(Field safety notice; reference no. 2006/012/014/081/002); Manufacturer.

Action Priority: Normal

Accession No.: A8163

☐ **None Present** ☐ **Action Taken:**_____

MAQUET—Model HCU 30 Type 1 Jostra Heater-Cooler Units: May Overheat during Cleaning Cycle

Warming/Cooling Units, Patient, Circulating-Fluid, Intravascular [21-566]

Device: Model HCU 30 Type 1 Jostra Heater-Cooler Units *[Capital Equipment]*

Identifier: Catalog No. 00939001; units distributed in the U.S. and in Argentina, Australia, Austria, Belgium, Bosnia, Canada, Chile, China, Cuba, the Czech Republic, Denmark, Estonia, France, Germany, Greece, Hong Kong, Iceland, India, Iran, Italy, Japan, Jordan, Lebanon, Mexico, Morocco, The Netherlands, New Zealand, Norway, Pakistan, Poland, Portugal, Russia, Saudi Arabia, Singapore, South Korea, Spain, Sri Lanka, Sweden, Switzerland, Syria, Taiwan, Thailand, Tunisia, Turkey, the U.K., the United Arab Emirates, Venezuela, and Yemen

Distributor: MAQUET Inc A Getinge Group Co [336117], 1140 Rt 22 E Suite 202, Bridgewater NJ 08807 (U.S. distributor)

Manufacturer: MAQUET Critical Care AB A Getinge Group Co [439169], Rontgenvagen 2, S-171 95 Solna, Sweden

Problem: If the cleaning cycle is run in the above heater-cooler units when the water level is too low, the device may overheat, creating smoke or a burning smell. No incidents of fire or injury related to this problem have been reported. The manufacturer initiated a field correction by Safety Alert letter dated November 20, 2006. Health Canada has designated this action Type II Recall No. 33014. The U.K. Medicines and Healthcare Products Regulatory Agency (MHRA) is currently assessing the nature of this action and may issue further advice. MHRA has designated this action reference no. 2006/012/011/291/037.

Action Needed: Verify that you have received the November 20, 2006, Safety Alert letter from MAQUET. Identify any affected product in your inventory. To avoid the above problem when using affected product, ensure that the water level is approximately 1 cm above the cooling spirals during any operation with the unit, per the "MAINTENANCE—Daily" section of the user manual. At the next scheduled preventive maintenance inspection, correction of the installed base of affected units should be performed. For further information, contact your MAQUET local representative.

Source: Health Canada. Medical device recall listings [online]. 2006 Dec 25 [cited 2006 Dec 28]. Available from Internet: http://www.hc-sc.gc.ca/dhp-mps/compli-conform/recall-retrait/list/rec-ret_md-im_date_oct-dec_2006_e.html; Great Britain. Medicines and Healthcare Products Regulatory Agency. Infusion & transfusion, heart lung circuits: bypass—Maquet Critical Care AB—Jostra HCU30 Type 1. London: Department of Health; 2007 Jan 8. 1 p. (Field safety notice; reference no. 2006/012/011/291/037); Distributor; Manufacturer.

Action Priority: Normal

Accession No.: A8193

☐ **None Present** ☐ **Action Taken:**_____

Medical Devices: MHRA Issues Advice on Reporting Adverse Incidents and Disseminating Medical Device Alerts [U.K.]

Medical Devices [00-000]

Device: Medical Devices *[Capital Equipment, Consumable]*

Problem: The U.K. Medicines and Healthcare Products Regulatory Agency (MHRA) has issued a Medical Device Alert (MDA) informing healthcare workers how to report adverse incidents involving medical devices to MHRA and how to disseminate MDAs.

Action Needed: MHRA recommends the following:

(1) Establish, review, and maintain local procedures, and encourage staff and users to report adverse incidents involving medical devices in accordance with published MHRA guidance.

(2) Ensure that a medical device liaison officer (MDLO), who may collaborate with a Safety Alert Broadcast System (SABS) liaison officer, has been appointed to encourage and train staff and users to report adverse incidents.

(3) Advise MHRA of changes to MDLO contact information.

(4) Ensure local dissemination of MDAs by the SABS liaison officer.

(5) Facilitate and encourage use of MHRA's online adverse-incident reporting system (available on the MHRA Web site at http://www.mhra.gov.uk).

(6) Register on the MHRA Web site to receive e-mail notification of new publications, or ensure that the MHRA Web site is checked regularly for updates and further information.

Inquiries to MHRA regarding reporting of adverse incidents should be addressed to the MHRA Adverse Incident Centre by mail at Market Towers, 1 Nine Elms Lane, Vauxhall, London SW8 5NQ, England; by telephone at (0207) 084 3080; by fax at (0207) 084 3109; or by e-mail at aic@mhra.gsi.gov.uk. Inquiries to MHRA regarding dissemination of MDAs should be addressed to MHRA DTS Services by mail at the above address, by telephone at (0207) 084 3272, by fax at (0207) 084 3124, or by e-mail at dts@mhra.gsi.gov.uk.

Source: Great Britain. Medicines and Healthcare Products Regulatory Agency. Reporting medical device adverse incidents and disseminating Medical Device Alerts. London: Department of Health; 2007 Jan 2. 5 p. (Medical device alert; no. MDA/2007/001)

Action Priority: Normal

Accession No.: A8201

☐ **None Present** ☐ **Action Taken:**_____