

Safety Communication

رسالة سلامة

Prismaflex Control Units May Result in Serious Injuries due to Communication Errors

Device/ Product Description:	Prismaflex Control Units
Affected Programmers :	Software versions 8.10, 7.20 and lower
Affected Devices:	Product Codes: 106913, 107493, 113082, 113874, 114489, 114870, 955052 and 6023014700
Manufacturer:	Baxter Healthcare
Problem:	<p>Communication error alarms may result in unintentional delay and interruption of treatment due to system shutdown.</p> <p>This Communication error alarms may result in interruption of therapy, delay in therapy, or blood loss due to non-restitution of blood in the extracorporeal circuit. In the event of a communication error, the user instructed to manually return blood in the extracorporeal circuit to the patient.</p>
Recommendation/Actions:	<ul style="list-style-type: none"> Baxter is advising customers that they may continue to safely use the Prismaflex control units until the upgrade is performed. If a communication error alarm does occur, customers are advised to follow the instructions presented on the graphical user interface and/or in the operator's manual. A local Baxter service representative will contact your facility to arrange for the software upgrade of all affected Prismaflex devices. Your facility will be receiving this software upgrade from Baxter at no charge.

Devices/Products photo:



**Authorized Representative
Details**

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