



Medical Devices Bureau, Ministry of Health Malaysia
 Level 4&5, Block E6, Parcel E, Precint 1,
 Federal Government Administration Centre,
 62590 Putrajaya
 Tel: 03-8883 2248/2249/2264
 Fax: 03-8888 6184

Medical Device / Equipment **ALERT**

Date Issued : 20 JUNE 2008

Ref:MDB/A/2008/005

IMMEDIATE ACTION	
ACTION	√
UPDATE	√
INFORMATION REQUEST	

**Notes:- This Medical Device Alert is an update version of MDB/R/2008/002 issued on 8th April 2008*

PRODUCT	Invasive blood pressure monitoring sets: LogiCal, NovaTrans and TranStar models with trigger flush device. <i>Manufactured by Smiths Medical from October 2007 to February 2008 inclusive.</i>
CLASS	Not Mentioned
USE	<p>These devices are <i>disposable blood pressure monitoring sets with a trigger flush device</i> to maintain patency of the line during invasive pressure monitoring.</p> <p>The trigger flush device <i>delivers a nominal flow rate and activation of the trigger flush device allows a transient higher flow of fluid to flush the patient line.</i> The sets are indicated for adult and paediatric/neonatal use. The flush device is available as an integral part of a set or as an accessory.</p> <p>Codes of affected product are <u>prefixed by DPSxxxxxx / MX95xxxx / MX96xxxx / MXxxx / SXxxxxxx</u> and were manufactured between October 2007 and February 2008 only.</p> <p>All lot numbers manufactured within these dates are therefore affected. The manufacturing date can be</p>

	found on the device's packaging.
SOURCE OF MEDICAL DEVICE RECALL / ALERT	MHRA website, date issued: 3rd June 2008
RECALLING / ALERTING FIRM	<p>* For United Kingdom, since this data is extracted from the official MHRA website.</p> <p>Smiths Medical International (United Kingdom Office) St. Crispin Way Haslingden Rosendale Lancashire BB4 4PW</p> <p>E-mail: omar.khan@smiths-medical.com</p>
REASON FOR RECALL/ALERT	<i>A fault in the manufacture of the trigger flush device can lead to over-infusion of fluid and falsely elevated blood pressure measurements.</i>
SCENARIO IN MALAYSIA	No details available at this moment in Malaysia.
ACTION	<p>To all users and healthcare providers having the abovementioned device used in their premises, please identify product codes of affected devices (see above).</p> <p>In the United Kingdom, the manufacturer has issued a Field Safety Notice to their customers. According to the MHRA website, users are advised to:</p> <ul style="list-style-type: none"> • Identify the affected products. • Conduct a pre-test to identify whether this issue exists on the affected devices by performing a check during priming of the device and before connecting to the patient as described below. <p><u>Pre-test</u></p> <ol style="list-style-type: none"> 1. Prime the set under gravity as described in the device's current instructions for use. 2. Pressurise the set to 300 mmHg as described in the instructions for use and operate the trigger flush device for 2-3 seconds and observe the device as follows: <ul style="list-style-type: none"> • During flushing, fluid should flow freely from the end of the set and fluid flow will be visible in the drip

	<p>chamber.</p> <ul style="list-style-type: none"> • After flushing, fluid should not be visibly flowing from the end of the line/set and flow in the drip chamber should be two drops but not more than seven drops per minute for the upper end of the performance specification of a single line. • If the line divides below the drip chamber to provide two or more pressure lines, then: <ul style="list-style-type: none"> – for two lines flow should be <u>no more than 12 drops per minute</u> – for three lines flow should be <u>no more than 14 drops per minute</u> – for four lines flow should be <u>no more 18 drops per minute.</u> <p>If a higher flow is observed after flushing, the device is not functioning correctly and should not be used.</p> <p>If the device fails the pre-test, immediately contact your Smiths Medical representative to arrange for collection and replacement.</p>
<p>RECOMMENDATION</p>	<p>Users of the abovementioned device should contact the distributors/supplier of this device (if available) and inform the Medical Devices Bureau, Ministry of Health providing the following information:-</p> <ol style="list-style-type: none"> a. Name of healthcare centre/hospital/clinic b. Contact person and contact number c. Numbers of units available
<p>CONTACT/ENQUIRIES</p>	<p>Please refer to the supplier of the device(s) if available for enquiries:-</p> <p>LOCAL DISTRIBUTOR FOR SMITH MEDICAL:</p> <p>BUMI T. T. C. (SABAH) SDN BHD Erh-Ling Chang Shop No. 21 & 22, Kepayan Ridge Commercial Centre, Phase 2, Lrg. Bunga Tanjung 2, Kepayan, 88100 Kota Kinabalu, Sabah, Malaysia (For the region of Sabah) Tel: +60 88 250017</p>

	<p>Fax: +60 88 230409</p> <p>Primed Medical Sdn Bhd Mr R Kugarajah - Managing Director 15A, Jalan SG 3/15 Pusat Bandar Sri Gombak 68100 Batu Caves Sentul Perdana Selangor Darul Ehsan Malaysia Tel: +603 6185 1824 Fax: +603 6185 1834</p> <p>Syarikat Perniagaan Miscell Sdn Bhd Patrick Lim Unit B, Lot 8826, Section 64, K.T.L.D., Jalan Datuk Abang Abdul Rahim, 93450 Kuching, Sarawak, East Malaysia (For the region of Sarawak) Tel: +60 82 485 442 Fax: +60 82 330 967</p>
<p>REFERENCES FOR DETAILS</p>	<p>http://www.mhra.gov.uk/Publications/Safetywarnings/MedicalDeviceAlerts/CON017938</p>