Recall detail

Type of Product[i]	Medical Device
TGA Recall Reference[ii]	RC-2015-RN-00986-1
Product Name/Description[iii]	Plum 360 Infusion Pump, Software Version 15.01.XX.009 List number 30010-27 All serial numbers affected ARTG Number: 234421
Recall Action Level[iv]	Hospital
Recall Action Classification[v]	Class I
Recall Action Commencement Date[vi]	13/10/2015
Responsible Entity[vii]	Hospira Pty Limited
Reason / Issue[viii]	Hospira has determined if "Yes" is selected at the "New Patient" screen, and the program was not cleared prior to powering off the infuser, the Distal Occlusion Pressure setting is assigned a value of 15 PSI (775 mmHg) instead of the default value. In addition, the User Interface will incorrectly display the default Distal Occlusion Pressure value, which is set at 6 PSI (310 mmHg) from the manufacturer, or can be reset in Biomed Mode or received from the Hospira MedNet in a Custom Drug Library. The user would not be immediately aware of the unintended occlusion pressure setting unless the user views the Current Distal Pressure value on the infuser display and it is greater than the Distal Pressure Alarm Limit. Both the Current Distal Pressure and the Distal Pressure Alarm Limit are visible on the same User Interface screen. This may result in a delay of therapy related to the delay in identifying the occlusion cause, such as kinked tubing.
Recall Action[ix]	Recall for Product Correction
Recall Action Instructions[x]	Hospira is in the process of developing a software update to correct this issue and will contact you when the new software is available to make arrangements to receive the correction. Until a software update is available, Hospira is recommending that users follow temporary workaround instructions provided in the customer letter for every infusion to prevent this issue from occurring.
Contact Information[xi]	1300 046 774 - Option 1. - Hospira Customer Service

Footnotes

[i] Type of Product: Medicine, Medical Device, or Biological

[ii] TGA Recall Reference: Unique number given by the TGA