

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-000560
Customer: Maidstone hospital /ITU
Complaint received: 29-APR-2025
Product Name: Gas Sampling Line H
Ref code: 8090121313V
Lot Number: N/A

Complaint Description

Gas sample line is the new Viamed line and it is a disaster waiting to happen. It looks like a feed line whereas the old line was a shiny plastic one which could not be confused with other lines.

Summary of Investigation Results

DHR Review Results

Batch number not available.

Similar complaints

There are no similar complaints.

Sample Investigation Results

No sample received

Conclusion

No patient involved. Severity for mistakes is potentially high. However, it requires two mistakes or intention to connect it wrong. Gas Sampling Line H is Luer lock male/male and IV-line for propofol is male/female and Feed line is also male/female or other type of connection. Of course an adapter can be used but protecting against the use of any adapter is not possible. The number of lines from different suppliers is practically unlimited and even to investigate it is not possible. New lines comes constantly so it is a Sisyphus work that never will be complete. By the different type of connectors between the lines as much as possible has been done to protect mistakes from happening, And so far, it has not happened, neither for the Gas Sampling Line H nor the Gas Sampling line from Intersurgical. See pictures provided on page 2 and 3.

This is reported to Viamed and Bluepoint that is the legal manufacturer for the Gas Sampling Line H and they do not see the high risk with this. The Gas Sampling Line H has a yellow tag that informs of not connecting it to syringes and different it from other lines.

We apologize for the inconvenience this has caused.

Please contact us if you require any additional information.



Morgan Nilsson
Quality Manager

Date: 11-Jun-2025

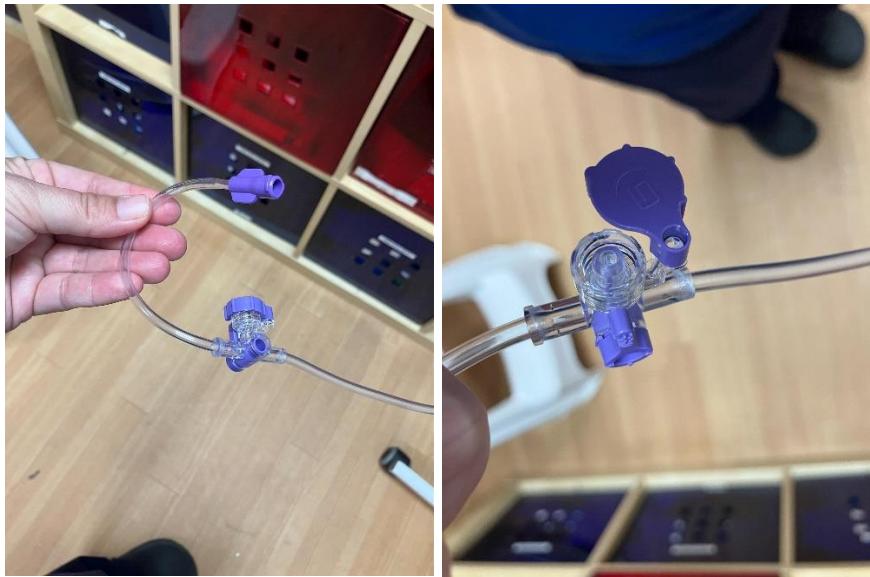
Gas sampling Line H



Pictures provided
Feed line and Propofol line



Feed line



Feed line

