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Monitoring and Alarm system for the use of VPAP ST as an invasive bi-level ventilator

Operating Instructions: Configuring a GE CARESCAPE B450 into a Standalone Ventilator Monitor and Alarm System

Standalone Low-Pressure Alarm Primer

Advisory on the Use of ResMed VPAP ST

(ResMed, Australia; ResMed USA, San Diego)

Because of an automatic shut-off feature in the ResMed bilevel (S9 VPAP™ and AirCurve™), these devices should NOT be used for invasive ventilation without additional modification to the circuit unless no other options exist.

The ResMed VPAP™ ST is designed to be a *noninvasive* ventilator. Incorporation of supplemental oxygen at > 15 l/min into the circuit anywhere distal to the blower should be undertaken with extreme caution and only after modifying the circuit with a second exhalation valve close to the blower and proximal to the O_2 bleed in.

At a set CPAP or EPAP > 10 cmH_2O, oxygen flows > 15 l/min in a circuit with a single standard exhalation port can result in an unanticipated device shut-off and patient harm. This shut-off does not occur at EPAP ≤ 10 cmH_2O or when O_2 flow < 15 l/min.

At supplemental oxygen flows of 15 l/min, the maximum achievable FiO_2 will be no higher than 60%. If a patient requires FiO_2 > 60% or PEEP > 10 cmH_2O, the circuit must be modified with the addition of a second exhalation port, or the use of another brand of bilevel or a conventional invasive ventilator should be considered.

Exercise extreme caution when EPAP requirements exceed 10 cmH_2O and FiO_2 requirements exceed 60% unless 2 exhalation ports are used!

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Monitoring and Alarm system for the use of VPAP ST as an invasive bi-level ventilator

Version 3.0 [Apr 24 2020]

Mount Sinai Health System

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For additional information and associated documents, please see below links:
Primer - Theory and Background for Bilevel Repurposing
Protocol - Repurposing of Bilevel Devices for Invasive Ventilation
Clinical Guidelines / Operating Checklist - Philips Respironics Devices
Clinical Guidelines / Operating Checklist - ResMed Devices
Monitoring and Alarm Guidelines / Construction
Construction of an Anesthesia Circuit Component Diagram
Construction of a Bilevel Circuit Component Diagram
Frequently Asked Questions

BACKGROUND

Many bilevel devices, including the ResMed VPAP™ ST, intrinsically lack audible alarms. In addition to standard ECG, SpO_2, and blood pressure monitoring per ICU protocol, intubated patients ventilated with any bilevel device **must** be connected to a dedicated external monitor with an audible alarm system that is capable of continuous pulse oximetry (SpO_2), end-tidal carbon dioxide ($EtCO_2$), and inspired oxygen concentration (FiO_2) monitoring. This system can provide crucial clinical data about the patient's physiologic state and alert providers of life-threatening events such as circuit disconnect or blockage, while limiting staff exposure to pathogens by reducing the need to enter the patient's room. Spirometric data obtained with specialized respiratory modules may provide additional information that can guide clinicians in optimizing ventilator settings.

MONITORING CONFIGURATION

A bilevel device preset has been configured in GE CARESCAPE™ B450 monitors to allow for ease of standardized monitoring among patients using the bilevel devices, including the ResMed VPAP™ ST. In the device-specific preset, alarms for SpO_2, $EtCO_2$, and FiO_2 are "locked in" to prevent alarm inactivation by practitioners. Alarm parameters can be individualized for each patient's unique ventilatory needs. Alarm max and min thresholds should be set within approximately 15% of the patient's ventilation parameters. A narrow alarm threshold range allows the monitor to detect not only mechanical insults to the circuit, but also patient-related events such as ventilator dyssynchrony, bronchospasm, or mucus plugging.

Table 1: Example alarm setting for a patient on bilevel S/T ventilation mode:

Parameter	**Value**	**Alarm min-max**
SpO_2	94%	*78% - 96%**
$EtCO_2$	50 mmHg	*42 mmHg – 60 mmHg*
FiO_2	50%	*35% - 75%*
Respiratory Rate (CO_2)	30 breaths/min	*25 - 45*
Respiratory Rate (Impedance)	30 breaths/min	*25 - 45***
Tidal volume (Insp and Exp)	300 ml	*255ml - 345ml*
Minute Ventilation	9 l/min	*7 l/min - 12 l/min*
PEEP	10 cmH_2O	*8 cmH_2O - 12 cmH_2O*
Peak pressure (P_{peak})	25 cmH_2O	*21 cmH_2O - 29 cmH_2O****

*Target SpO_2 in patients with COVID-related lung injury should go no higher than 96%.
** Sensitivity for impedance-based respiratory rate should be set based on ECG electrode positioning and adjusted for body habitus and positioning. Sensitivity set to > 50% may lead to inaccurate data from excessive movement or capture of cardiac oscillations leading to miscounting.
*** This is unlikely to alarm because the IPAP is preset on the VPAP™ ST.

