





Respimatic 100



Respimatic 100 - Preliminary and Confidential

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00 - Preliminary and Confidential

Setting the Context

The Motivation

The Problem Statement

RESPIMATIC 100 (Patent Pending)

Is it right for you?

Need adult respiratory support?

Support from Initiation to Weaning?

No compressed air or piped Oxygen?

Connect to O, Cylinder or Concentrator?

Full range of Respiration parameters?

Breath Synchronization for Patient Comfort?

Remote monitoring capability?

Handle harsh-uncontrolled Environment?

Easy-to-use System?

Budget Friendly?

Respiration Assist Devices

Categories - Usage and Pricing











BiPAP

Big Hole

ICU Ventilator

CPAP v/s BiPAP v/s RESPIMATIC 100 v/s ICU-VENTILATOR

CPAP	BiPAP	Respimatic 100	ICU Ventilator	
Continuous Positive Airway Pressure	Continuous Bi-Level Airway Positive Pressure	Mechanical Ventilation with 4 most- used ventilation modes and controls	Mechanical Ventilation with very sophisticated modes and controls	
Non-invasive	Non-invasive	Non-invasive + Invasive	Non-invasive + Invasive	
High Flow + PEEP	Inspiratory Pressure + PEEP	Tidal Volume + Support Pressure + PEEP	Tidal Volume + Support Pressure + PEEP	
Useful for Type 1 respiratory Failure (Hypoxemic)	Useful for Type 2 respiratory Failure (Hypercopnic)	Useful for Hypoxemic and Hypercopnic respiratory failure	Useful for Hypoxemic and Hypercopnic respiratory failure	
Continuous flow of air at a constant pressure. Increases mean airway pressure to recruit collapsed alveoli	Continuous flow of air at different constant pressures during inspiration and expiration breathing phase	Independent control over the volume, the respiration rate and pressure	Independent control over the volume, the respiration rate and pressure	
Useful only when patient can breathe on his own			Useful when patient can or CANNOT breathe on his own	
Only Spontaneous breaths that are	Only Spontaneous breaths that are	Spontaneous breaths + Mandatory breaths controlled by RR and I:E	Spontaneous breaths + Mandatory breaths controlled by RR and I:E	
External FiO2 control	patient triggered. patient triggered. External FiO2 control External FiO2 control		Direct FiO2 control	
Breath Synchronization N/A	Breath Synchronization N/A	System assisted FiO2 control Full Breath Synchronization	Full Breath Synchronization	
No Tidal Volume control	Indirect Tidal Volume control (IPAP-EPAP)	Direct Tidal Volume control	Direct Tidal Volume control	
No Respiration Rate control	No Respiration Rate control No Respiration Rate control		Direct Respiration Rate control	
No Inspiration: Expiration ratio control	Inspiration: Expiration ratio control No Inspiration: Expiration ratio control		Direct Inspiration:Expiration control	
External Humidity control	External Humidity control External Humidity control		Direct Humidity control	
No display of Peak, Plateau or PEEP	No display of Peak, Plateau or PEEP	Full display of Peak, Plateau and PEEP	Full display of Peak, Plateau and PEEP	
Minimal alarm signals	Minimal alarm signals	Full set of Alarm signals	Full set of Alarm signals	
No remote monitoring	No remote monitoring	Sophisticated Remote WEB Dashboard	Minimal Remote monitoring (if any)	

Observations on Ventilator Evolution



Iron Lung Age



Pneumatic Age



μController Age



Smart "E"-Age

Most-used Ventilation Modes have not changed

- Volume and Pressure Control
- Control BPM, I/E, VT and PS
- Monitor pressures and flow
- Safety Alarm systems

Diminishing Returns from what has evolved ...

