

RISK ASSESSMENT		CCR / QIR No.		
Customer:	NOTTINGHAM UNIVERSITY HOSPITAL	Date:	19/1/12	
File No.:	00003910	P.O.	200269473	
Address:	CITY HOSPITAL CAMPUS NGS 1PB	Invoice:	IN 117596	
Product:	4310001	Despatched:	16/09/11	
Serial No.(s):	LOT 2035530216 07-2011			
Manufacturer / Supplier	BLUEPOINT MEDICAL			
		Possibility 1-4	Probability 1-4	Risk 1-16
Is the problem likely to occur on other units		4	1	4
<u>1. Mechanical</u>				
1.1 Can anything fall on patient or user		1	1	1
1.2 Can anything trap the patient or user		1	1	1
1.3 Can the patient fall off		1	1	1
<u>2. Electrical</u>				
2.2 Is the product electrically hazardous		1	1	1
2.3 Is the fault a design fault		1	1	1
2.4 Is the fault outside of normal wear and tear		1	1	1
2.5 Is the fault due to user misuse caused by inadequate instructions and / or training		3	1	3
<u>3. Heat</u>				
3.1 Is excessive temperature likely to come into contact with the patient		1	1	1
3.2 Is excessive temperature likely to come into contact with the operator		4	1	4
<u>4. Compliance</u>				
4.1 Does the device fail to comply with ANY relevant standards		1	1	1
Summary: STILL UNDER INVESTIGATION - AWAITING REPLY FROM MHRA. ISOLATED EVENT, NEVER OCCURRED BEFORE WITH OUR SENSORS. EITHER DUE TO USER ERROR OR FAULT WITH DRAEGER VENTILATOR.				
SW 26.3.12				
Signed:		Date:		
MDA CMDCAS Informed?	Yes / No Yes / No			QC 44