



15 November 2013

MEDICAL DEVICE CORRECTION

Spacelabs Healthcare

SunTech Orbit ABP Cuffs

Part Numbers; 015-0710-00, 015-0711-00, & 015-0712-00

Dear Hospital Administrator/Biomedical Manager/Office Manager:

Details on affected devices:

SunTech Orbit ABP cuffs:

- PN: 015-0710-00, Orbit Adult Cuff, 25-35 cm
- PN: 015-0711-00, Orbit Adult Plus Cuff, 33-40 cm
- PN: 015-0712-00, Orbit Large Adult Cuff, 39-46 cm

Description of the problem:

This letter is to inform you that you have been shipped the wrong SunTech Orbit ABP cuffs. The hose is only 15 cm instead of the required 72 cm. No one has been injured as a result of this issue.

Advice on action to be taken by user:

Spacelabs recommends you purge the affected cuffs from your inventory. Replacement cuffs will be sent to you at no charge as soon as possible.

Contact reference person:

We confirm that this notice has been sent to the appropriate Regulatory Agencies.

David J Geraghty
Regulatory Affairs & Compliance
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If you have any questions about this corrective action program, please contact Spacelabs Healthcare Ltd. at 1 Harforde Court, John Tate Road, Hertford, SG13 7NW United Kingdom, Telephone No. +44 (0) 1992 507708, or email Simon.Auger@spacelabs.com for Technical Support.