NEW OPTIONS FOR MASS CASUALTY CARE

Guidelines for Acquisition of Ventilators to Meet Demands for Pandemic Flu and Mass Casualty Incidents

American Association for Respiratory Care

May 25, 2006

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Ventilator Characteristics

- FDA approved for adults/peds
- Ability to operate without compressed gas
- Battery life 4 hrs
- Volume control
- CMV and IMV
- PEEP to 20 cm H2O
- Utilize both high and low pressure O2 sources
- Control of RR, PEEP, VT, Flow or I:E
- Monitor Paw and VT
- Alarms
  - Disconnect, apnea, high/low pressure, high pressure source gas disconnect

Ventilator Characteristics

- Rugged
- Light weight
- Easy to use
- Gas consumption
- Battery life
- Easy to trigger
- <$10 k
- Vendor support and longevity
- Maintenance
- Training

Ventilators for Mass Casualty Care

- What did we learn from the last pandemic flu?
- What ventilator characteristics were tested?
- Did we make the right recommendations?
- How did what we learn change our plans for the future?

H1N1

- Novel flu strain of Influenza A emerged in Mexico in the Spring of 2009
- 195 countries with confirmed cases
- First global pandemic since 1968
- Most illness is mild to moderate
- Severe cases of fatal disease are reported

H1N1

- Why is it different?
- The majority of the human population has no immunity
- Compared to seasonal flu which typically affects the elderly and immunocompromised this flu reaches across all ages
- Young children and young adults are disproportionately affected

H1N1

- As much as 30 - 50% of the US population infected, symptoms in 20 - 40% of the population (60 -120 million people)
- Concentrated in children and young adults; high risk individuals including pregnant women, asthma, diabetes, respiratory or neurological disorders, severe obesity
- 1.8 million US hospital admissions
- 300,000 ICU admissions, many with ALI/ARDS; most intubated and mechanically ventilated, some with refractory hypoxemia

H1N1

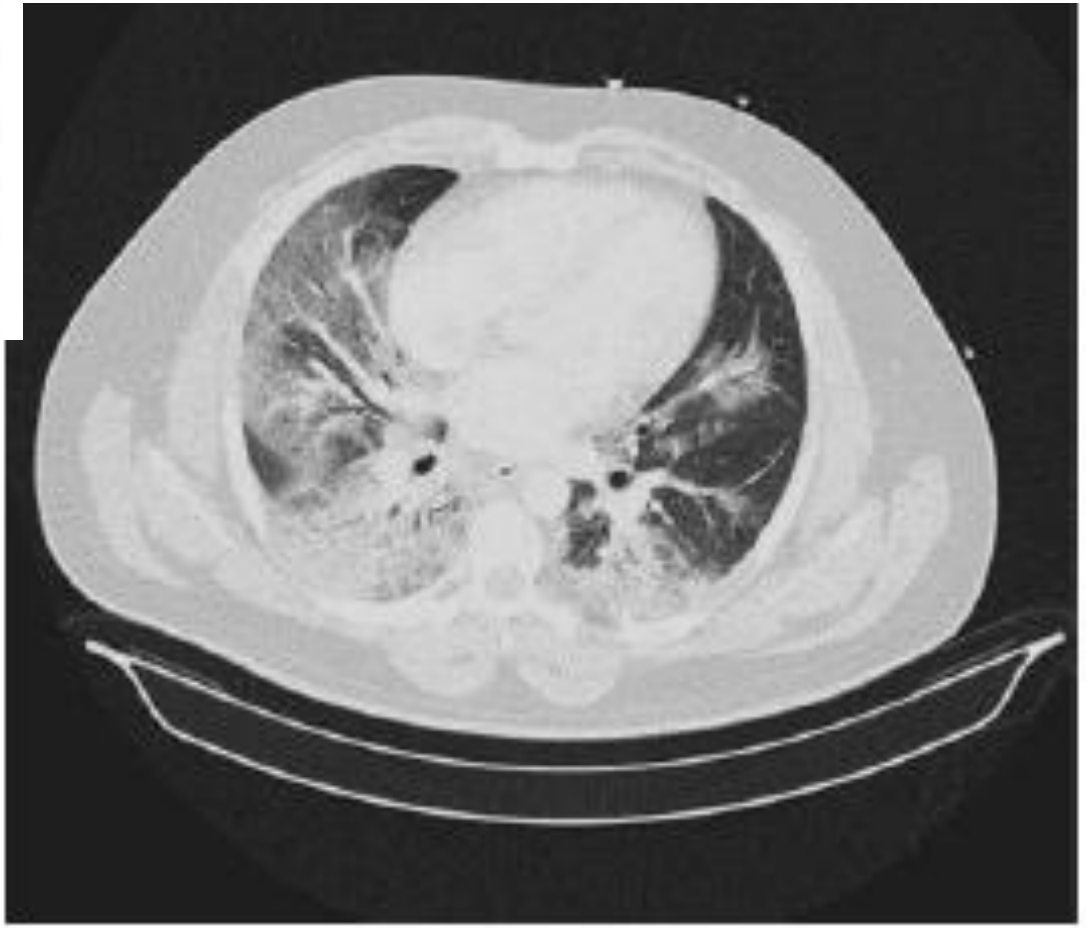
- What can we do?
- Practice universal precautions
- Practice good hand hygiene
- Practice cough etiquette
- Receive both the seasonal and H1N1 vaccination
- Limit visitors
- Don't come to work if you are sick

H1N1

- Severity of disease
- A small percentage of patients present with severe viral pneumonia
- The time from symptoms to ARDS is fast
- Refractory hypoxemia is common
- Survival is good in patients who can achieve adequate oxygenation
- Appropriate ventilator management

H1N1

- Approximately 10-30% of hospitalized patients in some countries have required admission to ICU.
- Critically ill patients experienced rapidly progressive lower respiratory tract disease, respiratory failure, and ARDS with refractory hypoxemia.
- Other severe complications have included secondary invasive bacterial infection, septic shock, renal failure, multiple organ dysfunction, myocarditis, encephalitis, and worsening of underlying chronic disease conditions such as asthma, COPD, or congestive cardiac failure



H1N1

- Principles
- Standard lung protective approaches
- Limit VT (6 ml/kg) and Plateau pressure
- Provide sufficient PEEP
- Appropriate sedation
- Evaluate recruitability of the lung and use appropriate measures
- Consider rescue strategies only if these are routinely practiced
- Consider transfer to a major medical center

MMWR
Morbidity and Mortality Weekly Report
www.cdc.gov/mmwr

MMWR Dispatch
Vol. 58 / July 10, 2009

Intensive-Care Patients With Severe Novel Influenza A (H1N1) Virus Infection — Michigan, June 2009

TABLE. Selected characteristics of intensive-care patients with severe novel influenza A (H1N1) virus infection — Michigan, June 2009

Patient	Age (yrs)	Sex	Underlying conditions	Initial signs or symptoms	BMI*	No. days between onset and first hospitalization	No. days between illness onset and SICU† admission	Advanced mechanical ventilation	Diagnosis		Vaso-pressors	Outcome**
									PE§	MODS¶		
1	28	M	Asthma	High fever, cough, sore throat that progressed to blood-tinged sputum, decreasing mental status	34.2	7	8	HFOV††	Yes	Yes	Yes	Death
2	21	M	None	Fever, sore throat, dry cough, sneezing; progressed to tachypnea and dyspnea	50.5	7	8	Bilevel	Yes	Yes	Yes	Improved, transferred
3	48	F	Asthma, smoker	Shortness of breath, rhinorrhea, non-productive cough	58.9	5	9	HFOV	No	Yes	Yes	Improved, transferred
4	35	M	None	Upper respiratory tract illness symptoms	51.7	6	8	HFOV	Yes	No	No	Improved, transferred
5	43	M	None	Fever, cough, malaise, chills, sweats	48.7	4	5	HFOV to ECMO§§	Yes	Yes	Yes	Death
6	52	M	None	Sinus drainage, cough with clear sputum production, decreased appetite	NA¶¶	6	13	HFOV	Yes	Yes	Yes	Improved, transferred
7	44	M	None	Fever, productive cough with black/red sputum, nausea, vomiting, diarrhea	50.2	5	7	HFOV	No	Yes	Yes	Death
8	51	M	Granulomatous chronic lung disease	Fever, worsening dyspnea, rigors, nausea, vomiting, malaise	39.7	1	9	HFOV to ECMO	No	Yes	Yes	ECMO plus ventilator
9	53	M	None	Fever, chills, cough, shortness of breath	38.5	7	16	HFOV	No	Yes	Yes	Improved, transferred
10	53	M	None	Fever, cough	47.8	6	6	HFOV	No	Yes	Yes	HFOV