- Exotic Ventilation modes
- Multitude of Sensors
- Fancy Touch-screen LCD Displays

Respimatic 100 Details

System Components

Technical Details

US and INDIA IP Protection



(19) United States

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(54) VENTILATOR

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- Foreign Application Priority Data

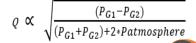
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ABSTRACT

Provided is a ventilator that includes a breathing system, a mechanical system coupled to breathing system, and a control system coupled to breathing system and mechanical system. The control system includes pressure sensors, processing circuitry, and memory configured to store a look-up table. The processing circuitry receives a set of values for plurality of parameters, identifies a compression value from a plurality of compression values in the look-up table based on the received set of values. The processing circuitry causes the mechanical system to compress a bag valvabreathing system in accordance with the identify sion value. The compression of the bag gaseous inhalant to flow through the breathi a time-interval. The processing circuitry actual volume of the gaseous inhalant and iter fies the compression value of the bag valve desired volume of the gaseous inhalant.



An important and necess and F 62 encountered in our system are of the order of tens of cmH₂O wh is of the of a thousand cmH2O of pressure. At sea level, Patmosphere is O. Even at an altitude of 15,000 feet,

 $\underline{)}$. On the other hand, the P_{G1} and P_{G2} in the system Patmosphere is appro range from 1

term is negligible compared to (2* Patmosphere), even more so since it ued a square root. The flow equation can be simplified to the one below.

$$Q \propto \sqrt{\frac{(P_{G1} - P_{G2})}{Patmosphere}}$$

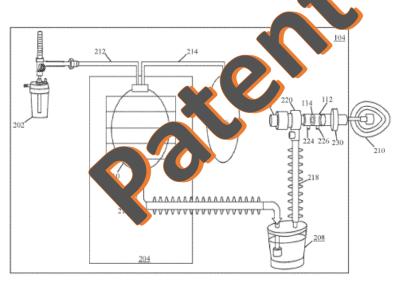
Recalling Equation 2 from the theory section above, this equation can be recast as below given that the orifice characteristics and pressure tap locations are the same for every system.

$$Q = C * \frac{\sqrt{(P_{G1} - P_{G2})}}{\sqrt{(Patmosphere)}}$$
 where $\underline{C} = f(Re)$ Reynold's number

At a given geographical location, *Patmosphere* is also a constant. So, the above equation further reduces to the one below.

$$Q = \left(\frac{C}{\sqrt{Patmoshpere}}\right) * \sqrt{(P_{G1} - P_{G2})}$$

The equation needs further simplification to ease the computation burden of the square root computation for and inexpensive micro-controller. The constraints are as below.



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Our Solution RESPIMATIC 100

4 Commonly Used Ventilation Modes CMV, ACV, SIMV, PSV

Respiration Rate, Tidal Volume, PEEP, Pressure Support & FiO2 Controls

Volume Controlled and Pressure Supported
Breaths

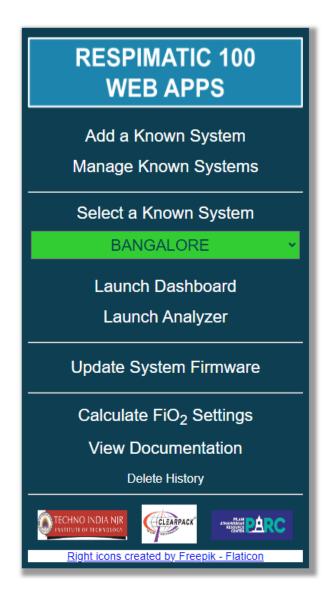
Mandatory &
Spontaneous Breaths
with Full Breath
Synchronization

