

Device Incident Report Recommendations - Automated Pressure Infusion System, Level 1, Inc.

Following representations from the Consultative Council on Anaesthetic Mortality and Morbidity pointing out the risks of air embolism, the Therapeutic Goods Administration (TGA) has completed an evaluation on the Automated Pressure Infusion System, Level 1, Inc. The recommendations are as follows:

The manufacturer has now developed an "add-on" air detector/clamp for use with all existing Level 1 infusion systems, and this will be supplied with all newly distributed systems. This system has been evaluated for safety by the TGA. A Safety Alert will also be distributed to all existing users, in conjunction with the TGA, recommending these systems only be used with the "add-on" air detector clamp. The manufacturer is also developing an infusion system with an integrated air detector/clamp for expected release in June 2003.

This is a good resolution. The air detector "add-on" allows for shut down of the flow as with cardiopulmonary bypass and dialysis units.

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