Critical Care

CRITICAL CARE

Intensive care adult patients with severe respiratory failure caused by Influenza A (H1N1)v in Spain

Critical Care 2009, **13**:R148 doi:10.1186/cc8044

Jordi Rello (jrello.hj23.ics@gencat.cat)

Table 3. Most common risk factors for pandemic H1N1 Influenza in the ICU

Risk Factor	Cases (n=32)
Obesity	10
BMI>40	4
BMI 30-40	6
Asthma	5
COPD	4
Pregnancy	2
Heart Failure	1
Arterial Hypertension	1
Chronic Renal Failure	1
Diabetes mellitus	1
HIV	1
Neuromuscular disease	1
Hematologic disease	1
None	15

Rello J et al Crit Care 2009

Spanish Report n =31

- Mechanical Ventilation at admission
  - None 8 (25%), NIV 2(6%), Invasive 22 (69%)
  - 8 NIV attempts – 6 failures – 33% mortality
  - Overall mortality – 28%
- Adverse events
  - Refractory hypoxemia tx with prone position 8 (25%)
  - Vasopressors 20 (62%)
  - Renal failure – 7 (22%)

Rello J et al Crit Care 2009

Critically Ill Patients With 2009 Influenza A(H1N1) Infection in Canada
Kumar A, et al JAMA Online Oct. 12th, 2009

169 Patients

- Major comorbidity 51 (30.4)
- Chronic lung disease 69 (41.1)
- Asthma 38 (22.6)
- COPD 16 (9.5)
- Bronchopulmonary dyplasia 3 (1.8)
- Other 31 (18.5)
- Neurological disease 26 (15.5)
- Obesity 56 (33.3)
- Hypertension 41 (24.4)
- Ever smoker 38 (22.6)
- Type 1 or 2 diabetes 35 (20.8)
- Immune suppression 33 (19.6)
- Corticosteroid use 26 (15.5)
- Chemotherapy 6 (3.6)
- HIV/AIDS 2 (1.2)
- Other 14 (8.3)

Critically Ill Patients With 2009 Influenza A(H1N1) Infection in Canada
Kumar A, et al JAMA Online Oct. 12th, 2009

- 169 Patients
  - Mortality 17 (29%)
  - 136 patients were mechanically ventilated on the first day of
  - ICU admission; 128 (76.2%) invasively and 55 (32.7%) noninvasively.
  - Forty-seven patients (85.4%) who received noninvasive ventilation ultimately required invasive ventilation

Critically Ill Patients With 2009 Influenza A(H1N1) Infection in Canada
Kumar A, et al JAMA Online Oct. 12th, 2009

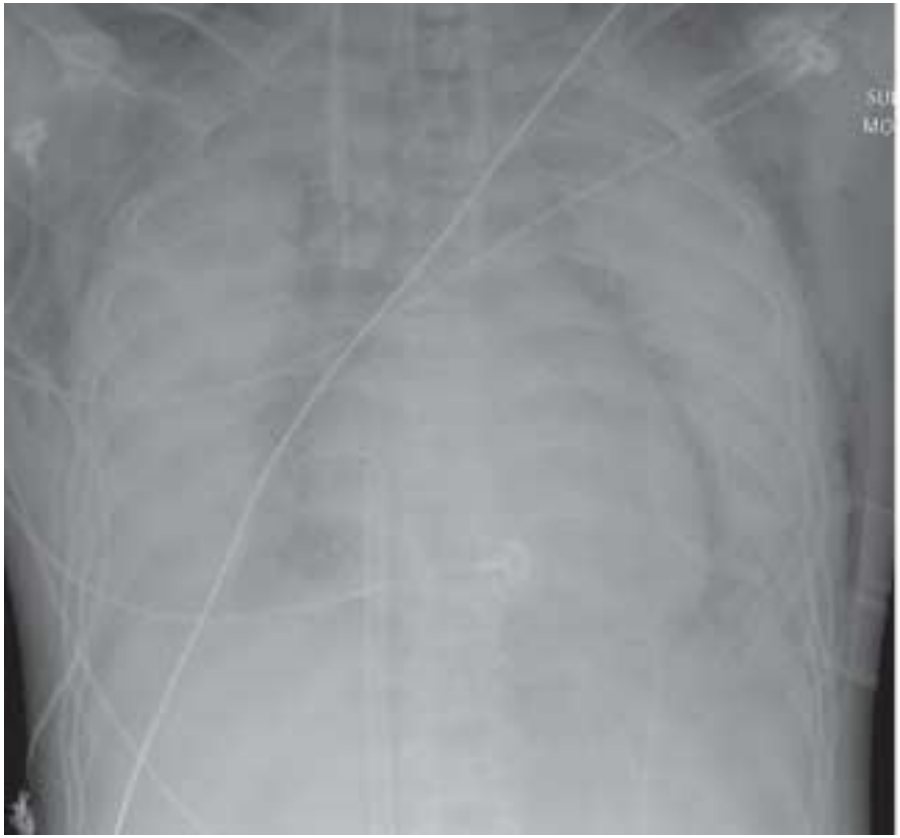
- 169 Patients
  - Barotrauma occurred in 14 patients (8%).
  - Therapies for oxygenation failure included
    - neuromuscular blockade (47 patients; 28.0%),
    - inhaled nitric oxide (23 patients; 13.7%),
    - high-frequency oscillatory ventilation (20 patients; 11.9%),
    - extracorporeal membrane oxygenation (7 patients; 4.2%)
    - prone positioning ventilation (5 patients; 3.0%)

Critically Ill Patients With 2009 Influenza A(H1N1) in Mexico D. Cherit, et al JAMA Online Oct. 12th, 2009

- 58 Patients
  - 44 yrs median age
  - Obesity 21 (36%)
  - 54 patients were ventilated (95%)
  - 48 invasive, 22 non-invasive, 16 – both
  - 4 patients prone, 1 HFO, 0 NO or ECMO
  - Barotrauma in 6 patients (10%)
  - Mortality rate 44%

Extracorporeal Membrane Oxygenation for 2009 Influenza A(H1N1) Acute Respiratory Distress Syndrome et al JAMA Online Oct. 12th, 2009

- 201 Patients
  - 68 treated with ECMO
  - 2.6 per million people in Australia
  - 133 patient MV with no ECMO
  - Barotrauma 15 (10%)
  - 21% mortality rate – 23% ECMO, 13% MV alone



