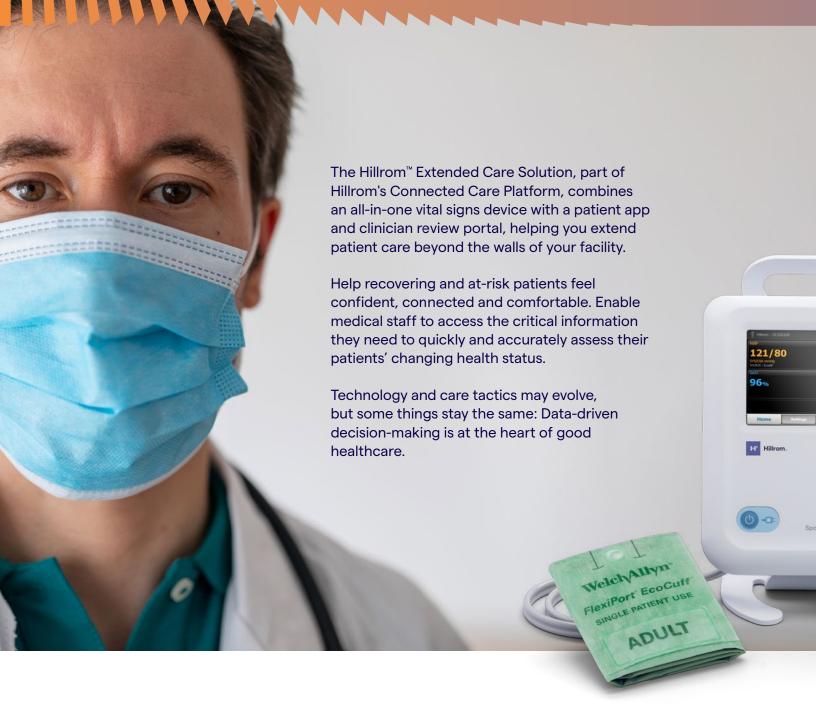




The Hillrom™ Extended Care Solution makes providing essential remote care possible—today.



EASY AS 1-2-3



The Welch Allyn® Spot Vital Signs® 4400 device is a comprehensive, clinical-grade solution that takes a patient's vital signs from their home—temperature, SpO₂, blood pressure and pulse rate.

The Hillrom Connex App provides a simple connection to the Spot Vital Signs 4400 device and relays patient data securely through their phone at the push of a button.

Clinicians can then log in to the easy-to-use Hillrom™ Connex®
Portal to review data and help make vital care decisions.

Welch Allyn® Spot Vital Signs® 4400 Device & Hillrom™ Connex® App | Section | Sectio

HOSPITAL AND PATIENT SAFETY

A clear case of less is more: Sending a patient home with the Welch Allyn Spot Vital Signs 4400 device can help reduce hospital patient load, risk of exposure and the use of critical protective gear.

And the essential communication provided by the Hillrom Connex App and Hillrom Connex Portal makes room for more consistent, capable care.

MONITOR WITH CONFIDENCE

Get the vital data you need to help make informed care decisions, from a distance. Through our Extended Care Solution, the Welch Allyn Spot Vital Signs 4400 device gives you accurate, clinical-grade tools and results to provide care with confidence.

DISTANCE DOESN'T MEAN DISCONNECTED

Consider it a house call without the close quarters: Multiple vital signs are measured by one accurate device, and results are delivered to your desktop for consistent, reliable monitoring and management. You can trust the data, and your patients can trust they're being taken care of.

SIMPLE. SAFE. SECURE.

- The Hillrom™ Extended Care Solution allows recovering and at-risk patients to feel safe and cared for while recuperating at home, helping you manage your caseload with confidence.
- Patients take vital signs, then send readings to our clinical portal with the push of a single button.
- No IT infrastructure required—the secure, web-based portal is designed for easy access to current patient information, when and where you need it.



ORDERING INFORMATION

Part Number	Description
4400-RPMKIT	Welch Allyn® Spot Vital Signs® 4400 Device Remote Patient Monitoring Kit

WE CAN HELP MANAGE DEVICE LOGISTICS, SO YOU CAN HELP YOUR PATIENTS.

We can provide equipment management for your fleet of Welch Allyn Spot Vital Signs 4400 devices through our SmartCare[™] Protection plan^{*} for the Hillrom[™] Extended Care Solution. This helps ensure you always have devices ready for use and relieves the burden of equipment management from your team.



ABOUT HILLROM

Hillrom is a global medical technology leader whose 10,000 employees have a single purpose: enhancing outcomes for patients and their caregivers by advancing connected care. Around the world, our innovations touch over 7 million patients each day. They help enable earlier diagnosis and treatment, optimize surgical efficiency and accelerate patient recovery while simplifying clinical communication and shifting care closer to home. We make these outcomes possible through connected smart beds, patient lifts, patient assessment and monitoring technologies, caregiver collaboration tools, respiratory care devices, advanced operating room equipment and more, delivering actionable, real-time insights at the point of care. Learn more at hillrom.com.

See more at hillrom.com/ExtendedCareSolution or call your representative.

hillrom.com

4341 State Street Road, Skaneateles Falls, NY 13153

*Must have at least 10 devices at each location to be eligible for a SmartCare Protection program.

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.



Hillrom[™] Extended Care Solution Special Information For US Only

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. The Hillrom Connected Care Platform solution 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.

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

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 health care 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 health care provider. It is not intended for emergency use or real-time monitoring.

FDA guidance

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.

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 this Quick reference for a complete list of Warnings and Cautions.

For further information on the Hillrom Welch Allyn Spot 4400 Home, including the Instructions for use, Addendum, and this Quick reference, visit hillrom.com.