HEALTH DEVICES ALERTS FORMAT GUIDE

The following is a comprehensive guide to understanding our Medical Device Alerts, section by section. For further clarification or information about *Health Devices Alerts*, please e-mail us at hda@ecri.org.

Priority

Each Alert is assigned an action priority to guide your response to the provided information. For an explanation of how each priority is defined, please click here.

UMDNS Device Terms

Each Alert contains applicable UMDNS (Universal Medical Device Nomenclature System) terms related to the devices referred to in the Alert. For an explanation of this classification system, please click here.

Product Identifier

This section contains affected product names and any lot/model/product numbers we have received from our source material or the manufacturer. We may also include expiration dates where necessary, as well as dates of manufacture or distribution. Devices will be labeled with one or both of the following:

- ***Capital Equipment***

  Generally, devices labeled "Capital Equipment" are durable goods that cost >$500 and are not disposable. Alerts that involve capital equipment contain the "Clinical/Biomedical Engineering" distribution category.

- ***Consumable***

  Generally, devices labeled "Consumable" cost <$500 and are disposable or implantable. Alerts that involve consumables are assigned to the "Materials Management" distribution category.

Geographic Regions

The geographic regions in this field are either listed by our source material (e.g., FDA's Center for Devices and Radiological Health and Enforcement Report listings), or reflect the area from which we received information (e.g., if our source is Health Canada, Canada will be listed). This field will be updated or deleted as we receive information from additional sources or confirmation from the manufacturer.

If the statement "Geographic distribution has not yet been confirmed" is included in the section, ECRI Institute does not have manufacturer confirmation of the geographic distribution of affected product at the time of posting. If it is possible that affected product is in your inventory, ECRI Institute recommends that you check regardless of where you are located.

Problem

This section contains the problem affecting the device as described in our source material. If the statement "the manufacturer has not confirmed the information provided in the source material" is included in the problem field, we have not yet received manufacturer confirmation of the information.

Action Needed

This section will contain any necessary actions needed to address this alert, as described in our source material and/or by the manufacturer. The section will be removed if the manufacturer or the regulatory agency declares that the action is complete.

Comments

This section will contain any additional information we wish to bring to your attention regarding the Alert. One standard comment will always be listed:

- This alert is a living document and may be updated when ECRI Institute receives additional information. In circumstances in which we determine that it is appropriate for customers to repeat their review of an issue (e.g., when additional affected product has been identified), we will post a separate update alert. In other cases, we may add information, such as additional commentary, recommendations, and/or source documents, to the original alert.

This comment is included in every medical device alert to ensure that readers are aware that additional information, such as clarification or confirmation from the manufacturer, may be added to the alert after it has been posted to the *Health Devices Alerts* website. In the event that significant additional information about the action (e.g., additional serial numbers, additional model numbers, major additions/clarifications to the Problem or Action Needed sections) becomes available, we may issue an update alert so that members can be aware of the new information.

Suggested Distribution

This is a list of departments or specialties that would be relevant for each Alert. This list also guides the distribution of Alerts through our Alerts Tracker system. For definitions and inclusion criteria for each category, please click here.