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## 1. Introduction

The purpose of this test is to determine whether Viamed's "Premium" 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:

- 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*

<b>Inspiratory:Expiratory</b>	1:2
<b>PEEP</b>	5 mbar
<b>Anaesthetic Agent</b>	Isoflurane / Sevoflurane
<b>Bowl Temperature</b>	37 ± 0.5 °C
<b>Chamber Temperature</b>	37 ± 0.5 °C
<b>Sample Flow Rate (Vamos):</b>	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

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### 3. Test Setup



Figure 1 – Test Setup (Picture)

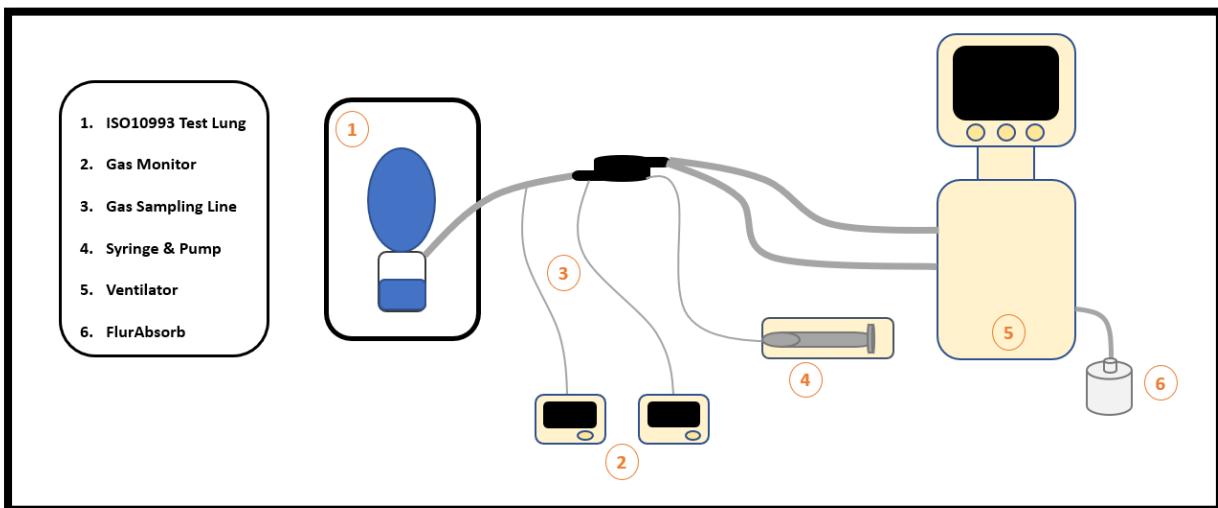


Figure 2 – Test Setup (Diagram)

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## 4. Test Equipment

### 4.1 Test Subject

#### Gas Sampling Line

Model: Viamed H-Line  
Reference Number: 8090121313V  
Lot Number: S-074-2020-09

### 4.2 Test Support Equipment

#### AnaConDa-S (50ml)

Manufacturer: Sedna Medical Ltd.  
Reference Number: 26050  
LOT Number: N001390

#### 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

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**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)

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## 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 60-minute intervals. (NOTE: since no CO<sub>2</sub> 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 24hr test is complete.
- Complete the procedure outlined above using both isoflurane and sevoflurane.

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## 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	1.0	1.1	1.1	
		2.0	1.1	1.0	- 0.1
	Change ventilator settings at 2.5 hours				
	500 mL x 15 bpm	3.0	0.6	0.6	
		4.0	0.6	0.6	
		5.0	0.6	0.6	
	Change ventilator settings at 5.5 hours				
	750 mL x 10 bpm	6.0	0.3	0.3	
		7.0	0.3	0.3	
		8.0	0.3	0.3	

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Infusion Rate	Ventilator Settings	Time [hours]	Viamed Line H [Fet%]	Control [Fet%]	Difference [Fet%]
4.5 mL/hr	250 mL x 20 bpm	1.0	2.2	2.2	
		2.0	2.4	2.4	
	Change ventilator settings at 2.5 hours				
	500 mL x 15 bpm	3.0	1.1	1.2	+ 0.1
		4.0	1.2	1.2	
		5.0	1.2	1.2	
	Change ventilator settings at 5.5 hours				
	750 mL x 10 bpm	6.0	1.1	1.0	- 0.1
		7.0	1.1	1.2	+ 0.1
		8.0	0.9	0.9	

