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## 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). 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 two key performance criteria that will be investigated are:

- 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. Water Absorption** – the H-line should prevent water absorption into the water trap, at a similar efficiency to the Nafion Line.

## 2. Test Parameters

*Table 1 – Constant Test Settings*

<b>Rate of Nebulisation</b>	8ml every 2.5hrs
<b>Inspiratory:Expiratory</b>	1:2
<b>PEEP</b>	5 mbar
<b>Anaesthetic Agent</b>	Isoflurane
<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*

<b>Setting</b>	<b>Infusion Rate [mL/h]</b>	<b>Tidal Volume [mL]</b>	<b>Breath Rate [bpm]</b>
1	2.0	250	20
2	2.0	500	15
3	2.0	750	10
4	4.5	250	20
5	4.5	500	15
6	4.5	750	10
7	7.0	250	20
8	7.0	500	15
9	7.0	750	10

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### 3. Test Setup

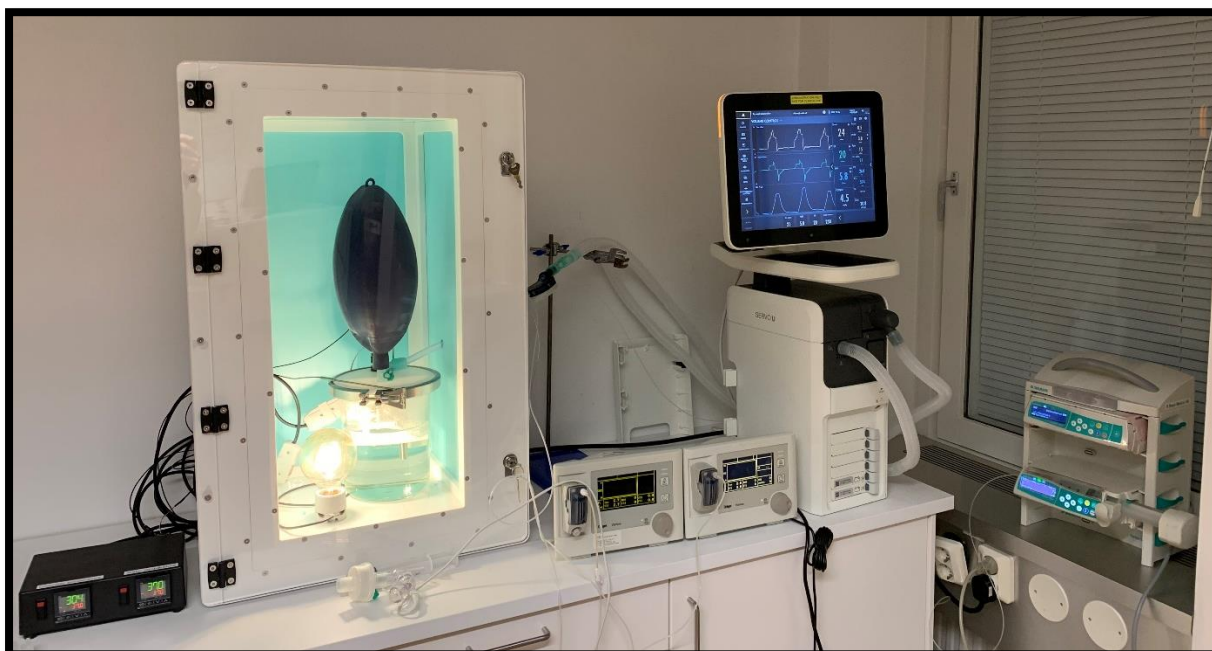


Figure 1 – Test Setup (Picture)

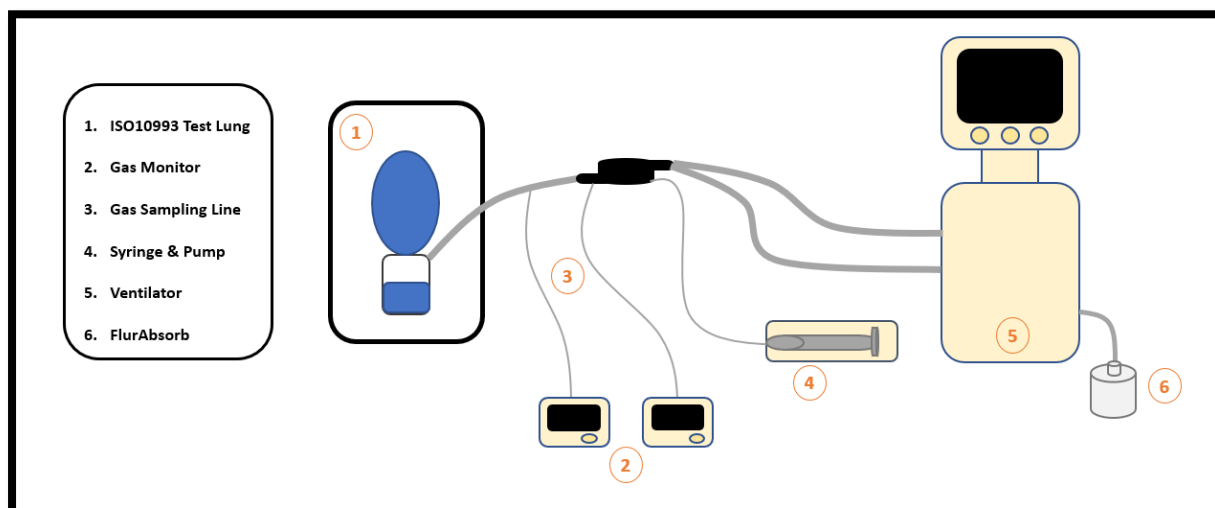


Figure 2 – Test Setup (Diagram)

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## 4. Test Equipment

### 4.1 Test Subject

#### Gas Sampling Line

Model: Viamed H-Line  
Reference Number: 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

#### Anaesthetic Agent

Anaesthetic: Isoflurane  
Manufacturer: Piramal Critical Care  
LOT Number: G145G19A

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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 (Drug)**

Manufacturer: BBraun  
Model: Unknown

#### **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

- Weigh both water traps before any moisture is absorbed.
- 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 Fet% displayed on both gas monitors at 30-minute intervals.
- Nebulise 8ml of water into the system during each of the 9 different test settings
- After 2.5 hours (3 hours for 500x15 settings), weigh both water traps and 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.

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## 6. 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	

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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	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	

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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	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



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## 7. Summary of Results

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) 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 points and gas monitors were swapped at several random recording points but no difference was observed in the data.

The water traps were weighed at various intervals during the test but there were no weight changes observed in either one.

Nebulising water into the system at various intervals did not affect the performance of either gas sampling line.

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%

## 8. 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 study, with a maximum difference of only 0.2%. It is worth noting that the Viamed H-Line somewhat consistently recorded a lower Fet% than the Control line (albeit just a small difference), the Viamed line never recorded a value greater than the Control line. A further risk assessment of this data is recommended to determine what clinical significance it has from the perspective of an ICU doctor or nurse. The key question to be addressed is: “will 0.1-0.2% difference in displayed Fet% affect patient safety?” Further consideration should also be given to the “stability” of the readings produced by both lines and how this would be interpreted by a doctor/nurse in the ICU. Currently its significance is unknown as the peak Fet% is generally recorded for any given breath during lab validation testing.

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	Date	Time	Signature
<b>Test Start:</b>	07-02-2021	13:15	
<b>Test Complete:</b>	08-02-2021	13:15	