

Thursday, May 14, 2015

FDA alerts health care facilities to infusion pump cybersecurity vulnerability

Awareness and active evaluation of new and emerging threats and vulnerabilities is critical for hospitals to effectively prepare and manage cybersecurity risks. To keep hospitals informed of significant threats and vulnerabilities that may affect the health care sector, the AHA is working with federal agencies to share important cybersecurity intelligence.

The Food and Drug Administration (FDA) is alerting users of the Hospira LifeCare PCA3 and PCA5 Infusion Pump Systems to security vulnerabilities with these pumps.

The Hospira LifeCare PCA3 and PCA5 Infusion Pump Systems are computerized infusion pumps designed for the continuous delivery of anesthetic or therapeutic drugs. These systems can be programmed remotely through a health care facility's Ethernet or wireless network.

The FDA and Hospira have become aware of security vulnerabilities in Hospira's LifeCare PCA3 and PCA5 Infusion Pump Systems. An independent researcher has released information about these vulnerabilities, including software codes, which, if exploited, could allow an unauthorized user to interfere with the pump's functioning. An unauthorized user with malicious intent could access the pump remotely and modify the dosage it delivers, which could lead to over- or under-infusion of critical therapies.

The FDA is not aware of any patient adverse events or unauthorized device access related to these vulnerabilities.

The FDA has listed in its alert (<http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm446809.htm>) specific actions that health care facilities can take to reduce the risk of unauthorized access, such as isolating the LifeCare PCA Infusion Pump System from the Internet and untrusted systems. The AHA encourages you to identify whether you have any of the affected pumps, and if you do, review the FDA's suggested actions carefully.

The FDA is actively investigating the situation based on current information and close engagement with Hospira and the Department of Homeland Security and will provide

new information about patient risks and any additional steps users should take to secure these devices, as it becomes available.

The agency encourages users that experience problems with their device to report them, and provides guidance on how to do so in the alert (<http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm446809.htm>). Prompt reporting of adverse events can help the FDA identify and better understand the risks associated with medical devices.

For additional information or questions about the Hospira LifeCare PCA3 and PCA5 Infusion Pump Systems, contact Hospira at 800-241-4002.

If you have questions for the FDA, please contact the Division of Industry and Consumer Education (DICE) at DICE@FDA.HHS.GOV, 800-638-2041 or 301-796-7100.

For additional AHA resources on cybersecurity, visit www.aha.org/cybersecurity.