Addendum: Centrella® Smart+ Bed with Heart and Respiration Rate Monitoring System Powered by EarlySense®

Products:	Centrella®[1] Bed
Parts:	Wireless Heart Rate and Respiration Rate Feature
Reference documents:	*Centrella® Smart+ Bed Instructions for Use* (193587)

NOTE:

On March 24, 2020, the FDA issued a guidance document (updated June 2020 and October 2020) "*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 public health emergency and while the policy is in effect, the FDA will not object to limited modifications to the FDA-cleared indications without prior submission of a 510(k) where the modifications do not create undue risks. Hill-Rom does not have FDA 510(k) clearance for the use of the Wireless Heart Rate and Respiration Rate feature on the Centrella® Smart+ Bed. Additional testing was performed for the new functionality and the device performs as intended. Hill-Rom will comply to FDA's recommendations to market the Centrella® Smart+ Bed with Heart and Respiration Rate Monitoring System powered by EarlySense®[2] with appropriate testing and labeling while the policy is in effect.

INTENDED USE

The Hill-Rom® Heart and Respiration Rate Monitoring System powered by EarlySense® is used with compatible bed system models and is intended for continuous measurement of respiration rate (RR) and heart rate (HR) in an automatic, contact-less manner. The system is indicated for use in children, adolescents, and adults in hospitals or clinical settings. It is intended to be used for the same patient populations and the same settings, within these ranges, as the bed with which it is used. The system has been validated to withstand up to 700 lb (318 kg).

The Hill-Rom® Heart and Respiration Rate Monitoring System powered by EarlySense® and the Hill-Rom® Vitals Monitoring System powered by EarlySense® share many characteristics and performance standards (see Table 1-2 on page 2). The differences between the systems are outlined in Table 1-1 on page 2.

During the release, there were no changes made to the indications for use and also no new risks associated with the new characteristics.

In alignment with the *Centrella® Smart+ Bed Instructions for Use* this device is intended to provide data to the clinician that should be used in an adjunctive (supportive) manner and is not intended to be used as a primary means to make diagnosis, prevention, or treatment recommendations.

1. Centrella® and Hill-Rom® are registered trademarks of Hill-Rom Services, Inc.
2. EarlySense® is a registered trademark of EarlySense Ltd.

Table 1-1. New Characteristics (not cleared by the FDA)

Element	Heart and Respiration Rate Monitoring System (not cleared by the FDA)	Vitals Monitoring System (previously cleared by the FDA)
Connectivity (see **Note 1** below)	Can connect to the Hill-Rom® Connectivity solution through both wired and wireless connection.	Can connect to customer nurse call system through a hard-wired connection.
Usage Life	5 years of continuous use The HR/RR Monitoring sensor must be replaced after 5 years of continuous use to make sure the system operates correctly. A notification will show on the GCI when it is time to replace the sensor.	1 year continuous use The EarlySense® sensor must be replaced after 1 year of continuous use to make sure the system operates correctly. A notification will show on the GCI when it is time to replace the sensor.
Classification or Standards Hill-Rom® Heart and Respiration Rate Monitoring System powered by EarlySense® These new functionalities were designed, evaluated and validated in accordance with following FDA-recognized standards:		
• AAMI TIR69: 2017 – Technical Information Report Risk Management of Radio-Frequency Wireless Coexistence for Medical Devices and Systems		
• ANSI/IEEE C63.27: 2017 – American National Standard for Evaluation of Wireless Coexistence		
• AIM 7351731 – Medical Electrical Equipment and System Electromagnetic Immunity Test for Exposure to Radio Frequency Identification Readers		
Note 1: The Heart and Respiration Rate Monitoring System powered by EarlySense® is designed to provide a Contact-Free Continuous Monitoring Solution (CFCM) of heart and respiration rate with the use of the HR/RR Monitoring sensor. Refer to the *Centrella® Smart+ Bed Instructions for Use* (193587) for detailed information about wired data connection and wireless WiFi Radio data connection.		

Table 1-2. Shared Characteristics

Element	Description
FDA Product Code	BZQ
FDA Class	Class II
FDA Common Names	Breathing Frequency Monitor
Measures and Displays	Respiratory Rate Heart Rate
User Interface and Display	Graphical display and interface unit integrated into a bed
Analysis Algorithms Manufacturer	EarlySense®
Total System Accuracy (including undetected signals)	90% (measured as ± 10% of predicate)
Heart Rate	Beats per minute (BPM)
• Detection Range	30 - 170 BPM
• Accuracy	± 4% or ± 5 BPM whichever is greater

• Default Threshold Low	40 BPM
• Default Threshold High	130 BPM
• Lowest Settable Threshold	35 BPM
• Highest Settable Threshold	150 BPM
Respiratory Rate	Breaths per minute (Br./min)
• Detection Range	6 - 45 Br./min
• Accuracy	± 4% or ±1.5 Br./min whichever is greater
• Default Threshold Low	8 Br./min
• Default Threshold High	32 Br./min
• Lowest Settable Threshold	8 Br./min
• Highest Settable Threshold	44 Br./min
Charts	Separate charts for heart rate and respiratory rate
Time Periods	Default 8 hours Range 10 minutes to 7 days
Log	Shows a list of Log Alerts
For Use With	Hospital beds
Sensor	Contactless piezoelectric sensing unit
Sensor Dimension (with handle)	42 x 21 x1.4 cm
Weight	730 g
Material	ABS and Polycarbonate
Water Resistance	IPX4
Manufacturer	EarlySense
Sensor Location	Located on bed deck, under mattress - knobs to facilitate placement
Element	**Description**
Hardware "Host" (non-sensor)	Bed System
Software for Analysis	Analyzes and interprets information from sensor and user input
Software for Display	Acts as a conduit to send data to/from bed system display
Additional Capabilities	None
Energy Source	AC power source
Backup Battery	No
Environments	Professional healthcare facilities
Alert Indications	Visible and audible
Software Level of Concern	Moderate
Classification or Standard	
IEC 60601-1: Medical Electrical Equipment Part 1: General Requirements for Basic Safety and Essential Performance	

IEC 60601-1-2: Medical Electrical Equipment Part 1: General Requirements for Basic Safety and Essential Performance: Electromagnetic Compatibility – Requirements and Tests
IEC 60601-1-6: Medical Electrical Equipment Part 1-6: General Requirements for Basic Safety and Essential Performance
IEC 60601-2-49: Particular Requirements for the Basic Safety and Essential Performance of Multifunctional Patient Monitoring Equipment
ISO 10993-1: Biological Evaluation of Medical Devices Part 1: Evaluation and Testing of Medical Devices Within a Risk Management Process
ISO 14971: Medical Devices – Application of Risk Management to Medical Devices
IEC 62304: Medical Device Software – Software Life Cycle Processes