

# 1 Problem

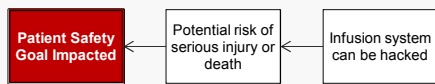
<b>What</b>	Problem(s)	Hospira Symbiq Infusion System vulnerable to hacking
<b>When</b>	Date	FDA Safety Communication issued July 31, 2015
	Different, unusual, unique	Can connect to a Hospital Information System via a wired or wireless connection
<b>Where</b>	Facility, site	Healthcare facilities
	Unit, area, equipment	Hospira Symbiq Infusion System
	Task being performed	Continuous delivery of general infusion therapy

## Impact to the Goals

<b>Patient Safety</b>	Potential risk of serious injury or death
<b>Compliance</b>	FDA recommended discontinuing use of infusion system
<b>Property/ Equipment</b>	Potential for new equipment to be required
<b>Labor/ Time</b>	Resources required to transition to different pumps

# 2 Analysis

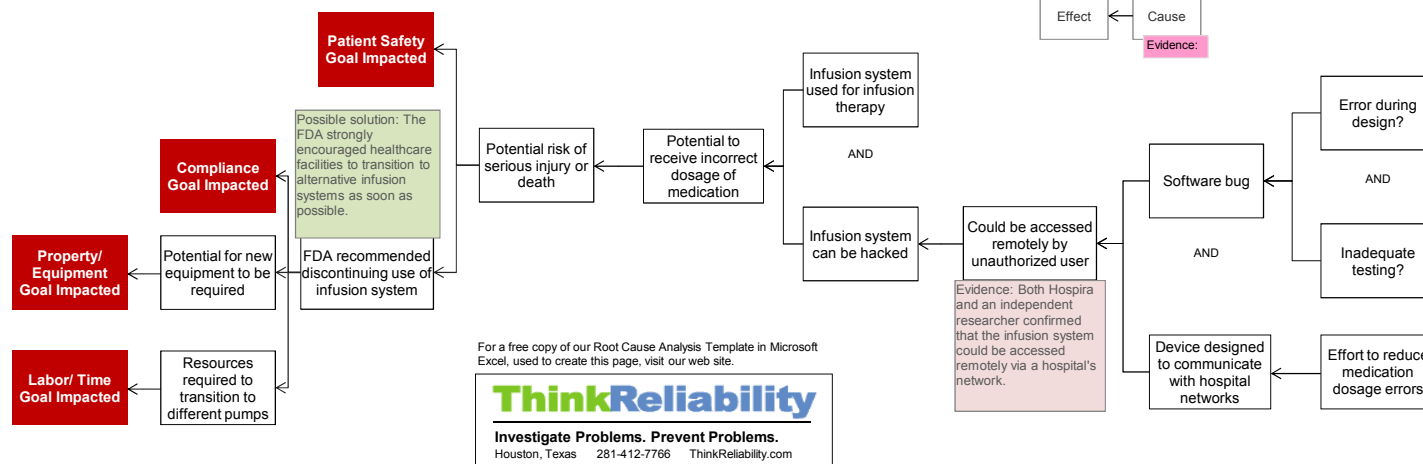
**Basic Level Cause Map** - Start with simple Why questions.



**Basic Cause-and-Effect**

There have been no reported cases where this infusion pump system has been hacked, but both Hospira and an independent researcher have confirmed that it is possible. This system is vulnerable to hacking because it is designed to communicate with hospital networks and the design has a software bug that could allow it to be accessed remotely via a hospital's network.

**More Detailed Cause Map** - Add detail as information becomes available.



For a free copy of our Root Cause Analysis Template in Microsoft Excel, used to create this page, visit our web site.

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# MEDICAL DEVICE VULNERABLE TO HACKING

Cause Map

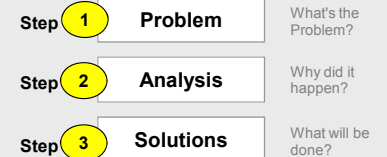
## FDA encourages transition to alternative infusion system

The Food and Drug Administration (FDA) made headlines when they issued a warning that a computerized pump used for infusion therapy, Hospira Symbiq Infusion System, has cybersecurity vulnerabilities. Hacking is scary enough when talking about a laptop, but the stakes are much higher if someone had the ability to alter the dosage of critical medication.

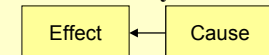
Cause Mapping is a Root Cause Analysis method that captures basic cause-and-effect relationships supported with evidence.

## CAUSE MAPPING

Problem Solving • Incident Investigation • Root Cause Analysis



## Why?



NOTE: Read the Cause Map from left to right with the phrase "Was Caused By" in place of each arrow.

# 3 Solutions

The final step in the Cause Mapping process is to develop solutions to help reduce the risk of similar errors in the future. The FDA has strongly encouraged healthcare facilities to transition to alternative infusion systems as soon as possible. Hospira discontinued this specific design of infusion system in 2013, reportedly due to unrelated issues, but it is still available for sale by third-party companies and used by many healthcare facilities. There will not be a software patch provided or any other means to make the Hospira Symbiq Infusion System less vulnerable to hacking so the only option going forward will be to switch to a different infusion system.