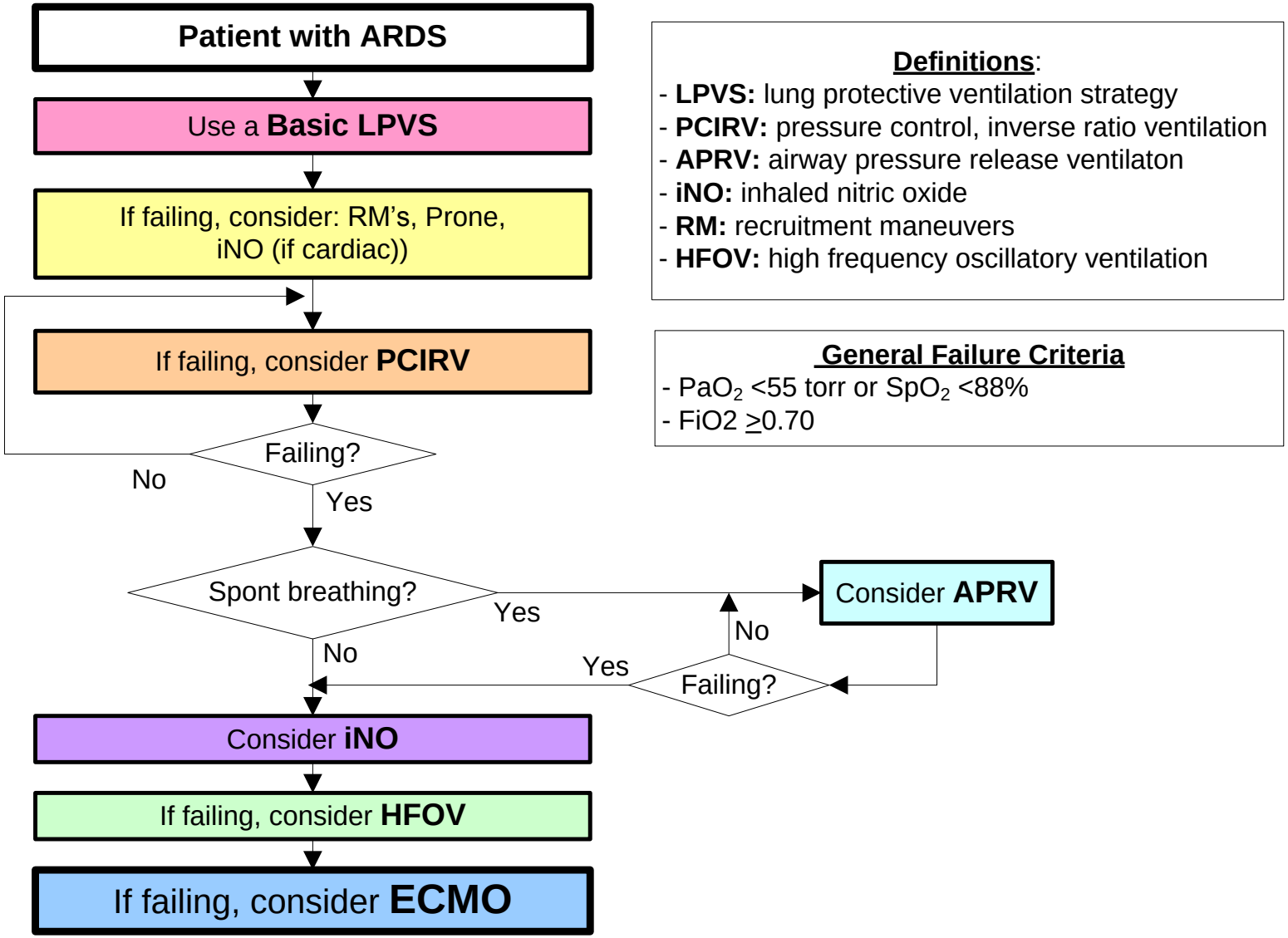
Extracorporeal Membrane Oxygenation for 2009 Influenza A(H1N1) Acute Respiratory Distress Syndrome et al JAMA Online Oct. 12th, 2009

- 201 Patients
  - Rescue therapies
    - Recruitment maneuvers 38 (67%)
    - prone position 12 (20%)
    - high-frequency oscillation 3 (5%)
    - inhaled nitric oxide 20 (32%)
    - prostacyclin in 14 (22%)
  - 55 patients (81%) received at least 1 of these therapies.

H1N1

- Severe hypoxemic respiratory failure in a small number of patients
- Taxing ICU resources
- Primary goal is lung protection with conventional ventilation
- Rescue therapies should be decided on and triaged based on availability and experience
- Know before the first patient what steps will be taken

UM ARDS Vent Management Algorithm



Definitions:
- **LPVS:** lung protective ventilation strategy
- **PCIRV:** pressure control, inverse ratio ventilation
- **APRV:** airway pressure release ventilaton
- **iNO:** inhaled nitric oxide
- **RM:** recruitment maneuvers
- **HFOV:** high frequency oscillatory ventilation

General Failure Criteria
- PaO_2 <55 torr or SpO_2 <88%
- FiO2 ≥0.70

H1N1 and Ventilators for Stockpiling

- The H1N1 pandemic did not overwhelm the ventilator supply
- Stockpiles were not tapped
- ICU's were taxed, but hospitals were not
- Nature always proves that we are bad at predicting what will happen
- No reason to change the AARC reccommendations

New Findings

- Research findings pertinent to mass casualty respiratory failure

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Clinical paper

Mechanical ventilators in the hot zone: Effects of a CBRN filter on patient protection and battery life☆

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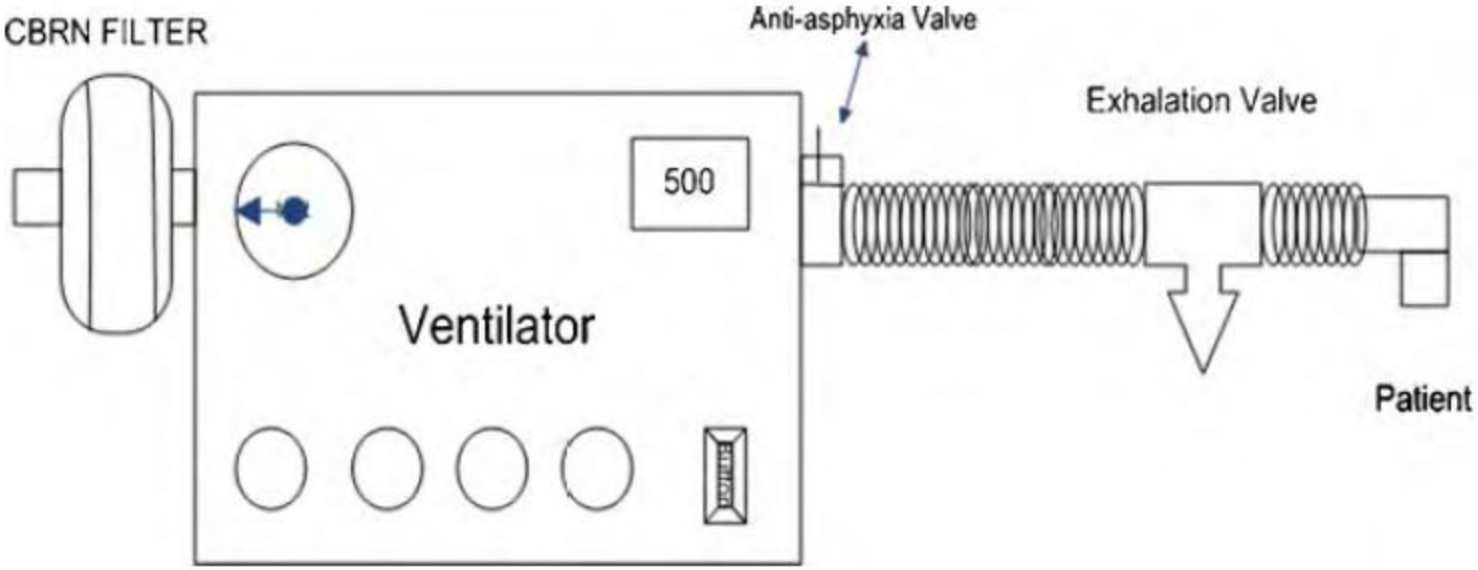


Fig. 1. CBRN filter placement.

