1. Introduction

The purpose of this test is to determine whether Viamed's Gas Sampling Line H is compatible with AnaConDa and the delivery of volatile anaesthetics (Isoflurane and Sevoflurane). This test will compare the performance of Sedana Medical's current recommended gas sampling setup with the proposed 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. The key performance criteria that will be investigated is:

1. **End-Tidal Concentration (Fet%) Reading** – both lines should display identical Fet% values as they will be placed in series and will use identical Gas Monitors.

2. Test Parameters

Table 1 – Constant Test Settings

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

Table 2 – Variable Test Settings

Setting	Tidal Volume [mL]	X	Breath Rate [bpm]		Isoflurane Infusion Rate [mL/h]	Sevoflurane Infusion Rate [mL/h]
1	250	x	20		2.0	4.0
2	500	x	15	→	2.0	4.0
3	750	x	10		2.0	4.0
4	250	x	20		4.5	7.0
5	500	x	15	→	4.5	7.0
6	750	x	10		4.5	7.0
7	250	x	20		7.0	10.0
8	500	x	15	→	7.0	10.0
9	750	x	10		7.0	10.0

3. Test Setup

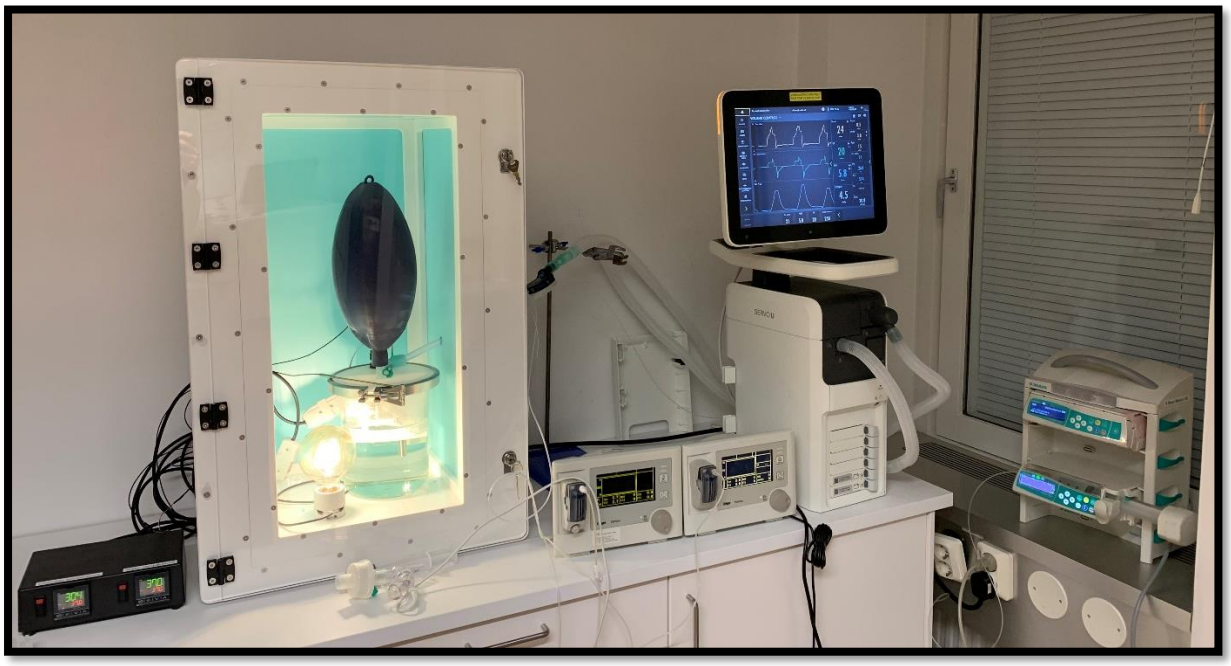

Figure 1 – Test Setup (Picture)