Complete set of WEB Apps
Remote Dashboard
Remote Recorder
Remote Analyzer

Low-speed Wi-Fi sufficient Phone Hot-spot sufficient

Uses secure HTTPS protocol

Field upgradable with new Firmware releases



Breathing Circuit

Proprietary, <u>patent-pending</u> Pressure line connector with Orifice plate

COTS single-limb Breathing Circuit with NRBM

BVM or Ambu Bag with Reservoir

Pressure sensing lines

PEEP valve

HME Filter

Oxygen Source

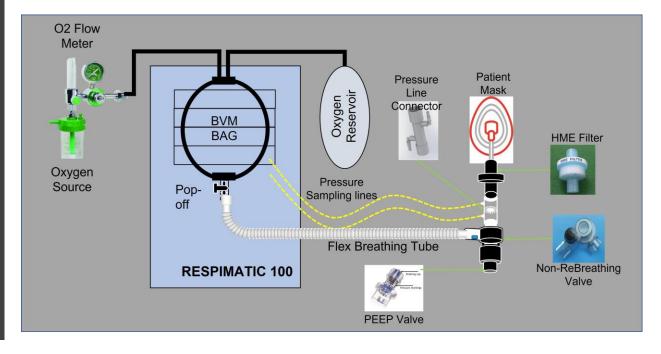




Off-the-Shelf Single limbed Circuit with NRBM



Proprietary Dual
Pressure line Connector



Front Panel The Human-Machine Interface

No delicate touch screen etc.

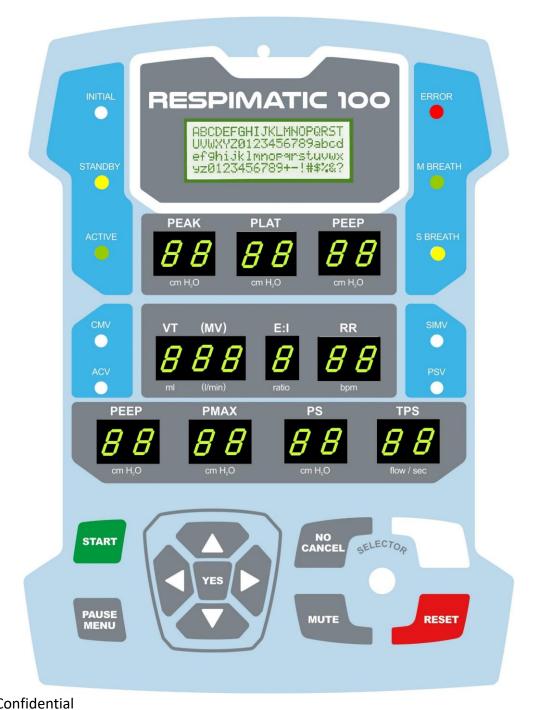
Easy to read 7-seg
LED Parameters
Display

Parameter selection using navigation arrow buttons

4-line LCD Display for displaying Messages and Menus

Peak, Plateau, PEEP pressures displayed after each breath

Shows Delivered
Volumes, Lung
Compliances, Breath
types etc.



Dashboard Snapshot View

Anyone can monitor any patient via the WEB One-to-many and many-to-one monitoring

5 Dashboard views

- Snapshots
- Breath Waveforms
- Charts
- Statistics
- Alerts (Audible or not)

Breath Range Selector on every view to display data for different breath ranges

 For instance, use to compare the statistics for the first hour of ventilation against the second hour.



