

Connection Points Between the APM-Plus™ and Respironics V60 Ventilator

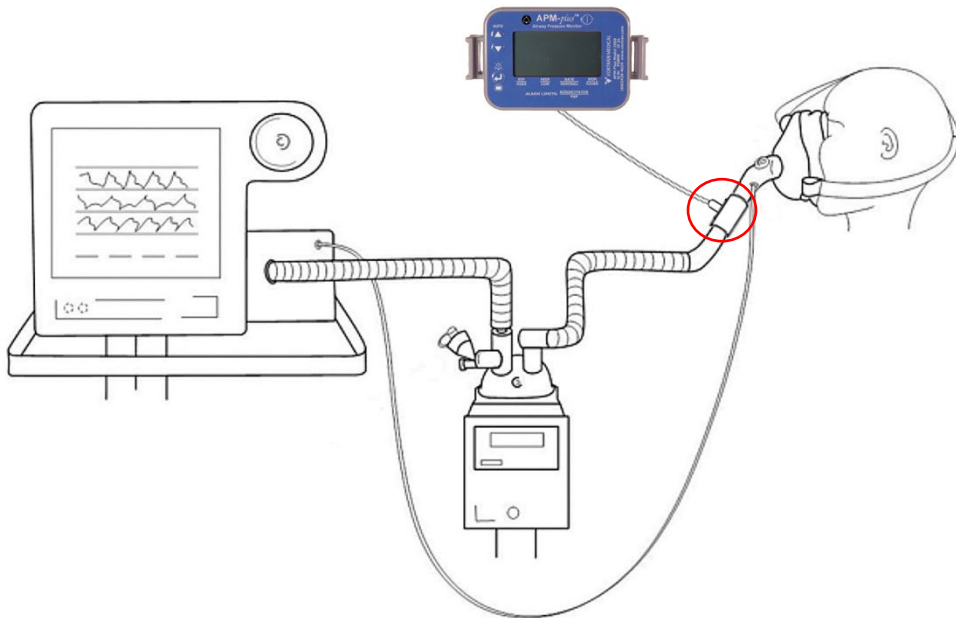
Devices:

- VORTRAN APM-Plus™ Model 3960
- Respironics V60 Ventilator

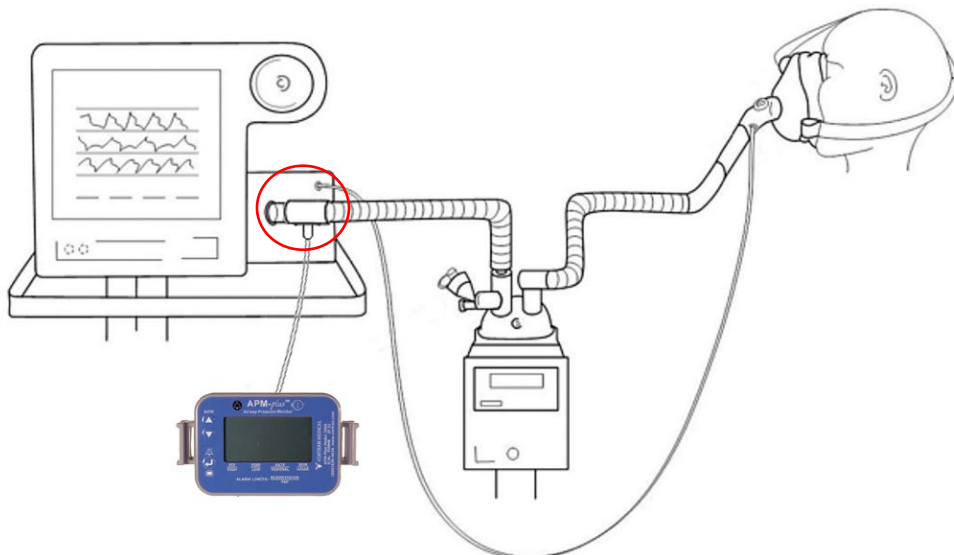
Overview:

- Use the APM-Plus to monitor ventilatory parameters & provide audible backup alarms.
- The VORTRAN APM-Plus will detect any failures within the circuit that may cause the patient to stop receiving breaths.

Position #1 – Patient proximal position: This will provide the most accurate results of any leakage rates while allowing easy connection using our 22mm tee adapter.



Position #2 – Proximal to V60 outlet: If intending to only use the APM-Plus's Non-Cycling Alarm (to detect circuit disconnects or ventilator failures), this option allows for easy connection using our 22mm tee adapter without having to connect near the patient interface.



Note: Please be aware that large circuit leaks will cause the V60 to generate a flow increase to compensate. In Position 2 the APM-Plus may detect local pressure spikes that may not occur in the patient proximal position (Position 1).