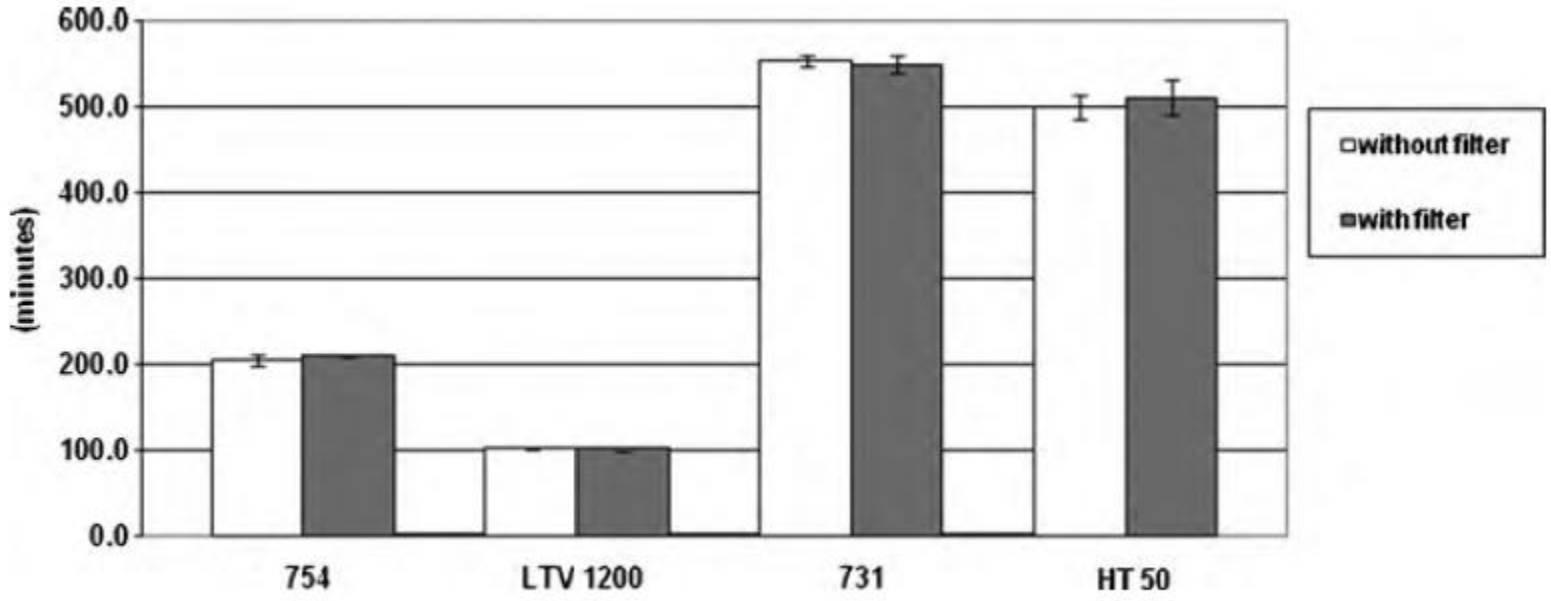


Fig. 2. Battery duration with and without CBRN filter.

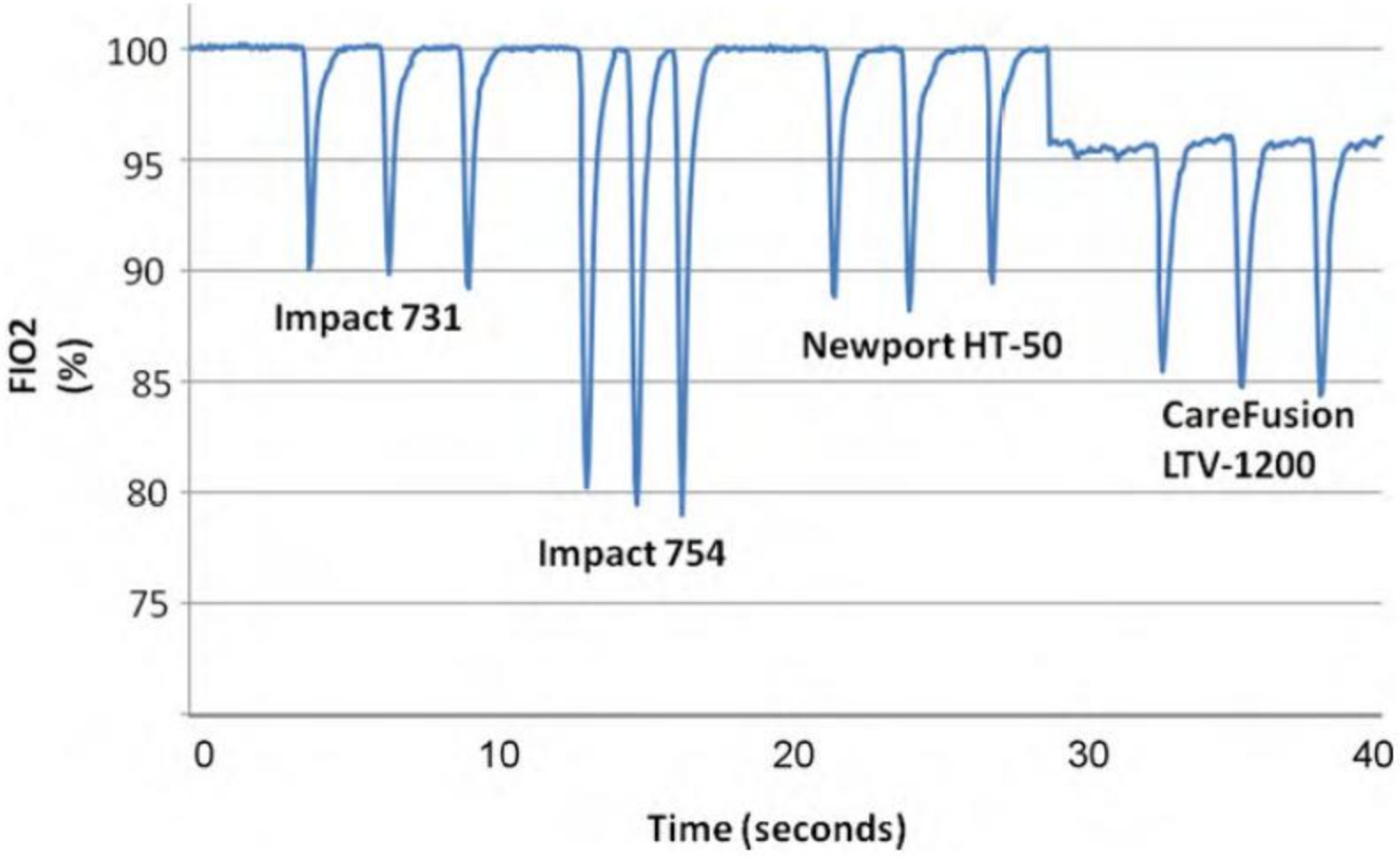


Fig. 3. Air entrainment through anti-asphyxiation valve and effect on FIO_2.

