

URGENT FIELD SAFETY NOTICE
Power Supply for Covidien Shiley™ Pressure Control Automatic Cuff Controller

October 21, 2015

Attention: Risk Management Director and Materials Management

Please forward this communication to all respiratory personnel, and any other potential users of the product.

Dear Valued Customer:

Medtronic, formerly Covidien, has been notified by VBM Medizintechnik GmbH, the manufacturer of the power supply for Shiley™ Pressure Control Automatic Cuff Controller, of a Field Safety Corrective Action which they have initiated related to the power supply. We are passing this information on to you as Medtronic also distributed some of the affected units.

Attached to this letter is the Urgent Field Safety Notice issued by VBM Medizintechnik GmbH. This notice provides specific details of the issue and how to identify affected units. Please record the lot numbers of affected devices on the attached verification form and FAX or EMAIL this information to Medtronic using the contact information listed on the attached form.

Medtronic is requesting that customers quarantine and destroy all remaining inventory of power supplies with lot numbers list below for the affected serial number range of Shiley™ Pressure Control Automatic Cuff Controller in the chart. Power supply lot numbers are etched on directly on the power supply. Any power supply with a different lot number is not affected by this field action. If your facility has distributed these devices to other persons or facilities, please promptly forward a copy of this letter to those recipients.

| Item Code | Item Description | Shiley™ Cuff Controller Serial Number | Power Supply Lot Number |
|-----------|--|--|---|
| 109-03 | Shiley™ Pressure Control Automatic Cuff Controller | 1405-CC02-0007Y to 1410-CC02-0709Y (Excluding: 1410-CC02-0628Y to 1410-CC02-0637Y) | 50130 51130 52130 01140 03140 04140 05140 |

Required Actions

1. Please quarantine, discontinue use of the affected power supply units for the lot numbers listed above. Record the quantity and lot numbers of the power supplies in your inventory on the attached form and destroy the affected power supply units.
2. Please complete the attached form in its entirety and E-mail it to audrey.doyle@medtronic.com or fax to 01 439 3039.

| | Customer with inventory: | Customer with Zero Inventory | Where to send the completed form |
|--|---|---|---|
| Purchased DIRECTLY from Medtronic | Upon receiving your form, Customer Service will organize for replacement product to be shipped to you. | If you do not have any units at your facility, simply return the form indicating you have zero (0) units. | E-mail or fax the completed form to the Medtronic contact provided on the verification form |
| Purchased from a Distributor | Complete ALL fields on the form & contact your Distributor directly to arrange for replacement of product. | Complete form indicating that you do not have any stock to return | E-mail or fax the completed form to the Medtronic contact provided on the verification form |

If you are aware of any incidents related to this issue, please contact your local Medtronic Representative using the contact information stated above to provide information regarding those events so regulatory reporting obligations can be fulfilled.

VBM Medizintechnik GmbH, the manufacturer of the power supply has notified the Irish Competent Authority, The Health Products Regulatory Authority (HPRA) about this Field Safety Notice

We apologize for this inconvenience. If you have any questions or concerns, please do not hesitate to contact your Medtronic representative or Customer Service at 01 4073173.

Sincerely,



Audrey Doyle
RA Specialist, Email: audrey.doyle@medtronic.com Tel: 01 4381609

Attachment A

Distinguish affected product by Item Code and Serial Number.

Type: 109-03 Shiley Pressure Control

SN 1405-CC02-1234Y 2014-05-13

Working Pressure: 120 hPa
 Only use with Power Supply Friwo FW7556M/12
 12 VDC max 1.5 A



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VBM Medizintechnik GmbH
 Einsteinstrasse 1, 72172 Sulz a.N. | Germany | www.vbm-medical.de

(01)04250106826268
 (1)140513
 (2)1405-CC02-1234Y

COVIDIEN
 posilivnosti prišče
Shiley™
 Pressure Control

REF 109-03

2014-05-26

Régulateur automatique de pression de ballonnet

Automatische Druck-Regler
 Automatische Cuff-Druck-Regler
 Controlador de presión automática
 Automatische Luftdruckregler
 Automatische pneumatische
 Automatische Inflationsregler
 Manometer Pressure Regulator
 Automatische regulierbare Druck
 Otolaryngology Pressure Control
 Automatische Inflation-Regulator
 Regulador de presión automática
 Automatische Inflation-Regulator
 Controlador de Balão automático
 Smerčički Regulator Pritisila




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Distinguish affected Power Supply by lot number

