there is now increased respiratory testing demand due to the virus. It is important that Bacterial Viral Filters (BVF) be in use during these procedures to reduce the contamination risk to equipment such as spirometers as well as the surrounding test environment. This practice, in addition to routine cleaning procedures, will significantly reduce the chance of transmission among patients and staff. Professor Colum Dunne of the University of Limerick and colleagues tested Vitalograph BVFs to assess their effectiveness in preventing bacterial or viral transfer to and from respiratory testing equipment. Results showed >99.99% effectiveness for the prevention of microbial transfer to the testing equipment. BVFs also reduced potential transfer from the equipment to the users to a level below detectable limits. This suggests that BVFs should be used whenever possible during the use of respiratory diagnostic equipment. Vitalograph also recommends surface cleaning of flowheads between each patient using 70% isopropyl alcohol. Professor Dunne believes that these practices will reduce the risk of spreading COVID-19, and other bacteria or viruses, between patients in clinical settings.

Ventilator Specs Shared

Medtronic, is publicly sharing the design specifications for the (PB 560) ventilator to enable participants across industries to evaluate options for rapid manufacturing to help doctors and patients dealing with COVID-19. This decision is consistent with the recent FDA Guidance and in accordance with the public health and medical response of governmental agencies globally.

Introduced in 2010, the PB 560 is sold in 35 countries around the world and can be used in a range of care settings. PB 560 product and service manuals, design requirement documents, manufacturing documents, and schematics are now available at Medtronic.com/openventilator. The PB 560 design specifications are available today, software code and other information will follow shortly. The PB 560 ventilator is a compact, lightweight, and portable ventilator that provides airway support for both adults and children. It can be used in clinical



settings and at home and provides mobile respiratory support. Bob White, executive vice president and president of the Minimally Invasive Therapies Group at Medtronic, said: "Medtronic recognises the acute need for ventilators as life-saving devices in the management of COVID-19 infections. We know this global crisis needs a global response. Over the past few weeks, we have ramped up production of our Puritan Bennett 980 ventilators. But we also know we can do more, and we are. By openly sharing the PB 560 design information, we hope to increase global production of ventilator solutions for the fight against

COVID-19." Ventilators play a critical role in the management of patients with severe respiratory illness, such as COVID-19, who require assistance because they cannot breathe effectively. By placing a patient on a ventilator, the patient's lungs are permitted to rest and recover while the ventilator performs the functions of supplying oxygen and simulating the actions of breathing. Without ventilation support, some patients with severe respiratory disease might not survive.

Hospitals Facing Ventilator Shortage

A New York hospital system has begun treating two patients instead of one on some ventilators, a desperate measure that could help alleviate a shortage of the critical breathing machines and help hospitals around the country respond to the surge of coronavirus patients expected in the coming weeks. NewYork-Presbyterian Hospital, began "ventilator sharing" this week, said Dr Laureen Hill, chief operating officer at the Presbyterian/Columbia University Irving Medical Center system. Doctors have developed protocols for the maneuver and now are rapidly scaling it up while also sharing their methods with the federal and state governments and other hospitals. Ventilator sharing has been explored in a few scientific studies and has been used twice in crisis situations - the immediate aftermath of the 2017 Las Vegas shooting and, as of several days ago, by an emergency physician, Dr Marco Garrone, for coronavirus patients in Italy. This is believed to be the first time that it has been put forth as a longer-term strategy in the United States. "We're doing something that hasn't really ever been done before," said Dr Jeremy Beitler, a pulmonary disease specialist at NewYork-Presbyterian/Columbia. "Now is the time to do it." Gov Andrew M Cuomo of New York said on Thursday that the state had approved the new method, which is also being studied by federal officials. And this week, the Food and Drug Administration granted emergency use approval to a device called VESper, developed by the South Carolina-based Prisma Health, that adapts one ventilator for use with four patients. The New York action reflects the intense need felt worldwide to make ventilators serve more of the sickest COVID-19 patients. Generally, when patients are mechanically ventilated, a flexible tube is placed into their windpipe, and a finely calibrated pump



