Patient Safety Alert

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Item: In-line air filter requirement for Abbott Pumps

General Information: A new manufacturer requirement for air elimination filters and air-in-line

detection tests for Intravenous Infusion Pumps, <u>models AIM[®], AIM Plus, APMTM, APMII, and ANNETM, manufactured by <u>Abbott Laboratories</u></u>

Hospital Product Division.

Specific Incident: The manufacturer issued an "Important Device Information" notice in

March 2003 (attached) requiring the use of air eliminating filters during all IV administrations when using the pumps listed above. The notice also included a "Technical Service Bulletin" (attached) instructing users to perform air-in-line tests immediately for these pumps, with tests to be repeated every three months. Abbott further recommends that users perform an air-in-line test when one of the following occurs: (1) the pump is inadvertently mishandled, such as when it is dropped or jarred. (2) The pump is cleaned. Abbott defines cleaning as the procedure described in section 5.1 of the AIM/AIM Plus Technical Service Manual or section 5.1.2 of the APM/APM II Technical Service Manual, which includes the cleaning of the air detector's optics surfaces in the cassette channel. The air-in-line test should be performed after the optics surfaces are cleaned. A general wipe down of the pump between patients, however, should not affect the optics surfaces and would not require the performance of an air-in-line test. (3) The pump case is opened. (4) The pump is serviced.

Action:

1. If you use these pumps immediately acquire IV administration sets from the manufacturer that are configured with the required air elimination filters or IV extension sets configured with the required air

elimination filters for the pumps listed.

2. Immediately review and revise operating and maintenance procedures to incorporate air-in-line tests per manufacturer instructions for the

pumps listed.

Addl. Information: Because very few infusion pumps require inspections with the frequency

described for the pumps listed in this Alert and failure of in-line-air detectors is rare we recommend against further purchase of these pumps. The need to test the air-in-line detectors on these pumps at least four times a year introduces additional operations complexity and further

suggests reliability concerns.

Source: VA Center for Engineering Occupational Safety and Health (CEOSH)

and the VA National Center for Patient Safety (NCPS).

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