B. Braun Melsungen AG
Division Hospital Care

TO WHOM IT MAY CONCERN

Your reference	Our reference	Tel. +49/56 61/71-	Fax +49/56 61/71-	Date
	RECALL 2015-06-22 LS/STK			Jun 22, 2015

Urgent FIELD SAFETY NOTICE – Easypump II Recall

To whom it may concern,

we, the B. Braun Melsungen AG have decided to recall the following product in the context of a FIELD SAFETY CORRECTIVE ACTION from the market:

Article Number	Article Name	Batch
4540010	EASYPUMP II LT 60-30-S	14N18GE231

Reason for the Recall

In the course of our post market surveillance activities we discovered that a low number of Easypumps with a high flow rate of 250ml/h may have potentially been packed, labeled and distributed as Easypump II LT 60-30s with a low flow rate of 2ml/h. The mislabeling is limited to article no. 4540010, batch 14N18GE231. The actual flow-rate of an Easypump can be identified directly on the device with a label on its filter (see picture in Appendix 1). Up to now, no harm or any other adverse patient outcome which could be associated to the above described observation has been reported to the B. Braun Melsungen AG. As the mislabeling, however, bears the risk of serious over-infusion we have decided to recall the affected batch from the market.

Actions to be taken by the USER

Our records show that your hospital has received the potentially affected EASYPUMP II LT 60-30-S as specified in the table above.

We kindly ask you to initiate the following activities immediately and with priority:

- Identify, quarantine and return affected devices.
- Do not use affected devices anymore.
- Inform the responsible personnel in the affected facilities .
- Confirm the receipt of this information.

. . .

If more information is needed, please contact

Local contact 1
Name
Title
Email
telephone

Local contact 2

Kindly accept our apologies for any inconveniences.

Yours sincerely,

Appendix 1

The flow-rate of an Easypump II is labelled on its filter.	
	
Flow rate 2 ml/h	
Flow rate 250 ml/h