

Urgent Field Safety Notice

multiFiltratePRO devices (M205001) – blood leak detection

Date: February 20th, 2017

Dear Customer,

In the course of our post market surveillance activities, we have learned of some customer reports concerning observations that blood leak detector (BLD) doors have been opening inadvertently before treatment has started.

Internal investigations have found that it is not possible to rule out the risk of a BLD door opening inadvertently, including during treatment.

An open BLD door allows the filtrate tube to slip out, however, a device error message only appears if this happens before the filtrate tube is filled during preparation. If the tube moves out of the BLD during treatment and this is not noticed, the device may not detect a blood leak in the filter.

The BLD door is more likely to open inadvertently if tubes are inserted incorrectly (e.g., incorrect segment of the filtrate tubing system). Therefore, we strongly advise routing the tube in accordance with the requirements in the Instructions for Use and on the screen.

The tube emerging from the yellow positioner must be inserted into the pressure measurement unit with the filtrate pressure dome, routed through the BLD, and then inserted into the line holder (this includes checking the catch mechanism on the BLD door). See the illustrations below:



CVVHDF Post Heparin *circ* Preparation

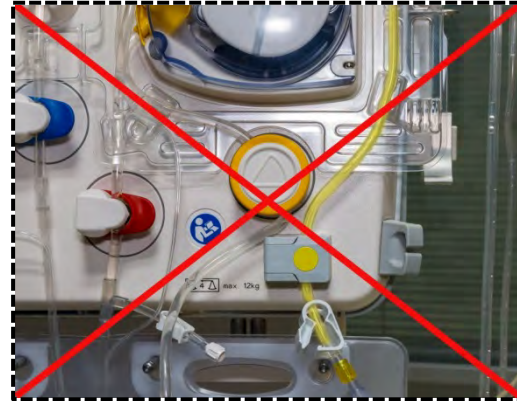
Filtrate system

1. Place positioner in filtrate pump until tone signal is sounded and close pump door
2. Place filtrate pressure dome in pressure measurement unit (d)
3. Insert filtrate line in blood leak detector (yellow)
4. Connect filter connection (yellow) with filter
5. Hang filtrate bag on scales 3 and 4
6. Connect filtrate line to filtrate bag. To connect two filtrate bags, use Y adapter

Filtrate bag monitoring:
10 liters (1 filtrate bag)

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Furthermore, we strongly advise regular checks to ensure that the catch mechanism of the BLD door is operating **fully** and **correctly**. In particular, this must be done if the tubing system has been moved; for example, during a bag change.



In order to continually improve our devices, we are devoting significant efforts to developing a constructive solution that will reliably prevent the BLD door from opening inadvertently.

Please forward this Urgent Field Safety Notice to all the people in your organization who require this information.

Please excuse the inconvenience caused by this matter. We expect to be in a position to offer you a free refitting solution starting in May 2017. We will contact you regarding this matter to arrange an appointment for the refitting; you will not need to contact us first.

Should you have any questions, please feel free to get in touch with us at any time:

Name: xxx
Telephone: xxx
E-mail: xxx