



# BEST CONTACT (M) SDN. BHD. (293091-M)

(A subsidiary of BCM Alliance Berhad)

No. 13-12, Jalan Jalil Perkasa 13, Aked Esplanad, Bukit Jalil, 57000 Kuala Lumpur. T: 603-8993 9139 F: 603-8993 9039

Website: [www.bestcontact.com.my](http://www.bestcontact.com.my)

## Field Safety Notice

To all users of the Arjo Nimbus 4

### Re: Remove the over-inflation risk

Dear customer,

This letter is to inform you of a potential malfunction and hence hazard to patients when using the Nimbus 4, serial number: 1800029716, 1800029717, 1800029718

### When does this malfunction occur and what are the potential risks ?

The malfunction might occur when inner mattress tubes is damages. In case of this malfunction, air pumped into the mattress can get to a sealed mattress cover. When the air flow is extensive, two grommets located in the cover are not sufficient to vent it out. This leads to air accumulation in the cover and subsequent over-inflation.

### What steps can the user take to avoid the potential risk of this issue?

Remove the over-inflation risk by puncture of the grommets membrane with a screwdriver.

### How will the issue finally be resolved?

Best Contact (M) Sdn.Bhd. is preparing a modification of Arjo Nimbus 4 that will resolve this potential malfunction. The field modification will be available from 28 June 2021.

We appreciate your understanding and cooperation with this Field Safety Notice and ask you to immediately instruct your personnel accordingly. Please ensure that this safety notice is placed in the System's instructions for use. Your personnel should maintain awareness over an appropriate defined period.

If you have sold this medical device and it is no longer in your possession, we kindly ask that you forward this safety notice to the new owner of this medical device. Please inform us about the new owner of the medical device.



Certificate No : FS613769  
MDA Establishment License No. : KP16101515



Certified to ISO 9001: 2008  
Certificate No. : 403868QM08



Certified to DIN EN ISO 13485  
Certificate No. : 403868MP23

The **Medical Device Authority** will be informed of this notice.

Sincerely Yours



Sew Wai Chun

14 June 2021

Contact person of this notification  
Mr Sew Wai Chun  
Department: Service  
Telephone: 03-89939139  
Fax: 03-89939139  
E-mail: [sewwc@bestcontact.com.my](mailto:sewwc@bestcontact.com.my)