

EXTEND YOUR CARE. EXTEND YOUR CONNECTION.

Healthcare from a distance shouldn't feel disconnected. Remotely monitor at-risk and recovering COVID-19 patients with ease.

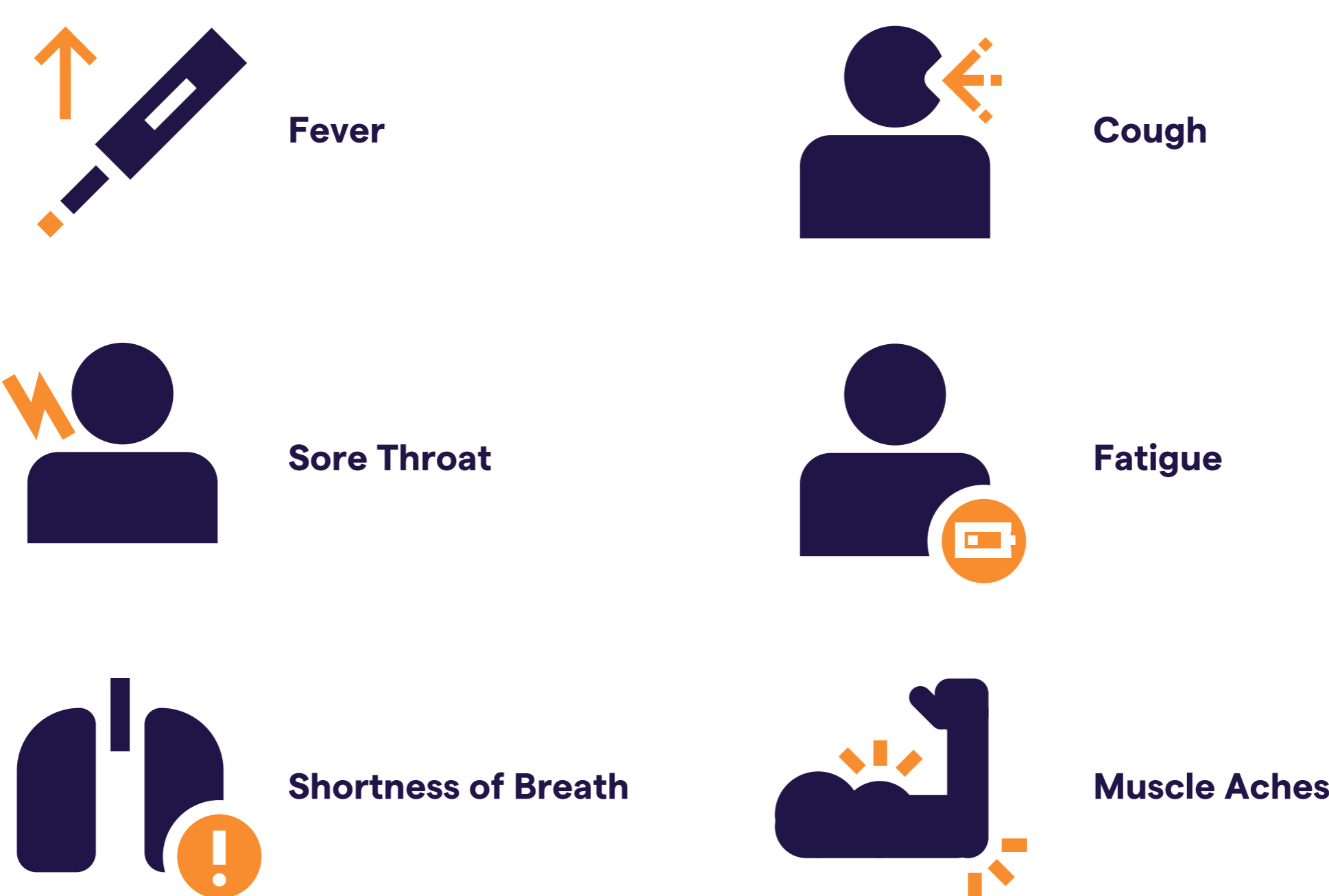
ASSESS PATIENT STABILITY

Initial data shows 80 percent of COVID-19 patients present zero to mild symptoms.* In these cases, hospitalization may not be clinically necessary. Instead, these cases may meet the criteria for remote symptom management, allowing patients to be treated at home with careful clinical monitoring.