sends oxygen-rich air into the lungs. In a video, a doctor uses a T-tube and three adapters to split two valves into four ports, and suggests positioning the patients headfirst around the machine. Dr Babcock and her colleague Dr Greg Nyman had published a study of the hack in 2006 - but tested it on four lung simulators, not patients. "Here's my disclaimer: This is off-label use for a ventilator," she says in the video. "If it was me, and I had four patients, and they all need intubation, and I only had one ventilator, I would simply have a shared discussion meeting with all four families and say, 'I can pick one to live, or we can try to have all four live." NewYork-Presbyterian is using ventilator sharing for only two patients at a time who need settings on the ventilator that are very similar. Dr Beitler emphasized that each patient is still receiving the same amount of oxygen and level of care as previously. Sharing will not immediately double ventilator access, he added, because many patients will need their own. The hospital has not yet run out of ventilators, but Dr Beitler said it was better to try the technique now than "when you have absolutely no choice." Notably, he believes the technique will not increase staffing needs. With about 175,000 ventilators in hospitals and the federal stockpile, other states are also braced for shortages. Coronavirus patients often need to stay on ventilators for days or weeks. The subject of splitting ventilators is "highly controversial" among respiratory specialists, said Dr Josh Farkas, an assistant professor of pulmonary

University of Vermont. "While this is a technique that potentially could work for maybe a few hours, there are some significant hurdles," said Dr MeiLan Han, a pulmonologist at the University of Michigan Health System and a spokeswoman for the American Lung Association. Among the concerns are the inability to monitor the impact on each individual; the potential for crosscontamination of infectious pathogens; and the possibility that instead of one person receiving lifesaving treatment, multiple patients would get dangerously subpar therapy.

Best Practices for Infection Control

As concern over the COVID-19 virus continues to grow and many labs are discontinuing all non-essential testing, MGC Diagnostics has received many inquiries as to the best practice for infection control when using our devices. Our products, although not critical care or emergency medical devices, are used to assess, diagnose and monitor the effect of COVID-19 on patients. The safety of our customers, their staff and patients is of utmost importance to us. Having clear and defined infection control policies is important for your protection. As such, we wanted to provide some guidance regarding infection control and cleaning options. MGC Diagnostics gives you three options for infection control - letting you make the choice that is right for your facility. 1. Change — Simply change the filter and keep the same preVent flow sensor and BreathPath patient circuit. 2. Re-Use — Change the flow sensor and patient circuit between patients and replace with disinfected components. **3. Dispose** — Dispose of the flow sensor and patient circuit after each patient. Changing out the patient test supplies can be done in 1 min with no warm-up time or recalibration of the system.

MGCD Partnership with University to Develop Low-cost Ventilator

As spread of COVID-19 continues throughout the country, demand for medical ventilators could skyrocket. Many are already expressing concerns about potential shortages, but there's a doctor at the University of Minnesota who says he just created a simpler, cheaper ventilator that could save lives. University of Minnesota Anesthesiology fellow Dr Steve Richardson started work on his ventilator last Sunday, sourcing equipment and resources from biomedical engineer friends and other private companies. MGC Diagnostics is a partner in the project. Within hours of starting, Richardson finished a simple, effective prototype that he is now perfecting. He says if the FDA clears a path for production, he could scale it quickly, producing thousands within three weeks at a fraction of the cost of a traditional hospital ventilator. "People have just been working around the clock every day since Sunday morning, and we have a ventilator that I would be comfortable being anesthetized with," Richardson said. If you would like to donate resources, supplies, research, manpower or funds to continue this project, visit www.coventors.com.

Company Working to Keep You Safe

A message from ResMed CEO Mick Farrell: "As a global leader in respiratory medicine, ResMed stands with the world in the face of the latest coronavirus disease COVID-19 and is ready to help mitigate its effects, helping people breathe while their immune system fights this virus. More than 7,500 ResMedians are working in over 140 countries for this purpose. We are working with governments, health authorities, hospitals, physicians, and patients worldwide to assess their needs, and to deliver the ventilation therapy that is essential to treat the respiratory complications of COVID-19. Our primary focus is to maximize the availability of ResMed ventilators and other respiratory support devices for the

and critical care medicine at the

patients that need them most. As global leaders in digital health, we're proud that many of our ventilators and bilevel respiratory devices are cloud-connected, enabling physicians and respiratory specialists to remotely monitor their patients. There could not be a clearer case for the use of digital health and remote monitoring of patients than this current crisis with a virus that is so contagious stemming from direct human contact. I'm grateful to our global team for working through today's challenges to help treat an increasing number of COVID-19 patients. I'd like to call out first-responder ResMedians in China's Hubei province, the epicenter of the coronavirus outbreak, in particular one ResMed hero who, since early January, has donned a positive pressure hazmat suit, and helped set up thousands of people on ResMed ventilators and ResMed masks. There are also 100-plus ResMedians from Malaysia who in mid-March volunteered to keep working in our Singapore manufacturing plant when Malaysia closed its borders, relocating to live near our plant in Singapore, spending weeks away from their families, so they can continue to produce as many lifesaving ventilators and ventilation masks as possible. ResMed is taking every measure possible worldwide to maximize the production of ventilators, masks, and other respiratory devices. We are looking to double or triple the output of ventilators, and scale up ventilation mask production more than tenfold. Our team is also taking precautions such as a work-fromhome policy for all employees who can do that, social distancing, and

