

January 26, 2023

Complaint Initiator: Steve Hardaker

Company Name: VIAMED

Contact Email: steve.hardaker@viamed.co.uk

Dear Customer,

This letter is to outline the investigation and actions taken by Maxtec, LLC designated personnel in response to the complaint references below.

Complaint Response

Maxtec Part #: R230P01-001

Maxtec Complaint #: COM-4402

Serial/Lot #: Not provided

Customer Complaint #: NCMR# 266313

PO/Invoice #: Not provided

Maxtec RMA #: N/A

Complaint Statement:

We routinely repair devices that have been knocked out of the basic pole clamp.

We are required to tether new devices using a hole drilled in the bracket and looped around the battery compartment ring.

This stops the monitor from hitting the floor when easily knocked out of the clamp. This is useful to stop damage, although NICU express their dislike for the system.

Complaint Investigation Summary:

Our processes require that all products undergo 100% functional and visual inspection prior to product release. A review of production records was conducted, and no indications of failures were documented. Based on the information provided, the underlying cause has not been determined. A review of previous complaints using the part number and defect statement was conducted and no additional failures of this nature were identified. A troubleshooting call was conducted with the customer and found the failure has only been reported by one customer and occurs when mounted to an IV pole.

Root Cause:

The root cause cannot be determined as the complaint could not be validated. After review of our records, the product was deemed to be fully functional. During review with the customer, it was found transportation may be a contributing factor.

Corrective and Preventive Actions:

No corrective actions have been identified at this time.

Maxtec, LLC has added the details of this complaint into our formal complaint system in which complaint trends are closely monitored. We will continue to monitor this defect trend and the effectiveness of our corrective actions.

We would like to thank you again for providing feedback that is critical to our commitment to Continual Improvement and Customer Satisfaction and apologize for any inconvenience this issue may have caused. If you have any questions or concerns regarding this response, please feel free to reference the complaint number provided and contact us.

Best Regards,