

RISK ASSESSMENT		CCR / QIR No.		
		Date:		
Customer:		P.O.		
File No.:		Invoice:		
Address:				
Product:		Despatched:		
Serial No.(s):				
Manufacturer / Supplier				
		Possibility 1-4	Probability 1-4	Risk 1-16
Is the problem likely to occur on other units				
<u>1. Mechanical</u>				
1.1 Can anything fall on patient or user				
1.2 Can anything trap the patient or user				
1.3 Can the patient fall off				
<u>2. Electrical</u>				
2.2 Is the product electrically hazardous				
2.3 Is the fault a design fault				
2.4 Is the fault outside of normal wear and tear				
2.5 Is the fault due to user misuse caused by inadequate instructions and / or training				
<u>3. Heat</u>				
3.1 Is excessive temperature likely to come into contact with the patient				
3.2 Is excessive temperature likely to come into contact with the operator				
<u>4. Compliance</u>				
4.1 Does the device fail to comply with ANY relevant standards				
Summary:				
Signed:		Date:		
MDA CMD CAS Informed?	Yes / No Yes / No			QC 44