https://www.respimatic.com

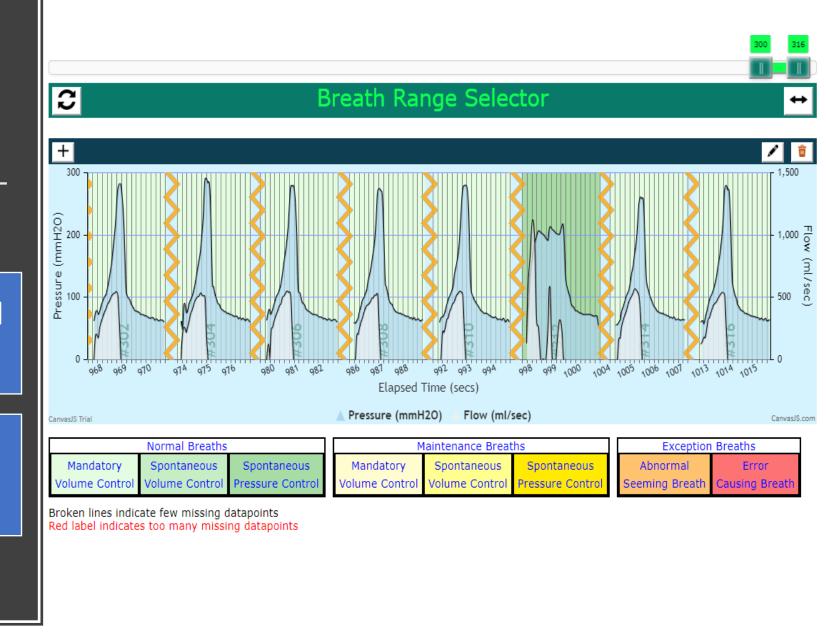
Dashboard Waveforms View

Pressure and Flow Graphs

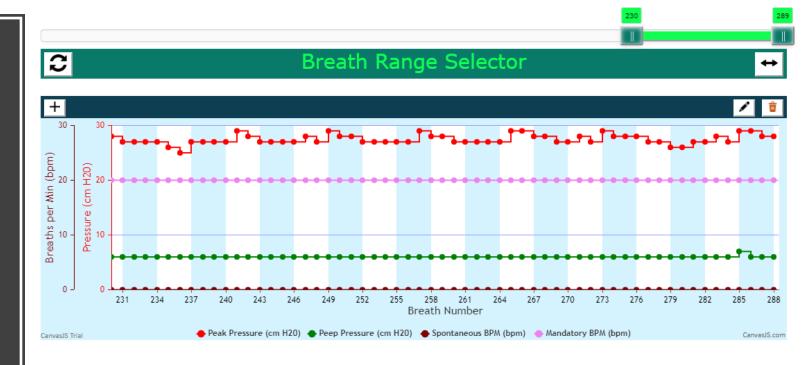
For Selected Breaths

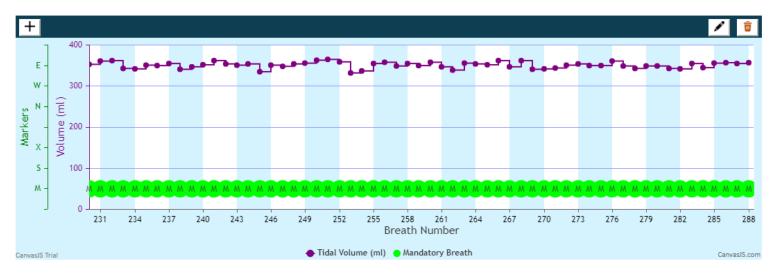
Periodic Display

Display on demand



Dashboard Charts View





Dashboard Statistics View







Parameters Measured

Parameter	Units	Min	Max	Av
Peak Pressure	cmH20	27.0	30.0	28.
Plateau Pressure	cmH20	17.0	29.0	27.
PEEP Pressure	cmH20	5.0	5.0	5.
Tidal Volume Delivered	ml	384.0	412.0	399.
Total Minute Volume	litres/min	8.0	8.1	8.
Mandatory Minute Volume	litres/min	8.0	8.1	8.
Spontaneous Minute Volume	litres/min			
Mandatory BPM	bpm	20.0	20.0	20.
Spontaneous BPM	bpm			
FIO2	%	21.0	21.0	21.
Static DeltaV/DeltaP	ml/cmH20	17.0	32.0	18.
Dynamic DeltaV/DeltaP	ml/cmH20	16.0	18.0	17.
System Temperature	degC	27.0	27.0	27.

