Abbott Releases Planned Updates For Implantable Cardiac Devices

- Latest in planned series of cybersecurity updates further strengthens security and performance of implantable cardioverter defibrillators

- Part of Abbott's ongoing commitment to continuously advance the security of connected devices and systems

ABBOTT PARK, Ill., April 17, 2018 – Abbott is releasing the latest in its planned series of cybersecurity and battery performance alert updates: a firmware upgrade to further strengthen the security and enhance the performance of certain high-voltage implantable cardiac devices. This series of updates began with Abbott's pacemakers, programmers and remote monitoring systems in 2017.

Firmware is a kind of software that is embedded in certain medical devices. Devices that use this type of software may require updates from time to time, as technology and security for connected devices and systems continue to advance.

The firmware upgrade released today incorporates an enhanced device-based battery performance alert, which will allow patients and physicians to better manage battery performance in certain implantable cardioverter defibrillators (ICDs) and cardiac resynchronization therapy defibrillators (CRT-Ds). It also includes a cybersecurity update, which will provide an additional layer of protection against unauthorized device access.

Each of these are planned updates, and part of Abbott's ongoing commitment to improve patient care and make our products more secure. There have been **no** reports of unauthorized access to any patient's implanted device and **no** new vulnerabilities have been identified.

"Technology and its security are always evolving, and this firmware upgrade is part of our commitment to ensuring our products include the latest advancements and protections for patients," said Robert Ford, executive vice president, Medical Devices at Abbott.

Abbott is communicating with regulatory authorities worldwide to implement the new upgrade to implantable ICDs and CRT-Ds, which will be made available over the next several weeks.

About the Battery Performance and Security Updates

These updates are part of a series of planned firmware releases that Abbott announced last year for pacemakers and are now available for ICDs and CRT-Ds.

The cybersecurity update provides an additional layer of security against unauthorized access to these devices, to prevent anyone other than a person's physician from changing device settings.

The battery performance alert update will allow the device to monitor for abnormal battery behavior and automatically vibrate to alert the patient if abnormal battery behavior is detected. The capability to detect this was previously only available on the Merlin.net remote monitoring system or during in-clinic office visits via the Merlin programmer.

The cybersecurity update applies to the following ICD and CRT-D device families: Fortify™, Fortify Assura™, Quadra Assura™, Quadra Assura MP™, Unify™, Unify Assura™, Unify Quadra™, Promote Quadra™ and Ellipse™. The battery performance alert update applies to the following high voltage devices manufactured between January 2010 and May 2015: Fortify™, Fortify Assura™, Quadra Assura™, Quadra Assura MP™, Unify™, Unify Assura™ and Unify Quadra™.

Recommendations for Patients

Abbott has reviewed these updates with its Medical Advisory Boards and recommends the firmware upgrade for all eligible patients. Patients should speak with their physicians about the risks and benefits of the update as part of their decision-making process at their next regularly scheduled visit, or whenever they and their physicians deem appropriate. The devices continue to function as designed and intended, and replacement of implanted devices is not recommended.

For more information about the ICD and CRT-D firmware update, please contact our hotline at 1-800-436-5056 or visit our website at sjm.com/notices.

About Abbott

Abbott is a global healthcare company devoted to improving life through the development of products and technologies that span the breadth of healthcare. With a portfolio of leading, science-based offerings in diagnostics, medical devices, nutritionals and branded generic pharmaceuticals, Abbott serves people in more than 150 countries and employs approximately 99,000 people.

Visit Abbott at www.abbott.com and connect with us on Twitter at @AbbottNews.

Abbott Media:
Kelly Morrison, (224) 667-3802

Abbott Financial:
Mike Comilla, (224) 668-1872