

QC 21 Non Conformance Report

Date	28th July 2022
Viamed / VST* Issue id unique identifier *delete as appropriate	Issues 266313 and 252744
BSI Ref (if applicable) unique identifier	n/a
Responsibility Person Overall responsible	Derek Lamb, Managing Director
Non-Conformance statement of the problem	MaxO2ME oxygen monitor can easily be knocked out of V-mounts, causing the device to fall to the floor.
Investigation By: Person responsible	Viamed - Steve Hardaker, Technical Support Manager. Maxtec - Vikash Dudhia and / or Maxtec's Quality Assurance Team.
Investigation Root Cause Analysis Issue id (if applicable)	Tested in-house with Maxtec mounts and Viamed pole mounts (0121181 & 0121182) and found that they can easily be dislodged. Created a report 'Technical Investigation – Stability of MaxO2 ME with V-Mount Pole Clamps v1.0' and sent to Maxtec 4th March 22. Re-sent and raised as non-conformance 28th July as no response was received. See issue 252744.
Corrective Action By: Person responsible	Vikash Dudhia and / or Maxtec's Quality Assurance Team.
Corrective Action Issue ID (if applicable): Relevant Immediate Corrective action (if applicable)	Requires a solution from Maxtec. No alternative mounts currently stocked by Viamed offer an immediate solution. The reported issue does not pose a risk to patient or user.
Time Scale for Immediate Corrective Action Time for completion of all identified actions	No immediate corrective action required from Viamed. Requires response and solution from Maxtec.
Corrective Action: Relevant and Proportionate Corrective Action	Requires a more stable mounting solution from Maxtec.
Time Scale for Corrective Action Time for completion of all identified actions	At Maxtec's discretion. To be followed up monthly for progress.
Risk Review Confirm action does not have negative affects and/or risks to any other part of the ISO system	

Follow-up future issue id (Effectiveness verification)	
Effectiveness verification	
Closed By:	
Closed on	