

RISK ASSESSMENT		CCR / QIR No.	
Customer:	NOTTINGHAM UNIVERSITY / HOSPITAL	Date:	19/1/12
File No.:	00003910	P.O.	200269473
Address:	CITY / HOSPITAL CAMPUS NGS IPB	Invoice:	1N117596
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 OCCURED BEFORE WITH OUR SENSORS. EITHER DUE TO USER ERROR OR FAULT WITH DRAEGER VENTILATOR.			
Signed:	Date:		
MHRA CMD CAS Informed?	Yes / No Yes / <u>No</u>		QC 44

SW
26.3.12