While this monitor setup closely approximates that of a typical invasive ventilator, it is not perfect. Although the monitor can detect abrupt changes in tidal volume, minute ventilation, PEEP, and peak pressure; GE's current firmware for the CARESCAPE™ B450 limits user configuration of priority and escalation times to hasten audible alarming, which can lead to adverse patient outcomes. Therefore, monitoring variables with **zero-second alarm delays**, such as SpO_2, $EtCO_2$, and FiO_2 should be prioritized. Spirometry monitoring as the *sole* monitoring modality for bilevel patients is **not recommended**.

Of note, redundant monitoring may provide an additional margin of safety in the event of equipment failure. For example, poor peripheral perfusion in critically ill patients can affect SpO_2 readings, in which case, a second sampling source may be preferred. In the event of respiratory module failure, a secondary source of airway pressure monitoring via a separate pressure transducer can serve as a backup alarm.

Figure 1: **Ventilator monitoring with a GE CARESCAPE™ B450 monitor fitted with the E-SCAiOV respiratory module and back up invasive airway pressure monitoring**

The screen is configured to display multiple spirometric variables, including a flow-volume loop, in real-time with audible alarms. A mean airway pressure, measured via a pressure transducer, is displayed on the bottom left corner. $EtCO_2$ will be displayed on the bottom row when the circuit is connected to a patient.

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Figure 2: GE E-SCAiOV respiratory module with a D-Fend Pro+ side-stream gas sampling and spirometry

Operating Instructions: Configuring a GE CARESCAPE B450 into a Standalone Ventilator Monitor and Alarm System

During the COVID-19 pandemic, numerous novel ventilator modalities have been proposed. While efforts to create freestanding ventilator alarms are in progress, the issue of patient monitoring and safety became a time-sensitive matter as these ventilator strategies are being urgently distributed and implemented worldwide. One of the solutions is to take a pre-existing, readily available monitor to convert into a standalone ventilator interface and alarm. At Mount Sinai Hospital, the GE CARESCAPE™ B450 Monitor (General Electric Healthcare, Waukesha WI) is widely used in the perioperative setting as an anesthesia monitor and for patient transport. The steps to convert the GE CARESCAPE™ B450 into a standalone ventilator monitor and alarm system are highlighted below.

This interface and alarm system is used assuming that the patient is already being separately monitored per unit protocol (e.g. BP, SpO_2, ECG, etc.).

Equipment

1. The GE CARESCAPE™ B450 monitor should have a CARESCAPE™ Patient Data Module (PDM) and E-sCAiOV respiratory modules. When possible, plug the GE CARESCAPE™ B450 into an AC outlet. When unplugged, the monitor's 2 lithium-ion batteries can provide up to 1-2 hours of operating time each when fully charged.

Figure 1. GE CARESCAPE ™ B450 monitor. It can be mounted on a rollaway stand or placed on a sturdy surface (e.g. Mayo stand).

Figure 2. The GE E-sCAiOV respiratory module for gas sampling and spirometry monitoring.

Figure 3. The back of the GE CARESCAPE™ B450 with the CARESCAPE PDM for vital signs, including invasive pressures. The E-sCAiOV module is also attached.

1. **Setup**
   On the touchscreen, press the UPPER RIGHT CORNER to open the "Case Setup" window. Under the "Patient" tab, the following should appear:

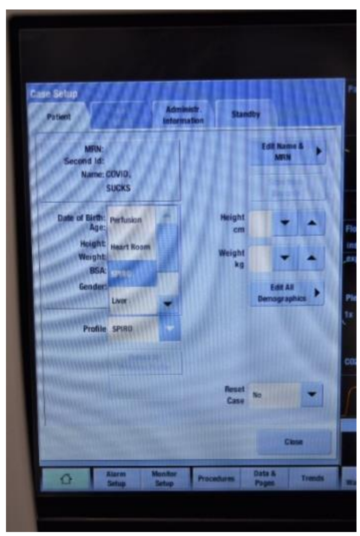

Figure 4. "Case Setup" window with "SPIRO" preset selected.

The "SPIRO" preset was created for the purposes of ventilator monitoring at Mount Sinai Hospital and configured for every GE CARESCAPE™ B450 monitor assigned for this task. In the event the preset is not available, this can be manually configured in the following manner:

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- Select "Monitor Setup" in the BOTTOM LEFT CORNER of the screen.
- Activate the following parameters with waveform:
  - Paw
  - Flow
  - SpO_2
  - $EtCO_2$
  - P1 Art 1

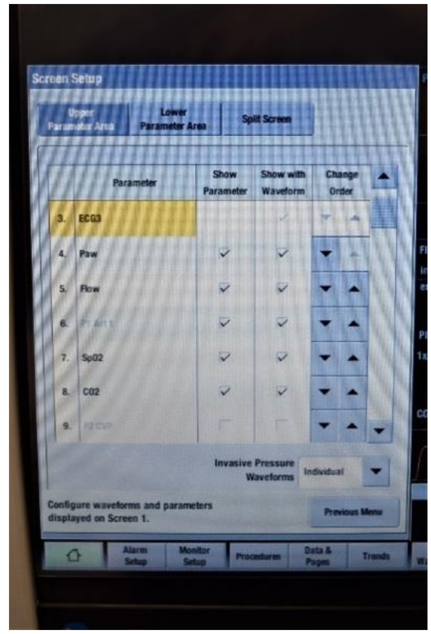

Figure 5. "Screen Setup" with parameters activated with waveforms showing.

