

CUSTOMER COMPLAINT REPORT		CCR No.	150
Customer:	Paul Derman	Date:	7/9/17
File No.:		P.O.	
Address:	Southmead Hosp	Invoice:	IN142679
Product:	R-30V	Despatched:	1/2/16
Serial No.(s):	V103005		
Manufacturer / Supplier	ENVITEC		
MHRA Risk assessment carried out Yes No			
<u>Nature of Complaint:</u> <p>Issue 102482</p>			
<u>Result of Investigation:</u>			
Signed:		Date:	
<u>Corrective Action:</u> <u>External:</u>			
<u>Internal:</u>			
Signed:		Date:	
MHRA Informed?	YES NO	QC 12	

RISK ASSESSMENT		CCR / QIR No.	156	
Customer:	Paul Derman	Date:	7/9/17	
File No.:		P.O.		
Address:	Southmead Hosp	Invoice:	11/142679	
Product:	R-30	Despatched:	1/2/16	
Serial No.(s):	V103005			
Manufacturer / Supplier	EMitec			
		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	1	
1.2 Can anything trap the patient or user		1	1	
1.3 Can the patient fall off		1	1	
<u>2. Electrical</u>				
2.2 Is the product electrically hazardous		1	1	
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		1	1	
3.2 Is excessive temperature likely to come into contact with the operator		1	1	
<u>4. Compliance</u>				
4.1 Does the device fail to comply with ANY relevant standards		1	1	
Summary:				
Signed:		Date:		
Informed?	Yes / No		QC 44	
MDA	Yes / No			
CMDCAS	Yes / No			
BSI	Yes / No			