MADVent Mark V OPERATING INSTRUCTIONS

The **MADVent Mark V** is a single-mode continuous, mandatory, closed-loop pressure controlled time-terminated emergency ventilator meant for sedated, intubated patients being cared for in a professional healthcare facility **only**. It employs an FDA-recognized single-use and disposable, automatically self-inflating manual ("ambu") ventilator bag with attached positive end-expiratory pressure (PEEP) valve.

1. *Method for checking the function of the alarm system by healthcare professional operator*

All alarm system checks are performed automatically during start-up.

The healthcare professional operator is only responsible for (1) reading the LED label adjacent any active alarm indicators and for (2) reading the LCD screen that will further indicate which alarm has been triggered.

2. *Uncertainty for each disclosed tolerance*

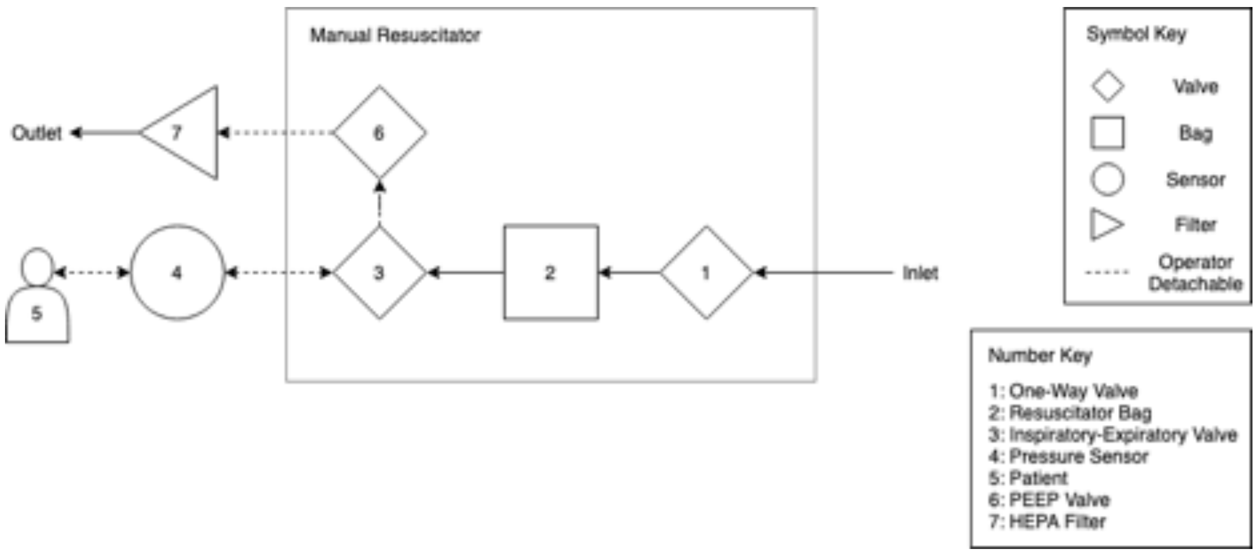
The measurement uncertainty for each disclosed tolerance is +/-5% in accordance with **ISO 80601-2-12:2020,** except as follows:

The Honeywell SSCMRRN060NDSA5 pressure measurement sensor measurement uncertainty is +/- 2%. The Bosch BMP180 pressure measurement sensor measurement uncertainty is +/- 0.12 cm H2O.

All time measurements are accurate to within 1000 ppm.

Motor rotation measurements are accurate to within 0.9 degrees.

3. *Pneumatic diagram of the ventilator*



4. *Summary description of the filtering or smoothing techniques for all measured or computer variables that are displayed or used for control*

There are two equivalent sensor configurations: (1) Two Bosch BMP180 pressure sensors, one measuring ambient air pressure and the other measuring inline ventilator pressure. (2) A single Honeywell SSCMRRN060NDSA5 differential pressure sensor that measures the differential pressure between ambient air pressure and the other measuring inline ventilator pressure. These sensors have been manufactured to comply with ISO 9001 and are suggested for use in medical devices, including ventilators.

The system reads raw data from the Bosch BMP180 every 3 ms for 30 ms and takes the average value. That average value is input into an algorithm provided by Bosch (see “Figure 4” below taken directly from the Bosch datasheet) to provide a pressure value in Pascals. The **Mark V** software converts this to cm H2O as 98 Pa = 1 cm H2O.