Miscellaneous Information

Information	Value
Number of Breaths	73
Number of Mandatory Breaths	73
Number of Spontaneous Breaths	0
Number of Maintenance Breaths	0
Number of CMV-mode Spontaneous Breaths	0
Number of Missing Intervals (Packet loss)	0
Number of WiFi or Server Disconnects	0
Number of Notifications	0
Number of Warnings	0
Number of Errors	0

Static Information

Patient Name: Rajnikanth Bond Gender: Male Age: 69yr Weight: 74kg Height: 181cm

System Location: Namma Bengaluru Location Altitude: 3000 ft (915 mtrs) Location Atmospheric Oxygen: 19%

Parameter Settings Used

Parameter	Units	Values
Ventilation Mode	mode	ACV
Tidal Volume	ml	400
Minute Volume	I/min	10
Respiration Rate	bpm	20
I:E Ratio	ratio	1:2
PEEP Pressure	cmH20	5
Maximum Pressure	cmH20	50
Support Pressure	cmH20	20
Support Pressure Termination	%flow,secs	20%
FIO2	%	21

Sequence of Parameter Combinations

MODE	VT/MV	RR	I:E	PEEP	PMAX	PS	TPS	FIO2	# of BREATHS	Before BREATH#
?	?	?	?	?	?	?	?	?	1	0
ACV	400	20	1:2	5	50	20	20%	?	2	2
ACV	400	20	1:2	5	50	20	20%	21	70	4

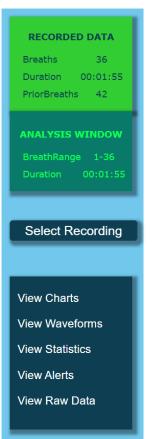
Dashboard Alerts View



Analyzer

Any patient Session can be recorded locally or remotely.

The recorded Session can then be analyzed off-line using the Analyzer.

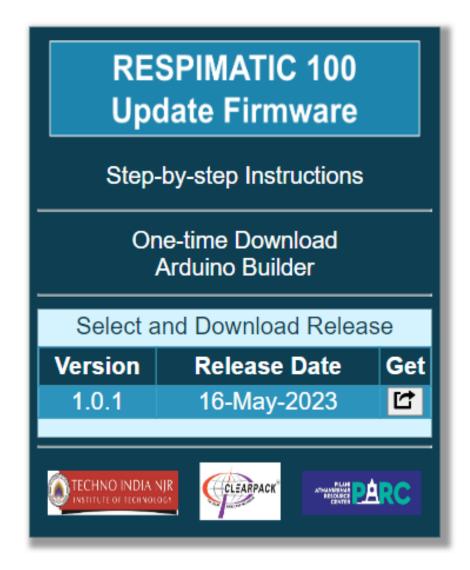




Updating Firmware

Firmware releases available on the WEB.

Step-by-step menu driven update procedure



Ventilation Modes

The 4 most frequently used

Continuous Mandatory Ventilation (CMV)

Volume Controlled Mandatory Breaths

Ignore spontaneous breaths

Synchronized Assist Control Ventilation (Sync ACV)

Volume Controlled Mandatory Breaths

Volume controlled breaths in response to spontaneous breaths

Breath Synchronization

Synchronized Intermittent Mandatory Ventilation (SIMV)

Volume Controlled Mandatory Breaths

Pressure supported breaths in response to spontaneous breaths

Breath Synchronization

Pressure Support Ventilation (PSV)

Pressure supported breaths in response to spontaneous breaths

Monitoring of Minute Volume

Fallback to SIMV if insufficient Minute volume

Volume Controlled Breaths (All modes)

Tidal Volume (ml)

200 to 600 ml increments of 50 ml

Respiratory Rate (bpm)

10 to 30 bpm increments of 1 bpm

Inspiration/Expiration Ratio (I:E)

1:1 1:2 1:3

PEEP (cmH₂O)

4 to 15 cmH₂O increments of 1 cmH₂O

Max Pressure (cmH₂O)

15 to 50 cmH₂O increments of 5 cmH₂O

FiO₂ Support

System Managed Externally Controlled 21% to 100%

Pressure Supported Breaths

(SIMV & PSV modes)

Support Pressure (PS)

5 cmH₂O to 35 cmH₂O in increments of 5 cmH₂O

Support Pressure Termination (TPS)

