AEOMED 谊安

VG70 technical analysis and verification of the manual altitude compensation

Author/Date: Fish 2020.12.7

Checked/Date: Changlynn 2020.12.7

Approved/Date: Bin 2020.12.7

1. How does BTPS flow transform?

When converting between different standard flows, you need to know the atmospheric pressure and temperature of your current environment. Since there is no atmospheric pressure sensor inside the ventilator, the user needs to manually input the altitude, and then the ambient atmospheric pressure is determined by the corresponding relationship between altitude and atmospheric pressure.

This ventilator uses a mass flow sensor at the suction end, and its output velocity is the volume flow at standard atmospheric pressure (1013mbr) at 21 degrees Celsius. The differential pressure sensor is used at the expiratory end to measure the flow, and need to verify it at the local area.

1.1 The corresponding relationship of atmospheric pressure and altitude

The operating range of this device is 0~3000 meters, and the corresponding relationship between atmospheric pressure and altitude within this range is shown in Table 1.

Table 1 Altitude corresponds to atmospheric pressure

Altitude (m)	0	250	425	500	750	1500	2250	3000
Atmospheric pressure (mBar)	1013	984	966	958	925	842	766	697

According to the data in the table, the line formula can be fitted as follows:

$$\mathrm{Pa}_{\mathrm{current}} = -0.1065 \cdot Altitude_{input} + 1009.3 \qquad (1)$$

$\mathrm{Altitude}_{\mathrm{input}}$ represents the altitude of the input, $\mathrm{Pa}_{\mathrm{current}}$ is the value of atmospheric pressure. The ventilator converts the user's input altitude into local atmospheric pressure according to formula 1.

1.2 Suction flow (FI) handling

The volume flow obtained by the suction mass flow sensor is referred to as standard atmospheric pressure (1013mbr) at 21℃, which needs to be converted into a volume flow under a user-specified standard, namely $\mathrm{FI}_{\mathrm{ATPS}}$ or $\mathrm{FI}_{\mathrm{BTPS}}$, using the conversion formulas (2) and (3).

$$FI_{ATPS} = \frac{Pa_{standard}}{Pa_{current} - P_{Tcurrent,\ S,H2O}} \times \frac{273+T_{current}}{273+21} \times FI_{STPD} \qquad (2)$$

$$FI_{BTPS} = \frac{Pa_{standard}}{Pa_{current} - P_{37,\ S,H2O}} \times \frac{273+37}{273+21} \times FI_{STPD} \qquad (3)$$

FI_{STPD} represents the volume flow of dry gas as standard atmosphere（Pastandard=1013mbr）at 21℃； FI_{ATPS} represents the volume flow of saturated humidity as current atmospheric pressure at current temperature； FI_{BTPS} represents the volume flow of saturated humidity as current atmospheric pressure at 37 ℃. $P_{T,S,H2O}$ represents the partial pressure of vapor saturation at T ℃. The partial pressure of vapor saturation is only affected by temperature（$P_{T,S,H2O}$ at current temperature is obtained by looking up table, see table 2）

Table 2 Water vapor saturation partial pressure - temperature contrast table

Temperature (℃)	Partial pressure (mbar)	Temperature (℃)	Partial pressure (mbar)	Temperature (℃)	Partial pressure (mbar)	Temperature (℃)	Partial pressure (mbar)
0	6.1	10	12.2	20	23.3	30	42.4
1	6.6	11	13.1	21	24.9	31	44.9
2	7.1	12	14.1	22	26.4	32	47.5
3	7.6	13	15.0	23	28.1	33	50.3
4	8.1	14	16.0	24	29.8	34	53.2
5	8.7	15	17.0	25	31.7	35	55.2
6	9.3	16	18.1	26	33.6	36	59.4
7	10.0	17	19.3	27	35.6	37	62.7
8	10.7	18	20.6	28	37.7	38	65.2
9	11.5	19	22.0	29	40.0	39	70.0

1.3 Expiratory flow（FE）handling

The ventilator out memory has a set of differential pressure flow sensor output voltage and the corresponding relationship between volume flow calibration environment, this is a corresponding relationship from the suction end mass flow sensor calibration, in the practice, due to changes in the environment (mainly is the atmospheric pressure and temperature caused the gas density change) need to expiratory flow sensor calibration. See 6.2.1.4 of the “Instruction for use” for the calibration process.

2. Analysis of the impact of weather changes on device

2.1 The influence of weather on atmospheric pressure

The factors that affect atmospheric pressure are mainly altitude and weather. The influencing factors of altitude are shown in Table 1. The daily variation amplitude of atmospheric pressure affected by weather in the same region is as follows: 3~5 mbar in tropical region, 1~3 mbar in temperate region, and less than 1 mbar in high latitude region. Except in the case of extreme weather anomalies, pressure fluctuations rarely exceed 33.86 mbar[1].

