FACT SHEET FOR PATIENTS

Ascom teleCARE IP Nurse Call System

May 11, 2020

You are being given this Fact Sheet because your healthcare provider, hospital, or temporary healthcare facility is using the teleCARE IP Nurse Call System to assist you in communicating with clinical staff.

This Fact Sheet contains information to help you understand the risks and benefits of using teleCARE IP Nurse Call System for communicating with clinical staff. 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 Coronavirus Disease 2019 (COVID-19) webpage: https://www.cdc.gov/COVID19

What is COVID-19?

COVID-19 is a disease 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. 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 teleCARE IP Nurse Call System?

The teleCARE IP Nurse Call System provides a means for you to communicate with clinical staff when you need assistance.

Why will the teleCARE IP Nurse Call System be used on me?

Nurse call systems are commonly used in hospitals and healthcare facilities to help patients communicate with clinical staff. The teleCARE IP Nurse Call System features wireless communication capabilities that make it more readily installed in temporary hospital facilities. If your healthcare provider recommends that you be placed on a ventilator, the teleCARE IP Nurse Call System may also be used to monitor ventilator status.

How is the teleCARE IP Nurse Call System used?

You will be provided with a wireless wristband or a wired handset connected to the bedside module that is mounted in close proximity to the bed.

- The wristband features a single large button. Press the button to initiate a call to your clinical staff, and a light on the wristband will illuminate to confirm that your call was sent.

- The handset features a large red call button. Press the button to initiate a call to your clinical staff, and a light on the handset will illuminate to confirm that your call was sent.

As necessary, bedside equipment, such as ventilators, can be connected to wireless transmitter modules that will initiate calls to clinical staff when the equipment indicates that it needs attention.

For assistance and for reporting adverse events with the teleCARE IP Nurse Call System, contact Ascom (US) Inc. technical assistance at 1-877-712-7266, Option 3.

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. This product is expected to be low risk, and helps prevent healthcare exposure to COVID-19.

What are the known and potential benefits and risks of the teleCARE IP Nurse Call System?

Known and potential benefits of the teleCARE IP Nurse Call System include:

- The teleCARE IP Nurse Call System allows you to ask for assistance from clinical staff.

- The teleCARE IP Nurse Call System has specific call modules that can be connected to bedside medical equipment, such as ventilators. These modules may be used to help healthcare providers remotely monitor equipment used in your treatment.

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.

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

The teleCARE IP Nurse Call System is not likely to cause injury. However, potential risks include:

- If the batteries in your wristband or handset are low, calls may not be sent to clinical staff. Let clinical staff know if the light on your wristband or handset starts flashing, which will alert you of a low battery.

- While the teleCARE IP Nurse Call System may be used to help clinical staff monitor your ventilator status, it can only share status information that your ventilator is already designed to send. It may not detect all changes in ventilator status.

- 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.

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

Based on these factors, the potential benefits from the use of the teleCARE IP Nurse Call System are expected to outweigh the risks during the COVID-19 outbreak.

How long will use of the teleCARE IP Nurse Call System be required?
Your healthcare provider will determine duration for use. There is no limit to how long the product may be used and typically nurse call systems are provided for the duration of your inpatient clinical care.

How can I learn more?

CDC websites:
General: https://www.cdc.gov/COVID19

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:
Phone: 1-877-712-7266, Option 3

Limitations of the teleCARE IP Nurse Call System
The teleCARE IP Nurse Call System should only be used according to the *User Manual*.

The teleCARE IP Nurse Call System is intended for use by healthcare providers and patients in healthcare environments, including temporary hospital facilities.

Patients of any age may use the teleCARE IP Nurse Call System based on the judgment of clinical staff.

The only limitation of the product is battery life of the wristbands and handsets. Batteries typically last for a year or more and are readily replaced with standard consumer batteries, depending on the model.

Is the teleCARE IP Nurse Call System FDA-approved or cleared?
The teleCARE IP Nurse Call System is not FDA-cleared. The FDA has authorized this use of the teleCARE IP Nurse Call System through an emergency access mechanism called an Emergency Use Authorization (EUA).

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.

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 outbreak. The teleCARE IP Nurse Call 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 telecare IP Nurse Call System may be effective in preventing healthcare provider exposure to SARS-CoV-2, the virus that causes COVID-19. The EUA for the teleCARE IP Nurse Call System is in effect for the duration of the COVID-19 declaration justifying emergency use of the product, unless terminated or revoked (after which the product may no longer be used).

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