

Dear Customer,

This is to inform you of the investigation result of the issue communicated to Sedana Medical and confirmation that we have acted upon the information received.

Complaint number: QE-000603
Customer: Medway Maritime Hospital ICU
Complaint received: 03 Sep 2025
Product Name: Gas Sampling Line H from Bluepoint/Viamed
Ref code: 8090121313V
Lot Number: S-075-241108

Complaint Description

H Line not reading EtcO₂ & MAC after 5 minutes of starting therapy. Water trap etc changed with no improvement. The attachment of the H line was reversed and then could monitor both EtcO₂ & MAC.

Summary of Investigation Results

Similar complaints

There are no similar complaints for the Gas Sampling Line H.

Sample Investigation Results

No device received.

Conclusion

Since the device has not been received, it is not possible to come to a final conclusion regarding the issue. With some speculation the most probable cause would be some kind of blockage that was cleared when the line was reversed. The issue has been reported to the manufacturer of the Gas sampling Line H. However since there is no sample, there are limited possibilities to investigate for them.

We apologize for the inconvenience this has caused.

Please contact us if you require any additional information.

Sincerely,



Date: 10 Oct 2025

Morgan Nilsson
Quality Assurance Manager