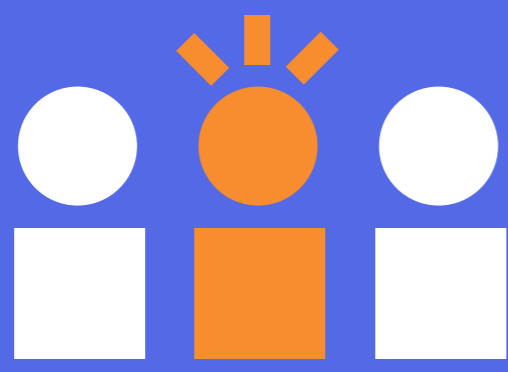
80%
SHOW MILD TO
NO SYMPTOMS

SIGNS AND SYMPTOMS

Potential candidates may present with any or all of the following symptoms:



RISK FACTORS



History of exposure

- Close contact with known COVID-19 case
- Exposure to sick family member
- Essential workers

65
OR OLDER

Age

- 65 or older
- Living in a nursing home or long-term care facility



Underlying medical conditions, at any age

- Chronic lung disease or moderate to severe asthma
- Chronic kidney disease and undergoing dialysis
- Diabetes
- Serious heart conditions
- Liver disease
- Severe obesity (BMI of 40 or higher)
- Immunocompromised patients (including poorly controlled AIDS/HIV, cancer, diabetes, organ or bone marrow transplant patients, prolonged use of corticosteroids, smokers)

EASY AS 1-2-3



The Welch Allyn® Spot Vital Signs® 4400 device goes home with your patient and spot checks blood pressure, pulse, SpO₂, and temperature.



Patients relay their results via the push of a single button on the Hillrom™ Connex® App on their smartphone.



You log in to the Hillrom™ Connex® Portal to review their results and make data-driven decisions about their care.

Contact your Hillrom representative for more information or visit hillrom.com/extendedcaresolution

*<https://www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-guidance-management-patients.html>

Hill-Rom reserves the right to make changes without notice in design, specifications and models. The only warranty Hill-Rom makes is the express written warranty extended on the sale or rental of its products.

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The FDA issued Enforcement Policy for Non-Invasive Remote Monitoring Devices Used to Support Patient Monitoring During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency. During this emergency and while the policy is in effect, the FDA does not intend to object to limited modifications to indications, claims, functionality, hardware or software of cleared non-invasive remote monitoring devices that are used to support patient monitoring without prior submission of a 510(K) where the modifications do not create an undue risk. Based on this guidance, Hillrom has released the Welch Allyn® Spot Vital Signs® 4400 device for use in the home with Hillrom™ Connex® software.

When the device is used in the home, it is not intended for use in the diagnosis, cure, treatment or prevention of disease on its own. It is not intended as a substitute for medical care by a healthcare provider. It is not intended for emergency use or real-time monitoring.

Modifications to FDA Cleared Indications for Use (Modifications are underlined)

Intended use (Spot 4400)

The Welch Allyn Spot Vital Signs 4400 (device) is intended to be used by patients to initiate spot-check/single measurement of noninvasive blood pressure, pulse rate, noninvasive functional oxygen saturation of arteriolar hemoglobin (SpO₂), and body temperature in oral and axillary modes of adult and pediatric patients greater than 12 years of age under the direction of clinicians or other medical professionals. The intended use locations for patients to be measured are in the home environment. Patient vitals captured on the device will be sent to a software designed to collect and transmit health information.

Intended use (Hillrom™ Connex® App)

The Hillrom Connex software is designed to collect, track, trend and retrospectively transmit health information (e.g., blood pressure, SpO₂, temperature and pulse rate) from commercially available wireless FDA cleared medical in-home devices, and health and wellness devices, to an online (cloud) database. With user's consent, this information will be shared with a healthcare provider.

The Hillrom Connex software is not intended for use in the diagnosis, cure, treatment or prevention of disease. It is not intended as a substitute for medical care by a healthcare provider. It is not intended for emergency use or real-time monitoring.

Device Performance

Validation of the integration of the Bluetooth® radio, the home user screen and power cord into the Welch Allyn Spot Vital Signs 4400 device was completed through software verification testing and design validation of the changes to the user interface, power cord and Bluetooth radio, and IFU. The Spot 4400 device has been tested and shown to comply with IEC 60601-1 Edition 3.1, IEC 60601-1-2 4th Edition and IEC 60601-1-11 2nd edition. A risk assessment has been performed according to ISO 14971. Any identified hazards have been found to be acceptable.

Potential Risks

See the Instructions for Use included on the enclosed CD, the Addendum, and the Quick Reference for a complete list of Warnings and Cautions.

For Further information on the Hillrom Extended Care Solution, including the Instructions for Use, Addendum and Quick Reference, please visit Hillrom.com.