

CE File: Tom Thumb.

Product Description: Gas Powered Resuscitation Unit

Risk Analysis Report.

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 use-adjustable blow-off valve is pre-set in the factory, to have a maximum blow-off value lower than that of the fixed valve.

Valves set at the factory are "Loctite" secured.

2. Over-pressure of unit on start-up can damage the gauge.

The solution was to High light clear warnings on the "User Guide"

3. Contamination, dirt may stiffen the adjustable blow-off valve, rendering it difficult to use.

The solution was that the unit should be sterilised and then returned to Viamed for service.

4. Incorrect tubing could be connected to the patient.

The solution was that the unit has a 15mm diameter outlet, and is supplied with the correct patient tubing of 15mm diameter