Indiana State Department of Health
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Michael R. Pence
Governor

William C. VanNess II, MD
State Health Commissioner

DATE: May 12, 2014

TO: All Local Health Departments
Attn: Chief Food Inspection Officer

FROM: Laurie Kidwell, RRT Supervisor
Food Protection Program

SUBJECT: Datascope Corp/MAQUET - RECALL [Medical Device]

AFFECTED PRODUCT: **System 98/98XT, CS100, CS100i and CS300 Intra-Aortic Balloon Pumps**

SUMMARY: **Class I Recall; The recall is due to an investigation that identified a potential mechanical failure of the fan assembly associated with the power supply. A fan assembly failure could result in the power supply overheating and cause the IABP to shut down without warning.**

Between January 1, 2003 and June 30, 2011, specific System 98/98XT, CS100/CS100i and CS300 IABPs were manufactured with an affected fan assembly, or may have received an affected fan assembly during an upgrade/service of the IABP in the field. The affected IABP's can be identified by part and serial number. Each MAQUET Service Representative has a list of the affected serial numbers and will check each affected part during the corrective action.

The affected IABP units were distributed in the US.

SUGGESTED ACTION: **For consumer inquiry only. For additional information regarding this field correction, please contact the Technical Support Department at 1-800-777-4222 and Press 3 (Monday through Friday from 8:00 am – 6:00 pm EST).**

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Recall -- Firm Press Release

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.

Datascope Corp/MAQUET Issues Worldwide Voluntary Recall of the System 98/98XT, CS100, CS100i and CS300 Intra-Aortic Balloon Pumps For Potential Mechanical Failure of the Power Supply Fan Assembly

Contact:
Consumer:
1-800-777-4222

FOR IMMEDIATE RELEASE - May 9, 2014 - In March 2014, Datascope Corp/MAQUET initiated a voluntary worldwide field correction of certain Intra-Aortic Balloon Pumps (IABPs) sold under the Datascope Corp. System 98/98XT (Part Numbers: 0998-00-0446-xx, 0998-UC-0446-xx, 0998-00-0479-xx, 0998-UC-0479-xx), CS100/CS100i (Part Numbers: 0998-00-3013-xx, 0998-UC-3013-xx, 0998-UC-0446Hxx and 0998-UC-0479Hxx) and CS300 (Part Numbers: 0998-00-3023-xx, 0998-UC-3023-xx) IABP brand names for a potential mechanical failure of the fan assembly associated with the power supply. All customers that may have an intra-aortic balloon pump affected by this field correction have been notified. There are approximately 12,360 affected units sold globally.

The intra-aortic balloon pump is an electromechanical system used to inflate and deflate an intra-aortic balloon to provide temporary support to the left ventricle via the principle of counterpulsation.

As a result of customer complaints related to a malfunction of the System 98/98XT, CS100, CS100i and CS300 Intra-Aortic Balloon Pumps (IABP), Datascope Corp/MAQUET conducted an investigation and identified a potential mechanical failure of the fan assembly associated with the power supply. A fan assembly failure could result in the power supply overheating and cause the IABP to shut down without warning. An IABP shutdown could result in worsened heart failure, decreased blood flow to the heart, and/or decreased blood flow to the body and brain.

Between January 1, 2003 and June 30, 2011, specific System 98/98XT, CS100/CS100i and CS300 IABPs were manufactured with an affected fan assembly, or may have received an affected fan assembly during an upgrade/service of the IABP in the field. The affected IABP units were distributed in the US and worldwide (in over 100 countries). The affected IABP's can be identified by part and serial number. Each MAQUET Service Representative has a list of the affected serial numbers and will check each affected part during the corrective action.

The affected System 98/98XT, CS100, CS100i and CS300 Intra-Aortic Balloon Pumps involved in the field correction can be used while waiting for parts and service. Customers should adhere to the instructions for use when using an affected intra-aortic balloon pump.

The U.S. Food and Drug Administration ("FDA") has classified this action as a Class 1 recall. FDA defines Class 1 recalls as, "a situation in which there is a reasonable probability that the use of or exposure to a violative product will cause serious adverse health consequences or death." To date, there have been no reported patient injuries or deaths related to the power supply malfunction.

The corrective action associated with this recall is to provide a replacement fan assembly to all IABPs containing an affected fan assembly. A MAQUET Service Representative will contact those facilities with affected IABP's to schedule corrective action and document this corrective action during a visit to the customer.

For additional information regarding this field correction, please contact the Technical Support Department at 1-800-777-4222 and Press 3 (Monday through Friday from 8:00 am – 6:00 pm EST).

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report **Online:** www.fda.gov/medwatch/report.htm
- **Regular Mail or Fax:** Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

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