

This Fact Sheet informs you of the significant known and potential risks and benefits of the emergency use of the Ascom teleCARE IP Nurse Call System (hereafter referred to as “teleCARE IP Nurse Call System”). The teleCARE IP Nurse Call System is for use by healthcare providers and patients in healthcare environments, including temporary hospital facilities, as a powered environmental control system intended for medical purposes with additional hardware and software modifications implementing the capability for remote communication between patients and healthcare providers, and, for those patients utilizing a ventilator, remote monitoring of ventilator status updates to alert the healthcare provider. During the COVID-19 outbreak, the remote communication and monitoring capabilities of the teleCARE IP Nurse Call System may reduce the amount of contact by healthcare providers with patients who are in isolation rooms, thereby reducing healthcare provider risk of exposure to SARS-CoV-2, the virus that causes COVID-19.

What do I need to know about COVID-19 infection, symptoms, and treatment?

Current information on COVID-19 infection for healthcare providers, including case definitions and information about clinical signs and symptoms and/or epidemiological criteria, is available on the CDC website listed below.

What do I need to know about the emergency use of the teleCARE IP Nurse Call System?

The teleCARE IP Nurse Call System is a system that facilitates wireless communication between healthcare providers and patients being treated during the COVID-19 outbreak in healthcare environments, including temporary hospital environments. Patients may request assistance from healthcare providers through a wireless wrist- or neck-worn transceiver.

The teleCARE IP Nurse Call System also connects a ventilator to the wireless nurse call system via the “nurse call interface” available on most ventilators. This allows issues and alarms from the ventilator to be sent to alert the healthcare provider through the nurse call system. The teleCARE IP Nurse Call System has the potential to remotely provide alerts related to ventilator status and to allow patients to communicate that they are in distress to the healthcare provider, which may reduce exposure of healthcare providers to SARS-CoV-2.

What are the known and potential benefits of remote communication and remote ventilator monitoring with the teleCARE IP Nurse Call System?

- The teleCARE IP Nurse Call System facilitates communication between healthcare providers and patients, while limiting person-person contact.
- The teleCARE IP Nurse Call System can connect to a relay available on many ventilator models to communicate changes in ventilator status, including alarms.
- The teleCARE IP Nurse Call System may reduce exposure of healthcare providers to SARS-CoV-2, the virus that causes COVID-19, because the system provides remote monitoring capabilities.
- The teleCARE IP Nurse Call System is a wireless system, which facilitates greater flexibility for temporary hospital environments.

What are the known and potential risks of remote communication and remote ventilator monitoring with the teleCARE IP Nurse Call System?

- The teleCARE IP Nurse Call System cannot perform ventilator status monitoring beyond the capabilities of the ventilator to which it is connected.
- 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 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.

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**

What is an EUA?

The United States (U.S.) FDA issued an Emergency Use Authorization (EUA) for the teleCARE IP Nurse Call System when used during the COVID-19 outbreak in healthcare environments, including temporary hospital environments, for remote communication between patients and healthcare providers, and, for those patients utilizing a ventilator, remote monitoring of ventilator status updates to alert the healthcare provider. During the COVID-19 outbreak, the remote communication and monitoring capabilities of the teleCARE IP Nurse Call System may reduce the amount of contact by healthcare providers with patients who are in isolation rooms, thereby reducing healthcare provider risk of exposure to SARS-CoV-2. 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 products used as medical devices, due to insufficient supply during the COVID-19 outbreak.

The teleCARE IP Nurse Call System made available under this EUA has not undergone the same type of review as an FDA approved or cleared device. However, based on the totality of scientific evidence, it is reasonable to believe that the use of the teleCARE IP Nurse Call System may be effective in preventing exposure to SARS-CoV-2 in healthcare providers in the absence of an FDA-approved or cleared alternative.

The EUA for this teleCARE IP Nurse Call System is in effect for the duration of the COVID-19 emergency, unless terminated or revoked (after which the product may no longer be used).

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>

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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