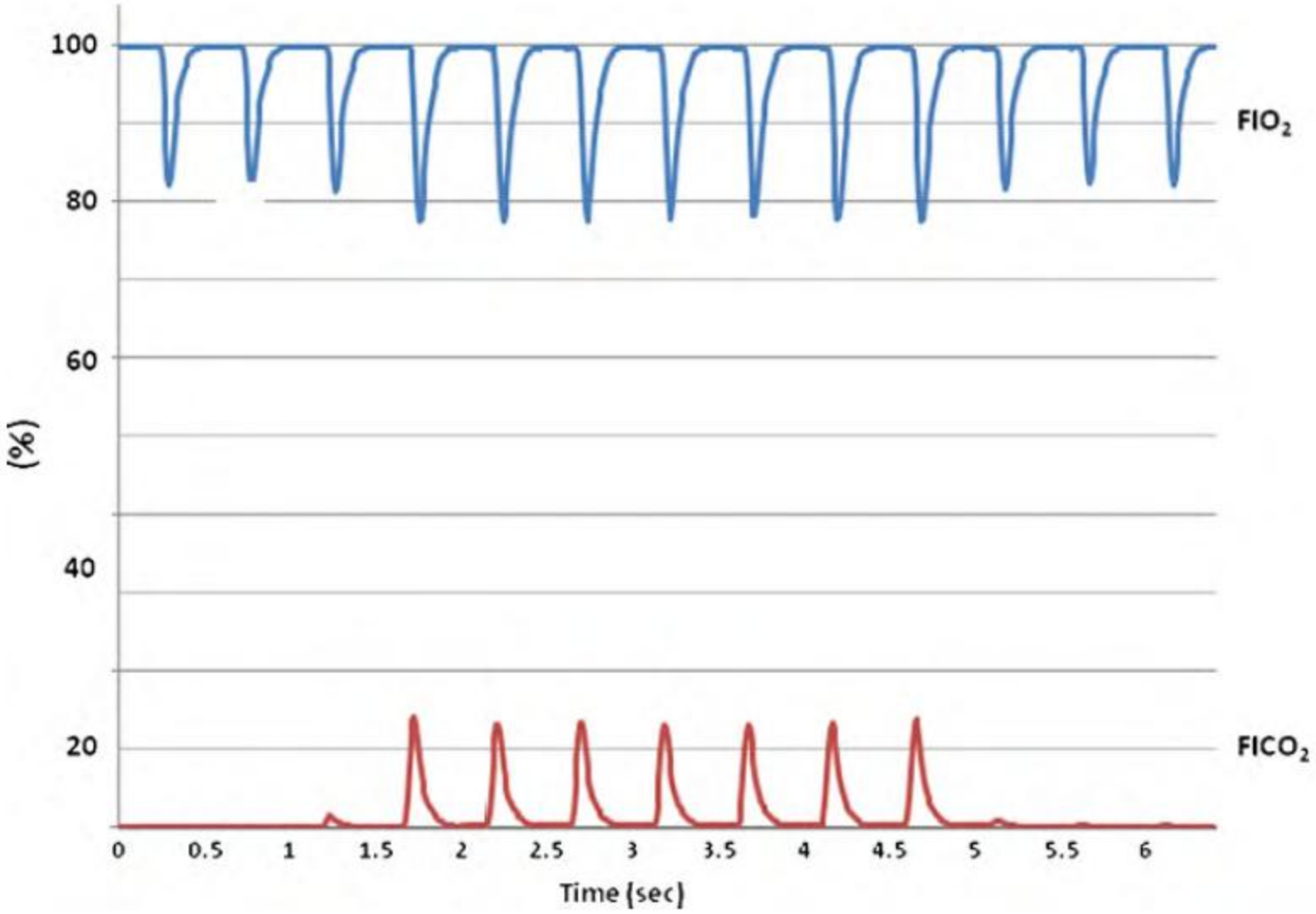


Fig. 4. Entrained CO_2 through anti-asphyxiation valve.

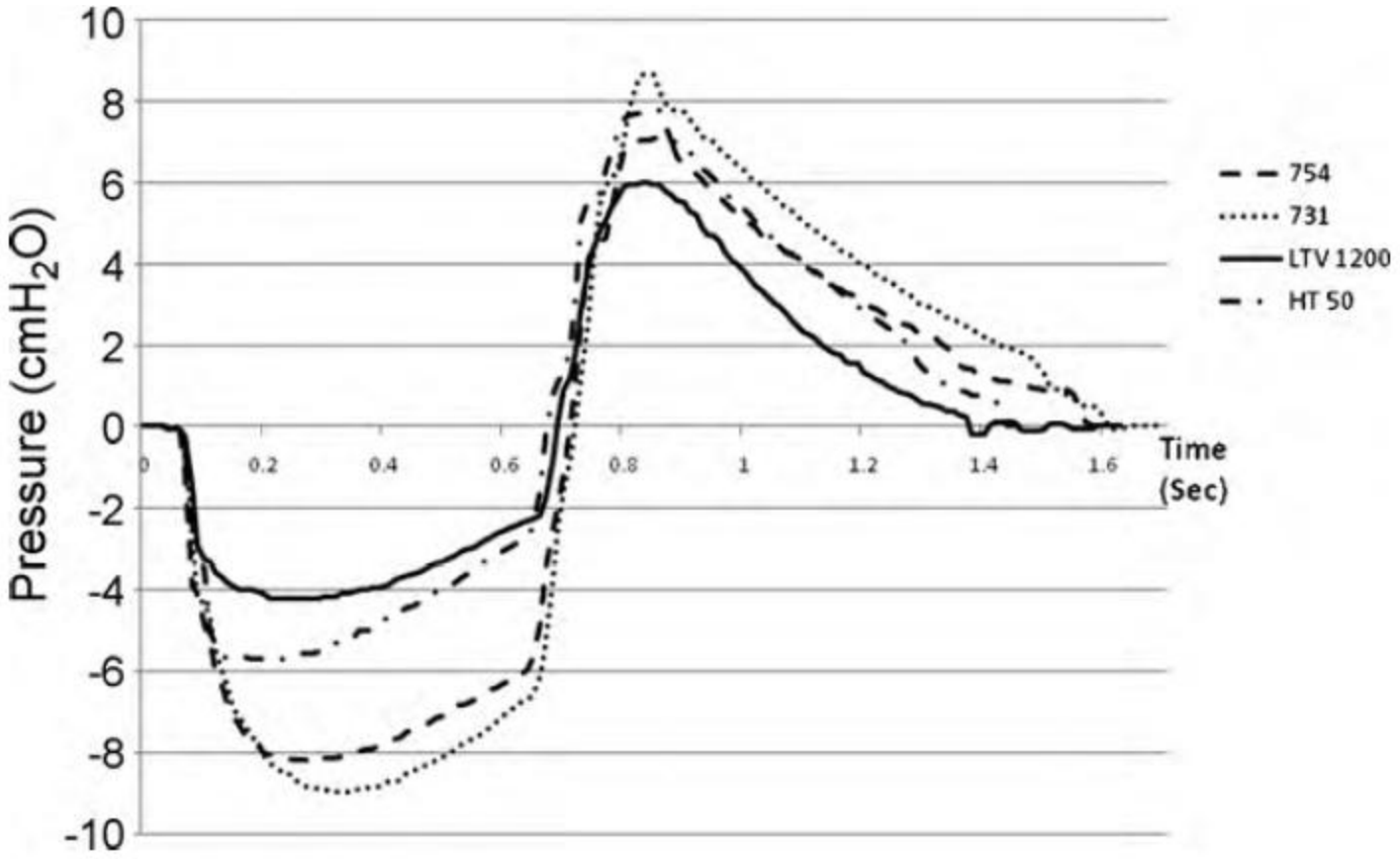


Fig. 5. Peak negative pressure when breathing through a failed device.

