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Protecting and Promoting Your Health

Cybersecurity Vulnerabilities of Hospira Symbiq Infusion System: FDA Safety Communication

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Date Issued: July 31, 2015

Audience: Health care facilities using the Hospira Symbiq Infusion System

Device: Symbiq Infusion System, Version 3.13 and prior versions

The Hospira Symbiq Infusion System is a computerized pump designed for the continuous delivery of general infusion therapy for a broad patient population.

It is primarily used in hospitals, or other acute and non-acute health care facilities, such as nursing homes and outpatient care centers. This infusion system can communicate with a Hospital Information System (HIS) via a wired or wireless connection over facility network infrastructures.

Purpose:

The FDA is alerting users of the Hospira Symbiq Infusion System to cybersecurity vulnerabilities with this infusion pump. We strongly encourage that health care facilities transition to alternative infusion systems, and discontinue use of these pumps.

Summary of Problem and Scope:

The FDA, the U.S. Department of Homeland Security's Industrial Control Systems Cyber Emergency Response Team (ICS-CERT), and Hospira are aware of cybersecurity vulnerabilities associated with the Symbiq Infusion System.

Hospira and an independent researcher confirmed that Hospira's Symbiq Infusion System could be accessed remotely through a hospital's network. This could allow an unauthorized user to control the device and change the dosage the pump delivers, which could lead to over- or under-infusion of critical patient therapies. The FDA and Hospira are currently not aware of any patient adverse events or unauthorized access of a Symbiq Infusion System in a health care setting.

Hospira has discontinued the manufacture and distribution of the Symbiq Infusion System, due to unrelated issues, and is working with customers to transition to alternative systems. However, due to recent cybersecurity concerns, the FDA strongly encourages health care facilities to begin transitioning to alternative infusion systems as soon as possible.

Recommendations for Health Care Facilities:

While transitioning to an alternative infusion system, consider taking the following steps to reduce the risk of unauthorized system access:

- Disconnect the affected product from the network.

CAUTION: Disconnecting the affected product from the network will have operational impacts. Disconnecting the device will require drug libraries to be updated manually. Manual updates to each pump can be labor intensive and prone to entry error.

- Ensure that unused ports are closed, including Port 20/FTP and Port 23/TELNET.
- Monitor and log all network traffic attempting to reach the affected product via Port 20/FTP, Port 23/TELNET and Port 8443. Contact Hospira's technical support to change the default password used to access Port 8443 or close it.

While these infusion pumps are currently not available for purchase through Hospira, the FDA is aware that the Symbiq Infusion System is potentially available for purchase from third parties not associated with Hospira. The FDA strongly discourages the purchase of the Symbiq Infusion System from these parties. The FDA recommends health care facilities follow the good cybersecurity hygiene practices outlined in the FDA Safety Communication [Cybersecurity for Medical Devices and Hospital Networks](#) ([/MedicalDevices/Safety/AlertsandNotices/ucm356423.htm](#)), posted in June 2013.

FDA Activities:

The FDA is actively investigating the situation based on current information. If new information becomes available about patient risks and any additional steps users should take, the FDA will communicate such information publicly.

Reporting Problems to the FDA:

Prompt reporting of adverse events can help the FDA identify and better understand the risks associated with medical devices. If you are experiencing problems with your device, we encourage you to file a voluntary report through [MedWatch, the FDA Safety Information and Adverse Event Reporting program](#) ([/Safety/MedWatch/HowToReport/ucm2007306.htm](#)).

Health care personnel employed by facilities that are subject to the [FDA's user facility reporting requirements](#) ([/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/ucm2005737.htm](#)) should follow the reporting procedures established by their facilities.

Device manufacturers must comply with the [Medical Device Reporting \(MDR\) regulations](#) ([http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=803](#)).

Other Resources:

ICS-CERT communicated these Symbiq cybersecurity concerns in a [safety advisory](#) ([https://ics-cert.us-cert.gov/advisories/ICSA-15-174-01](#)) issued on June 23, 2015 and updated on July 21, 2015.

Hospira issued two communications on their website: [Reported Symbiq Cybersecurity Vulnerabilities](#) ([http://www.hospira.com/en/about_hospira/newsroom/cybersecurity/cybersecurity_vulnerabilities](#)) and [Infusion Device Cybersecurity](#) ([http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm](#)) and ([http://www.hospira.com/en/about_hospira/newsroom/cybersecurity](#)) and ([http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm](#)).

ICS-CERT also references Symbiq Infusion System cybersecurity issues in this safety advisory: [ICS-CERT Advisory: Hospira Plum A+ and Symbiq Infusion Systems Vulnerabilities \(ICSA-15-161-01\) \(https://ics-cert.us-cert.gov/advisories/ICSA-15-161-01\)](https://ics-cert.us-cert.gov/advisories/ICSA-15-161-01).



In June 2013, the FDA published a [Safety Communication on Cybersecurity for Medical Devices and Hospital Networks \(/MedicalDevices/Safety/AlertsandNotices/ucm356423.htm\)](/MedicalDevices/Safety/AlertsandNotices/ucm356423.htm).



Contact Information:

For additional information or questions about the Symbiq Infusion System, contact Hospira's technical support at 1-800-241-4002.

If you have questions about this communication, please contact the Division of Industry and Consumer Education (DICE) at DICE@FDA.HHS.GOV (<mailto:DICE@FDA.HHS.GOV>), 800-638-2041 or 301-796-7100.

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