- Next, select "Lower Parameter Area" to configure the bottom half of the interface.
- Select "Double Height".
- Select the following parameters for monitoring:
  - O_2 (to monitor FiO_2 and EtO_2)

Note: Selecting "Spiro 2" on the "Split Screen" tab will allow visualization of spirometry loops on the interface, but this is optional.

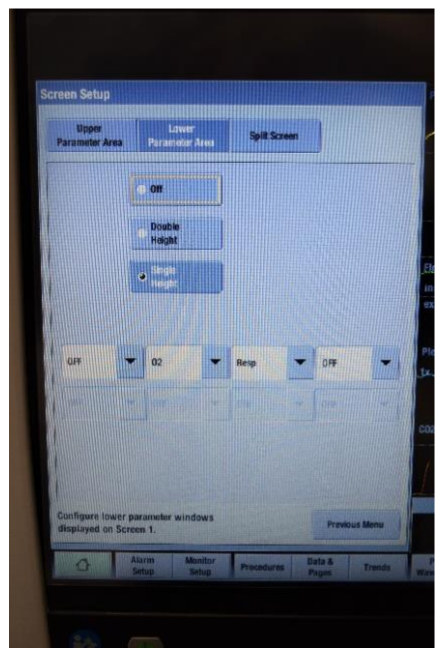

Figure 6. "Lower Parameter" adjustments.

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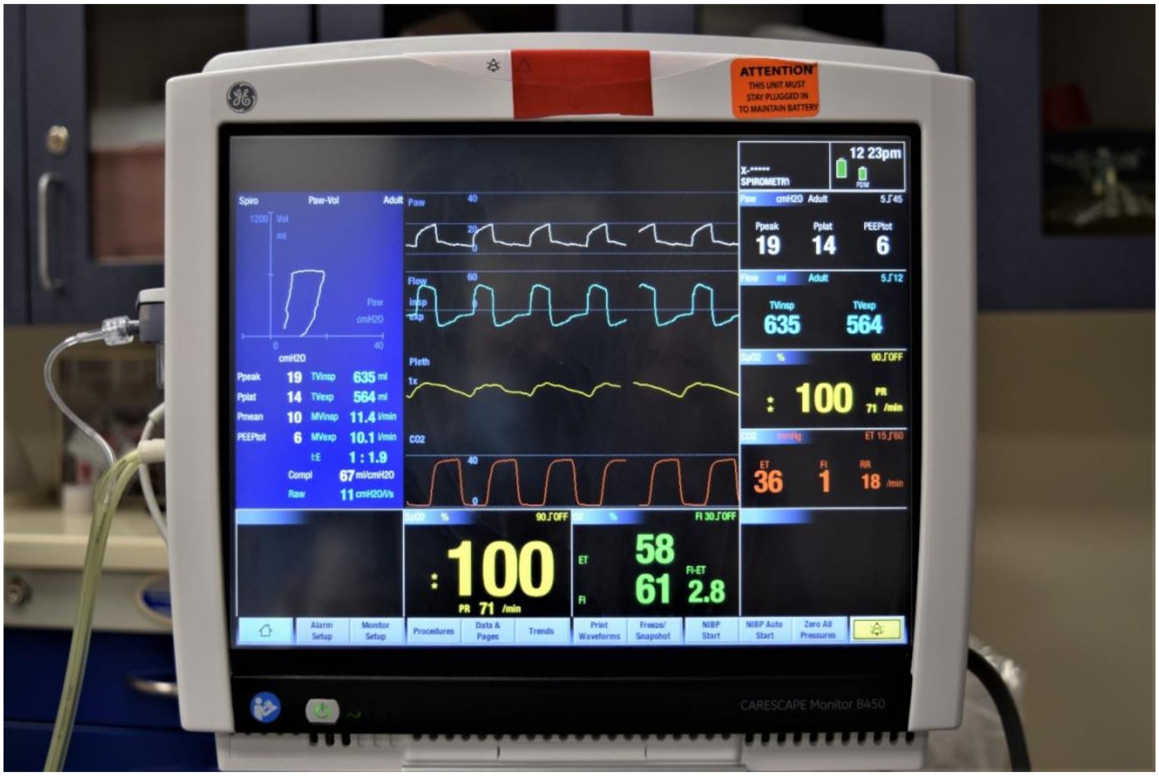

Figure 7. GE CARESCAPE ™ B450 with a customized interface for ventilator monitoring. The lower panel has been customized with additional SpO_2 monitoring for redundancy. A pressure-volume spirometry loop with additional data on minute ventilation, plateau pressure, I:E ratio, compliance, and airway resistance is on display to the left, which can be changed to a flow-volume loop if desired. Note: coloring of each parameter can be changed under "Monitor Setup". Accuracy of data is dependent on calibration of the E-sCAiOV module and is subject to error.

2. Alarms

The GE CARESCAPE™ system allows for alarm configuration with varying degrees of priority (i.e. informational, escalating, medium, high). Triaging alarms based on severity of events helps prevent alarm fatigue and alerts providers to life-threatening events. For example, an alarm for desaturation – an immediate life-threatening event - may be much higher in priority than elevated blood pressure, which is typically less urgent in nature.

