Patient Monitoring for COVID-19 Outside the ICU

Role of Hillrom's Patient Vital Signs Monitoring and Diagnostic Cardiology Devices

Background and Purpose

With the overwhelming demand on intensive care units (ICU) due to the COVID-19 pandemic, there is an immediate need to effectively risk stratify patients and identify patients most appropriate for the ICU. For patients treated outside the ICU, appropriate monitoring must be deployed to identify those with increasing severity early.

COVID-19 disease due to the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) presents with a spectrum of clinical features from mild to severe life-threatening disease. Major complications include severe pneumonia, acute respiratory distress syndrome (ARDS), and septic shock.[1] Patients with chronic conditions or comorbidities such as hypertension, diabetes mellitus, and/or cardiovascular disease are at greatest risk of deterioration and death.[2]

The majority of COVID-19 cases are non-critical. In a study of all reported cases in China through February 11, 2020 (N = 44,672), 80.9% of cases were mild.[2] Among hospitalized patients in China, studies have shown 73.9% to 93.9% of cases did not require admission to ICU.[1,3] Data from the US CDC shows 21.7 – 31.4% of COVID-19 cases in the US were hospitalized with only 4.9 – 11.5% admitted to the ICU.[4]

With such a large proportion of patients treated outside the ICU, determining the appropriate monitoring for clinical deterioration is important. The purpose of this document is to show how Hillrom vital signs and diagnostic cardiology products support the monitoring needs of COVID-19 patients outside the ICU.

Clinical Application

Vital Signs Monitoring for COVID-19 Patients Outside the ICU

Vital signs are important identifiers of early deterioration of COVID-19 patients. According to the World Health Organization (WHO) guidance on COVID-19 pneumonia, "early identification of those with severe illness, such as severe pneumonia, allows for optimized supportive care treatments and safe, rapid referral" to appropriate COVID-19 treatment settings.[5]

A retrospective study looking at clinical outcomes and risk factors for COVID-19 showed the importance of vital sign derangement on mortality. Specifically, admitting vitals signs such as respiratory rate > 24 was present in 63% of non survivors

vs. 16% in survivors and pulse rate ≥ 125 /min in 4% of non-survivors vs 0% in survivors. Zhou et al., 2020 found an 8.89 (95% confidence interval 4.34 – 18.19) odds ratio of death in patients with a respiratory rate > 24.[6]

Sun et al. 2020 demonstrated vital signs play a significant role in mortality reduction. Using a protocol with vital signs-based triggers to escalate care, researchers noted a COVID-19 cure rate of 96.67%: a better rate than data at the national level in China. The mortality rate in this population was 3.3% as compared to 4.34% in Hubei province. This example demonstrates the benefit of establishing an early identification system of deteriorating patients before they progress to critical illness severity.

For non-critical COVID-19 patients, in the Sun et al. study, the determining factors to transfer patients to critical care management were these vital signs:

- Respiratory rate > 30 breaths per minute
- SpO_2 < 93%
- Heart rate > 120 beats per minute.[7]

Interestingly, WHO guidance on the clinical management of respiratory infection in COVID-19 patients uses the same respiratory rate and oxygen saturation cutoffs to identify severe pneumonia.[5] The 2019 American Thoracic Society guideline on community-acquired pneumonia also identifies a respiratory rate ≥ 30 as a criterion for severe disease.[8]

High risk patients had their vital signs monitored continuously whereas low risk patients were monitored twice per day. Differentiation between high risk and low risk patients was determined based on several demographic, lab and radiographic findings (see Figure 1 in appendix).[7]

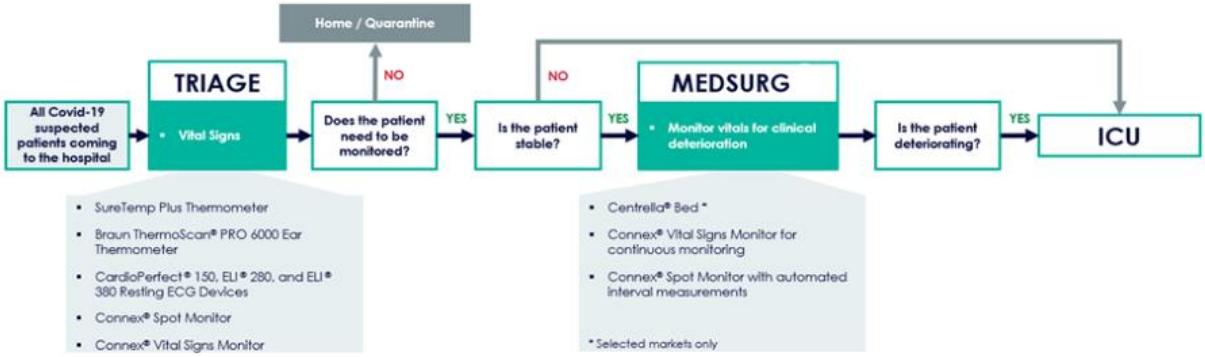
On **Centrella® Smart Bed with Contact-Free Continuous Monitoring**, respiratory rate and heart rate are automatically and continuously monitored when a patient lies in the bed and provides trending data for these vital signs. These trending data provide clinicians with easy access to respiratory rate and heart rate changes over time. The **Welch Allyn® Connex® Vital Signs Monitor** continuously monitors end-tidal CO_2 and oxygen saturation (SpO_2). These technologies, with alarm thresholds, alert clinicians when there is a significant vital sign change.

