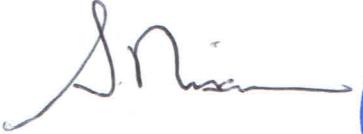


Design Changes QC28 B

Product: Tom Thumb Infant Resuscitators: 0310030 & 0310094	Y/N
Personnel involved: S. Nixon, P. Crossley, S. Hardaker, D. Lamb	
Reason for Change Consolidate the two mounting screws, so that the same dimension part (M6) is used with both the standard Medirail mounted TT480 (0310030) and the pole clamp used with the TT480-PC (0310094)	
Proposed design change & action to be taken Increase the bore of the two spacer/mounting screw sockets on the rear of the Tom Thumb body block (0330201), from M5 to M6. Also change the type of hex screw from dome shaped button head to standard hex socket screw M5 x 10mm	
Change of functional & action to be taken	
Change to performance & action to be taken The mounting is effectively strengthened with the increase in screw thread bore size.	
Change of usability & action to be taken The screws can be more easily and effectively affixed by using a standard hex socket, less chance of tool slippage and unintentional wear to the screw head.	
Change in safety features & action to be taken The mounting is effectively strengthened with the increase in screw thread bore size.	
Application of new standards Not applicable	

Design Changes QC28 B

Does this have an effect on	
constituent parts 0330216 existing M5 x10mm screw to be replaced with 0330245 new part M6 x 10mm screw	✓
Product in process To be implemented on the next production batch.	✓
Product already delivered	✓
Inputs of risk management	✓
Outputs of risk management	✓
Product realization P. Crossley to source new part and for it to be added to Opera. Production procedures to be updated. Revised body block drawing to be uploaded to the top level of the drawing file.	
Risk Analysis on any design change Refer QC22	
Signed:  Steve Nixon Director – Viamed Ltd.	