MILITARY MEDICINE, 176, 1:84, 2011

Laboratory Evaluation of the SAVe Simplified Automated Resuscitator

Thomas Blakeman, BA; SMSgt Dario Rodriquez, USAF†; Maj Michael Petro, USAF MC†; Col Warren Dorlac, USAF MC†; Richard Branson, MSc**

SAVe – Simplified Automatic Ventilator

- One rate – 10 bpm
- One VT – 600 ml
- No triggering
- Control mode ventilation
- Low flow O2 inlet
- DARPA funded for far forward military use
- $2000

Tidal Volume Consistency

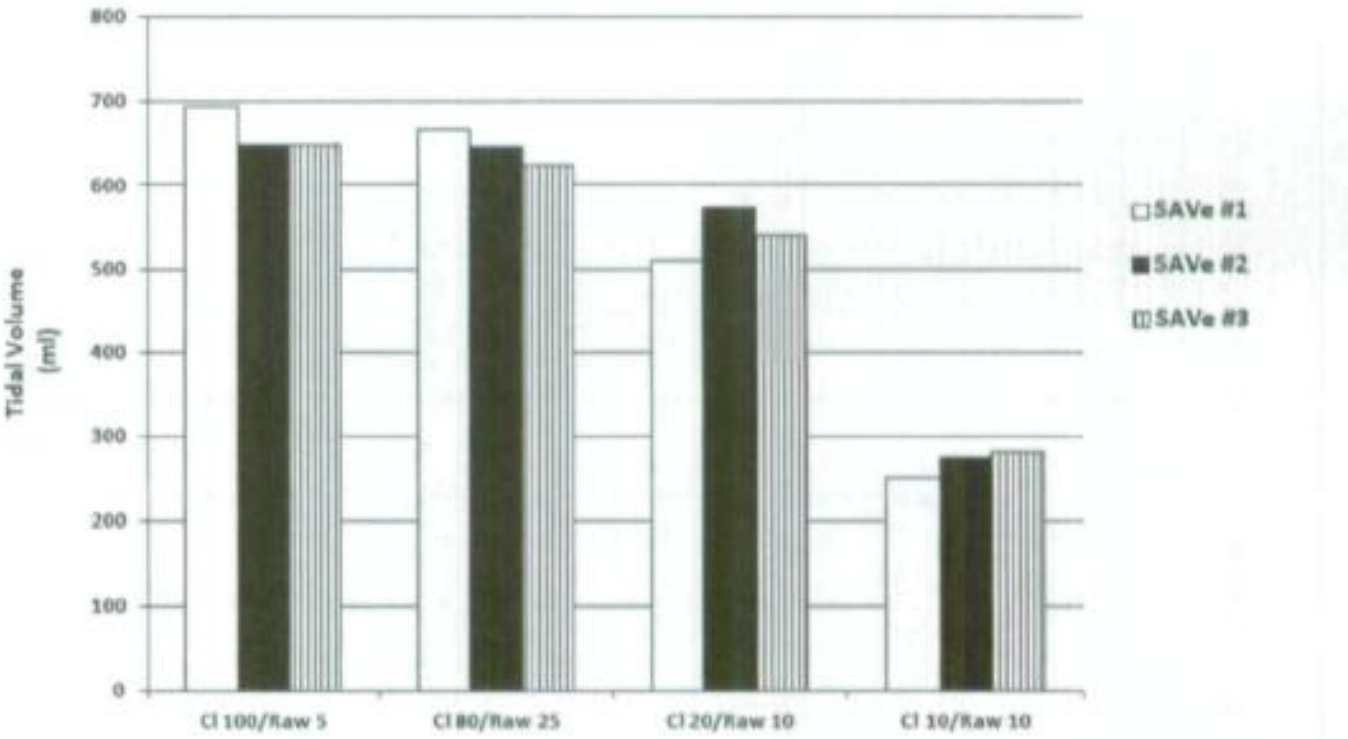
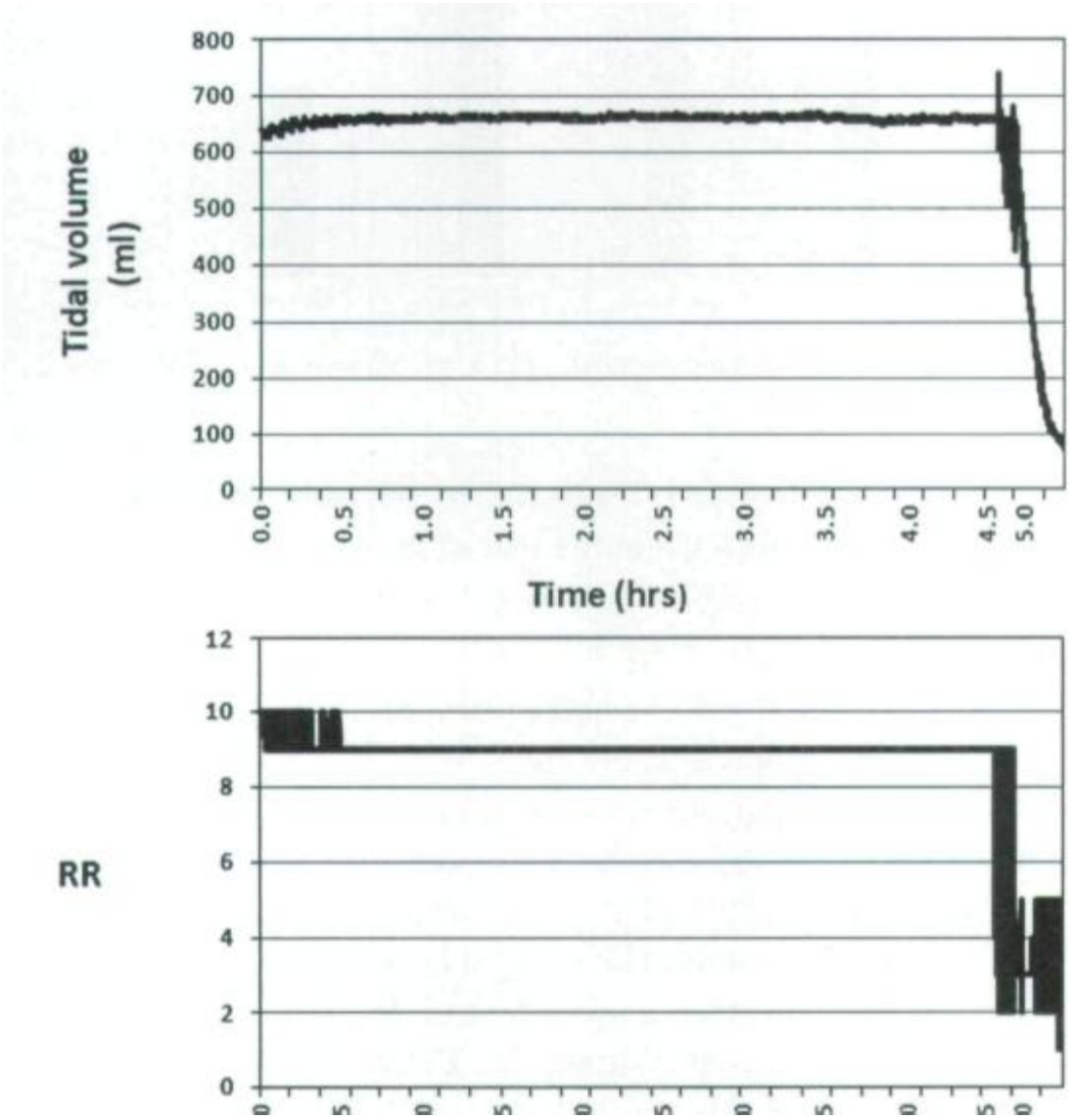
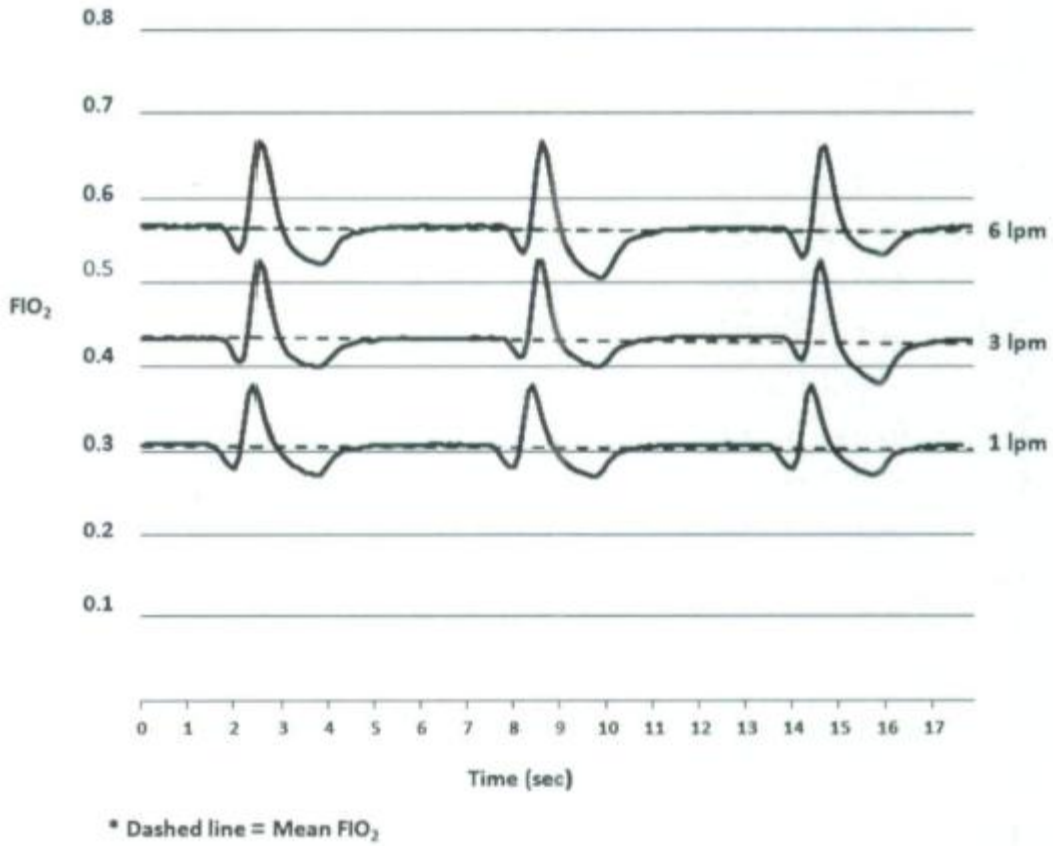