V60 and APM-Plus Connection and Volume Evaluation

Prepared By:	Nam Nguyen Mechanical Engineer	<u>Nam Nguyen</u> Date: 5/18/2022
Pre-Test Protocol Review:	Reza Saied Vice President of Engineering & Regulatory Affairs	<u>Reza Saied</u> Date: 5/18/2022
Tested By:	Nam Nguyen Mechanical Engineer	<u>Nam Nguyen</u> Date: 5/18/2022
Reviewed By:	Adam Palumbo Vice President of Engineering & Technical Marketing	<u>Adam Palumbo</u> Date: 5/19/2022
Approved By:	James Lee, MBA Executive VP & COO	<u>James Lee</u> Date: May 19, 2022

1.0 Objective

- 1.1 To determine the differences in accuracy of data and alarming conditions of the APM-Plus when it is attached to the breathing circuit of the Respironics V60 ventilator.
- 1.2 Three APM-Plus will be connected at 3 separate points. We will also verify and compare the alarm volume levels of the APM-Plus with respect to the Respironics V60 ventilator.

2.0 Scope

- 2.1 The information gathered will be used to determine the optimal connection point for the APM-Plus to the V60 breathing circuit.

3.0 References

- 3.1 Respironics V60 Ventilator User Manual 1047358 Rev C
- 3.2 3970 Rev. B3 – VORTRAN APM-Plus Instructions for Use

4.0 Equipment

- 4.1 Respironics V60 ventilator
- 4.2 Fisher & Paykel #RT219 - RT-Series Ventilator Circuit Expandable Tube 60 Inch Tube Adult Without Bag Single Patient Use Heated Circuit
- 4.3 Noninvasive ventilation Mask
- 4.4 3 units of APM-Plus (PN3960)
- 4.5 Sound level meter (E-057)

5.0 Testing Procedure - Accuracy

- 5.1** Connect 3 different APM-Plus units at 3 different locations on the circuit of the V60 as shown in Diagram 5.1.
- 5.1.1** APM-Plus #1 to be connected with a 3-way tee proximal to the V60 pressure line port, cut approximately 2 inches from the beginning of the pressure line for tee placement. (Diagram 5.1 - APM-Plus #1)
- 5.1.2** APM-Plus #2 to be connected proximal to the V60 outlet. (Diagram 5.1 - APM-Plus #2)
- 5.1.3** APM-Plus #3 to be connected proximal to the patient's mask. (Diagram 5.1 - APM-Plus #3)

