FACT SHEET FOR PATIENTS

Emergency Use of the COViage System During the COVID-19 Pandemic

September 24, 2020

Coronavirus Disease 2019 (COVID-19)

You are being given this Fact Sheet because you are hospitalized and your healthcare provider is using a clinical decision support system device called the *COViage* System (or "COViage") during the COVID-19 outbreak. The *COViage* System is being used to assist with the early identification of patients who are likely to be diagnosed with hemodynamic instability or respiratory failure, which are common complications associated with COVID-19, in order to guide further assessments and treatment.

This Fact Sheet contains information to help you understand the risks and benefits of your provider using the *COViage* System as part of your care plan. After reading this Fact Sheet, if you have any questions or would like to further discuss the information provided, please talk to your healthcare provider.

For the most up to date information on COVID- 19, please visit the CDC Coronavirus Disease 2019 (COVID-19) webpage: https://www.cdc.gov/COVID19

What is the COVID-19?

COVID-19 is caused by the SARS-CoV-2 virus, which is a new virus in humans causing a contagious respiratory illness. COVID-19 can present with a mild to severe illness, although some people infected with COVID-19 may have no symptoms at all. Older adults and people of any age who have underlying medical conditions have a higher risk of severe illness from COVID-19. Serious outcomes of COVID-19 include hospitalization and death. The SARS-CoV-2 virus can be spread to others not just while one is sick, but even before a person shows signs or symptoms of being sick (e.g., fever, coughing, difficulty breathing, etc.). A full list of symptoms of COVID-19 can be found at the following link: https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html.

What is the *COViage* System?

The *COViage* System is a software program that analyzes your patient data from electronic medical records (EMR) systems. Examples of this data include your heart rate, respiratory rate, temperature, and blood pressure. The *COViage* System aims to give your healthcare provider advance, one-time notification of patients who are predicted to 1) experience unstable blood pressure, which may require medications, or 2) experience respiratory decline, which may require mechanical ventilation, at any point during hospitalization. The COViage System generates this notification to your healtcare provider only once during your hospitalization.

Why will the *COViage* System be used as part of my care?

During hospitalization, your individualized patient data may be generated from electronic monitoring systems that record continuous updates to your vital signs. A software-based prediction system may be able to use these data to identify subtle signs of deterioration before healthcare providers notice them. This warning system would then give your care team the advance notice to conduct additional tests to make a complete diagnosis and/or make changes in your care plan.

The *COViage* System analyzes available patient data with artificial intelligence and predictive analytics one time to identify these clinically meaningful data and notify providers if deterioration of a patient's condition is expected.

Because this is a clinical decision support system, your healthcare providers will use their clinical judgment regarding how to incorporate COViage notifications into your care. The *COViage* System is not intended to replace patient monitoring.

What are the known and potential benefits and risks of the *COViage* System?

Some of the known and potential benefits include:

- The *COViage* System provides healthcare providers with an early, one-time notification that a patient may be at risk for deterioration. Early prediction of deterioration may:

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- help identify patients who would benefit from increased clinical care;
- assist with the optimal allocation of limited resources for patient monitoring;
- help providers make proactive treatment decisions, which may allow for earlier intervention, possibly preventing the need for more invasive therapy; and/or
- allow the providers more time to prepare for escalating care, if necessary.

Because it is a non-interventional software product, the *COViage* System is not used on or inside the body. Therefore, there is no risk of direct physical harm from the use of COViage. Some known and potential risks include:

- The *COViage* System may be falsely positive or falsely negative. That is, there may be false predictions of instability or deterioration, as well as instabilities or deteriorations for which no early warning was provided.

You have the option to refuse this product. If you choose to decline use of this device, you should discuss any alternative options with your healthcare provider.

How is the *COViage* System Used?
The *COViage* System uses existing data from the EMR, which is automatically generated as part of your patient care. No additional testing is required, nor are any additional data collected.

Limitations of the *COViage* System
The *COViage* System is intended for use with adult patients aged 18 and over who are admitted to the hospital as the result of being COVID-19 positive.

Due to possible variability in the *COViage* System results, system output should be viewed as one clinical data point that should be integrated by an appropriately trained clinician with the patient's monitoring data, diagnostic test results, best clinical judgment, other clinical observations, patient history, and epidemiological information.

The *COViage* System is not able to predict sudden-onset instabilities or deteriorations, or those not related to its intended prediction of risk of COVID-19 complications, because the tool is designed to collect and analyze your data only until there are sufficient data for the system to make a one-time risk assessment.

Is the *COViage* System FDA-approved or cleared?
No. The *COViage* System is not approved or cleared by the United States (U.S.) FDA. Rather, the FDA has made the *COViage* System available under an emergency access mechanism called an Emergency Use Authorization (EUA).

What is an EUA?
The EUA is supported by the Secretary of Health and Human Services declaration that circumstances exist to justify the emergency use of medical devices during the COVID-19 pandemic.

The use of the *COViage* System available under this EUA has not undergone the same type of review as an FDA-approved or cleared device. FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, or available alternatives. In addition, the FDA decision is based on the totality of scientific evidence available demonstrating that it is reasonable to believe that the COViage System may be effective when used by your healthcare provider to assist with the early identification of patients who are likely to be diagnosed with hemodynamic instability or respiratory failure, which are common complications associated with COVID-19, and the known and potential benefits of the COViage System outweigh the known and potential risks.

This EUA will remain in effect for the duration of the COVID-19 declaration justifying emergency

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use of the product, unless it is terminated or revoked (after which the product may no longer be used).

What are the approved alternatives?
There are no approved, available alternatives. FDA has issued EUAs for other products that can be found at: https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.

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