When the Honeywell SSCMRRN060NDSA5 is incorporated, the system will again read data every 3 ms for 30 ms and take the average value. However, this sensor has a built-in *Application Specific Integrated Circuit* (ASIC) that performs a calibration before it is read by the system. This calibration consists of calculating the “Pressure” based on the “Output” of the sensor via Equation 1 below (taken from Honeywell documentation) for each port and then subtracting a known zero-level stored on the ASIC for each port in order to get a corrected pressure in mbar. The **Mark V** software then converts 1 mbar = 1.02 cm H2O.

In both cases, during start-up the system will check that the difference between ambient and inline measurements is less than or equal to 50 Pa. If not, the LED corresponding to the pressure sensor will flash red and the LCD will display "Pressure Read Error".

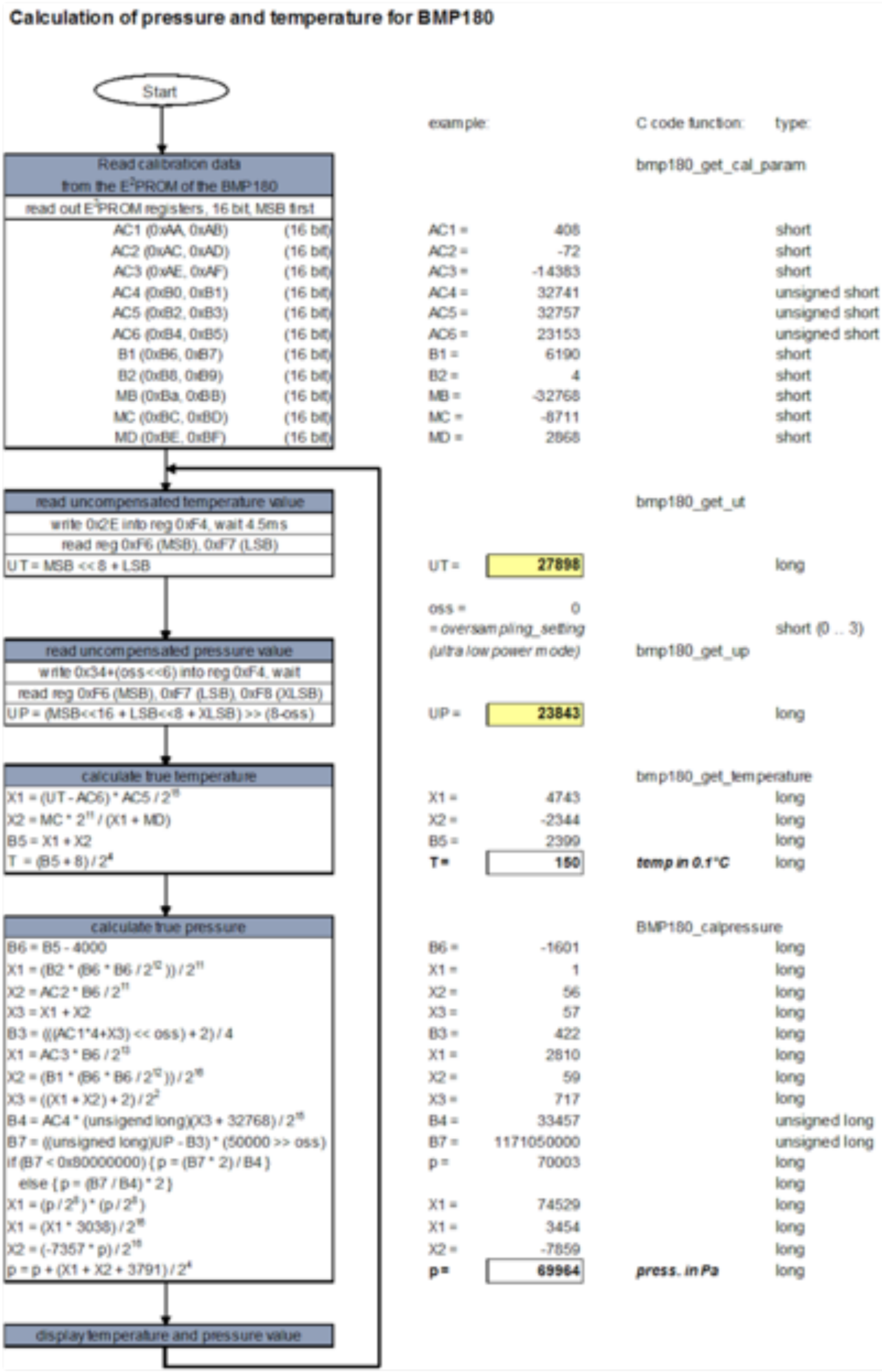


Figure 4: Algorithm for pressure and temperature measurement

Equation 1:

$$\text{Output} = \frac{\text{Output}_{max.} - \text{Output}_{min.}}{P_{max.} - P_{min.}} * (\text{Pressure} - P_{min.}) + \text{Output}_{min.}$$

where:

