1. Introduction

The purpose of this test is to determine whether Viamed's Gas Sampling Line H is compatible with Sedaconda®ACD and the delivery of volatile anaesthetics (Isoflurane) for a duration of 72hrs. This test is a follow-up from the 2021 test report, which approved the Viamed Gas Sampling Line H for 24hrs with isoflurane and sevoflurane. This test report assesses the performance of Sedana Medical's current recommended gas sampling setup against the Viamed H-Line. Currently, Sedana recommend the use of a standard gas monitoring line such as Intersurgical's Gas Monitoring Line (1.2mm ID Male/Male Luer Lock 2.45m) in combination with a dryer line such as Perma Pure's Nafion Line. A control line consisting of Intersurgical's standard gas sampling line, without any dryer line, is also assessed for comparison. The key performance criteria is:

1. **End-Tidal Concentration (Fet%)**– all lines are expected to display the same Fet% values as they are placed in series after the Sedaconda®ACD and will all use Dräger Vamos gas monitors.
2. **Moisture Absorption** – The Viamed line and Nafion line are expected to absorb a minimal volume of moisture into the gas monitor's water trap, in comparison to the control line with no drying function.

2. Test Parameters

Table 1 – Variable Test Settings

Infusion Rate [mL/h]	Tidal Volume x Respiratory Rate [Vt x RR]	Time [hrs]
Low 2.0	750 x 12	4
	250 x 20	4
	500 x 15	16
Medium 4.0 – 4.5	750 x 12	4
	250 x 20	4
	500 x 15	16
High 6.0 – 7.0	750 x 12	4
	250 x 20	4
	500 x 15	16

Table 2 – Constant Test Settings

Inspiratory:Expiratory	1:2
PEEP	5 mbar
Anaesthetic Agent	Isoflurane
Bowl Temperature	37 ± 0.5 °C
Chamber Temperature	37 ± 0.5 °C
Sample Flow Rate (Vamos):	200 ± 20 ml/min

3. Test Setup

Figure 1 – Test Setup (Picture)

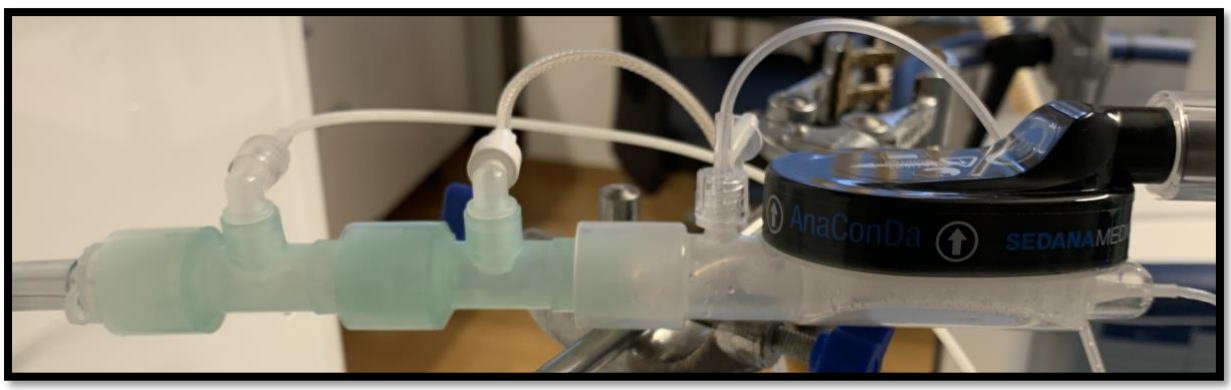


Figure 2 - Test Setup (Gas Sampling Lines)