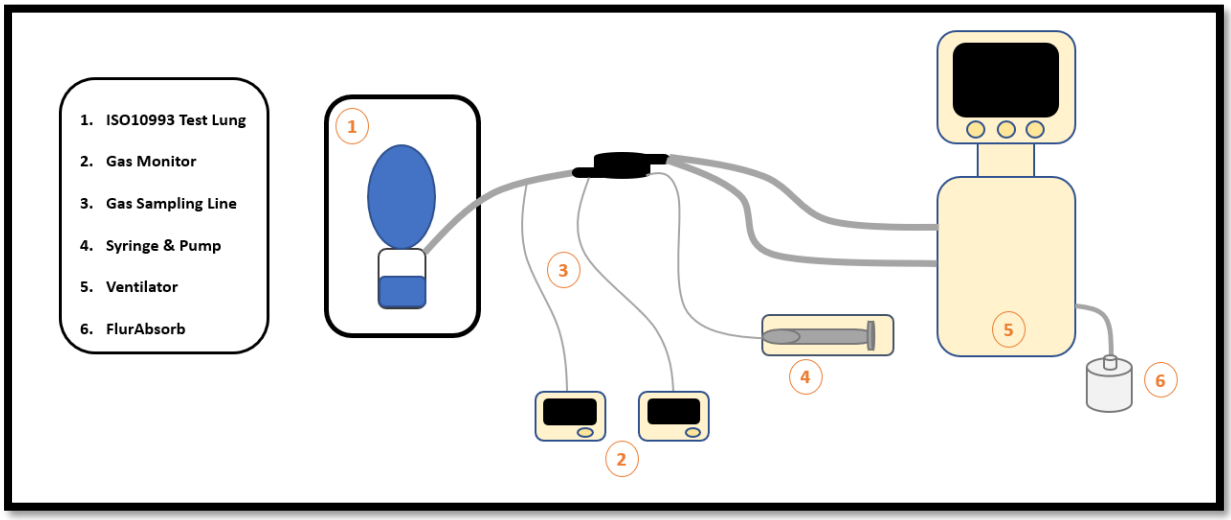

Figure 2 – Test Setup (Diagram)

4. Test Equipment

4.1 Test Subject

Gas Sampling Line

Model: Viamed H-Line
Reference Number: 8090121312V
Lot Number: S-074-2020-09

4.2 Test Support Equipment

AnaConDa-S (50ml)

Manufacturer: Sedna Medical Ltd.
Reference Number: 26050
LOT Number: N001405

Water Traps (x2)

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

Gas Sampling Line

Manufacturer: Intersurgical Ltd.
Reference Number: 2732000
LOT Number: 31952634

Dryer Line / Nafion

Manufacturer: Perma Pure LLC
Reference Number: 26053
LOT Number: M5121317-01

AnaConDa Syringe

Manufacturer: Sedna Medical Ltd.
Reference Number: 26022
LOT Number: N001233

Isoflurane

Manufacturer: Piramal Critical Care
LOT Number: G145G19A

Sevoflurane

Manufacturer: Piramal Critical Care
LOT Number: S2209109

Mechanical Ventilator

Manufacturer:	Maquet Critical Care AB
Model:	Servo-U

Gas Monitor #1

Manufacturer:	Dräger AG
Model:	Vamos
Date of Manufacture:	10/26/2020

Gas Monitor #2

Manufacturer:	Dräger AG
Model:	Vamos
Date of Inspection:	05/09/2019

Infusion Pump

Manufacturer:	BBraun
Model:	Infusomat® Space

Mass Balance

Manufacturer:	Kern & Sohn GmbH
Model:	KB10K0.05N

Test Lung

Model:	ISO 10993

Air Compressor

Manufacturer:	Clarke Air Ltd.
Model:	SHHHAIR (100/24)

5. Test Procedure

- Set up the test apparatus as described in figure 1 and figure 2, with the two 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 two gas sampling lines by recording the peak Fet% displayed on both gas monitors at 30-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.)
- After 2.5 hours (3 hours for 500x15 settings), adjust the ventilator / infusion pump to the next set of parameters outlined in table 2.
- Repeat the same procedure for each of the 9 parameter settings until the 24hr test is complete.
- Complete the procedure outlined above using both isoflurane and sevoflurane.