ensuring world-class quality, safety, good manufacturing practices, and top-level hygiene procedures at our manufacturing, service, and distribution centers to help ensure quality, safety, and business continuity. I urge all of us to do our part to help reduce the spread of the coronavirus, whether that is self-quarantining, working from home, sheltering in place, or just staying healthy for our families, particularly the elderly and those with compromised immune systems. Let me close with this: I would like to personally thank the front-line clinical heroes-many thousands of respiratory therapists, respiratory nurses, pulmonary and critical care medicine physicians, as well as hospital and clinical staff who set up our ventilators and masks for patients in need and deliver the lifesaving gift of breath... You are the superheroes of this COVID-19 crisis, and we salute you!"

Ventilation Production Stepped Up

GM and Ventec Life Systems, in cooperation with StopTheSpread.org, the nation's coordinated private sector response to COVID-19, are collaborating to enable Ventec to increase production of its respiratory care products to support the growing fight against the COVID-19 pandemic. Ventec will leverage GM's logistics, purchasing and manufacturing expertise to build more of their critically important ventilators. To support these efforts, StopTheSpread.org will continue to unite business leaders across the country to collect resources to complement and support government efforts. "With GM's help, Ventec will

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increase ventilator production," said Chris Kiple, Ventec Life Systems CEO. "By tapping their expertise, GM is enabling us to get more ventilators to more hospitals much faster. This partnership will help save lives." "We are working closely with Ventec to rapidly scale up production of their critically important respiratory products to support our country's fight against the COVID-19 pandemic," said Mary Barra, GM Chairman and CEO. "We will continue to explore ways to help in this time of crisis."

As Coronavirus Looms, Mask Shortage Gives Rise to Promising Approach

3B Medical filed an Emergency Use Application (EUA) with FDA seeking authorization to market Lumin to reprocess N95 face masks. There is a huge shortage in protective apparel for healthcare workers. Lumin exceeds the UVC irradiance output required to kill human coronavirus and is useful for disinfecting N95 masks for reuse. We have been bombarded with healthcare workers urging us to file an EUA application with FDA, which we have now done. As an example, see the attached. Facing a dire shortage of protective face masks for health care workers, administrators at the University of Nebraska Medical Center decided they had no choice. Masks are certified for one-time use only. But on Thursday, the center began an experimental procedure to decontaminate its masks with ultraviolet light and reuse them. Administrators plan to use each mask for a week or longer. To the knowledge of the



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program's administrators, the medical center is the first to disinfect and reuse masks. "We have talked with a lot of others around the country who are going after a similar approach," said John Lowe, the medical center's assistant vice chancellor for health security training and education, who designed the program. When administrators made the decision, they knew the procedure violated regulations promulgated by the Centers for Disease Control and Prevention, which said that if masks were decontaminated they could no longer be certified for use. But agency has issued new guidance, saying that "as a last resort, it may be necessary" for hospitals to use masks that were not approved by the National Institute for Occupational Safety and Health. That change would seem to mean it is now acceptable for hospitals to decontaminate and reuse masks during the coronavirus pandemic, said Shawn Gibbs, a professor of environmental health at Indiana University. If that were not the case, he added, then many hospitals would find themselves in a tightening bind as gear shortages spread: "What is preferred — not using respirator protection equipment, or using a decontaminated respirator whose certification is voided?" No one thinks reuse of face masks is ideal, and the practice may raise legal liability issues. But there seemed to be little choice. Doctors and administrators at the

University of Nebraska Medical Center calculated that if they continued to use masks only once, they would run out of masks in just weeks. "We are making the best of bad choices," said Dr Mark Rupp, the medical center's chief of infectious diseases. He feels confident that the masks will still protect health care workers. "The data is very clear that you can kill and inactivate viruses with UV germicidal irradiation," he said. "It is also very clear that you will not damage the respirators." The alternative, Lowe said, would be to ask health care workers to carefully store their masks and reuse them without cleaning them. Handling a mask repeatedly also increases the chances that it will be contaminated. "Health care workers are very apprehensive about that," he said.

