

Document Title	Revision	Pages
Viamed H-Line 72hr Compatibility Test Report (Additional Data)	01	Page 1 of 7

1. Introduction

The Viamed H-Line has been previously validated and approved for 24hr use by Sedana Medical R&D engineers (see report “VIAMED 24hr Compatibility Test” & “VIAMED 24hr Compatibility Test Premium”). After requests to extend the scope of the product specification, the Viamed H-Line has been re-tested and approved for use up to 72hrs in 2023 (see report “Viamed H-Line 72hr Compatibility Test Report”). The Viamed H-Line was tested with isoflurane at a range of infusion rates and ventilator parameters, while comparing the Fet concentration readings for three different gas sampling lines on three Draeger Vamos gas monitors. The test report concluded that the Viamed H-Line showed no signs of material degradation over 72hrs while accurately sampling/reading isoflurane Fet% compared to other gas sampling alternatives. The Viamed H-Line has also proven to be effective in terms of moisture absorption, allowing no water to enter the gas monitor’s water trap over the full 72hr test (effective alternative to Nafion tubing).

The purpose of this test report is to confirm the previous findings of 72hr compatibility, by providing additional Viamed H-Line 72hr test data with isoflurane and sevoflurane, giving close attention to material compatibility, ensuring no degradation over time. The tests were performed with intermittent monitoring of end-tidal concentration (Fet%).

2. Test Parameters

Table 1 – Variable Test Settings

Volatile Anaesthetic	Infusion Rate [mL/h]	Tidal Volume x Respiratory Rate [Vt x RR]	Time [hrs]
Isoflurane	3.5 – 7	500 x 15	72+
Sevoflurane	3 – 15	500 x 15	72+

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

Document Title	Revision	Pages
Viamed H-Line 72hr Compatibility Test Report (Additional Data)	01	Page 2 of 7

3. Test Setup



Figure 1 – Test Setup (Picture)

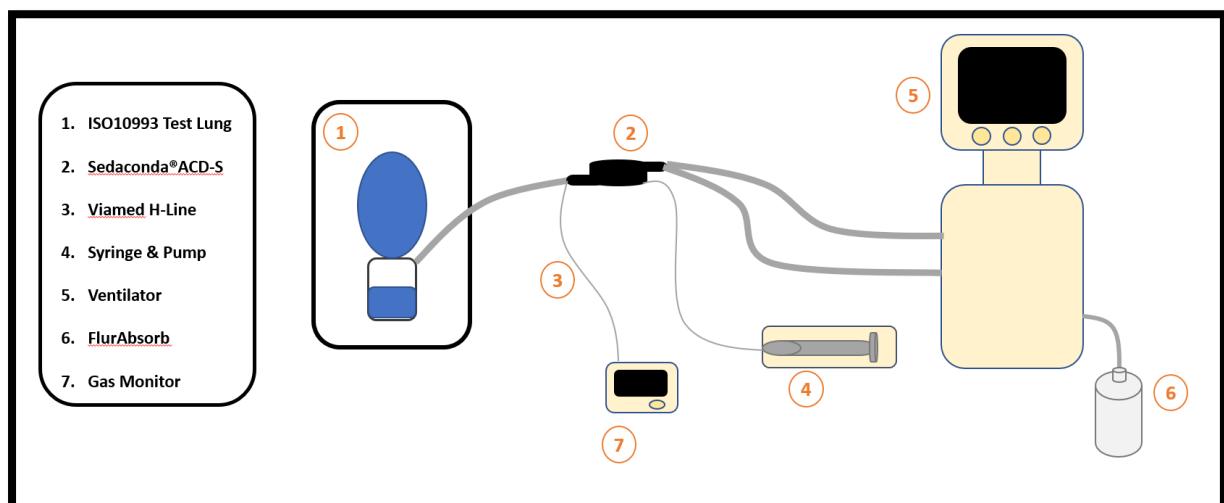


Figure 2 – Test Setup (Diagram)

Document Title	Revision	Pages
Viamed H-Line 72hr Compatibility Test Report (Additional Data)	01	Page 3 of 7

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: F000060

Water Trap

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

Isoflurane

Manufacturer: Piramal Critical Care
 LOT Number: H25M21C

Mechanical Ventilator

Manufacturer: Maquet Critical Care AB
 Model: Servo-U

Gas Monitors

Manufacturer: Dräger AG
 Model: Vamos

Infusion Pump

Manufacturer: Smiths Medical
 Model: Medfusion 3500

Test Lung

Model: ISO 10993

Document Title	Revision	Pages
Viamed H-Line 72hr Compatibility Test Report (Additional Data)	01	Page 4 of 7

5. Test Procedure

- Set up the test apparatus as described in figure 1 and figure 2.
- Set the ventilator and infusion pump to the parameters outlined in table 1 and 2. (Provide a bolus of 1.2ml for the initial start-up).
- Adjust the infusion pump settings as outlined in the results section below.
- Allow the system to run continuously for 72+ hours, occasionally monitoring the Fet%.
- Note whether any material degradation has occurred, any moisture has entered the water trap, or any unusual Fet% readings throughout the 72 hour test.

6. Test Results

After 72 hours of testing with continuous sampling of both isoflurane and sevoflurane, no material degradation was observed, no residue was observed, no moisture was absorbed by the water trap and no unusual Fet% readings were observed. Overall, the Viamed H-Line performed effectively throughout the 72hr tests, confirming compatibility with the Sedaconda®ACD standard setup.



Figure 3 – Images after 72hrs (no material degradation or residue)

The full 72hrs data is outlined in Table 3 and Table 4 below. A total of 350ml isoflurane and 470ml sevoflurane was used throughout the test, indicating good compatibility with volatile anaesthetics in the gas pathway.