6. Isoflurane Test Results

Infusion Rate	Ventilator Settings	Time [hours]	Viamed Line H [Fet%]	Control [Fet%]	Difference [Fet%]
2 mL/hr	250 mL x 20 bpm	0.5	0.9	0.9	
		1.0	1.2	1.2	
		1.5	1.2	1.2	
		2.0	1.4	1.4	
		2.5	1.2	1.2	
	500 mL x 15 bpm	3.0	0.7	0.7	
		3.5	0.6	0.6	
		4.0	0.7	0.7	
		4.5	0.8	0.8	
		5.0	0.5	0.6	+ 0.1
		5.5	0.5	0.5	
	750 mL x 12 bpm	6.0	0.4	0.5	+ 0.1
		6.5	0.4	0.4	
		7.0	0.5	0.6	+ 0.1
		7.5	0.3	0.3	
		8.0	0.4	0.4	

Infusion Rate	Ventilator Settings	Time [hours]	Viamed Line H [Fet%]	Control [Fet%]	Difference [Fet%]
4.5 mL/hr	250 mL x 20 bpm	8.5	1.8	2.0	+ 0.2
		9.0	1.8	2.0	+ 0.2
		9.5	1.8	2.0	+ 0.2
		10.0	1.8	2.0	+ 0.2
		10.5	2.1	2.3	+ 0.2
	500 mL x 15 bpm	11.0	0.8	0.9	+ 0.1
		11.5	0.7	0.9	+ 0.2
		12.0	0.7	0.9	+ 0.2
		12.5	0.8	0.9	+ 0.1
		13.0	0.8	0.9	+ 0.1
		13.5	0.8	0.9	+ 0.1
	750 mL x 12 bpm	14.0	0.5	0.6	+ 0.1
		14.5	0.6	0.8	+ 0.2
		15.0	0.7	0.9	+ 0.2
		15.5	0.7	0.8	+ 0.1
		16.0	0.7	0.7	

Infusion Rate	Ventilator Settings	Time [hours]	Viamed Line H [Fet%]	Control [Fet%]	Difference [Fet%]
7 mL/hr	250 mL x 20 bpm	16.5	2.6	2.7	+ 0.1
		17.0	2.7	2.7	
		17.5	2.8	2.8	
		18.0	2.8	2.8	
		18.5	2.8	2.9	+ 0.1
	500 mL x 15 bpm	19.0	1.7	1.8	+ 0.1
		19.5	1.6	1.7	+ 0.1
		20.0	1.6	1.7	+ 0.1
		20.5	1.6	1.7	+ 0.1
		21.0	1.6	1.7	+ 0.1
		21.5	1.6	1.6	
	750 mL x 12 bpm	22.0	1.2	1.4	+ 0.2
		22.5	1.2	1.3	+ 0.1
		23.0	1.2	1.3	+ 0.1
		23.5	1.1	1.2	+ 0.1
		24.0	1.2	1.3	+ 0.1

7. Sevoflurane Test Results

Infusion Rate	Ventilator Settings	Time [hours]	Viamed Line H [Fet%]	Control [Fet%]	Difference [Fet%]
4 mL/hr	250 mL x 20 bpm	0.5	1.7	1.8	+0.1
		1.0	1.7	1.8	+0.1
		1.5	1.6	1.7	+0.1
		2.0	1.6	1.7	+0.1
		2.5	1.6	1.6	
	500 mL x 15 bpm	3.0	1.1	1.1	
		3.5	1.0	1.1	+0.1
		4.0	1.0	1.1	+0.1
		4.5	1.0	1.0	
		5.0	1.0	1.0	
		5.5	1.0	1.0	
	750 mL x 12 bpm	6.0	0.7	0.7	
		6.5	0.6	0.5	-0.1%
		7.0	0.5	0.4	-0.1%
		7.5	0.5	0.5	
		8.0	0.5	0.5	

Infusion Rate	Ventilator Settings	Time [hours]	Viamed Line H [Fet%]	Control [Fet%]	Difference [Fet%]
7 mL/hr	250 mL x 20 bpm	8.5	2.0	2.0	
		9.0	1.7	1.7	
		9.5	2.1	2.1	
		10.0	2.1	2.1	
		10.5	2.1	2.1	
	500 mL x 15 bpm	11.0	1.5	1.5	
		11.5	1.4	1.5	+0.1
		12.0	1.4	1.4	
		12.5	1.4	1.4	
		13.0	1.4	1.4	
		13.5	1.4	1.5	+0.1
	750 mL x 12 bpm	14.0	1.1	1.2	+0.1
		14.5	0.9	1.1	+0.2
		15.0	0.9	1.0	+0.1
		15.5	0.9	1.0	+0.1
		16.0	0.9	1.0	+0.1