Ventilator alarms primarily focus on acute changes in airway pressures (i.e. Ppeak, PEEP), tidal volumes, SpO_2, and end-tidal CO_2. These variables may warn providers of life-threatening events such as a ventilator disconnect, patient-ventilator dyssynchrony, airway obstruction, bronchospasm, hypoxemia, and hypercarbia.

To configure alarm priorities and parameters:

- Select "Alarms Setup" on the BOTTOM LEFT CORNER. This panel should show up:

Figure 8. Alarms Setup. Note that the interface is slightly adjusted to view invasive airway pressures (See Section 4 – Additional surrogate monitoring).

- Alarm limits should be set within 25% of the patient's baseline values (See Alarms Protocol for details).
- Next, select "Alarm Priorities", then click other parameters
- The following parameters should be set to **High** priority to minimize delay time and maximize volume:
    - SpO_2 high
    - SpO_2 low
    - RR (CO_2) high/low
    - Apnea (CO_2)
    - CO_2 high/low
    - P1 high/low

- Next click Invasive Pressures on the same page (Fig. 9.2). The following parameters should be set to High priority.
    - Art high/low

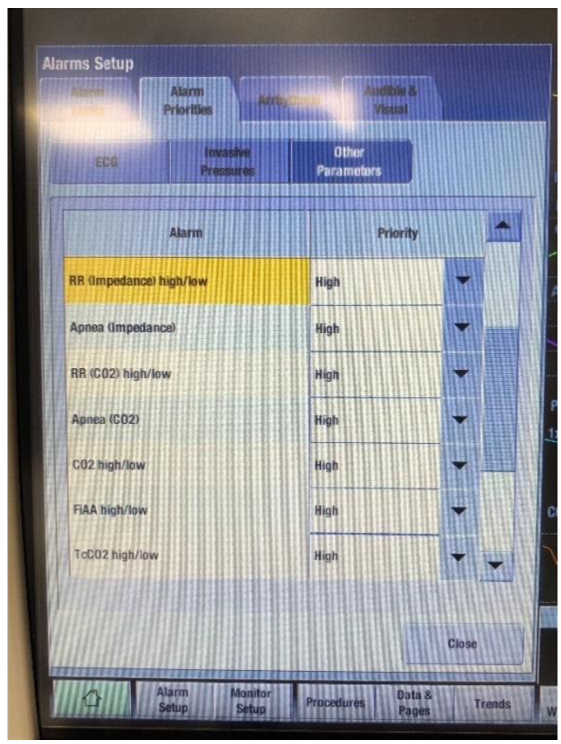

Figure 9.1. Alarm Priorities.

When using the Art 1 Alarm, you must ensure that the lower end of the HR is set to 20. The default option on most systems is 30, therefore you must go into

- "Monitor Setup"
  >defaults
  >enter for username "Clinician"
  >password "Change Me"
  >(There must be a capital C, capital M and a space between those two words.)
  >Care Unit Setting
  >parameter
  > ECG
  > ECG HR
  > change from single to multiple (Fig. 10).

This change will lower the HR on the alarm page to 20. To setup the RR alarm (which is actually the HR on the monitor), click on

- "P1 Art 1" display on the main pane
  >PR(Art 1) Alarms.
  >"Alarms On" (Fig. 11).

Make sure to make the maximum HR 20, and the maximum should be 25% above your desired RR. Note that when using this alarm setting, the patient's actual RR cannot be below 20, otherwise the alarm will continuously go off. Therefore, if the RR is below 20, turn off the alarm using the same instructions for how to turn it on. Simply click the "alarm on" button and switch to off.
To turn on the pressure alarms within Art 1, click:

- "P1 Art 1" on the main display page, click
  >"Art 1 Alarm"

Make sure the alarm is turned on. Lower the Systolic to 25% below the pressure you intend to use on the patient, and 25% above the pressure you intend to use. This wave form will be the pressure within the breathing circuit. Note that this pressure is in mmHg, not cmH_2O, so it will appear lower. The way to convert cmH_2O to mmHg is to multiply cmH_2O by 0.7.