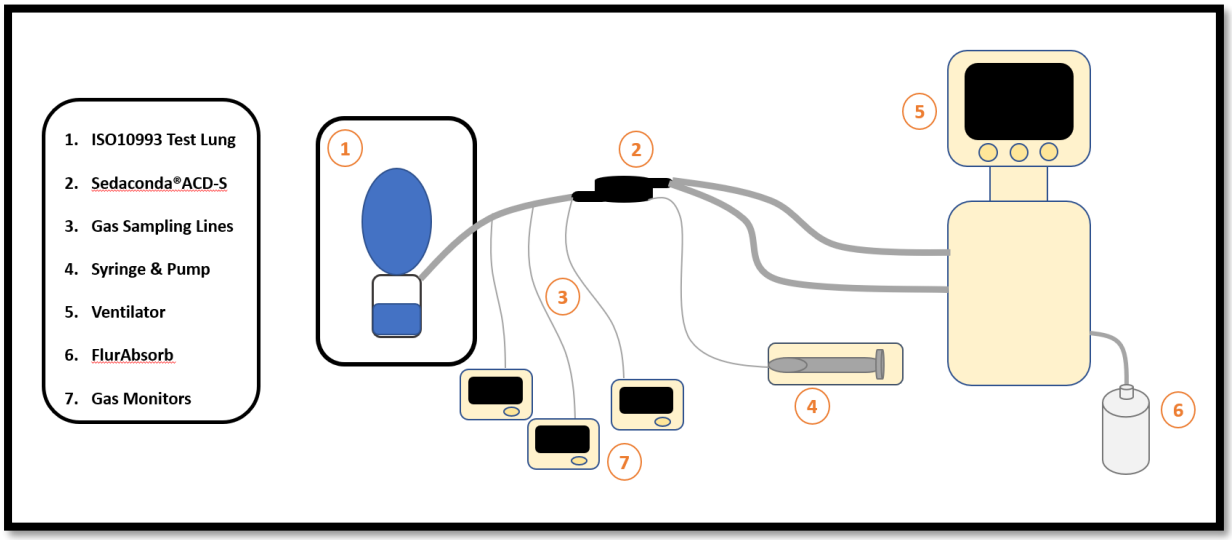


Figure 2 – Test Setup (Diagram)

4. Test Equipment

4.1 Test Subject

Gas Sampling Line

Model:	Viamed H-Line
Reference Number:	8090121313V
Lot Number:	S-075-210621

4.2 Test Support Equipment

Sedaconda®ACD-S

Manufacturer:	Sedna Medical Ltd.
Reference Number:	1026050
LOT Number:	N001736

Sedaconda® Syringe

Manufacturer:	Sedna Medical Ltd.
Reference Number:	1026022
LOT Number:	F000070

Water Traps (x3)

Manufacturer:	Dräger AG
Model:	WaterLock2
Reference Number:	6872130
LOT Number:	1000806626

Gas Sampling Line

Manufacturer: Intersurgical Ltd.
Reference Number: 2732000
LOT Number: 7200894

Dryer Line / Nafion

Manufacturer: Perma Pure LLC
Reference Number: 26053
LOT Number: M7102220-02

Connector 22M-15M Gas Sampling Port

Manufacturer: Intersurgical Ltd.
Reference Number: 2713000
LOT Number: 32054187

Isoflurane

Manufacturer: Piramal Critical Care
LOT Number: H25M21C

Mechanical Ventilator

Manufacturer: Maquet Critical Care AB
Model: Servo-U

Gas Monitors (x3)

Manufacturer: Dräger AG
Model: Vamos

Infusion Pump

Manufacturer: Smiths Medical
Model: Medfusion 3500

Mass Balance

Manufacturer: Kern & Sohn GmbH
Model: PCB 350-3

Test Lung

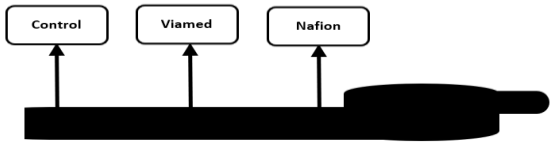
Model: ISO 10993

5. Test Procedure

- Set up the test apparatus as described in figure 1 and figure 2, with the three gas monitoring lines and gas monitors in series.
- Set the ventilator and infusion pump to the first set of parameters outlined in table 1 and 2. (Give a bolus of 1.2ml for the initial start-up).
- Compare the three gas sampling lines by recording the peak Fet% displayed on both gas monitors at 60-minute intervals. (NOTE: since no CO2 is used during the test, the gas monitor cannot determine an accurate end-tidal concentration. The gas monitor will read live Fet% at various sample points. The end-tidal concentration is determined as the peak Fet% observed at each breath.)
- Adjust the ventilator / infusion pump settings as outlined in the results section below.
- Repeat the same procedure for each of the 9 parameter settings until the 72hr test is complete.

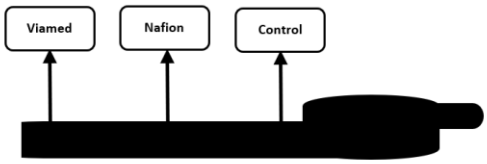
6. Test Results

6.1 Low Settings (2 mL/h)

09:00 – 13:00 → 2.0 mL/h 13:00 – 17:00 → 2.0 mL/h 17:00 – 09:00 → 2.0 mL/h	

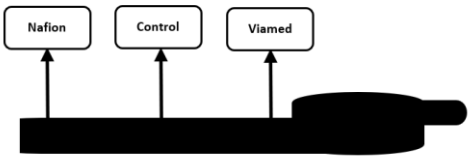
Settings	Hours	Control	Nafion	Viamed
750 x 12	**1**	0.3	0.3	0.3
	2	0.3	0.3	0.3
	3	0.4	0.3	0.3
	4	0.3	0.3	0.3
250 x 20	**5**	1.0	0.9	0.9
	6	1.0	1.0	1.0
	7	1.0	1.0	1.0
	8	1.0	1.0	1.0
500 x 15	**9**	0.5	0.5	0.5
	10	0.6	0.6	0.6
	11	0.6	0.6	0.6
	12	0.6	0.6	0.6
	13	0.6	0.6	0.6
	14	0.6	0.6	0.6
	15	0.6	0.6	0.6
	16	0.6	0.6	0.6
	17	0.6	0.6	0.6
	18	0.6	0.6	0.6
	19	0.6	0.6	0.6
	20	0.6	0.6	0.6
	21	0.6	0.6	0.6
	22	0.6	0.6	0.6
	23	0.6	0.6	0.6
	24	0.6	0.6	0.6

