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## 1. Introduction

The purpose of this test is to determine whether Viamed's H-Line (sampling line) is a suitable replacement for the current setup which combines an Intersurgical gas sampling line with a Nafion dryer line. Switching from the current setup to Viamed's H-Line offers Sedana a cost saving on its current setup. It also opens up an affordable possibility for Sedana to package the H-Line in the AnaConDa blister pack (not feasible with the current price of Nafion).

To be a suitable replacement, the Viamed H-Line must function without fault (gas monitor failure) for an uninterrupted 24hr period at standard ventilator parameters and must compare well with the current Nafion setup in terms of water entering the water trap. Constant nebulisation replicates a worst-case scenario in terms of the quantity of water vapour in the gas pathway during ventilation.

This test is a follow on from a previous test performed on Viamed's H-Type gas sampling line. The previous test was successful, indicating that Viamed's H-Line will act as a suitable replacement to the current setup assuming the modified sampling line (removed yellow strip per Sedana's request) performs equally well. This test was run over 24hrs but with several interruptions (24 consecutive hours is much preferable). The Draeger water trap and Viamed H-Line will be weighed every 2 hours throughout the 24-hour test to determine the sampling line's efficiency. A brief Fet% comparison will also be conducted between the Viamed H-Line and Nafion + Intersurgical combination.

## 2. Test Parameters

This test is conducted at standard ventilator settings and drug infusion rate. Continuous nebulisation of water allows for an oversaturated air pathway that replicates "extreme conditions".

*Table 1 – Ventilator Settings & Test Parameters*

Tidal Volume ( $V_t$ )	350 mL
Respiratory Rate (f)	12 bpm
Rate of Nebulisation	Continuous
Drug Infusion Rate	4.0 mL/h
Max Volume ( $\dot{V}_{max}$ )	23
Inspiratory:Expiratory	1:2
PEEP	3.0 cmH <sub>2</sub> O
Anaesthetic Agent	Isoflurane
Bowl Temperature	37 ± 0.5 °C
Chamber Temperature	37 ± 0.5 °C

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### 3. Test Setup



*Figure 1 – Test Setup*

### 4. Test Equipment

#### 4.1 Test Subject

##### **Gas Sampling Line**

Model: Viamed H-Line  
Reference Number: VHL-T1  
Lot Number: For Investigational Use Only

#### 4.2 Test Support Equipment

##### **AnaConDa-S (50ml)**

Manufacturer: Sedna Medical Ltd.  
Reference Number: 26050  
LOT Number: N001127

##### **Water Trap**

Manufacturer: Draeger AG  
Reference Number: 6872130  
LOT Number: 1000750741

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#### Sampling Line

Manufacturer: Intersurgical Ltd.  
Reference Number: 2732000  
LOT Number: 31655478

#### Dryer Line

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

#### Delivery Syringes

Manufacturer: Sedna Medical Ltd.  
Reference Number: 26022  
LOT Number: N001033

#### Anaesthetic Agent

Manufacturer: Piramal Critical Care  
Serial Number: 30372.00.00  
LOT Number: B90L15B

#### Mechanical Ventilator

Manufacturer: Nellcor Puritan Bennett  
Model: Puritan Bennett 840

#### Nebulizer

Manufacturer: ???  
Model: ???

#### Gas Monitor

Manufacturer: Draeger AG  
Model: Vamos

#### Infusion Pump (Drug)

Manufacturer: Arcomed AG  
Model: Syramed µSP6000

#### Infusion Pump (Water)

Manufacturer: Fresenius  
Model: Pilote Anastesi S

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#### Mass Balance

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

#### Test Lung

Model: ISO 10993

#### Silent Air Compressor

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

## 5. Test Procedure

### 5.1 Compatibility

1. Individually weigh the Viamed H-Line and Draeger water trap using an accurate mass balance.
2. Set up the test apparatus according to Figure 2 above **\*INSERT DIAGRAM ABOVE\***.
3. Set the ventilator, infusion pump, nebulizer and heaters according to the parameters outlined in Table 1 above.
4. Allow the ventilator to run continuously for 2 hours.
5. Temporarily pause the ventilator, nebulizer and infusion pump.
6. Disconnect the water trap and gas sampling line from the circuit.
7. Individually weigh the Viamed H-Line and Draeger water trap using the Kern mass balance.
8. Re-connect the gas sampling line and water trap.
9. Restart the ventilator and repeat steps 4-8 until a total of 12 measurements have been taken, after a total of 24 hours run time.

### 5.2 Fet% Comparison

1. During the 24hr study, at the 4hr mark, disconnect the water trap and Viamed H-Line from the circuit in order to take the necessary measurements for section 5.1 Compatibility.
2. Briefly replace the water trap with a fresh one and the sampling line with a Nafion dryer line and Intersurgical sampling line combination.
3. Allow the gas monitor a few moments to re-calibrate and settle, then read the Fet% displayed on the Vamos gas monitor.
4. Compare the Fet% for the Viamed H-Line and the Intersurgical + Nafion combination.