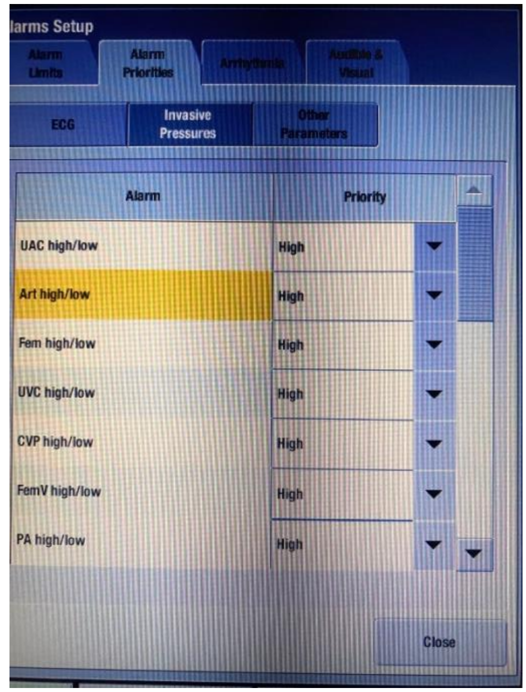

Figure 9.2. Alarm Priorities

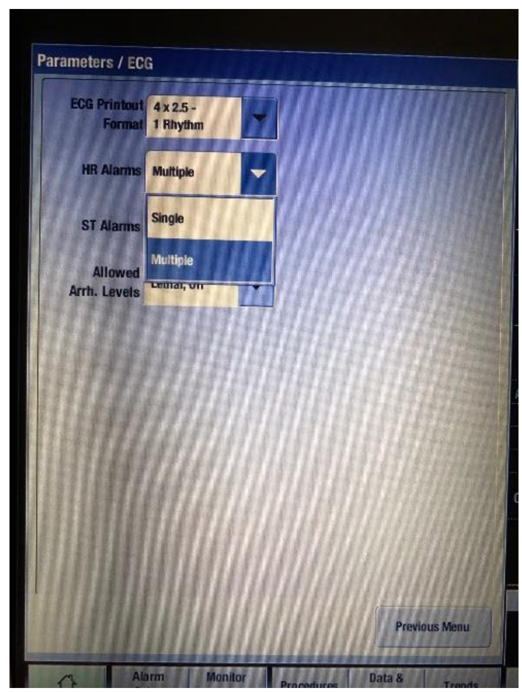

Figure 10. HR Alarm Setup

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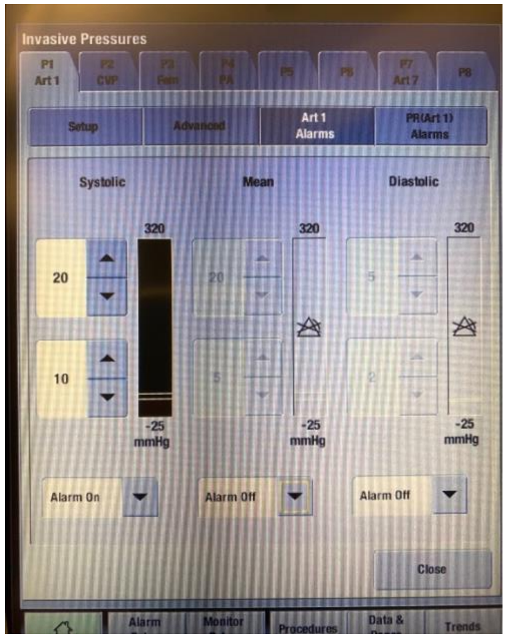

Figure 11. PR(ART1) Alarms

- Note: Due to an intrinsic alarm delay with the spirometry modules, E-sCAiOV module parameters such as minute ventilation, tidal volumes, and airway pressures alarms may only be set to **Medium** with a 30-second delay. **Therefore, it is highly recommended to include zero-second delayed SpO_2 and end-tidal based alarm**

Selecting individual parameters on the touchscreen and setting alarm limits separately is also possible:

Figure 12. Selecting individual parameters

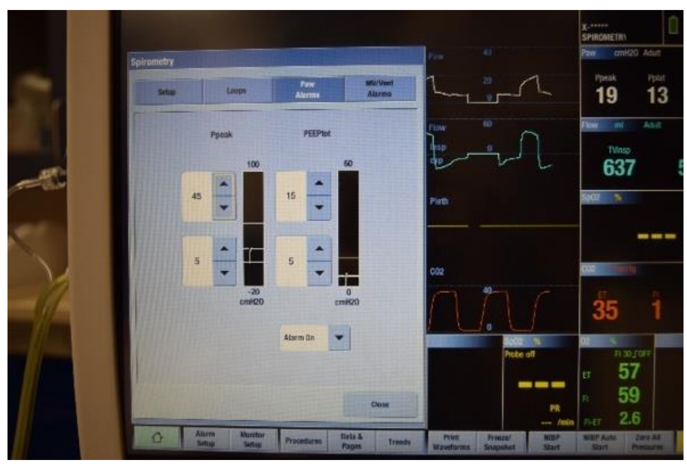

Figure 13. Adjusting alarm limits for Ppeak and PEEP

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3. Additional surrogate monitoring

To compensate for the delayed alarm response from the E-sCAiOV respiratory module, the circuit can be modified to include an **invasive pressure monitor transducer** attached near the patient's airway device:

A

B

C

D

Figure 14 A-D. Invasive pressure monitoring devices. A. An Edwards TruWave pressure monitoring kit. B. Pressure monitoring components. C. Pressure monitoring components with excess tubing removed and the proximal port capped. D. This transducer is then attached directly at the elbow connector adjacent to the patient's endotracheal tube.

After connecting the transducer to the **P1** port in the CARESCAPE™ PDM, the transducer should be zeroed and calibrated. It should show an approximation of the patient's peak and mean airway pressure:

Figure 15. GE CARESCAPE ™ B450 ventilator interface with an added invasive airway pressure monitoring, shown in red and labeled as "Art 1".