For lower risk patients, the **Welch Allyn® Connex® Spot Monitor** can measure vital signs at preset time intervals. (see Figure 3 in Appendix)

Connex® Monitors display patients' vitals remotely to decrease infection risk. Continuous vitals monitoring or automated interval measurements can be used with a **Welch Allyn Connex® Central Station** and/or the EMR to display the values. Similarly, **Centrella® Smart Bed with Contact-Free Continuous Monitoring** sends alarms to the

nurse call system to alert clinicians when thresholds have been crossed. These methods of remote monitoring may decrease the frequency of exposure and risk of transmission for healthcare providers and preserve personal protective equipment (PPE). (see Figure 2 see Appendix)

In addition, the **Connex® Monitors** may be configured for automated early warning scoring (e.g. MEWS, NEWS, PEWS) or a facility preferred score. These scores can be visualized at the bedside, integrated into the EMR, as well as the **Connex® Central Station** to support remote monitoring of patients outside the ICU.



Product	Heart Rate	Resp. Rate	Temp.	SpO_2	Blood Pressure*	ECG	$EtCO_2$	EWS
Centrella®	✓	✓						
Connex® Vital Signs Monitor	✓	✓	✓	✓	✓	3/5-Lead	✓	✓
Connex® Central Station	✓	✓	✓	✓	✓	✓	✓	✓
Connex® Spot Monitor	✓	✓	✓	✓	✓			✓
ELI® 280 ECG / ELI® 380 ECG						12-Lead		

* Non-invasive blood pressure can be automated on a pre-set interval
Highlighted cells can be continuously monitored

Clinical Application
ECG Monitoring for Cardiac Abnormalities

Cardiac injury is another manifestation of COVID-19 including arrhythmia, myocarditis, and acute coronary syndrome.[9] Arrhythmias, as a complication of COVID-19, occurred in 16.7% of cases in one study.[1] Acute myopericarditis can occur as a complication associated with the disease as seen from a case study in Italy. This presented on ECG analysis minimal diffuse ST segment elevation and associated ST segment depression with T wave inversion in different leads on a 12-lead ECG.[10] A meta-analysis showed that at least 8.0% patients with COVID-19 suffered acute cardiac injury.[11] Another meta-analysis from COVID-19 literature shows an increase in cardiac biomarkers. The authors of the study hypothesize that identification of patients with possible cardiac injury could predict the progression of COVID-19 towards a worse clinical picture.[12]

Additionally, in those admitted with multiple comorbidities, the effect of medication interaction and risk of QT prolongation is of concern. Hospitalized patients come under higher risk for developing Torsades de Pointes than outpatients with the same QT prolonging drugs. Hospitalized patients may include the elderly with underlying heart disease who may also have renal or hepatic dysfunction, electrolyte abnormalities, or bradycardia and to whom drugs may be administered rapidly intravenously. Concomitant administration of drugs inhibiting cytochrome P450 especially imidazole antifungals, macrolide antibiotics, and/or those that can prolong the QT interval, and those that cause electrolyte disturbance increase risk. For any patients on QT-prolonging drugs, surveillance EKGs are recommended before and after initiation of these drugs.[13]

The **Connex® Vital Signs Monitor** with continuous 3- and 5-lead ECG option alarms for critical arrythmias (ventricular tachycardia, ventricular fibrillation, and asystole) will alert and notify the clinician to immediately assess the patient.

In addition to arrhythmia monitoring, routine 12-lead resting ECG with the **ELI® 280 or ELI® 380** may help identify cardiac injury in COVID-19 patients. For patients on arrhythmogenic drugs (including those that prolong the QT-interval), routine baseline and post-administration 12-lead ECGs are recommended.[13] Furthermore, if signs of acute cardiac disease are identified while cardiac monitoring using a 3 or 5-lead ECG, a resting 12-lead ECG will provide a more detailed view to guide diagnosis and treatment.

