

(PAPERPORT)

CUSTOMER COMPLAINT REPORT		CCR No.	130
		Date:	16 JAN 06
Customer:	JAMES COOK UNIVERSITY HOSPITAL	P.O.	
File No.:	3710	Invoice:	
Address:	MARTON RD, MIDDLESBOROUGH, TS4 3BW		
Product:	TOM THUMB TT480	Despatched:	
Serial No.(s):	ALL		
Manufacturer / Supplier	VIAMED		
Why MHRA not informed		Signed	
Nature of Complaint: <p>THE TOM THUMB TT480 CAN BE MADE TO DELIVER PRESSURES IN EXCESS OF THE MAXIMUM PRESSURE SETTINGS OF THE ADJUSTABLE VALVE & PRECISION VALVE, BY THE USE OF FLOWRATES IN EXCESS OF THE SPECIFICATION OF THE TOM THUMB. THERE IS NO MEASURE IN PLACE TO PREVENT CONNECTION OF THE TOM THUMB TO EXCESSIVE FLOWRATES. - <i>USE MANUAL: TRAINING</i></p>			
Result of Investigation: <p>THE TOM THUMB IS DESIGNED TO VENT EXCESS PRESSURES WHEN USED WITHIN THE SPECIFICATION OF THE DEVICE, WHICH IS 0-10 LPM. TO ALLOW VENTING OF EXCESS PRESSURE UP TO INFINITE FLOWRATES WOULD DEMAND A TOM THUMB OF INFINITE SIZE, AS BACK PRESSURE IS CREATED DUE TO THE SIZE OF THE INTERNAL BORE OF THE BODY BLOCK AND THE DIAMETER OF THE OUTLET. ADDITIONALLY THE BORE DIAMETER OF PATIENT TUBING WOULD ADD BACK PRESSURE AT EXCESSIVELY HIGH FLOWRATES. INCREASING PATIENT TUBING DIAMETER WOULD HAVE DETRIMENTAL EFFECTS TO OPERATION OF THE DEVICE, COMPROMISING SAFETY.</p>			
Signed: <i>[Signature]</i>		Date: 3 MAR 06	
Corrective Action: <p>External: VISIT TO CUSTOMER'S SITE TO EDUCATE END USERS CONCERNING SAFE CONNECTION AND USAGE OF THE DEVICE.</p> <p>Internal: CREATED WARNING LABELS TO ATTACH TO ALL THE CUSTOMER'S TOM THUMBS. SENT NEW SETS OF INSTRUCTION CARDS TO USER. SOURCED "DAL A FLOW" STYLE FLOWMETERS WHICH CANNOT ENTER "FLUSH MODE" & DELIVER FLOWS HIGHER THAN THE MAXIMUM READING/SETTING OF THE FLOWMETER, AND ADVISED CUSTOMER OF PART NUMBERS & COST.</p>			
Signed: <i>[Signature]</i>		Date: 8/03/06	
MDA Informed?	YES	NO	QC 12