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## 6. Test Results

### 6.1 Compatibility

Time	Trap Weight	Line Weight	Total Weight	Fet %	Comments
0	14.15	6.85	21.00	-	
2	14.15	7.35	21.50	1.9	
4	14.15	7.35	21.55	1.7	
6	14.15	7.35	21.55	1.7	
8	14.15	7.35	21.50	1.8	
10	--	--	--	--	*GAS INOP* @ 9hrs
12					
14					

### 6.2 Fet% Comparison

Sampling Line Setup	Fet %	Reflection Efficiency
Viamed H-Line	1.7 %	80 %
Intersurgical + Nafion	2.1 %	83 %

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## 7. Summary

### 7.1 Compatibility

The Viamed H-Line appeared to be compatible with the simulated ICU test setup until the 9hr mark, when the gas monitor displayed a \*GAS INOP\* alarm continuously. The gas monitor's root cause of failure was not identified during the test. Upon failure, the H-Line was swapped back and forth several times with a standard setup (Intersurgical + Nafion) to determine if the fault was with the sampling line or the gas monitor. Introducing the standard setup caused the "GAS INOP" alarm to cease and the gas monitor began displaying measurements again. This leads to concern regarding the compatibility of the H-Line and its ability to function in extreme conditions for 24hrs. Potential causes of failure may be:

- A kink in the sampling line that was not noticed during testing. This may have occurred during the disconnection/weighing/connection phase at 8hrs (the sampling line was wound up and strapped in order to be easily weighed on the mass balance).
- Blockage in the sampling line caused by secretions or humidity. It can take the Vamos gas monitor some time to suction a blockage into the water trap if it is blocking the tube diameter. This prevents the gas monitor taking measurements.

Over the 9hrs that the test was running, the water trap accumulated no weight with no signs of any water or water vapour present.

Over the 9hrs that the test was running, the H-Line accumulated a maximum of 0.50g weight. The sampling line was expected to increase in weight as was observed in the previous test (see appendix 2). The weight increase was similar to the previous test (0.45g) with a negligible difference of 0.05g.

\* Note: "GAS INOP" = "Multi-Gas Monitor Device Failure"

### 7.2 Fet% Comparison

The Viamed H-Line and Intersurgical + Nafion combination produced significantly different Fet% at identical conditions. This is the cause of some concern and should be further investigated in a separate study.

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## 8. Conclusion

Overall, the test failed as the 24 hours could not be completed due to failure in the gas monitor. It should be noted that the test was performed at very extreme conditions and that failure of this test does not necessarily mean Viamed's H-Line is incompatible with AnaConDa and standard ICU conditions.

The recommended course of action is to make some adjustments to the test procedure/conditions and repeat the test using a fresh sampling line. The following important points should be considered when repeating this test:

- Constant/continuous nebulisation simulates very extreme conditions and would never occur in the ICU. Some research into average rates and limits of nebulisation in the ICU should be conducted prior to repeating the test. Choose a suitable rate of nebulisation that represents the higher end of realistic ICU conditions. This will result in a fairer compatibility test.
- Pay closer attention to the sampling line and exhaust tubing throughout the 24 hours of the test and ensure there are no kinks or bends that could cause any obstruction.
- The repeat test should last a minimum of 24 hours but ideally should be extended to 48 hours or more to remove any doubt.
- A separate test should also be conducted to investigate the significant difference in Fet% when using Viamed's H-Line against the Intersurgical + Nafion combination. This test should compare the two setups over a range of drug infusion rates (0.5, 1.0, 1.5, 2.0, 2.5, 3.0, 3.5, 4.0 ml/hr). If possible, other available sampling lines should also be included in this test for further comparison.

## 9.1 Viamed H-line 24hr Test

Time [hrs]	Trap Weight [g]	Total Trap Weight Change [g]	Line Weight [g]	Total Line Weight Change [g]	Total Weight [g]	Total Weight Change [g]	Fet %	Reflection Efficiency [%]	Comments
0	14.80	0.00	7.15	0.00	21.95	0.00	-	-	
2	14.80	0.00	7.50	0.35	22.30	0.35	1.0	90	
4	14.80	0.00	7.60	0.35	22.40	0.45	0.9	88	
6	14.80	0.00	7.50	0.35	22.30	0.35	0.8	87	
8	14.80	0.00	7.55	0.40	22.35	0.40	0.8	87	
10	14.80	0.00	7.55	0.40	22.35	0.40	0.6	83	
12	14.80	0.00	7.55	0.40	22.35	0.40	0.4	74	
14	14.80	0.00	7.60	0.45	22.40	0.45	0.4	74	
16	15.25	0.45	7.60	0.45	22.85	0.90	0.3	65	Lung Flooded @ 14.5 hrs
18	15.25	0.45	7.60	0.45	22.85	0.90	0.3	65	
20	15.25	0.45	7.60	0.45	22.85	0.90	0.3	65	
22	15.25	0.45	7.60	0.45	22.85	0.90	0.3	65	
24	15.05	0.25	7.55	0.40	22.60	0.65	0.3	65	*GAS INOP* @ 23.5 hrs



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