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

Medical Device / Equipment RECALL

Date Issued : 5th August 2008 **Ref:MDB/R/2008/012**

IMMEDIATE ACTION	√
ACTION	
UPDATE	
INFORMATION REQUEST	

PRODUCT	**Levitronix CentriMag Extracorporeal Blood Pumping System and Primary & Backup Consoles (manufactured by Levitronix, GmbH, Zurich, Switzerland).**
CLASS	Not Available
USE	The CentriMag Blood Pumping System (consisting of the blood pump and console) is used to provide short-term (up to six hours) extracorporeal (that is, outside the body) circulatory support during cardiac and other types of surgeries such as liver transplants. This device temporarily replaces the function of the heart and lungs in order to maintain the appropriate circulation of blood and oxygen levels in the body during the surgical procedure.
SOURCE OF MEDICAL DEVICE RECALL / ALERT	**United State Food and Drug Administration's website**, Date initiated: 17th March 2008
ALERTING / RECALLING FIRM	**Levitronix, Inc.** 45 First Avenue Waltham, Massachusetts 02451
REASON	**Use of the Valleylab Force FX-C or Valleylab SSE2L with the CentriMag Blood Pumping System may result in stoppage of the pump and may cause serious injury or death.** **It is advisable for the distributors or sales representative of the abovementioned companies in Malaysia to respond to this recall notice.**

SCENARIO IN MALAYSIA	**No details available at this moment.** For users, please check whether the device is available and contact the distributor.
ACTION	***Recommendations For Healthcare Professionals*** • Ensure that all relevant staff in your institution are informed of this safety alert/recall notice • Determine if you have the affected products • Stop the usage of the affected products • Follow the distributor / manufacturers recommendations for quarantine and disposal of product
RECOMMENDATION	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:- a. Name of healthcare centre/hospital/clinic b. Contact person and contact number c. Numbers of units available
CONTACT/ENQUIRIES IN MALAYSIA	As mentioned in the Levitronix website, the sales representative in Malaysia for **Levitronix's semiconductor products is**:- **1. Filterfine Advanced Technology SDN. BHD.** Ken Tan 46, 1st Floor, Persiaran Mahsuri 11900 Bayan Baru, Penang, Malaysia +60 46435761 Phone +60 46435793 Fax kentan@myjaring.net *No details available for their medical product distributors in Malaysia
REFERENCES	http://www.fda.gov/cdrh/recalls/recall-031708.html AND http://www.levitronix.com/Documents/Medical_us/Dear_Doctor-Final.pdf