Of note, invasive pressure alarms have a zero-second delay and when alarm parameters are set properly, it should be able to detect a ventilator disconnect in less than 20 seconds. The **PR alarm** function in the Art 1 parameter should reflect **respiratory rate**, which can serve as an additional alarm.

Standalone Low-Pressure Alarm Primer:

Arduino Based Standalone Low Pressure Alarm for Breathing Circuits

Version 3.0 [Apr 24, 2020]

Mount Sinai Health System

Primer developed by:

Ankit Parekh, PhD

David M. Rapoport, MD

Alarms

Most critical if using devices for invasive "life-support"

- Most CPAP and bi-level devices designed for OSA and home use do not have alarms. Most hospital units do. Typical displays and outputs used to trigger alarm include
    - Disconnect (low pressure in circuit, but must be measured near the patient)
    - Low/high tidal volume, minute ventilation (less reliable in mask vent)

In this primer, we detail an Arduino based standalone low-pressure / disconnect alarm. This alarm can be implemented for any closed breathing circuit.

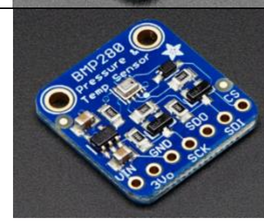
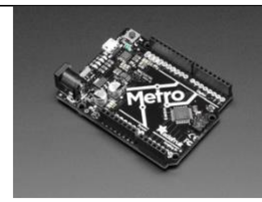
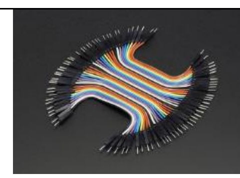
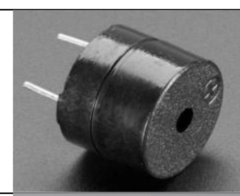
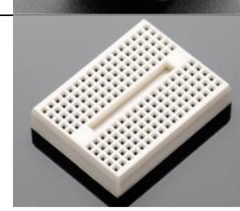
Advantages

- A standalone low-pressure alarm that does not require the use of monitoring devices.
- Pressure within the circuit near the patient can be measured distally outside the room while still providing a less than 2 second delay in triggering an alarm condition
- Can be modified to use for either high-pressure or low-pressure settings

Disadvantages

- Large scale manufacturing needed for rapid deployment (see appendix for a PCB layout)

PARTS AND EQUIPMENT LIST

Required Qty.	Description	Picture
1	Ported Pressure sensor (https://www.adafruit.com/product/3965)	
1	BMP280 Barometric Pressure and Altitude Sensor	
1	Microcontroller Recommended: https://www.adafruit.com/product/2488 Alternatives: https://www.adafruit.com/product/2590	
10+	Jumper wires (set of 40) https://www.adafruit.com/product/759 Alternatives: Use any 22-30 AWG wire	
1	Buzzer https://www.adafruit.com/product/1536	
(Optional) 1 * You can solder the parts directly to the Arduino board, provided it does not contain headers.	Breadboard https://www.adafruit.com/product/64 Alternatives: https://www.adafruit.com/product/1609	

