

Usage Logs for Sample Flowsensors (p/n 4310001)

End-users were asked to perform a blind trial of 2 batches of flowsensors: batch A manufactured September '12 and batch B manufactured June '12.

The following results were obtained from a trial carried out in the Intensive Care Unit of a specialist Heart & Chest hospital and no attempt was made to select specific patient conditions; some patients were undergoing full mechanical ventilation, some were 'weaning' and various nebulized medications and humidity levels may have been employed but not documented.

Ref: A1 1090901MB								
Uses	Ventilator		Installation		Removal		Hours in use	Comments
	Model	S/N	Date	Time	Date	Time		
1 st use	Evita 4	BG4990	13/10/12	08:00	No data	No data	No data	Removed and reprocessed for next use.
2 nd use	Evita 4	BG4943	5/11/12	08:00	8/11/12	08:30	72.5	Removed and reprocessed for next use.
3 rd use	Evita 4	BG4979	12/11/12	08:00	23/11/12	08:00	264	Removed and reprocessed for next use.
4 th use	Evita 2	BG4385	8/11/12	11:30	10/11/12	08:30	45	Removed and reprocessed for next use.
5 th use	Evita 4	BG4943	29/11/12	08:00	30/11/12	No data	No data	Removed from service, displays signs of cracking.
Summary						>381.5	Sensor retrieved for investigation. Cracks appearing around the pin assembly and the narrowest part of the sensor body, to within 5 mm of meeting up on the underside of the sensor. Electrical continuity on both sets of pins but wires looked non-uniform and kinked.	

Ref: A2 1090901MB								
Uses	Ventilator		Installation		Removal		Hours in use	Comments
	Model	S/N	Date	Time	Date	Time		
1 st use	Evita 2	BG4385	13/10/12	08:00	29/10/12	08:00	384	Broke into 2 pieces upon removal.
Summary						384	Sensor retrieved for investigation. Cracked around the pin assembly and broken in half at the narrowest part of the sensor body.	

Ref: A3 1090901MB

Uses	Ventilator		Installation		Removal		Hours in use	Comments
	Model	S/N	Date	Time	Date	Time		
1 st use	Evita 2	BG4171	13/10/12	08:00	15/10/12	20:20	60:20	Removed and reprocessed for next use.
2 nd use	Evita 4	BG4466	16/10/12	11:00	17/10/12	14:00	27	Broke into 2 pieces upon removal.
Summary							87:20	Sensor retrieved for investigation. Cracked around the pin assembly and broken in half at the narrowest part of the sensor body. Cracks also running from the pin assembly towards the wider part of the sensor body.

Ref: A4 1090901MB

Uses	Ventilator		Installation		Removal		Hours in use	Comments
	Model	S/N	Date	Time	Date	Time		
1 st use	Evita 2	BG4375	13/10/12	08:00	No data	No data	No data	
Summary							No data	Sensor was not retrieved for investigation. Sensor is no longer in use. Confirmed only 1 use but not possible to determine lifespan or whether this was a successful calibration.

Ref: A5 1090901MB

Uses	Ventilator		Installation		Removal		Hours in use	Comments
	Model	S/N	Date	Time	Date	Time		
1 st use	Evita 4	BG4992	12/10/12	15:15	16/10/12	11:00	91:45	Removed and reprocessed for next use.
2 nd use	Evita 2	BG4379	17/10/12	08:30	18/10/12	15:45	31:15	Broke into 2 pieces upon removal.
Summary							123	Sensor retrieved for investigation. Cracked around the pin assembly and broken in half at the narrowest part of the sensor body.

Ref: B1 6060701B

Uses	Ventilator		Installation		Removal		Hours in use	Comments
	Model	S/N	Date	Time	Date	Time		
1 st use	Evita 2	BG4380	12/10/12	09:00	18/10/10	08:30	95:30	Removed and reprocessed for next use.
2 nd use	Evita 4	BG4991	18/10/12	14:45	26/10/12	13:00	190:15	Removed and reprocessed for next use.
3 rd use	Evita 4	BG4986	29/10/12	08:30	30/10/12	08:30	24	Removed and reprocessed for next use.
4 th use	Evita 2	BG4171	30/10/12	15:30	1/11/12	08:00	40:30	Removed and reprocessed for next use.
5 th use	Evita 4	BG4943	2/11/12	09:00	5/11/12	No data	>63	Removed and reprocessed for next use.
6 th use	Evita 4	BG4989	9/11/12	09:00	9/11/12	09:15	0	Failed to calibrate.
Summary						>413	Sensor retrieved for investigation. Electrical continuity on 1 set of pins, platinum wire observably broken on other set.	