Flow-dependent

Terminate when flow falls to 10%, 20%, 30%, 40%, 50% or 60% of peak flow

Time dependent

Terminate after 1.0 to 2.5 secs in increments of 0.5 secs

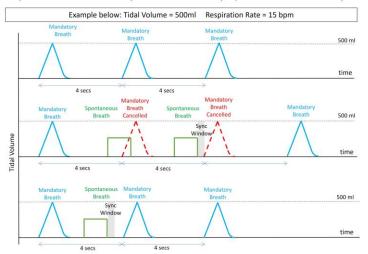
Breath Synchronization

Both ACV and SIMV modes

- A must for patient comfort
- Synchronize Mandatory breaths with Spontaneous breaths
- Prevent breath stacking

Breath Syncing in SIMV mode

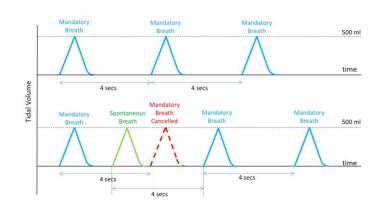
There is a sync-window - the next mandatory breath is rescheduled only if spontaneous breath within the sync-window



Breath Syncing in Synchronized AC Mode

There is no sync-window - the next mandatory breath is always rescheduled after a spontaneous breath

Example below: Tidal Volume = 500ml Respiration Rate = 15 bpm



FiO₂ Settings

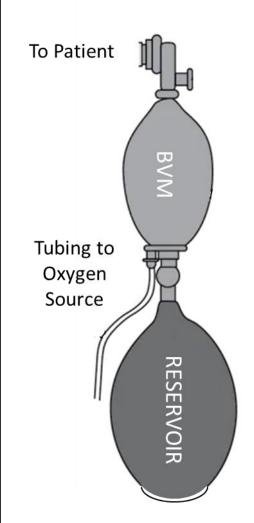
Without the Reservoir bag, FiO₂ delivered is the Atmospheric O₂ content at site

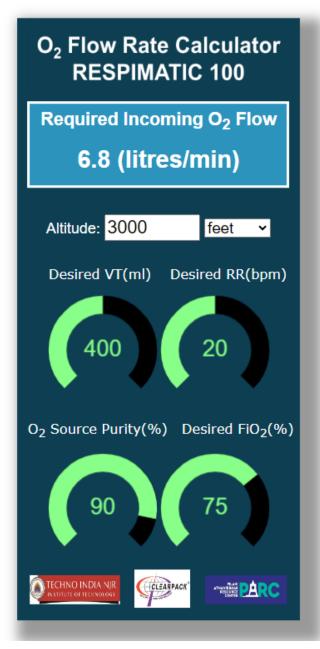
FiO₂ delivery with the Reservoir bag is mathematically modelled, calibrated and verified in the Lab to provide +/- 5% accuracy

Front-panel guides the user in setting the appropriate input O_2 flow rate from the O_2 source for a given FiO_2

The mathematical model provides for a possible O_2 concentrator as an O_2 source (purity < 100%)

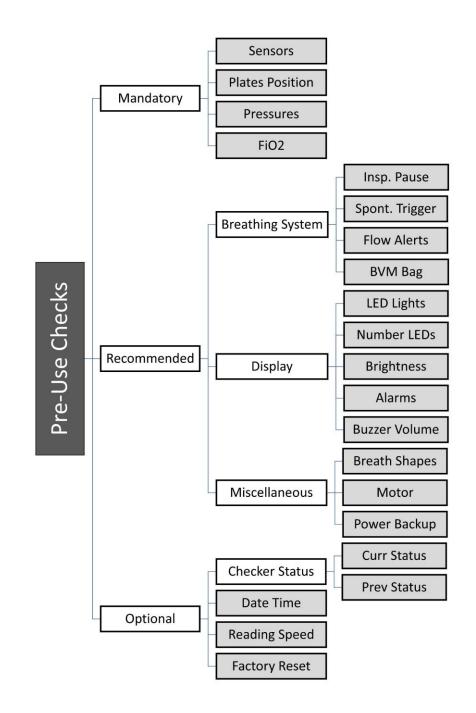
Online Web-accessible FiO₂ calculator is also provided for exploration purposes