FIGURE 3. Effect of lung compliance and airway resistance on delivered tidal volume.


Tidal volume (ml)
800
700
600
500
400
300
200
100
0
0.0
0.5
1.0
1.5
2.0
2.5
3.0
3.5
4.0
4.5
5.0
Time (hrs)
RR
12
10
8
6
4
2
0


0.8
0.7
0.6
0.5
0.4
0.3
0.2
0.1
FIO2
6 lpm
3 lpm
1 lpm
0 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17
Time (sec)
* Dashed line = Mean FIO2

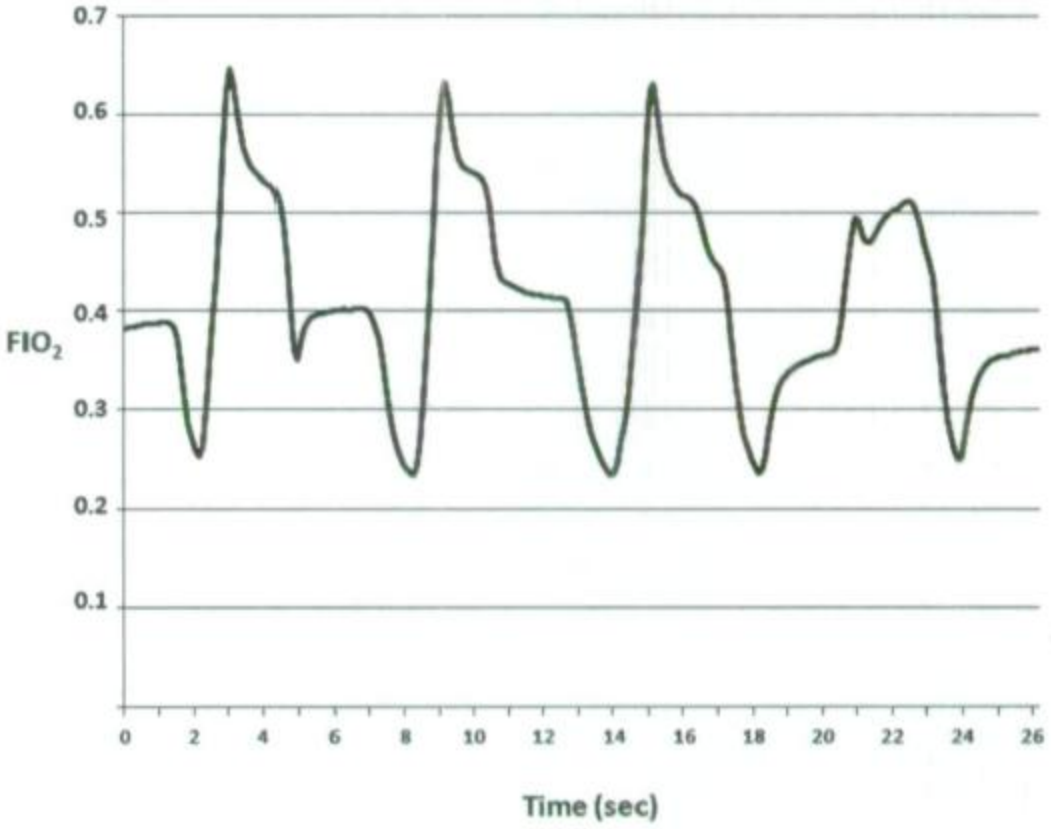


FIGURE 6. FIO_2 during spontaneous breathing.

Newport HT-70

Patient Range	Infant/Pediatric (≥5 kg) - Adult

Controls/Settings

Modes (Pressure or Volume)	A/CMV SIMV SPONT
NIV (non-invasive ventilation)	available in all modes
VT (Tidal Volume)	50 to 2,200 mL
RR (Respiratory Rate)	1 to 99 b /min
i Time (Inspiratory Time)	0.1 to 3.0 sec
PEEP/CPAP	0 to 30 cmH 2 O/0 to 30 mbar
PS (Pressure Support)	0 to 60 cmH 2 O/0 to 60 mbar *
Flow	6 to 100 L/min
I:E Ratio	1:99 to 3:1
PC (Pressure Control)	5 to 60 cmH 2 O/5 to 60 mbar
Ptrig (Sensitivity)	-9.9 to 0 cmH 2 O/-9.9 to 0 mbar
Manual Inflation	3 sec maximum
F I O 2 (Optional) +	.21 to 1.00
Bias Flow	7 L/min with PEEP 3 to 30 L/min (when NIV is On)
PS Max i time	0.1 to 3.0 sec
PS % Exp. Threshold	5 to 55%
Slope Rise	1 to 10
Flow Wave Pattern	square or descending

Monitored Parameters

Paw (Peak, Mean, Base)	VT I (insp. tidal volume)
MV I (insp. minute volume)	Peak Insp. Flow
Integrated Battery Pack	RR tot (total respiratory rate)
Back up internal battery	I:E Ratio
F I O 2 +	

Alarms

High Airway Pressure	Low Airway Pressure
High Baseline Pressure	Low Baseline Pressure
High Resp. Rate	Back-up Ventilation Alert
High Insp. Minute Volume	Low Insp. Minute Volume
Apnea	
High F I O 2 +	Low F I O 2 +
Device Alert	Low Battery