Ref: B2 6060701B

Uses	Ventilator		Installation		Removal		Hours in use	Comments
	Model	S/N	Date	Time	Date	Time		
1 st use	Evita 2	BG4143	12/10/12	09:00	12/10/12	09:15	0	Failed to calibrate.
2 nd use	Evita 4	BG4992	12/10/12	15:00	12/10/12	15:15	0	Failed to calibrate, removed from service.
Summary						0	Sensor retrieved for investigation. Electrical continuity on both sets of pins but wires looked non-uniform and kinked, despite never having been used for anything more than calibration attempts.	

Ref: B3 6060701B

Uses	Ventilator		Installation		Removal		Hours in use	Comments
	Model	S/N	Date	Time	Date	Time		
1 st use	Evita 2	BG4379	12/10/12	09:00	16/10/12	11:00	98	Removed and reprocessed for next use.
2 nd use	Evita 4	BG4989	17/10/12	08:30	18/12/12	08:30	24	Removed and reprocessed for next use.
3 rd use	Evita 2	BG4379	18/10/12	15:45	26/10/12	08:00	184:15	Removed and reprocessed for next use.
4 th use	Evita 4	BG6345	29/10/12	08:30	30/10/12	08:30	24	Removed and reprocessed for next use.
5 th use	Evita 4	BG4943	31/10/12	08:30	2/11/12	08:30	48	Removed and reprocessed for next use.
6 th use	Evita 2	BG4374	5/11/12	08:00	7/11/12	08:00	48	Removed and reprocessed for next use.
7 th use	Evita 4	BG4990	8/11/12	11:30	12/11/12	09:00	93:30	Removed and reprocessed for next use.
8 th use	Evita 4	BG4991	13/11/12	08:00	14/11/12	15:00	7	Removed and reprocessed for next use.
9 th use	Evita 4	BG4991	14/11/12	15:30	17/11/12	08:00	64:30	Removed and reprocessed for next use.
10 th use	Evita 4	BG4990	29/11/12	08:00	3/12/12	No data	>88	
Summary						>679	Sensor disposed of, not retrieved.	

Ref: B4 6060701B

Uses	Ventilator		Installation		Removal		Hours in use	Comments
	Model	S/N	Date	Time	Date	Time		
1 st use	Dura	BG4374	12/10/12	09:00	16/10/12	11:00	98	Removed and reprocessed for next use.
2 nd use	Evita 2	BG4649	16/10/12	14:30	17/10/12	08:00	17:30	
Summary						115:30	Sensor disposed of, not retrieved.	

Ref: B5 6060701B								
Uses	Ventilator		Installation		Removal		Hours in use	Comments
	Model	S/N	Date	Time	Date	Time		
1 st use	Evita 2	BG4376	12/10/12	09:00	22/10/12	09:00	240	Removed and reprocessed for next use.
2 nd use	Evita 2	BG4466	17/10/12	14:00	No data	No data	No data	
3 rd use	Evita 2	BG4374	23/10/12	08:30	23/10/12	09:00	0	Failed to calibrate, removed from service.
Summary						240	Sensor retrieved for investigation. Electrical continuity on both sets of pins but a small black particle approximately 1mm in diameter is visible on the lower platinum wire where it attaches to the pin.	

Summary of Results

Of the 5 sensors from batch A;

4 sensors were retrieved for investigation.

4 sensors were confirmed to have suffered cracking of the plastic, with 3 of them snapping completely into 2 pieces.

1 sensor was removed from service without logging the cause of failure.

Of the 5 sensors from batch B;

3 sensors were retrieved for investigation.

2 sensors failed to calibrate whilst retaining electrical continuity across the pins. 1 of these failed straight out of the box.

1 sensor retained electrical continuity across one set of pins, with the wire across the other set having broken.

2 sensors were removed from service without logging the cause of failure.