Baxter

Welch Allyn Connex Spot Monitor
Special information for US only

You have purchased a **Welch Allyn Connex** Spot Monitor that includes Masimo® SpO2 technology; this model may also include Masimo RRp® technology (obtaining respiration rate from the SpO2 photoplethysmogram) or is capable of being upgraded to include Masimo RRp. The FDA issued a guidance document on March 22, 2020, Enforcement Policy for Non-Invasive Remote Monitoring Devices Used to Support Patient Monitoring During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency and subsequently updated their Guidance October 2023. FDA does not intend to object to limited modifications to the FDA-cleared indications without prior submission of a 510(k) where the modification does not create an undue risk. Baxter does not yet have FDA 510(k) clearance on the combination use of the **Connex** Spot Monitor with Masimo RRp. However Masimo has received FDA clearance on RRp technology (K193242), and Baxter has received the CE Mark on the integrated solution. Baxter intends to adhere to FDA's recommendations to market **Connex** Spot Monitor with Masimo RRp with appropriate testing and labeling while the policy is in effect but does not have specific 510(k) clearance at this time.

This device is intended to provide recommendations that should be used in an adjunctive (supportive) manner and are not intended to be used as a primary means to make diagnosis, prevention, or treatment recommendations.

Revision date: 2024-03
REF 776991, 80030420 Ver. B

Addition to FDA cleared indications for use

Modification to Intended use (modifications are underlined)

The **Connex** Spot Monitors are intended to be used by clinicians and medically qualified personnel for monitoring of noninvasive blood pressure, pulse rate, noninvasive functional oxygen saturation of arteriolar hemoglobin (SpO2), and body temperature in normal and axillary modes of neonatal, pediatric, and adult patients. Monitoring respiration rate from photoplethysmogram (Masimo RRp®) is indicated for adult and pediatric patients greater than two years old.
The most likely locations for patients to be monitored are general medical or surgical floors and general hospital and alternate care environments. The product is available for sale only upon the order of a physician or licensed health care professional.

Device performance

Validation of the integration of Masimo RRp technology into the **Connex** Spot Monitor device was completed through software verification testing and design validation of the RRp parameter in the device user interface and IFU. The **Connex** Spot Monitor device has been tested and shown to comply with IEC 60601-1 Edition 3.1 and IEC 60601-1-2 4th 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 for a complete list of warnings and cautions.

For further information on the **Connex** Spot Monitor, including the Instructions for use, please visit baxter.com.

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