Urgent Field Safety Notice

August XX, 2019 **(to be adapted locally)**

Dear Healthcare Provider:

Problem Description

Baxter Healthcare has identified the potential for certain PrisMax devices to develop cracks in the blood pump raceway over time (refer to figure 1). The cracks are caused by varying material thickness in this specific area of the front panel. To ensure high quality, and to avoid any problems with the front panel over time, the front panel will be replaced on all potentially impacted units listed in the affected product table below.

Figure 1: Pictures of PrisMax device and cracks in the blood pump raceway

A crack in the blood pump raceway is likely to cause insufficient occlusion of the blood pump. If this occurs before treatment, the device will no longer pass the prime test. If this occurs during treatment, therapy will be interrupted. A device affected by this failure will not be usable until an off-site repair by Baxter Service is completed.

Baxter has implemented corrective actions to resolve this issue in newly manufactured PrisMax devices.

Affected Product

Product Code	Product Description	Serial Numbers
955558	PrisMax, V2, ROW	100745

Hazard Involved

This issue may result in interruption of therapy, delay in therapy, or blood loss due to non-restitution of blood in the extracorporeal circuit; however, adverse health

consequences are not likely. There have been no reports of serious injury associated with this issue.

Actions to be Taken by Customers

1. Operators may continue to safely use affected devices that have not exhibited failures of the blood pump raceway. If the device is not performing as intended as a result of this issue, the user will be alerted by Alarm T0850, Alarm T0525, or Alarm T0602.

2. A local Baxter service representative will contact your facility to determine the correction plan and schedule the off-site device repair. Loaner devices will be provided as needed. If you experience an alarm, please contact Baxter Technical Service at **(to be adapted locally).**

3. Complete the enclosed Baxter Customer Reply Form and return it to Baxter by faxing it to (+32 68 27 27 42) or scanning and e-mailing it to complaint_benelux@baxter.com **.** Returning the customer reply form promptly will confirm your receipt of this notification and prevent you from receiving repeat notices.

4. If you distribute this product to other facilities or departments within your institution, please forward a copy of this communication to them.

Further information and support

For general questions regarding this communication, contact Baxter at **(to be adapted locally)**

The local Ministry of Health (MoH) has been notified of this action.

We apologize for any inconvenience this may cause you and your staff.

Sincerely,

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Enclosure: Customer Reply Form