Document Title	Revision	Pages
Viamed H-Line 72hr Compatibility Test Report (Additional Data)	01	Page 5 of 7

Table 3 – Sevoflurane Test Data 72hrs

Time [hr]	Rate [ml/h]	Fet [%]	Total [ml]
0	10.0		10.0
1	10.0	1.5	20.0
2	10.0		30.0
3	10.0		40.0
4	10.0		50.0
5	10.0		60.0
6	10.0		70.0
7	10.0	1.6	80.0
8	10.0		90.0
9	4.0		94.0
10	4.0	0.8	98.0
11	4.0		102.0
12	4.0		106.0
13	4.0		110.0
14	4.0		114.0
15	4.0		118.0
16	4.0		122.0
17	4.0		126.0
18	4.0		130.0
19	4.0		134.0
20	4.0		138.0
21	4.0		142.0
22	4.0	0.8	146.0
23	4.0		150.0
24	8.0		158.0
25	8.0	1.2	166.0
26	8.0	1.3	174.0
27	10.0	1.4	184.0
28	10.0		194.0
29	10.0	1.5	204.0
30	10.0		214.0
31	10.0	1.5	224.0
32	3.5		227.5
33	3.5	0.7	231.0
34	3.5		234.5
35	3.5		238.0
36	3.5		241.5
37	3.5		245.0

Time [hr]	Rate [ml/h]	Fet [%]	Total [ml]
38	3.5		248.5
39	3.5		252.0
40	3.5		255.5
41	3.5		259.0
42	3.5		262.5
43	3.5		266.0
44	3.5		269.5
45	3.5		273.0
46	3.5	0.7	276.5
47	3.5		280.0
48	12.0		292.0
49	12.0		304.0
50	12.0		316.0
51	12.0	1.7	328.0
52	12.0		340.0
53	12.0		352.0
54	12.0		364.0
55	12.0		376.0
56	3.0		379.0
57	3.0	0.7	382.0
58	3.0		385.0
59	3.0		388.0
60	3.0		391.0
61	3.0		394.0
62	3.0		397.0
63	3.0		400.0
64	3.0		403.0
65	3.0		406.0
66	3.0		409.0
67	3.0		412.0
68	3.0		415.0
69	3.0		418.0
70	3.0	0.6	421.0
71	3.0		424.0
72	15.0	1.8	439.0
73	15.0	1.9	454.0
74	15.0		469.0

Document Title	Revision	Pages
Viamed H-Line 72hr Compatibility Test Report (Additional Data)	01	Page 6 of 7

Table 4 – Isoflurane Test Data 72hrs

Time [hr]	Rate [ml/h]	Fet [%]	Total [ml]
0	3.5	1.2	3.5
1	3.5		7.0
2	3.5		10.5
3	3.5		14.0
4	3.5		17.5
5	3.5		21.0
6	3.5	1.1	24.5
7	3.5		28.0
8	3.5		31.5
9	3.5		35.0
10	3.5		38.5
11	3.5		42.0
12	3.5		45.5
13	3.5		49.0
14	3.5		52.5
15	3.5	1.1	56.0
16	7.0		63.0
17	7.0	1.5	70.0
18	7.0		77.0
19	7.0		84.0
20	7.0		91.0
21	7.0		98.0
22	7.0		105.0
23	7.0	1.6	112.0
24	3.5		115.5
25	3.5	0.9	119.0
26	3.5		122.5
27	3.5		126.0
28	3.5		129.5
29	3.5		133.0
30	3.5		136.5
31	3.5		140.0
32	3.5	0.9	143.5
33	3.5		147.0
34	3.5		150.5
35	3.5		154.0
36	3.5		157.5
37	3.5		161.0

Time [hr]	Rate [ml/h]	Fet [%]	Total [ml]
38	3.5		164.5
39	3.5	0.9	168.0
40	7.0		175.0
41	7.0		182.0
42	7.0		189.0
43	7.0	1.4	196.0
44	7.0		203.0
45	7.0		210.0
46	7.0		217.0
47	7.0	1.5	224.0
48	3.5		227.5
49	3.5	1.0	231.0
50	3.5		234.5
51	3.5		238.0
52	3.5		241.5
53	3.5		245.0
54	3.5		248.5
55	3.5		252.0
56	3.5		255.5
57	3.5		259.0
58	3.5		262.5
59	3.5		266.0
60	3.5		269.5
61	3.5		273.0
62	3.5		276.5
63	3.5	0.9	280.0
64	7.0		287.0
65	7.0		294.0
66	7.0		301.0
67	7.0	1.7	308.0
68	7.0		315.0
69	7.0		322.0
70	7.0		329.0
71	7.0		336.0
72	7.0		343.0
73	7.0	1.6	350.0

Document Title	Revision	Pages
Viamed H-Line 72hr Compatibility Test Report (Additional Data)	01	Page 7 of 7

7. Conclusion

The data and observations made during this analysis, combined with previous compatibility test reports (24hrs in 2021 and 72hrs in 2023), indicates that the Viamed H-Line can be approved for use up to 72hrs with Sedaconda®ACD and relevant volatile anaesthetics, isoflurane and sevoflurane.

	Start	Finish	Signature
Isoflurane:	05/02/2024 (at 17:00)	08/02/2024 (at 18:00)	<i>Lyes D.</i>
Sevoflurane:	28/02/2024 (at 10:00)	02/03/2024 (at 12:00)	<i>Lyes D.</i>

Written by:	Lyes Djennadi R&D Engineer	<i>Lyes D.</i>
Approved by:	Harry Hennessy Senior R&D Engineer	<i>Harry Hennessy</i>