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Infusion Rate	Ventilator Settings	Time [hours]	Viamed Line H [Fet%]	Control [Fet%]	Difference [Fet%]
7 mL/hr	250 mL x 20 bpm	1.0	3.2	3.3	- 0.1
		2.0	3.3	3.4	- 0.1
	Change ventilator settings at 2.5 hours				
	500 mL x 15 bpm	3.0	1.6	1.6	
		4.0	1.6	1.6	
		5.0	1.6	1.6	
	Change ventilator settings at 5.5 hours				
	750 mL x 10 bpm	6.0	1.3 *	1.6 *	+ 0.3
		7.0	1.2	1.2	
		8.0	1.2	1.3	+ 0.1

\* Very unstable data

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## 7. Sevoflurane Test Results

8. Infusion Rate	Ventilator Settings	Time [hours]	Viamed Line H [Fet%]	Control [Fet%]	Difference [Fet%]
4 mL/hr	250 mL x 20 bpm	1.0	1.1	1.1	
		2.0	1.1	1.0	- 0.1
	Change ventilator settings at 2.5 hours				
	500 mL x 15 bpm	3.0	0.6	0.6	
		4.0	0.6	0.6	
		5.0	0.6	0.6	
	Change ventilator settings at 5.5 hours				
	750 mL x 10 bpm	6.0	0.3	0.3	
		7.0	0.3	0.3	
		8.0	0.3	0.3	

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Infusion Rate	Ventilator Settings	Time [hours]	Viamed Line H [Fet%]	Control [Fet%]	Difference [Fet%]
7 mL/hr	250 mL x 20 bpm	1.0	2.7	2.8	+ 0.1
		2.0	2.7	2.6	- 0.1
	Change ventilator settings at 2.5 hours				
	500 mL x 15 bpm	3.0	1.4	1.4	
		4.0	1.4	1.4	
		5.0	1.4	1.4	
	Change ventilator settings at 5.5 hours				
	750 mL x 10 bpm	6.0	1.3	1.3	
		7.0	1.0	1.0	
		8.0	1.0	1.0	

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Infusion Rate	Ventilator Settings	Time [hours]	Viamed Line H [Fet%]	Control [Fet%]	Difference [Fet%]
10 mL/hr	250 mL x 20 bpm	1.0	2.8	2.9	+ 0.1
		2.0	3.0	3.0	
	Change ventilator settings at 2.5 hours				
	500 mL x 15 bpm	3.0	1.8	1.8	
		4.0	1.8	1.8	
		5.0	1.8	1.8	
	Change ventilator settings at 5.5 hours				
	750 mL x 10 bpm	6.0	1.5 *	1.7 *	+ 0.2
		7.0	1.4	1.4	
		8.0	1.3	1.3	

\* Very unstable data

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## 9. Summary of Results

Overall, the Viamed Premium H-Line compared very well to Sedana's control/standard gas sampling line setup (Nafion + Intersurgical). The large majority of the measurements were equal on both lines throughout the two 24hr studies.

The maximum difference observed was 0.1%, with the exception of measurement number 22 during both the isoflurane and sevoflurane studies. This measurement point is considered an outlier due to the extremely unstable data observed on both monitors. It was notably difficult to take an accurate reading at this measuring point due to the unstable data. It is reassuring that both lines quickly stabilised and showed equal readings again during point 23 and 24.

## 10. 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 Sedana Medical's current 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.

	Date	Time	Signature
<b>Isoflurane Test Start:</b>	22-03-2021	09:00	
<b>Isoflurane Test Complete:</b>	23-03-2021	09:00	
<b>Sevoflurane Test Start:</b>	25-03-2021	09:00	
<b>Sevoflurane Test Complete:</b>	26-03-2021	09:00	

<b>Written by:</b>	<b>Lyes Djennadi</b> R&D and Manufacturing Engineer	
<b>Reviewed by:</b>	<b>Harry Hennessy</b> Senior R&D Engineer	
<b>Approved by:</b>	<b>Peter Fröberg</b> R&D and Technical Director	

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