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To whom it may concern,

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Announcement on Activation of HeartLogic Function and Release of its Clinical Use

Japan Lifeline Co., Ltd. (“the Company”) is pleased to announce that the Company has activated HeartLogic and released its clinical use. HeartLogic is a function within the RESONATE CRT-D (Cardiac Resynchronization Therapy Defibrillators) series manufactured by Boston Scientific Corporation, and it is designed to provide indexes related to changes in the patient’s physiologic information.

HeartLogic is a function to provide indexes related to changes in the patient’s physiologic conditions. HeartLogic utilizes a diverse set of physiologic sensors contained within the RESONATE CRT-D series and records physiologic information related to heart failure, such as heart sounds (S1, S3), thoracic impedance, respiration, activity level, and heart rate. These data are then analyzed by its unique algorithms developed with machine-learning of AI to calculate the HeartLogic Index. This index is computed automatically on a daily basis, monitors changes over time, and sends alert emails to hospitals when the index exceeds the reference values set for individual patients, allowing physicians to timely capture such changes.

HeartLogic’s alert emails and patient reports including various kinds of physiologic information are transmitted to hospitals through the LATITUDE remote monitoring system, which is placed in the patient’s home. This will enable physicians to confirm quantitative and time-dependent data at any time. In addition, it is expected to reduce the burden and risks associated with patients coming to hospitals, especially when the outbreak of the COVID-19 is prevalent and its preventive measures are required.

By activating HeartLogic, physicians can obtain physiologic information provided by the diverse set of physiologic sensors that the RESONATE CRT-D series uniquely have in a more timely and sophisticated manner. Therefore, the Company is expecting that this will further contribute to remote medical care.

The Company aims more than ever to contribute to the realization of a healthy society through the latest optimal medical device technologies.



CRT-D RESONATE

Notice

At present, the relationship between the information presented by HeartLogic and signs of worsening heart failure has not been established. When an HeartLogic alert occurs, it is necessary to comprehensively evaluate the patient's condition and other indicators, and then determine whether a treatment is necessary and what an optimal treatment plan will be.

Note that product falls under "3. Diagnostic Equipment for Measuring Physiological Parameters That Can Be Reference Information for Diagnosis" as shown in Yakuseikishinhatsu Notification No. 1117-1 and Yakuseianpatsu Notification No. 1117-1 of November 17, 2017, and that the clinical relevance of the information presented by the HeartLogic function of product has not been evaluated.