6.2 Medium Settings (4 – 4.5 mL/h)

09:00 – 13:00 → 4.5 mL/h 13:00 – 17:00 → 4.5 mL/h 17:00 – 09:00 → 4.0 mL/h	

Settings	Hours	Control	Nafion	Viamed
750 x 12	**1**	0.7	0.7	0.7
	2	0.7	0.8	0.7
	3	0.7	0.7	0.6
	4	0.6	0.8	0.6
250 x 20	**5**	2.0	2.2	1.9
	6	2.0	2.2	2.0
	7	1.9	2.0	1.9
	8	1.9	2.0	1.9
500 x 15	**9**	1.1	1.2	1.1
	10	1.1	1.3	1.1
	11	1.1	1.2	1.1
	12	1.1	1.3	1.1
	13	1.1	1.2	1.1
	14	1.1	1.2	1.1
	15	1.1	1.2	1.1
	16	1.1	1.2	1.1
	17	1.1	1.2	1.1
	18	1.1	1.2	1.1
	19	1.1	1.2	1.1
	20	1.1	1.1	1.0
	21	1.1	1.1	1.0
	22	1.1	1.2	1.0
	23	1.1	1.2	1.0
	24	1.1	1.1	1.0

6.3 High Settings (6 – 7 mL/h)

09:00 – 13:00 → 7.0 mL/h 13:00 – 17:00 → 7.0 mL/h 17:00 – 21:00 → 7.0 mL/h 21:00 – 09:00 → 6.0 mL/h	

Settings	Hours	Control	Nafion	Viamed
750 x 12	**1**	1.0	1.1	0.9
	2	0.9	1.1	0.8
	3	0.9	1.1	0.8
	4	0.9	1.1	0.9
250 x 20	**5**	3.2	3.3	3.1
	6	3.2	3.3	3.0
	7	3.2	3.3	3.1
	8	3.3	3.3	3.1
500 x 15	**9**	1.8	1.7	1.6
	10	1.8	1.7	1.6
	11	1.8	1.8	1.6
	12	1.8	1.7	1.6
	13	1.4	1.4	1.3
	14	1.4	1.4	1.3
	15	1.4	1.4	1.3
	16	1.3	1.3	1.3
	17	1.4	1.3	1.3
	18	1.3	1.3	1.3
	19	1.4	1.4	1.3
	20	1.3	1.3	1.3
	21	1.4	1.3	1.3
	22	1.3	1.3	1.2
	23	1.3	1.3	1.2
	24	1.3	1.3	1.2

6.4 Moisture Absorption

All water traps were weighed at the start and end of the test:

Gas Sampling Line	Weight at 0 hours	Weight at 72 hours	Weight Increase
Viamed H-Line:	14.0 g	14.0 g	0 g
Nafion:	14.0 g	14.0 g	0 g
Control:	14.0 g	20.64 g	6.64 g

Nafion

Control

Viamed

7. Summary of Results

Overall, the Viamed H-Line compared well to Sedana's control and standard gas sampling line setup throughout the duration of the 72hr test. The majority of the Fet% readings were equal on all monitors, or within 0.1% which is the lowest readability of the Dräger Vamos monitor.

Some unstable data and variation was observed at different points of the assessment, particularly at the higher concentration settings (7.0 mL/h). It was observed that the Nafion readings tended to be higher than both the Control line and Nafion line, by 0.1 – 0.3% at the worst instance. This instability was generally observed after setting changes, which can be attributed to "settling time". Continuous differences of 0.1% can most likely be attributed to gas monitor error, and are not considered significant.

No physical degradation was observed in the Viamed line or its connectors, indicating it can withstand direct contact with volatile anaesthetics (isoflurane and sevoflurane) for 72+ hours.

The Viamed line did not absorb any moisture into the water trap, similarly to the Nafion line setup. In comparison, the Control line absorbed a significant amount of water over the course of 72 hours. This result reaffirms the necessity of a dryer line during inhaled sedation gas sampling, for which the Viamed H-Line performs very well.

The overall stability and readability of the Viamed H-Line cannot be faulted, making it a good, compatible alternative to the Nafion line.

8. Conclusion

Feedback on the test data provided by Sedana Medical's CMO and Medical Director indicate that there is no clinical significance to such a minor difference in end-tidal concentration (0.1%). There is no relevant risk to patient safety or clinical usage caused by the differences observed between the Viamed H-Line and Nafion Line setup. Overall, it can be confidently stated that the Viamed H-Line offers an accurate and acceptable alternative to the current gas sampling line setup for durations up to 72 hours, as expected based on the initial 24hr Compatibility Test Report (2021).

	Date	**Time**	**Signature**
Test Start:	30-10-2023	09:00	
Test Complete:	02-11-2023	09:00	

Written by:	**Lyes Djennadi** R&D Engineer	
Approved by:	**Peter Fröberg** R&D and Technical Director