The ELI 280 and 380 have benefits in infection prevention as well. With the Wireless Acquisition Module (WAM), there are no cables from the cart to the patient; therefore, there is less opportunity for pathogens to transfer. Additionally, the ELI 280

touch screen and ELI 380 glass keyboard make cleaning easier (see Figure 4 and 5 in Appendix).

Conclusion

The majority of hospitalized COVID-19 patients will not require treatment in the ICU. For those patients, it is important to monitor vital signs to help identify clinical deterioration. In higher risk patients, continuous monitoring of vital signs outside the ICU can help identify deterioration earlier. Use of smart technology can help overburdened staff closely monitor patients and potentially decrease exposure to the SARS-CoV-2 virus.

Appendix

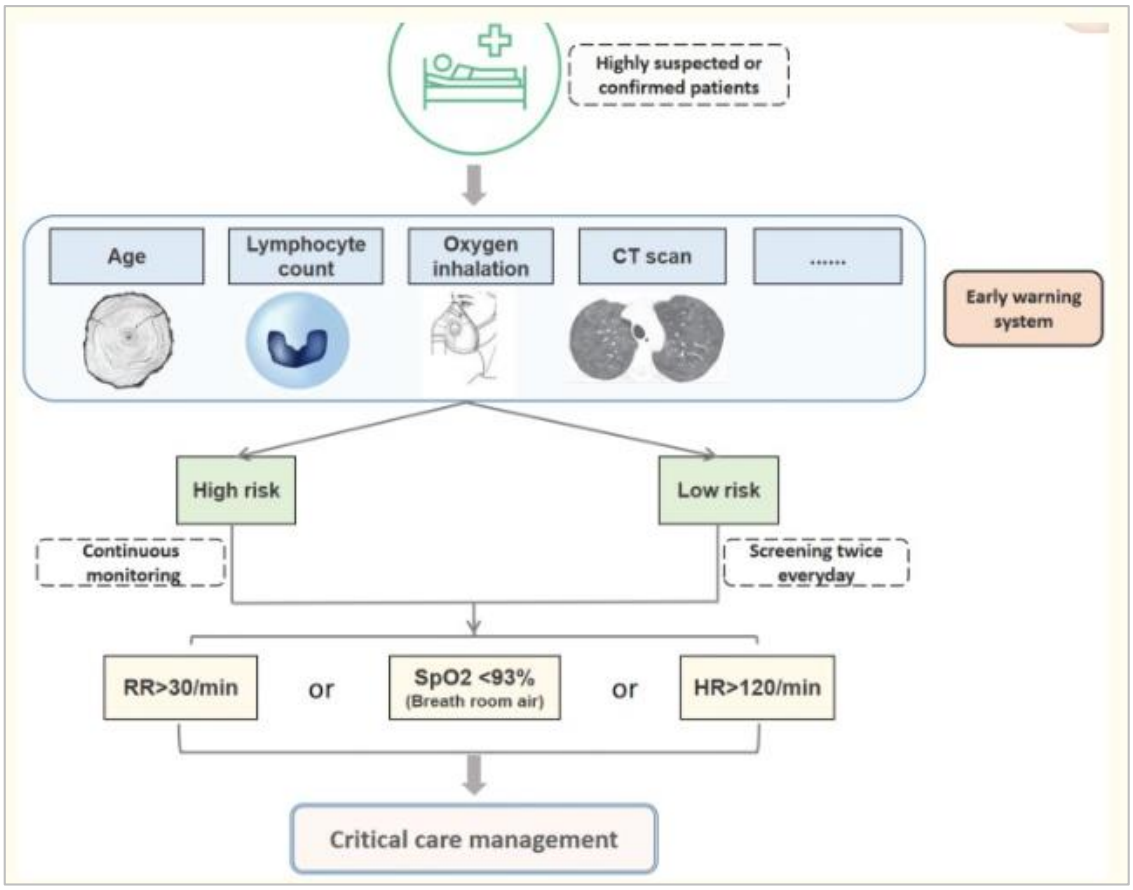


Figure 1: Risk Stratification to initiate continuous or intermittent monitoring on the general ward