Tube Holder Ready to Use

As you prepare for the possibility of treating COVID-19 patients, Dale Medical stands ready to assist. The Dale Stabilock Endotracheal Tube Holder is the preferred holder for prone position ventilation. Since the Stabilock is soft and low profile, the holder is a comfortable way to secure the tube and minimize risk of pressure sores. Clinicians have access to the patient's mouth to monitor and care for the ET tube. The Dale Stabilock Endotracheal Tube Holder helps prevent accidental extubation by providing a secure method of stabilization. The Stabilock provides fast and easy application to

secure endotracheal tubes sized 7.0-10.0mm. With four placement options for its Adhesive Base, the Dale Stabilock Endotracheal Tube Holder covers the full spectrum of patient needs.

Continuous Surveillance for Caregivers

There may not be an adequate number of skilled caregivers to manage the increased numbers of patients in respiratory distress that require assisted invasive and noninvasive ventilation. Adding continuous surveillance allows caregivers to view medical device settings, measurements and alerts for changing patient conditions from a centralized location. It can also help staff limit their exposure to infection, with fewer bedside visits, while still managing patients closely. Continuous clinical surveillance can help extend the reach of ICU staff over the full range of intensive care patients, wherever they receive care in the facility. Capsule Ventilated Patient Surveillance workstation (using the Bernoulli One Enterprise Software) can provide: Centralized view of ventilator data (FiO2, Set Tidal Volume, Exhaled Tidal Volume, Set RR; Total RR, Peak Inspiratory Pressure, Positive End Expiratory Pressure for each patient); Centralized alarming and alerting based on Surveillance pre-configured rules (smart rules) reviewed and approved by clinical decision makers. During the COVID-19

pandemic, Capsule are offering to add continuous clinical surveillance for ventilated patients to your Capsule Medical Device Information Platform (MDIP) installation: No-charge software license access for limited time use; Capsule Ventilated Patient Surveillance; Discounted implementation services; Remote, turnkey solution to speed deployment; Additional configuration beyond the base, may be billed at standard hourly rates; Hardware runs on any workstation that meets specifications. Upon request, Capsule will work jointly with customer on procurement.

Production Accelerated

Hillrom announced actions it is taking to support customers and caregivers with critical care products necessary to meet COVID-19 patient needs. Hillrom's business operations continue with no material interruption as global demand for several critical products has grown substantially. The company is working to significantly ramp up production of these products, with the goal of more than doubling capacity in the following areas: Respiratory health, especially Life2000, a non-invasive ventilator currently approved in the US that is portable, lightweight and ideal for treating patients with mild to moderate respiratory distress across various acute care settings, including the emergency department, med-surg and postventilator weaning support. Expanded use of non-invasive ventilation can free up capacity for invasive ventilators for the most serious COVID-19 patients. Hillrom is working to increase its production capacity of Life2000 fivefold on an annualized basis. ICU and med-surg unit smart beds, including the company's Progressa ICU bed, Centrella; Smart+ bed, and, for international

markets, the Hillrom 900 and Hillrom 900 Accella. Patient monitoring and diagnostics, including the company's Connex and Spot Vital Signs monitors as well as physical assessment tools and consumables, including thermometry, probe covers and blood pressure devices and cuffs. "We are committed to scaling production as rapidly as we can to meet the challenges the world is facing with COVID-19," said Hillrom President and CEO John Groetelaars. "Hillrom's critical care, vitals monitoring and respiratory products can help caregivers and patients as coronavirus continues to cause severe illness around the world. We are focused on our employees' health and safety, and on ensuring that our products are available when and where our customers and patients need them." Hillrom relies on a global supply chain and has a balanced global manufacturing footprint, with manufacturing facilities located in the US, Europe, Asia and Mexico. The company has seen no material disruption in its supply chain to date. Hillrom's suppliers are a critical component of successfully meeting customer demand, and the company is working with its supply chain partners to minimize any potential disruption. Given the fluidity of the coronavirus pandemic, Hillrom will continue to monitor and assess business operations, and will provide additional information as appropriate.