Equipment:
Soldering equipment; Wire terminal crimp tool

CIRCUIT DIAGRAM

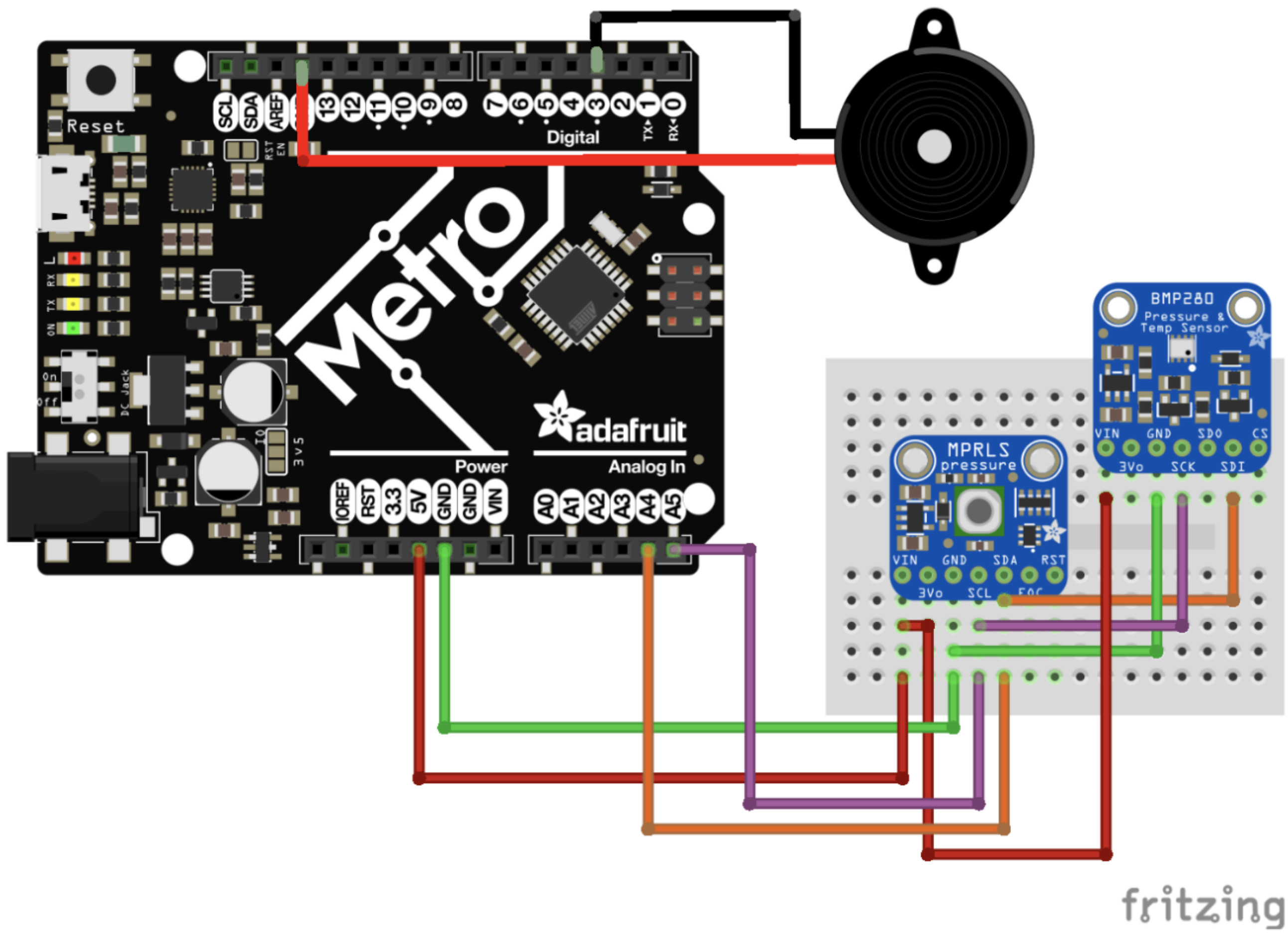
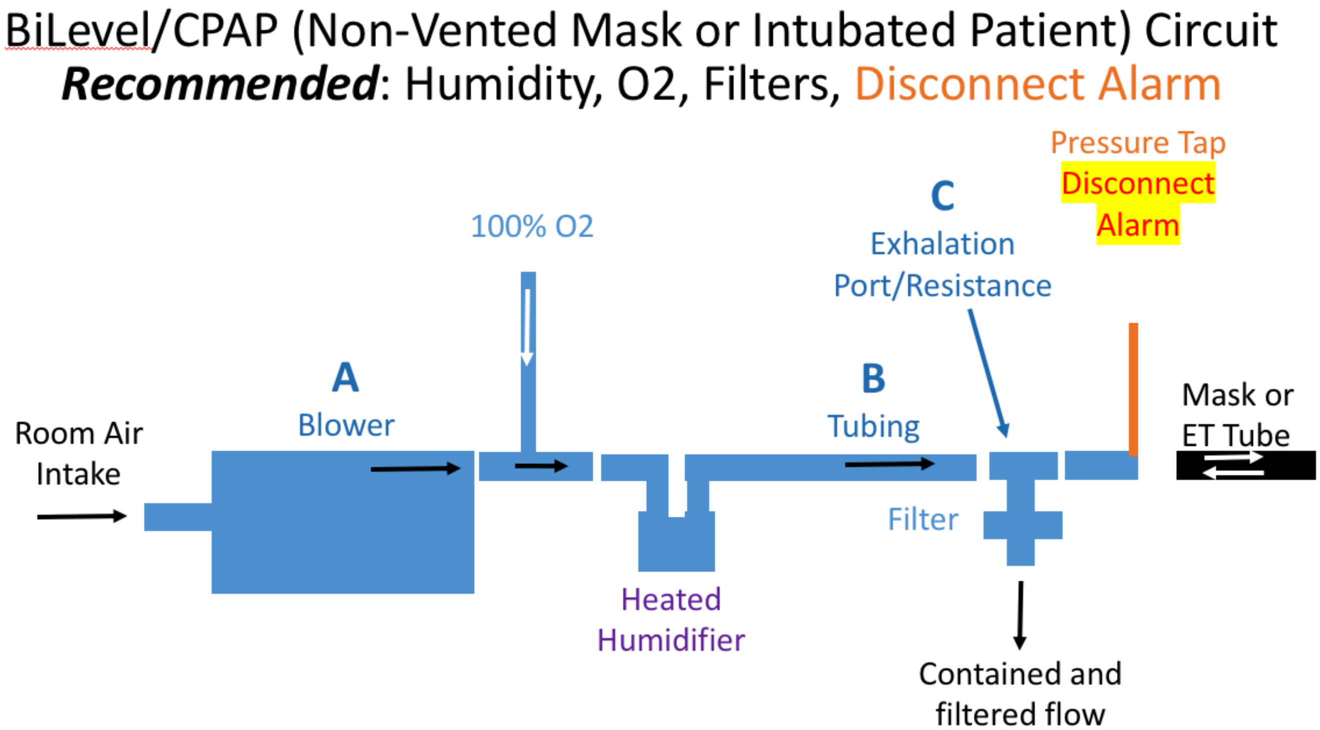


Figure 3: Low Pressure Alarm Prototype Circuit. The pressure tap is connected to the port atop the MPRLS sensor. The BMP280 sensor enables calculation of a differential pressure reading, thus eliminating any calibration.