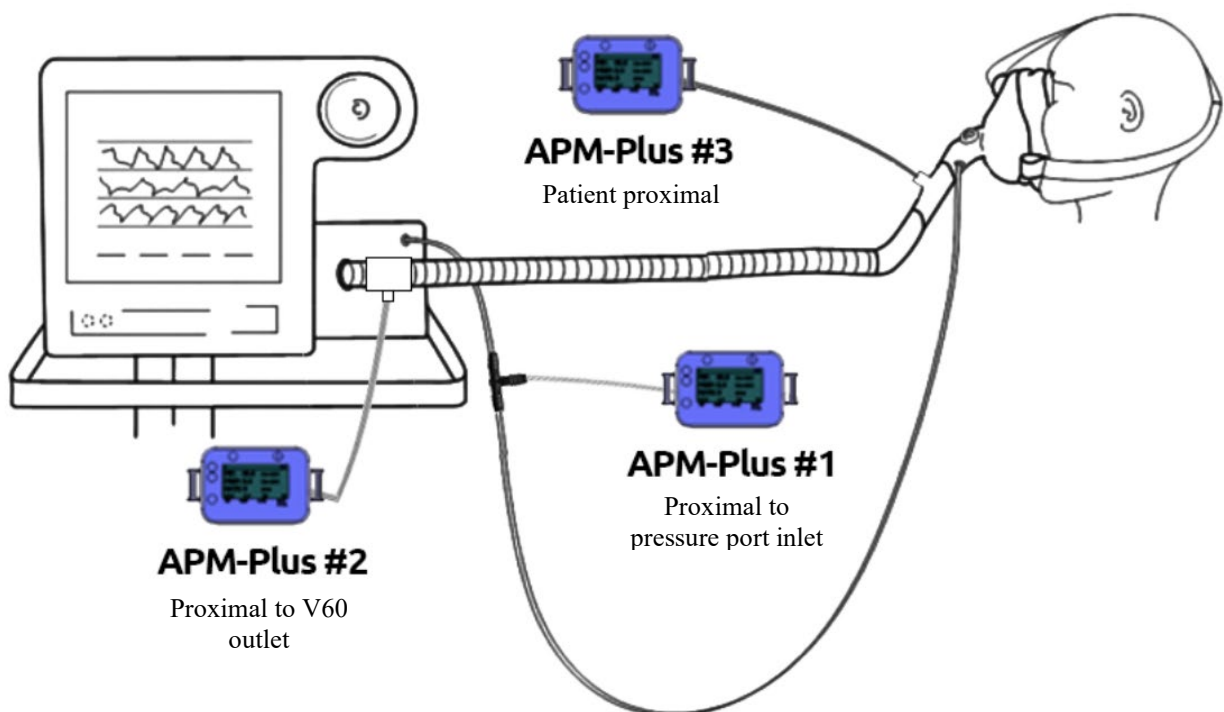


Diagram 5.1: Different connection points for the 3 APM-Plus units. Refer to photos on Page 6.

- 5.2** Make sure the rate is set to 12 then, set the IPAP at 10 and EPAP at 4 on the V60 and record the readings on each of the APM-Plus and fill out Table 7.1.
- 5.2.1** Repeat 5.2 three times and fill out table 7.1.
- 5.3** Make sure the rate is set to 12 then, set the IPAP at 14 and EPAP at 8 on the V60 and record the readings on each of the APM-Plus and fill out Table 7.2.
- 5.3.1** Repeat 5.3 three times and fill out table 7.2.
- 5.4** Make sure the rate is set to 12 then, set the IPAP at 18 and EPAP at 12 on the V60 and record the readings on each of the APM-Plus and fill out Table 7.3.
- 5.4.1** Repeat 5.4 three times and fill out table 7.3.

5.5 Make sure the rate is set to 12, then set the IPAP at 22 and EPAP at 16 on the V60 and record the readings on each of the APM-Plus and fill out Table 7.4.

5.5.1 Repeat 5.5 three times and fill out table 7.4.

6.0 Testing Procedure – Volume Level of Alarm

- 6.1 Place the decibel meter (E-057) 1 meter from the front of the APM-Plus. Measure the sound level and record the decibels on Table 7.5.
- 6.2 Place the decibel meter (E-057) 1 meter from the back of the APM-Plus so that it is directly at the speaker. Measure the sound level and record the decibels on Table 7.5.
- 6.3 Set the loudness on the Respironics V60 Ventilator to Level 1. Using a tape measure, place the decibel meter (E-057) 1 meter from the Respironics V60 Ventilator. Measure the sound level and record the decibels on Table 7.5.
- 6.4 Set the loudness on the Respironics V60 Ventilator to Level 5. Using a tape measure, place the decibel meter (E-057) 1 meter from the Respironics V60 Ventilator. Measure the sound level and record the decibels on Table 7.5.
- 6.5 Set the loudness on the Respironics V60 Ventilator to Level 10. Using a tape measure, place the decibel meter (E-057) 1 meter from the Respironics V60 Ventilator. Measure the sound level and record the decibels on Table 7.5.

7.0 Results

7.1 Accuracy

**Table 7.1: Reading on V60 with IPAP at 10, EPAP at 4
Setting on V60: IPAP at 10, EPAP at 4**

	V60	APM-Plus #1			APM-Plus #2			APM-Plus #3		
		Reading 1	Reading 2	Reading 3	Reading 1	Reading 2	Reading 3	Reading 1	Reading 2	Reading 3
PIP	10	9	9	10	10	10	10	9	9	9
PEEP	4	4	4	4	4	4	4	3	3	3
RATE	12	12	12	12	12	12	12	12	12	12

Table 7.2: Reading on V60 with IPAP at 14, EPAP at 8 Setting on V60: IPAP at 14, EPAP at 8										
	V60	APM-Plus #1			APM-Plus #2			APM-Plus #3		
		Reading 1	Reading 2	Reading 3	Reading 1	Reading 2	Reading 3	Reading 1	Reading 2	Reading 3
PIP	14	13	13	13	14	14	14	13	13	13
PEEP	8	7	7	7	8	8	8	7	7	7
RATE	12	12	12	12	12	12	12	12	12	12

Table 7.3: Reading on V60 with IPAP at 18, EPAP at 12 Setting on V60: IPAP at 18, EPAP at 12										
	V60	APM-Plus #1			APM-Plus #2			APM-Plus #3		
		Reading 1	Reading 2	Reading 3	Reading 1	Reading 2	Reading 3	Reading 1	Reading 2	Reading 3
PIP	18	17	17	17	18	18	18	17	17	17
PEEP	12	11	11	11	12	12	12	11	11	11
RATE	12	12	12	12	12	12	12	12	12	12