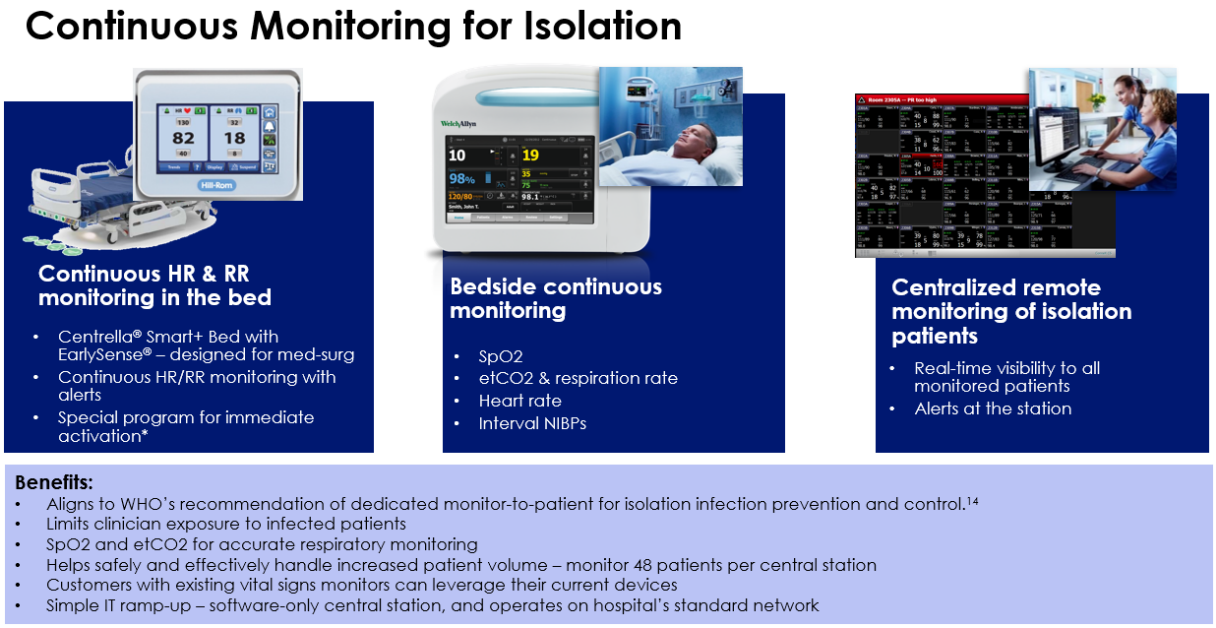


Figure 2: Continuous Monitoring for isolation with Centrella beds, Connex Monitors and Connex Central Station

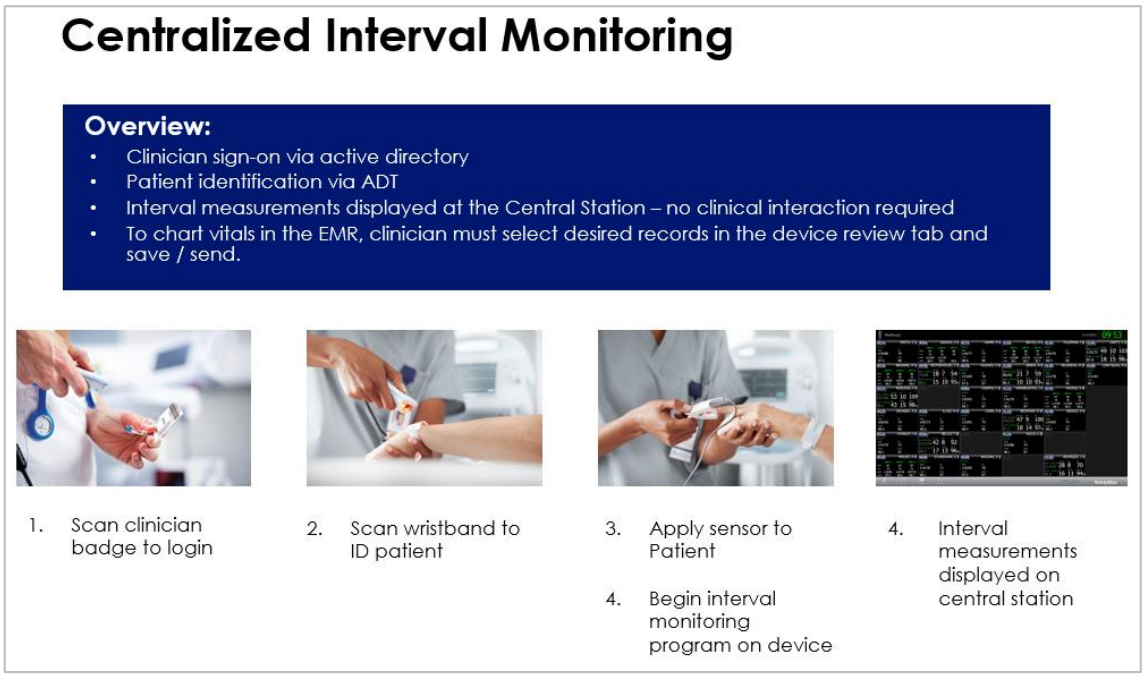


Figure 3: Connex Monitors in an interval workflow for intermittent monitoring

Figure 4: Resting ECG

(A) ELI® 280 ECG and ELI® 380 Resting ECG with the Wireless Acquisition Module WAM™

(B) Typical keyboard versus ELI 380 after cleaning

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