Output =	Pressure reading from the sensor [Volts, %2^{16} counts, %Vs, etc.]
$\text{Output}_{min.}$ =	Ideal output at minimum pressure [Volts, %2^{16} counts, %Vs, etc.]
$\text{Output}_{max.}$ =	Ideal output at maximum pressure [Volts, %2^{16} counts, %Vs, etc.]
$P_{min.}$ =	Minimum operating pressure [bar, mbar, psi, kPa, etc.]
$P_{max.}$ =	Maximum operating pressure [bar, mbar, psi, kPa, etc.]

5. *Summary description of the means of initiating and terminating the inflation phase in each ventilation mode of the ventilator*

The pressure-controlled mode of the ventilator takes input from a healthcare professional operator in setting a target pressure, inspiration time, and respiratory rate.

When inspiration begins the **MADVent Mark V** uses a differential pressure sensor to continuously monitor the inline pressure. The ideal inspiratory pressure is defined by a piecewise-linear profile, normalized by percentages such that at T=0, P=0, and at T=100, P=100 (see plot below). At each timestep in the inspiration cycle, the inline pressure is measured and the current time is computed as a percentage of the total inspiration time.

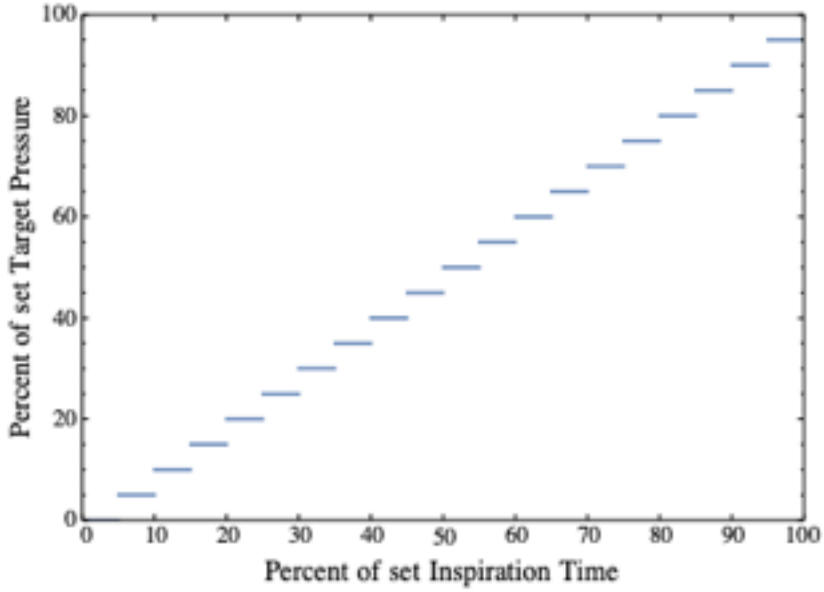
The target pressure (percentage) for that time is linearly interpolated from the ideal profile, then scaled by the peak pressure set by the operator.

The motor is then turned an angular amount proportional to the difference between the measured pressure and the target pressure. If the measured pressure is greater than the target, the motor is not moved.

Once the target peak pressure is reached or the inspiratory time limit is reached, the **MADVent Mark V** ceases compression of the bag ending the inspiration phase.

If the peak pressure was reached early, the proportionality constant is reduced by a fixed amount to discourage overshoot on the next cycle. If the inspiration time limit finishes without reaching the target peak pressure, the proportionality constant is increased to encourage tighter tracking on the next cycle.

Exhalation occurs passively at the natural rate of the patient. The next inspiration phase is then triggered by a timer such that the respiratory rate condition is met.


Percent of set Target Pressure
Percent of set Inspiration Time
0
20
40
60
80
100
0
10
20
30
40
50
60
70
80
90
100