Eagle II™

EMV+®

Rate (BPM) BPM High Limit Alarm BPM Low Limit Alarm	1 - 60 20 - 99 2 - 40
Tidal Volume (V_T) (ml ATPD) V_T High Limit Alarm V_T Low Limit Alarm	50 - 1500 100 - 2000 0 - 500
Minute Volume (Vmin) (L)	0 - 99.9
Flow Rate (LPM)	0 -100 @ 40 cm H_2O
Inspiratory Time (Sec)	0.3 - 3.0
I:E Ratio	1:1 - 1:99
Trigger Sensitivity (default)	-0.5 - -6.0
FiO_2 (%)	21 - 100
Peak Inspiratory Pressure (cm H_2O) High Peak Inspiratory Pressure Alarm Low Peak Inspiratory Pressure Alarm	10 - 60* 20 - 100 3 - 35 * 80 with confirmation by operator
SpO_2 / Heart Rate Monitor	Yes
PEEP (cm H_2O)	Off, 0 - 25
Altitude Compensation	0 - 25,000 ft.
Apnea Backup Ventilation	Yes
Indicators: LCD, LED, Audible	Control Setpoints, Alarms, Alarm Mute, Alarm Setpoints, Power (Internal/External), External Oxygen, Menu, Pop-Ups

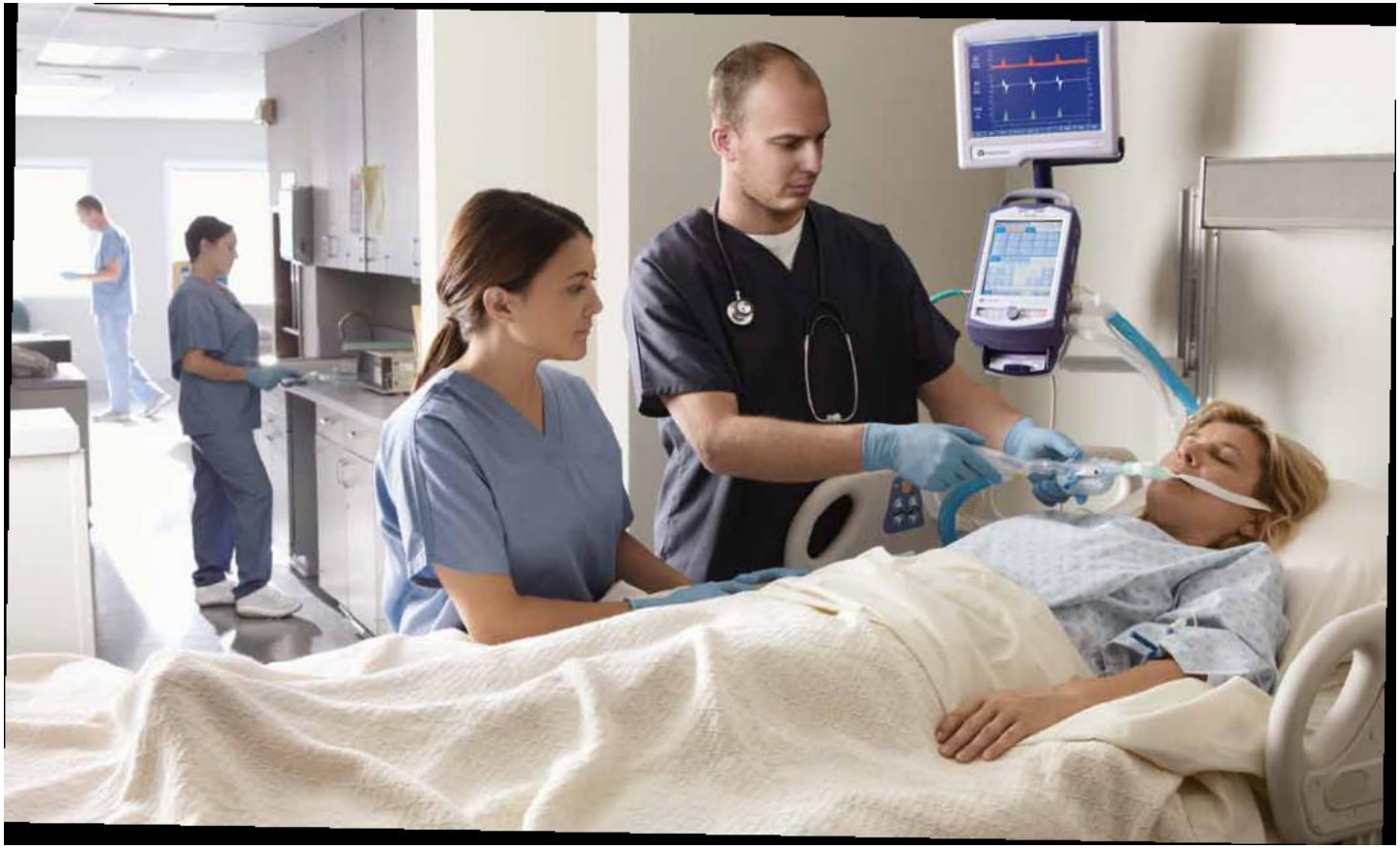
Alarms: Context sensitive help messages	Yes
Alarms: Non-operating: Audible, Visual	Yes
Alarms: Operating: Audible, Visual	Yes
Alarms: Advisory: Audible, Visual	Yes
Communications	USB
Enclosure: Material, size weight	Injection molded thermoplastic, 12.5" H x 8" W x 4.5" D, 9.5 lbs
Operating Time Battery (Hours)	10
Power	External, Autosensing: 100 - 240 VAC, 50-60 Hz 12.5 - 28.0 VDC Internal Battery, Li Ion

Data

- Battery life – 12 hours or more
- WOB similar to LTV-1200
- Low gas consumption
- Under evaluation

EnVe Ventilator

Enve Ventilator



EnVe

- **Controls Range**
- Mode
- Volume A/C, pressure A/C, PRVC A/C, volume SIMV,
- pressure SIMV, PRVC SIMV, CPAP/PSV (volume), CPAP/PSV
- (pressure), CPAP/VtPSV, NPPV pressure, NPPV CPAP/PSV, Standby
- Volume 50 to 2,000 mL
- Inspiratory pressure 1 to 99 cmH2O
- Inspiratory time 0.3 to 9.9 seconds
- Peak flow 0 to 120 LPM, 180 LPM spontaneous
- PEEP 0 to 30 cmH2O
- Rate 1 to 80 breaths per minute
- Bias flow 3 to 10 L/min
- FiO2 LPS, 21% to 100%
- Flow cycle Off, 10% to 40%
- Flow trigger “- -” (off), P, 1 to 9 L/min
- Pressure trigger 1 to 20 below PEEP
- High pressure
- alarm delay
- 0, 1, 2 breaths
- Inspiratory pause “- -” (off), 0.1 to 3.0 seconds
- O2 flush 2 to 3 “min”

EnVe

- **Breath modes**
- Assist/control (A/C), synchronized intermittent mandatory ventilation (SIMV),
- continuous positive airway pressure (CPAP), apnea backup ventilation,
- noninvasive positive pressure ventilation (NPPV)
- **Breath types**
- Pressure control, pressure regulated volume control (PRVC), pressure support (PSV),
- volume control, volume targeted pressure support (VtPSV)

EnVe

- **Physical dimensions (height x width x depth)**
- **Size** 11.3” h x 7.1” w x 3.3” d (28.7 cm x 18.0 cm x 8.4 cm)
- **Weight** 9.9 lbs (4.5 kg)
- **Monitor Range**
- Auto PEEP 0 to 99 cmH2O
- Delta pressure (dPaw) 1 to 99 cmH2O
- Expiratory pressure (Pexp) 0 to 100 cmH2O
- Plateau pressure (Pplat) 1 to 99 cmH2O
- Static lung compliance (Cstatic) 1 to 999 mL/cmH2O
- **Maneuvers**
- Expiratory-hold 0 to 6 seconds
- Inspiratory-hold 0 to 6 seconds
- **Patient and ventilator data**
- **Waveforms** Pressure, flow, volume and pleth
- **Loops** Flow/volume, volume/pressure
- **Trending** 24 hour trend of all patient monitors

Summary

- Recent evidence does not suggest a required change in device specifications
- New devices are available – some excellent, some useless
- Understand the requirements and use a device with characteristics which will meet with those requirements