Urgent Field Safety Notice

Commercial name/Model: *BeneFusion VP1, BeneFusion VP3 infusion pump*
FSCA-identifier: *JXXY-20170717*
Type of action: *Safety Notice and Device modification*

July, 2017

Attention: [Hospital/Distributor Name]

Dear Sir or Madam,

Through the continuous monitoring of the products distributed by Shenke Medical, we have become aware a potential issue with the BeneFusion VP1, BeneFusion VP3 infusion pump. This letter is intended to provide you with information as following:

Details on affected devices:
The affected products are *BeneFusion VP1 and BeneFusion VP3 infusion pump*. The affected devices and how to identify the serial numbers are listed in appendix 1 ***List of Affected devices***.

Description of the problem:
Shenke Medical has identified a potential issue with the BeneFusion infusion pump (BeneFusion VP1, BeneFusion VP3), which the plastic screw Joint used to fasten the pump body may crack under certain circumstance. The internal aging test revealed that, although in a rare case, the crack of the plastic screw Joint may lead to the abnormal infusion flow control. In some circumstances, this may result in over infusion.

Risk for patient:

Shenke Medical is not aware of any report of injury attributed to this issue, however this situation may cause the patient receiving more medication than prescribed, resulting in an over infusion and may require medical intervention. Especially the neonatal and pediatric patients, or those receiving critical drugs, at low infusion rates, would be considered to be the most at risk.

Corrective Action:
In order to eliminate any potential for the issue, Shenke Medical will arrange for a service engineer or approved service provider to replace a new front panel assembly for the affected BeneFusion infusion pump at no cost to the customer.

- **Schedule**

Shenke Medical has initiated the Field Safety Corrective action on 2017-7-24 and expected to complete the corrective action on EEA region before 2017-10-31.

- **Advise on action to be taken by the distributor:**

1. Please pass this Notice to all those who need to be aware within your organization or to any organization where the potentially affected device(s) have been transferred.

2. If any BeneFusion VP1 and BeneFusion VP3 infusion pump in your facility is on the

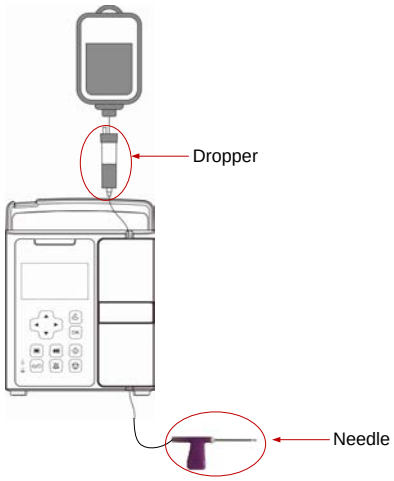
affected list, please do not sell or install these devices to the customers. Shenke Medical Service Representative will contact you to fix this problem.

■ **Advise on action to be taken by the Hospital administrator:**

1. Please pass this Notice to all those who need to be aware within your organization or to any organization where the potentially affected device(s) have been transferred.

2. Please stop using the BeneFusion VP1, BeneFusion VP3 infusion pump in your facility. However, If you do not have alternative devices and want to continue to use the BeneFusion VP1, BeneFusion VP3 infusion pump, we advise you to do the following test before each infusion:

   1). Fully prime the administration set with liquid;
   2). Load the administration set into the BeneFusion infusion pump and close the door;
   3). Open the Robert clamp and flow rate regulator of the set;
   4). Observe the dropper or needle for 30 seconds:
      a) If any drop drips or increases gradually, then the flow rate is abnormal, pump should be removed from clinical use and quarantined.
      b) If NO drop drips or increases gradually was observed, then the infusion pump could be used normally for this infusion.



Rate Abnormality Screening Method

3. Your local Shenke Medical Service Representative or approved service provider will contact you as soon as possible to fix this problem.

■ **Transmission of this Field Safety Notice:**

This Notice needs to be passed on all those who need to be aware within your organization or to any organization where the potentially affected device(s) have been transferred.

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

We would be grateful if you could confirm receipt of this letter. Please fill in below Acknowledgement Form and return via E-mail or Fax.

■ **Contact reference person:**

We apologize for the inconvenience caused by this situation. If you have any questions，please contact with your local Shenke Customer Service Engineer or designated Technical Support Engineer –Alex Wang

Organization: Shenzhen Shenke Medical Instrument Technical Development Co., Ltd.
Tel: +86 755 81886493
Fax: 0086-755-26582934-86493
Email: alex.ykwang@mindray.com

Your competent authority has already been notified of this Field Safety Notice by Shenke Medical's Authorized EU Representative.

(Closing paragraph)

Signature:

[redacted]
QA Department
Shenzhen Shenke Medical Instrument Technical Development Co., Ltd.
1203 Nanhuan Avenue, Guangming District, Shenzhen 518016, P.R. China
E-mail: skmedica@skmedica.com
Tel: +86 755 81889645

Acknowledgement Form

==========

Confirmation of Receipt of Field Safety Notice

Affected Products : *BeneFusion VP1, BeneFusion VP3 infusion pump*
FSCA-identifier: *JXXY-20170717*
Type of FSCA : *Safety Notice and Device modification*

==========

Please fill in this form and return this confirmation by E-mail or Fax immediately.

Fax: 0086-755-26582934-86493
Email: skmedica@skmedica.com

Name: _____

Tel. No.: _____

E-mail address: _____

Date and Signature: _____

Address of the Organization:

_____

_____

Appendix 1 List of Affected Devices.

Country	Commercial name/Model	Serial Number	Distributor/End User	Contact person	Address	Telephone	Email

The serial number is on the main unit label which is on the back of the device. If you do not know how to identify the machine serial number, please refer to below picture:

Figure 1 Main Unit Label