THE MEDICAL DEVICES VIGILANCE SYSTEM REPORT

Ref AIMD 90/385/EEC, art 8, MDD 93/42/EEC, art 10 and MEDDEV 2.12/1 March 1998-rev 3

This form should only be used for the exchange of information between National Competent Authorities only

1. Report from CA of: **United Kingdom** 2. Ref no: **20010228.012-4** 3. Date sent : **28/03/2001**

4. Contact point: **Medical Devices Agency, UK** 5. Contact person: **A Sant**

6. Tel: **+44 20 7972 8187** 7. Fax: **+44 20 7972 8109** 8. E.mail: **mb-mda-aic@doh.gsi.gov.uk**

9. Generic name/ kind of device: **Neonatal High Frequency Oscillation**

10. Nomenclature id: **ECRI UMNDS** 11. No: **14-361**

12. Type: **Various**

13. Software version: **Various**

14. Serial no: **N/A** 15. Lot/batch no: **N/A**

16. Manufacturer/authorised rep: 17. Country: **UK**

SLE: Mr M Burrel, Tel: 020 8681 1414

Sensormedics (UK distributer): Bill McAlesse, Tel: 01273 645 100

Draegar: Mr Doug Sims, Tel: 01442 213542

18. Concerned Notified Body no: **Various**

19. Was the Safeguard Clause used: **N/A**

20. Is the device CE marked? **Yes**
Class: **IIb**

21a. Background information: **While ventilating a neonate in high frequency oscillation the endotracheal tube was disconnected from its connector with no ventilator alarms. All high frequency oscillation ventilators distributed in the UK have been checked for failure to alarm on disconnect especially with 3mm and smaller size endotracheal tubes.**
The resistance to flow through the smaller size endotracheal tubes connectors is so great that the ventilator may not always detect the tube falling out of the patient or disconnection between the tube and its connector.

21b. Reason for report: **Potential risk to patient safety**

22. Conclusions/corrective action: **Investigations in the UK found the following information:**

- **SLE 2000 HFO – The removal/disconnection of smaller size endotracheal tubes will not trigger the pressure alarm for disconnection. SLE are changing their instructions for use to warn the users that a flow sensor is necessary to detected this type of problem and users must vigilantly monitor the patient. (See attached Technical Bulletin).**
- **SENSORMEDICS 3100A– With smaller size endotracheal tubes the ventilator will detect and alarm on tube removal/disconnection if the alarm levels are adjusted accordingly. This may require fine adjustments therefore the manufacturers recommend users must vigilantly monitor the patient.**
- **DRAEGER Babylog 8000 plus HFO mode– The ventilator will detect and alarm on tube removal/disconnection if the flow monitoring is enabled and the minute volume alarms are set appropriately.**

This incident may occur in any HFO ventilator and users must be aware of the potential risk in all ventilators with an HFO mode. It is known there are other ventilators not mentioned above but we have not been able to obtain information on these devices at this time.

23. Recommendation to receivers of this report: **To be aware of this problem and the change to the SLE Instructions for Use.**

24. This report has been sent to the following MDVS Contact Points: **all EEA states**
and to the manufacturer/authorised rep: **SLE, Sensormedics, Draegar**