2.2 Influence of atmospheric pressure fluctuation in the same area on measurement error:

According to the above formulas (2) and (3), the higher the altitude is, the greater the measurement deviation will be. This report analyzes the volume flow deviation at an altitude of 3000 m， P_{3000} =697 mbar，T = 37℃. According to formula (3), the output flow velocity of the ventilator is:

$$\mathrm{FI}_{BTPS} = \frac{1013}{697-62.7} \times \frac{273+37}{273+21} \times \mathrm{FI}_{STPD} = 1.684\mathrm{FI}_{STPD} \qquad (4)$$

If atmospheric pressure rises 33.86 mbar in extreme cases, the actual volume flow rate is:

$$\mathrm{FI}_{BTPS1} = \frac{1013}{(697+33.86)-62.7} \times \frac{273+37}{273+21} \times \mathrm{FI}_{STPD} = 1.599\mathrm{FI}_{STPD} \qquad (5)$$

In extreme cases, atmospheric pressure drops by 33.86 mbar, and the actual volume flow rate is:

$$\mathrm{FI}_{BTPS2} = \frac{1013}{(697-33.86)-62.7} \times \frac{273+37}{273+21} \times \mathrm{FI}_{STPD} = 1.779\mathrm{FI}_{STPD} \qquad (6)$$

As known above, when the pressure rises 33.86 mbar, the flow velocity error is:

$$\Delta\mathrm{F1} = \frac{1.684\mathrm{FI}_{STPD} - 1.599\mathrm{FI}_{STPD}}{1.599\mathrm{FI}_{STPD}} \times 100\% = 5.31\% \qquad (7)$$

When the pressure drops 33.86 mbar, the flow velocity error is:

$$\Delta\mathrm{F2} = \frac{1.684\mathrm{FI}_{STPD} - 1.779\mathrm{FI}_{STPD}}{1779\mathrm{FI}_{STPD}} \times 100\% = -5.34\% \qquad (8)$$

The above is the error value calculated in the worst case. According to formula (7) and (8), it can be known that the BTPS volume flow error in the extreme case is around 5.3%, and the ATPS flow rate is close to it. In fact, the pressure fluctuation of 3000 meters above sea level cannot be so large. In addition, the ventilator is mainly used in ICU, so the environment is relatively stable and atmospheric pressure will not fluctuate greatly. Therefore, the actual performance is much better than what we theoretically predict.

Experiments showed that fluctuations in atmospheric pressure due to weather conditions had an effect on volumetric flow, but were within the error range as described in the “RD-BNP-M4-045 VG70 Altitude Test Report”.

3 ISO 80601-2-12：2011 Gas flowrates and leakage specifications

201.5.101.2 * Gas flowrate and leakage specifications

All requirements for gas flowrate, volume and leakage in this standard are expressed at STPD except for those associated with the VBS, which are expressed at BTPS.

NOTE 1 For the purposes of this standard, STPD (standard temperature and pressure dry) is 101,3 kPa at an operating temperature of 20 °C.

NOTE 2 For the purposes of this standard, BTPS (body temperature and pressure saturated) is local atmospheric pressure and a relative humidity of 100 % at an operating temperature of 37 °C.

Correct all test measurements to STPD or BTPS, as appropriate.

201.12.1.103 * DELIVERED VOLUME MONITORING

If the VENTILATOR is equipped with DELIVERED VOLUME MONITORING EQUIPMENT, the accuracy of the DELIVERED VOLUME MONITORING EQUIPMENT shall be disclosed in the instructions for use. For actual DELIVERED VOLUMES greater than 50 ml, the accuracy of the DELIVERED VOLUME MONITORING EQUIPMENT shall be within ± (4,0 ml + 15 % of the actual DELIVERED VOLUME).

4 This ventilator is in conformity with ISO 80601-2-12:2011

For the above gas flowrates and leakage specifications, the volume flow rate of STPD or BTPS shall be measured. For the volume flow of STPD, it has nothing to do with external conditions such as atmospheric pressure, and this scheme does not affect the test results. The BTPS volumetric flow analysis is also within the error range.

ISO 80601-2-12 has a tidal volume requirement of ± (4Ml+15% true value). According to experimental verification, after manually entering altitude compensation, the simulation of weather influencing factors can meet the requirements of ISO 80601-2-12:20:11 standard.

【1】 http://www.barometricpressureheadache.com/barometric-pressure-and-weather-conditions

Range of Barometric Pressure on Earth

Refer to Barometer Calibration

Average Sea-Level pressure:
101.325 kPa /1013.25 mbar / 760 mmHg / 29.921 inHg

Pressures seldom increase or decrease 1 inch of mercury (3.386 kPa /33.86 mbar / 25 mmHg) above or below the 30 inch mark (101.591kPa / 1015.91 mbar / 762 mmHg) unless weather conditions are extreme.

Typical readings that would provide a reasonable forecast for 12-24 hrs ahead:

READING	RISING OR STEADY	SLOWLY FALLING	RAPIDLY FALLING
OVER 102.269 kPa /1022.69 mbar /767 mmHg /30.20 inHg	Continued fair	Fair	Cloudy, Warmer
BETWEEN 102.269 kPa /1022.69 mbar /767 mmHg /30.20 inHg AND 100.914 kPa / 1009.14 mbar/757 mmHg / 29.80 inHg	Same as present	Little change	Precipitation likely
UNDER 100.914 kPa / 1009.14 mbar /757 mmHg / 29.80 inHg	Clearing, cooler	Precipitation	Storm