

## New Analysis Shows Medtronic Cardiac Resynchronization Therapy Feature Associated with Improved Patient Survival

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 Medtronic plc

### *Real-World Data on AdaptivCRT(TM) Algorithm Presented at Heart Rhythm 2018*

**DUBLIN - May 15, 2018** - Medtronic plc (NYSE: MDT) announced study results showing its exclusive AdaptivCRT(TM) algorithm is associated with improved patient survival. The data were recently presented at Heart Rhythm 2018, the Heart Rhythm Society's 39<sup>th</sup> Annual Scientific Sessions in Boston.

In a real-world, prospective registry of 1,835 patients, use of the AdaptivCRT algorithm was associated with a 31 percent relative reduction in all-cause mortality compared to conventional cardiac resynchronization therapy (CRT) ( $p=0.02$ ). The AdaptivCRT algorithm personalizes therapy, adjusting how the implanted CRT device paces the heart according to minute-to-minute evaluations of each patient's rhythm, and is being assessed for superiority over conventional CRT in a randomized clinical trial, AdaptResponse.

"Heart failure patients typically have several other medical conditions and are at risk for frequent hospitalizations and even death," said Jagmeet P. Singh, M.D., Ph.D., associate chief of the Cardiology Division of Massachusetts General Hospital in Boston. "The AdaptivCRT algorithm is not only linked to improved patient survival, but it also has previously been shown to reduce the risk of atrial fibrillation and hospital readmissions."

Atrial fibrillation (AF), an irregular quivering or rapid rhythm in the heart's upper chambers, is one of the most common heart rhythm disorders, and a large percentage of heart failure patients also have AF.<sup>1</sup> Prior analyses of AdaptivCRT have shown a 46 percent reduction in episodes of AF lasting more than 48 hours, compared to patients treated with conventional CRT.<sup>2</sup>

Additionally, AdaptivCRT allows physicians to tailor CRT to the individual needs of each patient, which has been shown to translate into a 59 percent reduction in a patient's odds of a 30-day heart failure readmission.<sup>3</sup> Evidence from the Adaptive CRT randomized clinical trial further demonstrated that AdaptivCRT increases CRT response rate, reduces unnecessary right ventricular pacing, and improves clinical outcomes for patients with normal AV conduction.<sup>4-7</sup>

"With AdaptivCRT, we are treating heart failure comprehensively, with technology designed to address the individual needs of each patient," said Kweli P. Thompson, M.D., M.P.H., vice president and general manager of the Cardiac Resynchronization Therapy business, which is part of the Cardiac Rhythm and Heart Failure division at Medtronic. "This analysis shows yet another benefit of AdaptivCRT, and we look forward to results from the randomized, superiority AdaptResponse trial in the coming years."

Heart failure is a progressive condition, affecting more than 26 million people worldwide, consuming intensive resources during hospitalizations and continuing to cause problems following hospital stays, with 90-day readmission rates of 40 percent.<sup>8</sup> CRT is an established treatment for some heart failure patients that uses an implantable defibrillator (CRT-D) or

pacemaker (CRT-P) to improve the pumping efficiency of the heart.

The Medtronic portfolio of therapies, diagnostic tools and services for patients suffering from heart failure includes CRT devices, including MR-conditional CRT-Ds and CRT-Ps; mechanical circulatory support therapy for advanced heart failure patients; heart failure diagnostics; and meaningful expert analysis through Medtronic Care Management Services.

Medtronic is a world leader in the diagnosis, management and treatment of AF. Innovative technologies across the company's portfolio can help detect AF<sup>9-11</sup>, reduce the duration<sup>12</sup> of and respond to AF<sup>13</sup>, and treat paroxysmal (fleeting) AF in patients - ultimately improving patient outcomes.

In collaboration with leading clinicians, researchers and scientists worldwide, Medtronic offers the broadest range of innovative medical technology for the interventional and surgical treatment of cardiovascular disease and cardiac arrhythmias. Medtronic strives to offer products and services of the highest quality that deliver clinical and economic value to healthcare consumers and providers around the world.

### **About Medtronic**

Medtronic plc ([www.medtronic.com](http://www.medtronic.com)), headquartered in Dublin, Ireland, is among the world's largest medical technology, services and solutions companies - alleviating pain, restoring health and extending life for millions of people around the world. Medtronic employs more than 84,000 people worldwide, serving physicians, hospitals and patients in approximately 160 countries. The company is focused on collaborating with stakeholders around the world to take healthcare Further, Together.

**Any forward-looking statements are subject to risks and uncertainties such as those described in Medtronic's periodic reports on file with the Securities and Exchange Commission. Actual results may differ materially from anticipated results.**

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<sup>1</sup> Kloosterman M, Maass AH, Rienstra M, Van Gelder IC. Atrial fibrillation during cardiac resynchronization therapy. *Card Electrophysiol Clin*. December 2015;7(4):735-748.

<sup>2</sup> Birnie D, et al. Continuous optimization of cardiac resynchronization therapy reduces atrial fibrillation in heart failure patients: Results of the Adaptive Cardiac Resynchronization Therapy Trial. *Heart Rhythm*. 2017;14:1820-1825.

<sup>3</sup> Starling RC, et al. Impact of a novel adaptive optimization algorithm on 30-day readmissions: Evidence from the Adaptive CRT Trial. *JACC Heart Fail*. 2015;3:565-572.

<sup>4</sup> Martin D, et al. Clinical outcomes with adaptive cardiac resynchronization therapy: Long-term outcomes of the Adaptive CRT Trial. HFSA Annual Scientific Meeting. September 23, 2013.

<sup>5</sup> Martin D, Lemke B, Birnie D, et al. Investigation of a novel algorithm for synchronized left ventricular pacing and ambulatory optimization of cardiac resynchronization therapy: Results of the Adaptive CRT Trial. *Heart Rhythm*. 2012; 9(11): 1807-1814.

<sup>6</sup> Birnie D, et al. Clinical outcomes with synchronized left-ventricular pacing: Analysis of the Adaptive CRT Trial. *Heart Rhythm* 2013; 10(9): 1368-1374.

<sup>7</sup> Singh JP, Abraham WT, Chung ES, et al. Clinical response with adaptive CRT algorithm compared with CRT with echocardiography-optimized atrioventricular delay: a retrospective analysis of multicentre trials. *Europace* 2013; 15(11): 1622-1628.

<sup>8</sup> Kilgore M, et al. Economic burden of hospitalizations of Medicare beneficiaries with heart failure. *Risk Management and Healthcare Policy*. 2017;10:63-70.

<sup>9</sup> Purerfellner H, et al. Accuracy of Atrial Tachyarrhythmia Detection in Implantable Devices with Arrhythmia Therapies. *Pacing Clin Electrophysiol*. 2004;27: 983-992.

<sup>10</sup> Ziegler PD, et al. Accuracy of Atrial Fibrillation Detection in Implantable Pacemakers. Presented at HRS 2013 (PO02-08).

<sup>11</sup> Medtronic data on file. QADoc DSN026170, Version 2.0, "AT/AF Duration Performance Comparison."

<sup>12</sup> Hudnall H. Reactive Atrial-based Antitachycardia Pacing Therapy to Slow Progression of Atrial Fibrillation. August 2017, Medtronic data on file.

<sup>13</sup> Plummer CJ, et al. A novel algorithm increases the delivery of effective cardiac resynchronization therapy during atrial fibrillation. The CRTee randomized crossover trial. Heart Rhythm. 2018;15:369-375.

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