STEPS FOR ADDING THE LOW PRESSURE ALARM WITHIN THE BILEVEL/CPAP CIRCUIT



Insert the MPRLS Ported sensor's port either directly at the pressure tap or with a gas sampling line shown here →

Figure 4 Optional Gas Sampling Line for connecting the sensor to the pressure tap in the circuit above

Note:** ***Although the standalone alarm is placed in the above circuit, it is intended for use on any device/circuit without alarms on an intubated patient

APPENDIX

Arduino Sketch

```
/************************************************************************
This sketch is for a low pressure standalone alarm
Last Edit: April 13, 2020

Developed by:
Ankit Parekh
Sinal Kumar
David M Rapoport

For questions: ankit.parekh@mssm.edu
************************************************************************/

#include <Wire.h>
#include<SPI.h>
#include <Adafruit_MPRLS.h>
#include <Adafruit_BMP280.h>

#define RESET_PIN  -1  // set to any GPIO pin # to hard-reset on begin()
#define EOC_PIN    -1  // set to any GPIO pin to read end-of-conversion by pin
#define HPA_TO_CMH2O (1.01974428892)

Adafruit_MPRLS mpr = Adafruit_MPRLS(RESET_PIN, EOC_PIN);
Adafruit_BMP280 bmp;
Adafruit_Sensor *bmp_pressure = bmp.getPressureSensor();

const int buzzer = 3;  //buzzer connected to pin
int numAlarm = 0;

const int numReadings = 10;
float readings[10];
float total = 0.0;
float average = 0.0;
int readIndex = 0;

void setup() {
  Serial.begin(9600);
  if (!mpr.begin()) {
    Serial.println("Failed to communicate with MPRLS sensor, check wiring?");
    while (1) {
      delay(10);
    }
  }
  Serial.println("Found MPRLS sensor");

  if (!bmp.begin()) {
    Serial.println(F("Could not find a valid BMP280 sensor, check wiring!"));
    while (1) {
      delay(10);
    }
```

```
  }
  Serial.println("Found BMP280 sensor");
  /* Default settings from datasheet. */
  bmp.setSampling(Adafruit_BMP280::MODE_NORMAL,     /* Operating Mode. */
                  Adafruit_BMP280::SAMPLING_X2,     /* Temp. oversampling */
                  Adafruit_BMP280::SAMPLING_X16,    /* Pressure oversampling */
                  Adafruit_BMP280::FILTER_X16,      /* Filtering. */
                  Adafruit_BMP280::STANDBY_MS_125); /* Standby time. */

  //Use LED instead of alarm for now to test
  pinMode(LED_BUILTIN, OUTPUT);
  pinMode(buzzer, OUTPUT);


  // Setup the moving average array
  // Initialize array to 0
  for (int thisReading = 0; thisReading < numReadings; thisReading++) {
    readings[thisReading] = 0;
  }
}

void loop() {
  sensors_event_t pressure_event;
  delay(50);
  float pressure_port = mpr.readPressure();
  delay(50);
  bmp_pressure->getEvent(&pressure_event);


  // Get hPa to cmH2O
  pressure_port *= HPA_TO_CMH2O;
  pressure_event.pressure *= HPA_TO_CMH2O;

  // TODO CALIBRATION???
  pressure_event.pressure -= 5.0f;

  bool alarm = false;
  float delta_p = pressure_event.pressure - pressure_port;

  //Moving Average calculations
  total = total - readings[readIndex];
  readings[readIndex] = fabs(delta_p);
  total = total + readings[readIndex];
  readIndex = readIndex + 1;

  if (readIndex >= numReadings) {
    //We are at end of array, so start over
    readIndex = 0;
  }

  average = total / numReadings;
```

```
 if (fabs(delta_p) < 7.0f && numAlarm >=5){
    alarm = true;
    digitalWrite(LED_BUILTIN, HIGH);
    tone(buzzer, 2000);
  }
  else if (fabs(delta_p) < 7.0f && numAlarm <5) {
    alarm = false;
    digitalWrite(LED_BUILTIN, HIGH);
    numAlarm += 1;
    noTone(buzzer);
  }
  else if (fabs(delta_p) > 0.8*fabs(average) && fabs(delta_p) < 1.1*fabs(average)) {
    if (numAlarm < 5) {
      numAlarm += 1;
    }
    else {
      alarm = true;
      digitalWrite(LED_BUILTIN, HIGH);
      tone(buzzer, 2000);
    }
  }
  else {
    alarm = false;
    digitalWrite(LED_BUILTIN,LOW);
    //noTone(buzzer);
    //reset alarm counter
    numAlarm = 0;
  }


  Serial.print(pressure_event.pressure);
  Serial.print(",");
  Serial.print(pressure_port);
  Serial.print(",");
  Serial.print(fabs(delta_p));
  Serial.print(",");
  Serial.print(fabs(average));
  Serial.print(",");
  Serial.print(alarm);
  Serial.println();
  delay(50);
}
```