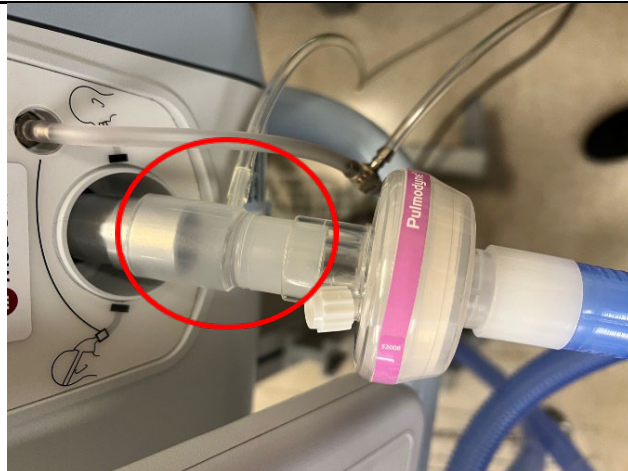
Table 7.4: Reading on V60 with IPAP at 22, EPAP at 16 Setting on V60: IPAP at 22, EPAP at 16										
	V60	APM-Plus #1			APM-Plus #2			APM-Plus #3		
		Reading 1	Reading 2	Reading 3	Reading 1	Reading 2	Reading 3	Reading 1	Reading 2	Reading 3
PIP	22	21	21	21	22	22	22	21	21	21
PEEP	16	15	15	15	16	16	16	15	15	15
RATE	12	12	12	12	12	12	12	12	12	12

Photos of Different Connection Points for the 3 APM-Plus Units (Diagram 5.1)

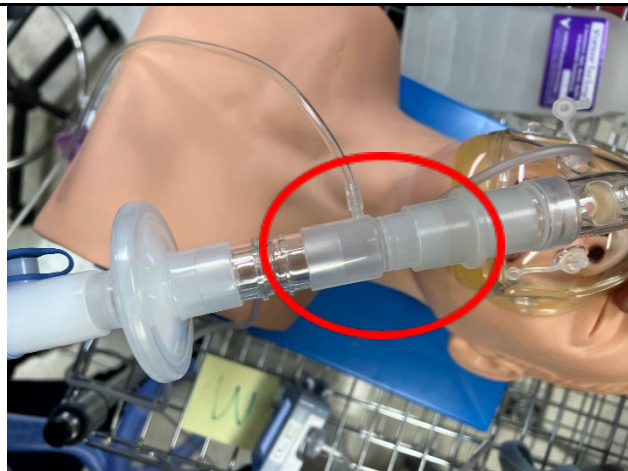
Setup for APM-Plus #1 – 2 inches from pressure port of V60



Setup for APM-Plus #2 – V60 Outlet



Setup for APM-Plus #3 – Patient Proximal



7.2 Volume Level of Alarm

Table 7.5: Volume recorded

<i>Device</i>	<i>Distance</i>	<i>Specification</i>	<i>Decibels (dB)</i>
APM-Plus	1 meter	Front of APM-Plus	67
APM-Plus	1 meter	Back of APM-Plus (Directly at speaker)	68
V60	1 meter	Level 1 Loudness (Min)	68
V60	1 meter	Level 5 Loudness (Mid)	74
V60	1 meter	Level 10 Loudness (Max)	85

8.0 Conclusion

- 8.1** Simulating an ideal scenario with minimal leaks, the 3 APM-Plus units performed within a range of 1 cm-H₂O difference with the V60. There were no deviations in respiratory rates among any readings of the APM-Plus and the V60.
- 8.2** Although APM-Plus #1 performs accurately (V60 pressure inlet position), it would require a third-party adapter to tee the APM-Plus into the existing pressure line; therefore, this location is not recommended.
- 8.3** The patient proximal position will produce the most accurate pressure readings at all leakage rates compared to the V60 outlet position.
- 8.4** If intending to mainly use the APM-Plus's Non-Cycling Alarm (to detect circuit disconnects or ventilator failures), the V60 outlet position (APM-Plus #2) provides ease of connection without having to connect near the patient interface. It must be noted that if there is a large leak, the V60 will generate extra flow to compensate; the APM-Plus may measure local pressure spikes when connected proximal to the V60 outlet that are not seen in the patient proximal position (APM-Plus #3) or at the pressure port inlet position (APM-Plus #1). Pressure accuracy at the V60 outlet will resume when leaks are corrected.
- 8.5** The volume on the APM-Plus when the back is facing front (directly at speaker) has the same decibel level as the V60 at level 1 loudness, both at 68 dB. The V60 has options to increase the volume; therefore, when the V60 is turned up to maximum volume, the V60 is louder than the APM-Plus by 18 dB. Please note that for this protocol, the main objective is comparing the relative difference in volume between the APM-Plus and the V60 rather than establishing an accurate specification level for the volume at 1 meter.

9.0 Process Deviation

- 9.1** There were no process deviations during the execution of this protocol.