Hillrom Makes Donations

Hillrom announced it is donating an additional \$3 million in medical devices well-suited for critical and intensive care environments to 25 US hospitals fighting COVID-19. Combined with prior donations in Asia, Europe and other philanthropic activities in our communities, Hillrom donations to assist caregivers and patients in the current pandemic total more than \$5.5 million to date. "Hillrom's diverse portfolio is uniquely suited to help caregivers and patients fighting the COVID-19 pandemic," said Hillrom President and CEO John Groetelaars. "We feel a deep responsibility as a healthcare company to help our communities expand access to critical care. We are honored that the American Hospital Association is supporting our initiative by spreading the word among the nation's hospitals so that we can get the Critical Care and Respiratory Support products where they are needed most." The Hillrom for Humanity Critical Care and Respiratory Support Program includes ICU beds, patient monitoring and respiratory health devices. Hospitals selected for the donations will each receive: Two Progressa ICU beds, One Welch Allyn Connex vital signs monitor; and three respiratory health technologies: the Life2000 non-invasive ventilator; the MetaNeb System, for oscillation lung-expansion therapy; and The Vest, which provides high-frequency chest-wall oscillation. Interested hospitals must meet certain eligibility criteria, including demonstration of need, community transmission of COVID-19, and the ability to put the devices to immediate clinical use. Applications may be submitted by any US hospital and will be vetted solely by Hillrom's Global Compliance Office and Medical Affairs and Informatics Department. Hospitals meeting the criteria will be chosen to receive the Hillrom for Humanity Critical Care and **Respiratory Support Program donations** on a first-come, first-served basis. The medical devices received as part of this program are unrestricted donations to the hospitals without any relationship to any current or future business



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opportunities. Interested US hospitals should visit the Hillrom COVID-19 Resource Center on Hillrom.com for more information and to apply. "The women and men of America's hospitals and health systems are on the front lines every day, treating and helping prevent the spread of COVID-19," said American Hospital Association President and CEO Rick Pollack. "We appreciate Hillrom's important donations to help hospitals, health systems and health care providers expand access to critical care technologies as they respond to the novel coronavirus pandemic."

"Close cooperation with the private sector has been a key piece of the Trump Administration's response to the COVID-19 outbreak, and Hillrom's donation of equipment for critical care units is the latest example of how those partnerships are bearing fruit," said HHS Secretary Alex Azar. "The active engagement we've seen from companies like Hillrom will be essential to ensuring that American healthcare providers have the supplies they need to combat the COVID-19 outbreak and save American lives." In January, Hillrom donated more than \$2 million in vital signs monitors to the Chinese Red Cross to assist with efforts to better diagnose and help treat COVID-19 during the initial spread of the coronavirus within China. Today, Hillrom made a \$50,000 cash donation

to the American Nurses Foundation to build upon the organization's efforts to support the needs of US nurses during and after the COVID-19 outbreak. And the company continues to provide local support in its communities as well.

High Level Disinfection via Pasteurization — a possible solution to COVID-19 limited supplies

Pasteurization has been used to destroy potentially pathogenic organisms in the food and beverage industry for decades. However, a medical device can also be pasteurized by fully immersing it in heated water for a specific amount of time at a specific temperature to achieve viral deactivation and microbial destruction. Global standards recommend that to achieve HLD, the process should apply, at minimum, a temperature of 65°C (ISO 15883). In the US, the amount of bioburden reduction required to achieve HLD is a 6-log reduction (which equates to a 99.9999% reduction) of the original population of organisms. A full immersion pasteurization using a Cenorin 610 Washer-Pasteurizer/High Level Disinfector at a temperature of $72^\circ\mathrm{C}$ for 30 minutes has been shown to achieve HLD for typical medical devices used in respiratory care, anesthesia, pulmonary procedures, and sleep labs. In a recent study, a 'worst-case' (time

and temp parameters) method was tested using a Cenorin 610 Washer-Pasteurizer/High Level Disinfector. The wash/pasteurization cycle achieved industry clean levels and a greater than 8-9 log reduction for Pseudomonas aeruginosa, Staphylococcus aureus, Escherichia coli and a representative of the Klebsiella-Enterobacter group. The Pasteurization cycle also yielded a 7-log reduction of Mycobacterium Terrae. Cenorin customers use the Cenorin 610 to clean and disinfect many devices that are critical in today's environment. These include oxygen administration masks and head bands, ventilator breathing circuits, ventilator inhalation/ exhalation check valve assemblies, and corrugated tubing. If there are additional devices, including PPE like masks and goggles, that you would like to have more information on, please reach out to us-we are available to help.