



**Medical Devices Bureau, Ministry of Health Malaysia**  
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## Medical Device / Equipment RECALL

**Date Issued : 8 April 2008**

**Ref:MDB/R/2008/002**

<b>IMMEDIATE ACTION</b>	√
<b>ACTION</b>	
<b>UPDATE</b>	
<b>INFORMATION REQUEST</b>	

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

	as an accessory.
<b>SOURCE OF MEDICAL DEVICE RECALL / ALERT</b>	MHRA website, date issued: 7 <sup>th</sup> April 2008
<b>RECALLING FIRM</b>	Smiths Medical International (United Kingdom Office) St. Crispin Way Haslingden Rosendale Lancashire BB4 4PW  E-mail: <a href="mailto:omar.khan@smiths-medical.com">omar.khan@smiths-medical.com</a>
<b>REASON FOR RECALL</b>	An error in the manufacture of the trigger flush device can lead to over-infusion of fluid.  This may also cause falsely elevated blood pressure measurements.
<b>SCENARIO IN MALAYSIA</b>	No details available at this moment.
<b>ACTION</b>	To all users and healthcare providers having the abovementioned device used in their premises, please identify product codes of affected devices (see above).  <ul style="list-style-type: none"> <li>• Check for excessive flow rate.</li> <li>• Malfunctioning devices should be retained and reported to the Medical Device Bureau.</li> </ul> <p>In the United Kingdom, the manufacturer has issued an Urgent Field Safety Notice to their customers.</p> <p>Contact the supplier and:</p> <ul style="list-style-type: none"> <li>• Identify the affected products.</li> <li>• Conduct a pre-test to identify whether this issue exists on the affected devices by performing a check during <b>priming</b> of the device and <b>before</b> connecting to the patient as described below.</li> </ul> <p><b>Pre-test</b></p> <ol style="list-style-type: none"> <li>1. Prime the set under gravity as described in the device's current instructions for use.</li> <li>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"> <li>• During flushing, fluid should flow freely from the end of the set and fluid flow will be visible in the drip chamber.</li> <li>• After flushing, fluid should not be visibly flowing from</li> </ul> </li> </ol>

	<p>the end of the set and flow in the drip chamber should be about 2 drops per minute.</p> <ul style="list-style-type: none"> <li>• If a higher flow than about 2 drops per minute is observed after flushing, the device is not functioning correctly and should not be used.</li> </ul> <p>If the device fails the pre-test, immediately contact your Smiths Medical representative to arrange for collection and replacement.</p> <p><b>Devices in use</b>  Devices already in use on patients can also be checked by observing the flow rate in the drip chamber as described above. When the flush is not being operated the flow rate observed in the drip chamber should be about 2 drops per minute. If the flow rate in the drip chamber is greater than this, the device should be replaced with a new one that has passed the pre-test.</p> <p>The manufacturer is intending to revise the instructions for use of these devices to incorporate the above pre-test checks.</p>
<p><b>RECOMMENDATION</b></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> <ul style="list-style-type: none"> <li>a. Name of healthcare centre/hospital/clinic</li> <li>b. Contact person and contact number</li> <li>c. Numbers of units available</li> </ul>
<p><b>CONTACT/ENQUIRIES</b></p>	<p>Please refer to the supplier of the device(s) if available.</p> <p><b>LOCAL DISTRIBUTOR FOR SMITH MEDICAL:</b></p> <p><b>BUMI T. T. C. (SABAH) SDN BHD</b>  Erh-Ling Chang  Shop No. 21 &amp; 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  Fax: +60 88 230409</p>

	<p><b>Primed Medical Sdn Bhd</b>  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><b>Syarikat Perniagaan Miscell Sdn Bhd</b>  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>
<b>REFERENCES</b>	<p><a href="https://www.mhra.gov.uk/Publications/Safetywarnings/MedicalDeviceAlerts/CON014530">https://www.mhra.gov.uk/Publications/Safetywarnings/MedicalDeviceAlerts/CON014530</a></p>