



Medical Devices Bureau, Ministry of Health Malaysia
 Level 5, Plot 3C4,
 No. 26, Jalan Persiaran Perdana,
 Precint 3, 62675 Putrajaya
 Malaysia
 Tel: 603-8885 0767 / 603-8885 0773
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Medical Device / Equipment ALERT*

Date Issued : 24 AUGUST 2009

Ref:MDB/A/2009/005

IMMEDIATE ACTION	√
ACTION	
UPDATE	
INFORMATION REQUEST	

**The dissemination of this information is based on the Alert Notification communication via electronic mail on 21st August 2009.*

PRODUCT	All TomoTherapy HI ART Systems
CLASS	n/a - software
USE	Software system being used for Tomography procedures.
SOURCE OF MEDICAL DEVICE RECALL / ALERT	E-mail communication by TomoTherapy Inc. representative, T-Medic Sdn. Bhd.
RECALLING / ALERTING FIRM	T-Medic Sdn Bhd (537463-D) H-0-11, Jalan Sri Hartamas 1 (1/70A), 60, Plaza Damas Sri Hartamas, Taman Sri Hartamas, 50480 Kuala Lumpur, Malaysia. Tel : (603) 6201 9060 Fax : (603) 6201 9062
REASON FOR RECALL/ALERT	- Refer attachment for details-
SCENARIO IN MALAYSIA	Customers have been notified by the responsible representative.
ACTION	<i>*any healthcare facilities possessing the abovementioned device are advised to respond to this communication immediately.</i>

RECOMMENDATION	<p><u>Users of the abovementioned device should contact the distributors/supplier of this device</u> (if available) and inform the Medical Devices Bureau, Ministry of Health providing the following information:-</p> <ul style="list-style-type: none"> a. Name of healthcare centre/hospital/clinic b. Contact person and contact number c. Numbers of units available d. Name of the supplier(s)
CONTACT/ENQUIRIES	<p>T-Medic Sdn Bhd (537463-D)</p> <p>H-0-11, Jalan Sri Hartamas 1 (1/70A), 60, Plaza Damas Sri Hartamas, Taman Sri Hartamas, 50480 Kuala Lumpur, Malaysia.</p> <p>Contact Person: Ms Jane Lee Tel : (603) 6201 9060 Fax : (603) 6201 9062</p>
REFERENCES FOR DETAILS	<p><i>Refer Attachments</i></p>