FACT SHEET FOR HEALTHCARE PROVIDERS

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)

This Fact Sheet informs you of the significant known and potential risks and benefits of the emergency use of the Philips IntelliVue Patient Monitors MX750 and MX850; Philips IntelliVue 4-Slot Module Rack FMX-4; and Philips IntelliVue Active Displays AD75 and AD85 (hereafter "IntelliVue Patient Monitors"). These devices are authorized for emergency use by healthcare professionals in the hospital environment for the monitoring of patients having or suspected of having COVID-19, to reduce healthcare provider exposure to COVID-19 .

All patients who are monitored with the IntelliVue Patient Monitors will receive the Fact Sheet for Patients regarding these devices.

What are the symptoms of COVID-19?

Many patients with confirmed COVID-19 have developed fever and/or symptoms of acute respiratory illness (e.g., cough, difficulty breathing). However, limited information is currently available to characterize the full spectrum of clinical illness associated with COVID-19. Based on what is known about the virus that causes COVID-19, signs and symptoms may appear any time from 2 to 14 days after exposure to the virus. Based on preliminary data, the median incubation period is approximately 5 days, but may range 2-14 days.

Public health officials have identified cases of COVID-19 infection throughout the world, including the United States, which may pose risks for public health. Please check the CDC webpage for the most up to date information.

What do I need to know about the emergency use of the IntelliVue Patient Monitors?

- The IntelliVue Patient Monitors MX750 and MX850 are indicated for use by healthcare professionals for monitoring the physiological parameters of patients, such as ECG, arrhythmia, ST, QT, SpO2, respiration rate, pulse rate, heart rate, invasive and non-invasive blood pressure, temperature, CO2, tcpO2/ tcpCO2, C.O., CCO, intravascular SO2, Sv02, ScvO2, EEG, BIS, NMT, and gas analysis, who have or are suspected of having COVID-19.

- The IntelliVue 4-Slot Module Rack FMX-4 is intended to connect up to four individual plug-in physiological measurement modules to the dedicated host patient monitors.

- The IntelliVue Active Displays AD75 and AD85 are intended for use by healthcare professionals as an additional independent remote display for the connected Philips patient monitor. The device can be used to view the screens and operation of the patient monitor. The device also provides visual and audible alarms generated by the patient monitor. The device can operate all screen-operable functions of the connected patient monitor, including start/stop physiological measurements, change measurement modes, change alarm limits and acknowledge alarms.

What are the benefits and risks of the emergency use of the IntelliVue Patient Monitors?

- The remote capabilities of the IntelliVue Patient Monitors could reduce the healthcare providers' risks of exposure to COVID-19.

- Although the device has remote alarm capability, do not rely exclusively on the audible alarm system for patient monitoring. Adjustment of alarm volume to a

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Report Adverse events, including problems with test performance or results, to MedWatch by submitting the online FDA Form 3500 (https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home) or by calling **1-800-FDA-1088**

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low level or off during patient monitoring may result in patient danger. Remember that the most reliable method of patient monitoring combines close personal surveillance with correct operation of monitoring equipment.

- The devices are intended for use by healthcare professionals in a hospital environment. The devices are not intended for home use.

Use appropriate personal protective equipment when caring for individuals suspected of having COVID-19 as outlined in the CDC *Interim Infection Prevention and Control Recommendations for Patients with Confirmed Coronavirus Disease 2019 (COVID-19) or Persons Under Investigation for COVID-19 in Healthcare Settings* or on the CDC webpage on *Infection Control*.

Current information on COVID-19 for healthcare providers is available at CDC's webpage, *Information for Healthcare Professionals* (see links provided in "Where can I go for updates and more information" section).

What is an EUA?

The United States (U.S.) FDA has made certain patient monitoring devices with remote capabilities available under an emergency access mechanism called an Emergency Use Authorization (EUA). The EUA is supported by a 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.

A patient monitoring device with remote capabilities made available under an EUA has not undergone the full validation of an FDA-approved or cleared patient monitoring device. However, based on the totality of scientific evidence, it is reasonable to believe that this patient monitoring device with remote capabilities may

be effective in the prevention of COVID-19, in the absence of an FDA-approved or cleared alternative. The EUA for patient monitoring devices with remote capabilities is in effect for the duration of the COVID-19 emergency, unless terminated or revoked (after which the test may no longer be used).

An FDA approved or cleared patient monitoring device should be used instead of a patient monitoring device with remote capabilities under EUA, when appropriate and available.

How can I learn more?

CDC websites:
General: https://www.cdc.gov/COVID19
Healthcare Professionals:
https://www.cdc.gov/coronavirus/2019-nCoV/guidance-hcp.html
Infection Prevention and Control Recommendations in Healthcare Settings: https://www.cdc.gov/coronavirus/2019-ncov/infection-control/control-recommendations.html
Infection Control: https://www.cdc.gov/coronavirus/2019-ncov/infection-control/index.html
FAQ on Personal Protective Equipment:
https://www.cdc.gov/coronavirus/2019-ncov/hcp/respirator-use-faq.html

FDA websites:
General: www.fda.gov/novelcoronavirus
EUAs: https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations

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For Technical Assistance:
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