

FACT SHEET FOR PATIENTS

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

May 26, 2020

Coronavirus
Disease 2019
(COVID-19)

You are being given this Fact Sheet because you are hospitalized in an Intensive Care Unit (ICU) that is using a decision support system device called the CLEWICU System, during the COVID-19 outbreak. The CLEWICU System is being used by your healthcare providers to assist with the early identification of patients who are likely to be diagnosed with respiratory failure or hemodynamic instability which are common complications associated with COVID-19.

This Fact Sheet contains information to help you understand the risks and benefits of your provider using the CLEWICU 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 COVID-19?

COVID-19 is caused by the SARS-CoV-2 virus. The virus, which can cause mild to severe respiratory illness, has now spread globally, including to the United States. The current information available to characterize the spectrum of clinical illness associated with COVID-19 suggests that symptoms include cough, shortness of breath or difficulty breathing, fever, chills, muscle pain, headache, sore throat or new loss of taste or smell.

What is the CLEWICU System?

The CLEWICU System is a computerized system that analyzes trends in the data that is being collected on you during your stay in the ICU. Examples of this data include your vital signs, nursing assessments, information about the medications you are taking, and your lab results. By looking for specific trends in the data, the CLEWICU System aims to give your healthcare provider advance notification of patients who are expected to experience either excessively low blood pressure requiring special medication support (also called hemodynamic instability) or breathing difficulty

that may require inserting a breathing tube (also called respiratory failure requiring intubation). These notifications, are provided up to 8 hours before the expected event.

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

During ICU hospitalization, vast amounts of data are generated, for instance, from the devices continuously monitoring your heart and the results of blood tests. A computer-based system may be able to use these data to identify subtle signs of deterioration before healthcare providers would have noticed them, giving them extra time to conduct additional tests or make changes in your care plan.

The CLEWICU System analyzes available patient data with artificial intelligence and predictive analytics to try to identify these clinically meaningful trends and notify providers if deterioration is expected.

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

What are the known and potential benefits and risks of the CLEWICU System?

Some of the known and potential benefits include:

- The CLEWICU System provides alerts that may help providers make proactive treatment decisions. This may allow for earlier intervention, possibly preventing the need for more invasive therapy. It may also give the providers more time to prepare for escalating care, if necessary.
- The CLEWICU System augments standard patient assessment and monitoring practices. This provides additional information for providers to make clinical decisions.

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

How can I learn more? The most up-to-date information on COVID-19 is available at the CDC General

Webpage: <https://www.cdc.gov/COVID19>. In addition, please also contact your healthcare provider with any questions/concerns.

FACT SHEET FOR PATIENTS

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

May 26, 2020

Coronavirus
Disease 2019
(COVID-19)

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

How is the CLEWICU System Used?

The CLEWICU System uses existing data from the Electronic Medical Record (EMR), generated as part of your patient-care. No additional testing is required, nor are any additional data collected.

Limitations of the CLEWICU System

The CLEWICU System is intended for use with patients over the age of 18 who are admitted to ICUs.

Due to possible variability in the CLEWICU 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 clinical history, continuous monitoring data, diagnostic test results, and clinical judgment.

The CLEWICU System is not able to predict sudden deteriorations (such as those caused by a clot blocking blood flow in the lungs), because the tool analyzes trends in data that occur over time.

Is the CLEWICU System FDA-approved or cleared?

No. The CLEWICU System is not approved or cleared by the United States (U.S.) FDA. Instead, FDA has made the CLEWICU 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 Service's declaration that circumstances exist to justify the emergency use of medical devices during the COVID-19 pandemic.

The use of the CLEWICU 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 showing that it is reasonable to believe that the CLEWICU System may be effective, and the known and potential benefits of the CLEWICU System outweigh the known and potential risks.

This EUA will remain in effect for the duration of the COVID-19 declaration justifying emergency use of the product, unless it is terminated or revoked (after which the product may no longer be used).

How can I learn more? The most up-to-date information on COVID-19 is available at the CDC General Webpage: <https://www.cdc.gov/COVID19>. In addition, please also contact your healthcare provider with any questions/concerns.