Alarms and Safety Features

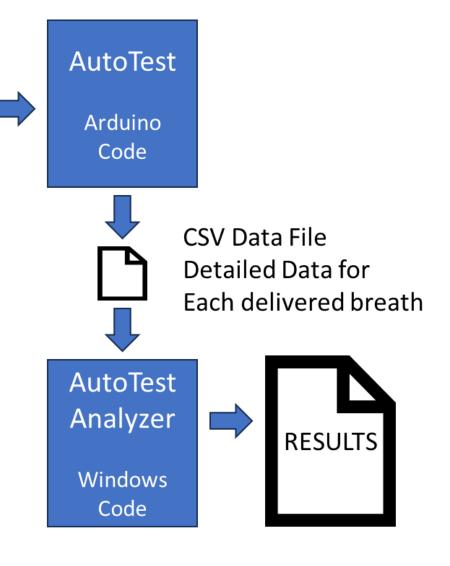
- Enforcement of Pre-use checks
- Alarms, Warnings and Notifications
- Maintenance Breaths till Alarm situation rectified
 - Max Pressure Alarm
 - Pressure Leak Alarm
 - Mask OFF Alarm
 - System Temperature Alarm
 - Sensor failure Alarm
 - Breathing Circuit Failure Alarm
 - Detect coughing/hiccuping fits
 - Inconsistent input parameters
 - Extreme parameter combination warnings
 - And many more ...



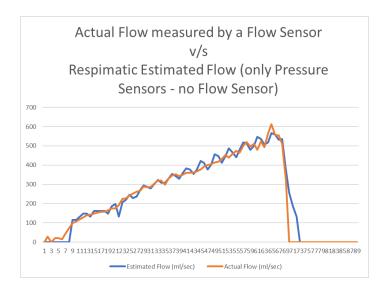
Automated Testing

AutoTest Controls

- 1. Select PEEP
- Run all combinations of Selected ranges of
 - Ventilation Modes
 - Respiration Rates
 - I:E ratios
- 3. # Breaths per Combo
- 4. % Spontaneous Breaths

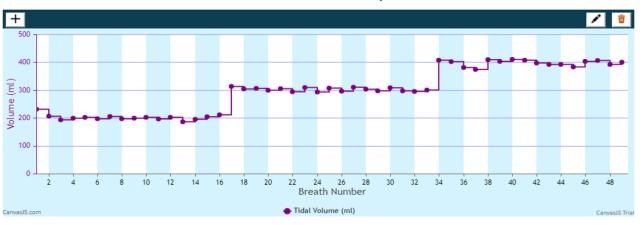


Some Results

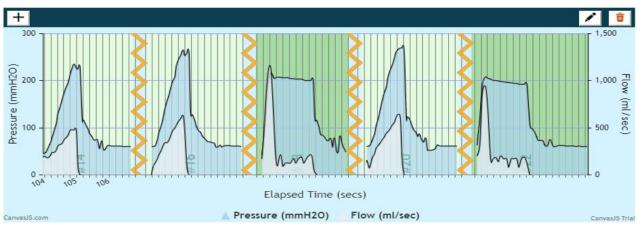


Sample FiO2 Data									
	PEEP=6,EI=2	2	Measured	Calculated	ERROR				
VT	RR	O2 (I/min)	FiO2(%)	FiO2(%)	%				
400	20	2	40.5	39	4%				
400	20	2.5	45.5	43.5	4%				
400	20	3	49	48	2%				
400	20	3.5	54	53.5	1%				
400	20	4	59.8	57	5%				
400	20	4.5	63.5	61.5	3%				
400	400 20		67.5	66	2%				
400 30		2	33	33	0%				
400	400 30		36.5	36	1%				
400	30	3	38.5	39	1%				
400	30	3.5	41.5	42	1%				
400	30	4	44.5	45	1%				
400	30	4.5	47.1	48	2%				
400	30	5	49.8	51	2%				

VT Titration for VT = 200, 300 and 400ml



A Mix of VC and PS Breaths



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Thank you