Viamed Risk Analysis Report

Product Description: **Gas Powered Resuscitation Unit Tom Thumb T occluder**

This product has been in continual use since 1984 without any recorded adverse effects.
Where hazards have been identified, solutions have been implemented to reduce any known risks
1.Over pressure to the patient.
The solution was to introduce two Blow-off valves: One Fixed & One User adjustable
The user-adjustable blow-off valve is pre-set in the factory. to have a maximum blow•-of: value lower than that of the fixed valve.
Valves set at the factory are secured only adjusted by a technician with the use of a tool
2.Over-pressure of unit on start-up usually by EBME can damage the gauge.
The solution was to Highight clear warnings on the `User Guide' and to stress in maintenance training
3 Contamination, dirt may stiffen the adjustable blow-off valve, rendering it difficult to use.
The solution was that the unit should decontaminated and then returned to Viamed for service
4. Incorrect tubing could be connected to the patient.
The solution was to use a 15mm diameter outlet and supply the correct patient tubing of 15mm diameter
The only hazard remaining is for the user to disconnect and by-pass the Tom Thumb, This has happe when the user has connected a standard mask with Green tubing to a flow-meter. In each incident the courts have ruled no blame attached to Tom Thumb it was user error or malpractice.
5, Jammed valves; jammed valves are a minute remote possibility and can only occur if
an obstruction almost the diameter of the internal bore connecting the over pressure valve is inserted into the Tom Thumb and it is screwed completely closed. (It needs a tool)
and the variable valve is turned passed its end limit, a
and the user fails to set the Tom Thumb up before using
and the user fails does not observe the pressure gauge.

J S Lamb
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