FACT SHEET FOR PATIENTS

Emergency Use of Philips IntelliVue Patient Monitors MX750 and MX850, Philips IntelliVue 4-Slot Module Rack FMX-4, and Philips IntelliVue Active Displays AD75 and AD85 During the COVID-19 Pandemic

APRIL 22, 2020

Coronavirus Disease 2019 (COVID-19)

You are being given this Fact Sheet because your healthcare provider believes it is necessary to monitor your physiological parameters (such as your heart rate and breathing rate) using the Philips IntelliVue Patient Monitors while you are under treatment for COVID-19.

This Fact Sheet contains information to help you understand the risks and benefits of using patient monitoring devices with remote capabilities for the treatment of COVID-19. After reading this Fact Sheet, if you have questions or would like to discuss the information provided further, please talk to your healthcare provider.

For the most up to date information on COVID-19, please visit the CDC 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, was first identified in Wuhan, China, and has now spread globally, including the United States. There is limited information available to characterize the spectrum of clinical illness associated with COVID-19, but it likely spreads to others when a person shows signs or symptoms of being sick (e.g., fever, coughing, difficulty breathing, etc.).

What are the patient monitoring devices?

The patient monitoring devices are connected to the different sensors (measuring tools) attached to your body. They display the measured values such as your heart rate and breathing rate on a monitor at the bedside or at a remote place outside your isolation room so that your healthcare provider can monitor you while reducing their exposure to COVID-19.

What do I need to know about the emergency use of patient monitoring devices?

Patient monitoring devices with remote capabilities that meet certain criteria for safety, performance, and labeling have been authorized under an Emergency Use Authorization (EUA) for emergency use in the hospital environment for remote monitoring of COVID-19 patients. A healthcare provider may monitor your physiological parameters with a monitoring device while you are being treated for COVID-19. This device is being authorized for emergency use during the COVID-19 pandemic because remote patient monitoring may reduce the risk of exposure for healthcare providers to COVID-19.

Is this patient monitoring device FDA-approved or cleared?

No. This patient monitoring device is not yet approved or cleared by the United States FDA. An FDA approved or cleared device should be used, when appropriate and available. FDA has made this patient monitoring device available for emergency use for patients having or expected of having COVID-19, under an Emergency Use Authorization (EUA). This EUA is supported by the Secretary of Health and Human Service's (HHS's) declaration that circumstances exist to justify the emergency use of medical devices, including alternative devices used as medical devices, due to shortages during the COVID-19 pandemic. This EUA will remain in effect (meaning this patient monitoring device with remote capabilities can be used) for the duration of the COVID-19 emergency, unless it is terminated or revoked by HHS or FDA (after which the device may no longer be used).

What are the benefits and risks of this device for emergency use?

Potential benefits include:

- The remote capabilities of the IntelliVue Patient Monitors enable healthcare personnel to set certain

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parameters and monitor your condition from outside your room.

- Remote monitoring could reduce the exposure of healthcare personnel to risks of exposure to COVID-19.

Potential risks include:
- Adjustment of alarm volume to a low level or off during remote patient monitoring may result in failure to identify a situation involving patient danger.

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