Infusion Rate	Ventilator Settings	Time [hours]	Viamed Line H [Fet%]	Control [Fet%]	Difference [Fet%]
10 mL/hr	250 mL x 20 bpm	16.5	2.3	2.3	
		17.0	2.7	2.7	
		17.5	2.8	2.8	
		18.0	2.7	2.7	
		18.5	2.7	2.7	
	500 mL x 15 bpm	19.0	2.1	2.1	
		19.5	1.8	1.7	-0.1%
		20.0	1.8	1.7	-0.1%
		20.5	1.8	1.8	
		21.0	1.8	1.8	
		21.5	1.8	1.9	+0.1
	750 mL x 12 bpm	22.0	1.3	1.3	
		22.5	1.2	1.3	+0.1
		23.0	1.2	1.3	+0.1
		23.5	1.2	1.2	
		24.0	1.1	1.2	+0.1

8. Summary of Results

8.1 Isoflurane 24hr Test

A total of 48 end-tidal concentrations (Fet%) were recorded during the 24hr test:

- 18/48 (37.5%) displayed the same Fet%
- 20/48 (~41.5%) displayed Fet% differing by 0.1%
- 10/48 (~21.0%) displayed Fet% differing by 0.2%

The Fet% recorded by the Viamed H-Line was always equal or less than the Fet% recorded by the control line (Intersurgical + Nafion).

The line sampling locations and gas monitors were swapped at several random recording points but no difference was observed in the readings.

8.2 Sevoflurane 24hr Test

A total of 48 end-tidal concentrations (Fet%) were recorded during the 24hr test:

- 27/48 (56.5%) displayed the same Fet%
- 20/48 (~41.5%) displayed Fet% differing by 0.1%
    - Control line displayed +0.1% 16 times
    - Viamed line displated +0.1% 4 times
- 1/48 (~2.0%) displayed Fet% differing by 0.2%

The Fet% recorded by the Viamed H-Line was generally equal or less than the Fet% recorded by the control line (Intersurgical + Nafion), except for 4 sample points.

The line sampling locations and gas monitors were swapped at several random recording points but no difference was observed in the readings.

8.3 Comments

During the course of one complete breath (inhalation + exhalation), the Viamed H-Line produced more stable readings when compared to the Control line. This was verified using both gas monitors and was observed throughout the entire 24hr test.

- The Control line produced readings that tended to “jump” up and down significantly. Example: for a peak reading of 1.3%, the gas monitor displayed up to 4 or 5 values within 0.4 – 1.3%
- The Viamed H-Line produced very stable readings with minimal “jumping”. Example: for a peak reading of 1.2%, the gas monitor displayed only 2 values, jumping from 1.1 – 1.2%

NOTE: the "jumping" phenomenon described above is due to the fact that no CO2 was used during testing which makes it difficult for the gas monitor to determine an accurate end-tidal concentration. Instead, the gas monitor displays a live Fet% at various sample points during each breath.

9. Conclusion

Based on the data obtained, it's clear that the Viamed H-Line compares quite well to Sedana Medical's standard recommended setup (Intersurgical + Nafion). The data shows that both lines recorded very similar Fet% throughout the 24hr study, with a maximum difference of only 0.2%. It is worth noting that the Viamed H-Line generally recorded an Fet% equal to or lower than the Control line (albeit just a small difference), rarely higher.

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 (0.1-0.2%). There is no relevant risk to patient safety or clinical usage caused by the differences observed between the Viamed H-Line and Sedana Medical's "control" setup.

	Date	Time	Signature
Isoflurane Test Start:	07-02-2021	13:15	
Isoflurane Test Complete:	08-02-2021	13:15	
Sevoflurane Test Start:	12-03-2021	06:00	
Sevoflurane Test Complete:	13-03-2021	06:00	

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Reviewed by:	**Harry Hennessy** Senior R&D Engineer	
Approved by:	**Peter Fröberg** R&D and Technical Director	