Medical Devices Bureau, Ministry of Health Malaysia
Level 5, Block E6, Complex E,
Federal Government Administration Centre,
62590 Putrajaya, MALAYSIA
Tel: 03-8883 2248/2249/2264
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Medical Device / Equipment ALERT

Date Issued : 10th July 2008 **Ref:MDB/A/2008/007**

IMMEDIATE ACTION	
ACTION	√
UPDATE	
INFORMATION REQUEST	

PRODUCT	**Gambro and Hospal blood sets (lot numbers 0806 – 0817)** These sets are used on Gambro Integra, BSM and AK series haemodialysis machines, as well as with other non-Gambro machines. **Refer the attachment for details.*
CLASS	n/a
USE	Blood sets
SOURCE OF MEDICAL DEVICE RECALL / ALERT	**Medicines and Healthcare products Regulatory Agency, United Kingdom's website**, Date issued: 30th June 2008
ALERTING / RECALLING FIRM	**Gambro Renal Products (United Kingdom)** Lundia House Ermine Business Park Huntingdon PE29 6XX Tel: 01480 444 019 E-mail: Claire.Hall@gambro.com
REASON	Gambro has identified the potential for a total or partial occlusion of the arterial (red) and/or venous (blue) dialyser connectors of these blood tubing sets.

	This is due to a moulding defect.
SCENARIO IN MALAYSIA	**No details available at this moment.** Please check whether the device is available and contact the distributor.
ACTION	Verify if product (box/single package) has a green dot on packaging. If no green dot is present on the blood tubing sets: • remove set from packaging and visually inspect sets prior to use to check for occlusions • if inspection shows set is occluded DO NOT USE THE SET, • quarantine device and contact Gambro for replacement.
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 FOR ENQUIRIES IN MALAYSIA	**Mr. Teo Boon Yang** **Gambro Renal Care (M) Sdn. Bhd.** **No. 16 C, Jalan Petaling Utama 8,** **46000 Petaling Jaya** **Selangor.** **Tel:03-77841978** **Fax:03-77849978** **E-mail:- Boon-Yang.Teo@gambro.com**
REFERENCES	http://www.mhra.gov.uk/Publications/Safetywarnings/MedicalDeviceAlerts/CON020521

Attachment

If your product (box/single package) has a green dot (see Appendix for details), this indicates that it has been inspected by Gambro personnel and will not need re-checking.
For product without the green dot, open the package and visually inspect the sets as follows:
(1) Remove cap from the red and blue connectors and inspect the interior of both coloured connectors for a partial or total occlusion (see figures 1 and 2 for examples).

Figure 1. Partial Occlusion red connector

Figure 2. Total Occlusion red connector

(2) If inspection identifies an occlusion in either the red or blue connectors, or in both connectors, then DO NOT USE THIS SET.
(3) If the inspection shows the set has no occlusion in either the red or blue connectors, the set is then safe to use (see figures 3 and 4 for examples of non-occluded connectors).

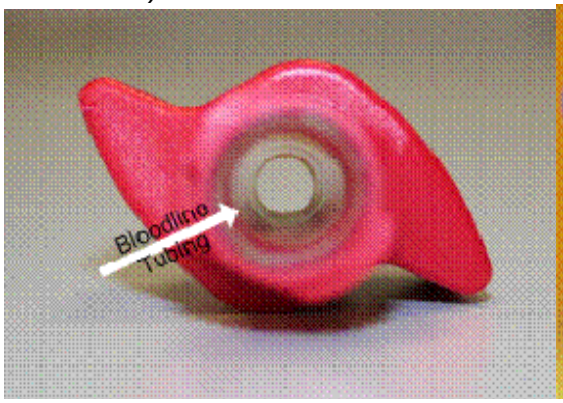

Figure 3. Non-occluded connector

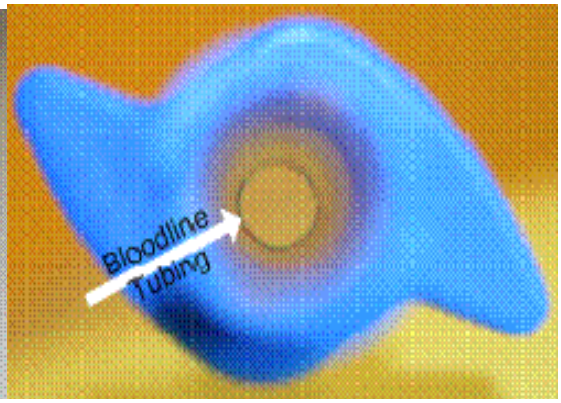

Figure 4. Non-occluded connector