Gmail **Ryan Swaine <viamed.ryan.swaine@gmail.com>**

FW: Use of Luer Lock

1 message

Morgan Nilsson <morgan.nilsson@sedanamedical.com> 17 June 2025 at 07:08
To: Ryan Swaine <ryan.swaine@viamed.co.uk>

Hi Ryan,

Would this do?

201.103 Port connectors for DIVERTING RGMs

(This is regarding the gas monitor exhaust - luer lock not permitted as gas could enter the patient blood - but not applicable to us)

The Joint Working Group considered both the inlet and the exhaust ports of DIVERTING RGMs and decided to specify the exhaust port connector only as it was thought this was the greater area of RISK where the RGM could provide gas to a PATIENT and if wrongly connected could cause HARM. Although the exhaust port connector is not a specified connector it was felt important to make sure it did not interconnect with any of the small-bore connectors specified in the ISO 80369 series which includes Luer connectors (ISO 80369-7).

(This is regarding the port connector - not specified as gas would not enter the blood due to one directional flow - applicable to the H line)

It was agreed that the inlet port connector should remain unspecified as it was agreed that this posed little RISK of HARM to the PATIENT especially as it is envisaged that the connection at the inlet of the RGM sample tubing would, in all probability, be changing to the R1 small-bore connector specified in ISO 80369-2 when this standard is published. It is also presumed that MANUFACTURERS that use a Luer connector at the inlet port will assess the RISK of HARM to the PATIENT should the sample tubing be misconnected to, for instance, an IV cannula.

BR

Morgan

From: Harry Hennessy <harry.hennessy@sedanamedical.com>
Sent: Friday, June 13, 2025 3:49 PM
To: Morgan Nilsson <morgan.nilsson@sedanamedical.com>; Jessica Westfal <jessica.westfal@sedanamedical.com>; Lucinda Kelly <lucinda.kelly@sedanamedical.com>; Lyes Djennadi <Lyes.Djennadi@sedanamedical.com>; Love Andréasson <love.andreasson@sedanamedical.com>
Subject: Re: Use of Luer Lock

Hi Morgan,

Yes, I believe the reason you have is correct. Please see extract from the gas monitor standard below (ISO 80601-2-55:2018) which may provide extra justification.

201.103 Port connectors for DIVERTING RGMs

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BR,

Harry

From: Morgan Nilsson <morgan.nilsson@sedanamedical.com>
Sent: Friday, June 13, 2025 04:26
To: Jessica Westfal <jessica.westfal@sedanamedical.com>; Lucinda Kelly <lucinda.kelly@sedanamedical.com>; Harry Hennessy <harry.hennessy@sedanamedical.com>; Lyes Djennadi <Lyes.Djennadi@sedanamedical.com>; Love Andréasson <love.andreasson@sedanamedical.com>
Subject: FW: Use of Luer Lock

Hi all,

Could you help in providing a rationale for the below?

I believe it is due to that most gas monitors has a Luer lock and Luer lock were chosen on the Sedaconda ACD due to convenience and to differentiate it from our special connection on the agent line?

BR

Morgan

From: Ryan Swaine <ryan.swaine@viamed.co.uk>
Sent: Thursday, June 12, 2025 6:06 PM

To: Morgan Nilsson <morgan.nilsson@sedanamedical.com>
Subject: Use of Luer Lock

Hi Morgan

I hope you can help with the following request. We need a written rationale explaining why your selected sampling line uses the Luer Lock connector.

This is being requested because ISO 80369 restricts the use of Luer connectors to vascular systems or hypodermic syringe applications. However, we understand that Luer connectors are still commonly used in gas monitoring systems, and we assume this is the basis for your choice.

Your rationale will be included as evidence of compliance with the essential principles, which justify the use of the Luer Lock connection in this context.

Best regards
Ryan

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