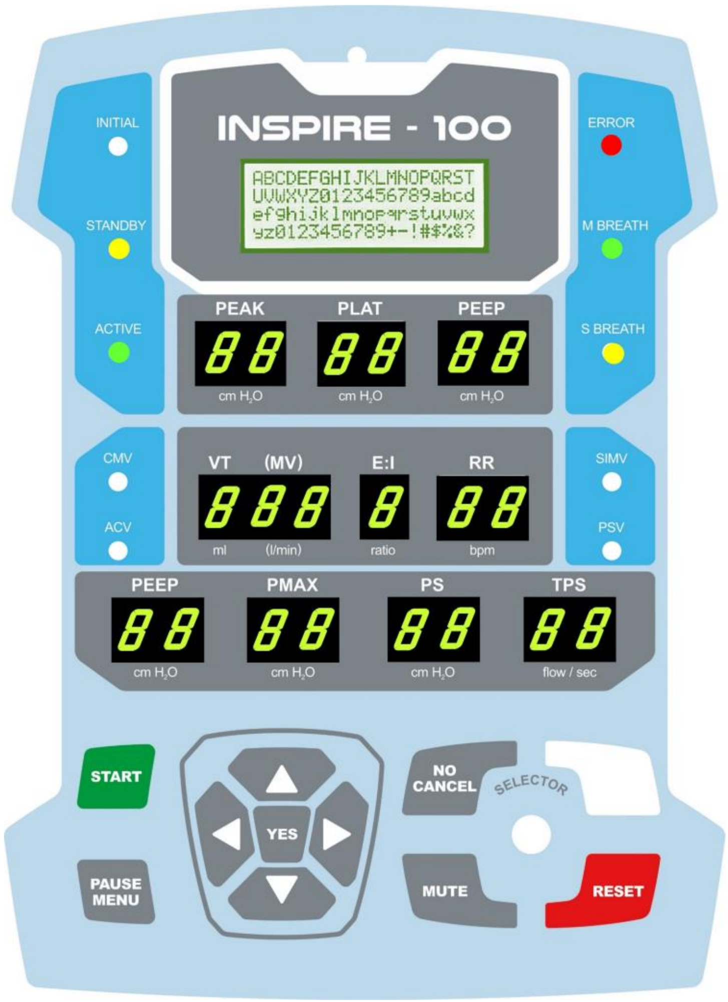
TekMedika



INSPIRE-100

Setting the Context

The Motivation

The Problem Statement

INSPIRE-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_2 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?*

NO PROBLEM!

Respiration Assist Devices

Categories – Usage and Pricing

Features

Less than Rs 50,000

CPAP

Less than Rs 1 Lakh

BiPAP

AFFORDABLE feature set for PHC, Small Clinic, and Ambulance Use?

Big Hole

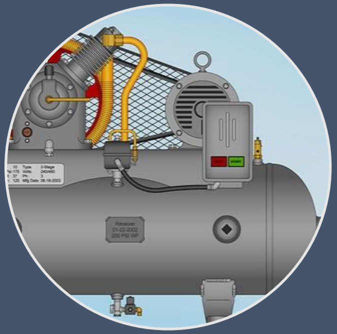
Rs 12 Lakhs ++

ICU Ventilator

CPAP *v/s* BiPAP *v/s* INSPIRE-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 only when patient can breathe on his own	Useful when patient can or CANNOT breathe on his own	Useful when patient can or CANNOT breathe on his own
Only Spontaneous breaths that are patient triggered.	Only Spontaneous breaths that are patient triggered.	Spontaneous breaths + Mandatory breaths controlled by RR and I:E	Spontaneous breaths + Mandatory breaths controlled by RR and I:E
External FiO2 control	External FiO2 control	System assisted FiO2 control	Direct FiO2 control
Breath Synchronization N/A	Breath Synchronization N/A	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	Direct Respiration Rate control	Direct Respiration Rate control
No Inspiration:Expiration ratio control	No Inspiration:Expiration ratio control	Direct Inspiration:Expiration 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

INSPIRE-100 Details

System Components

Technical Details

US and INDIA IP Protection

US 20230001126A1

(19) **United States**

(12) **Patent Application Publication** (10) **Pub. No.: US 2023/0001126 A1**

Nanda et al. (43) **Pub. Date: Jan. 5, 2023**

(54) **VENTILATOR**

(71) Applicants: **Sunil Nanda**, Bangalore (IN); **Pankaj Kumar Porwal**, Udaipur (IN)

(72) Inventors: **Sunil Nanda**, Bangalore (IN); **Pankaj Kumar Porwal**, Udaipur (IN)

(21) Appl. No.: **17/557,752**

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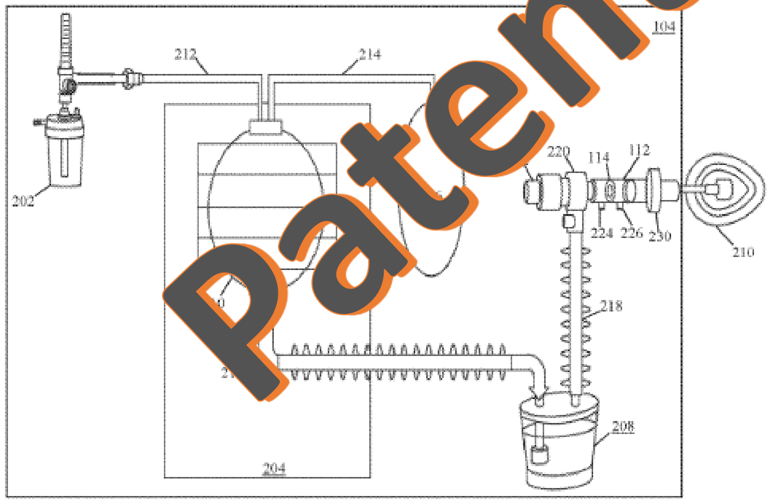
(57) **ABSTRACT**

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 valve [illegible] the breathing system in accordance with the identifi[illegible] sion value. The compression of the bag [illegible] gaseous inhalant to flow through the breathi[illegible]m wit[illegible] a time-interval. The processing circuitry [illegible] actual volume of the gaseous inhalant and itera[illegible] fies the compression value of the bag valve to [illegible] desired volume of the gaseous inhalant.



Patent Pending

$$Q \propto \sqrt{\frac{(P_{G1}-P_{G2})}{(P_{G1}+P_{G2})+2*Patmosphere}}$$

An important and necess[illegible] simplifi[illegible]n is t[illegible] and P_{G2} encountered in our system are of the order of tens of cmH_2O wh[illegible]mosp[illegible] is of [illegible]rder of a thousand cmH_2O of pressure. At sea level, *Patmosphere* is a[illegible] 1000[illegible]O. Even at an altitude of 15,000 feet, *Patmosphere* is appr[illegible]ely 60[illegible]O. On the other hand, the P_{G1} and P_{G2} in the system range from 1[illegible] 60[illegible]

[illegible](P_{G1}[illegible]) term is negligible compared to (2* *Patmosphere*), even more so since it [illegible]ed [illegible] 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.

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

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.

Our Solution INSPIRE-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

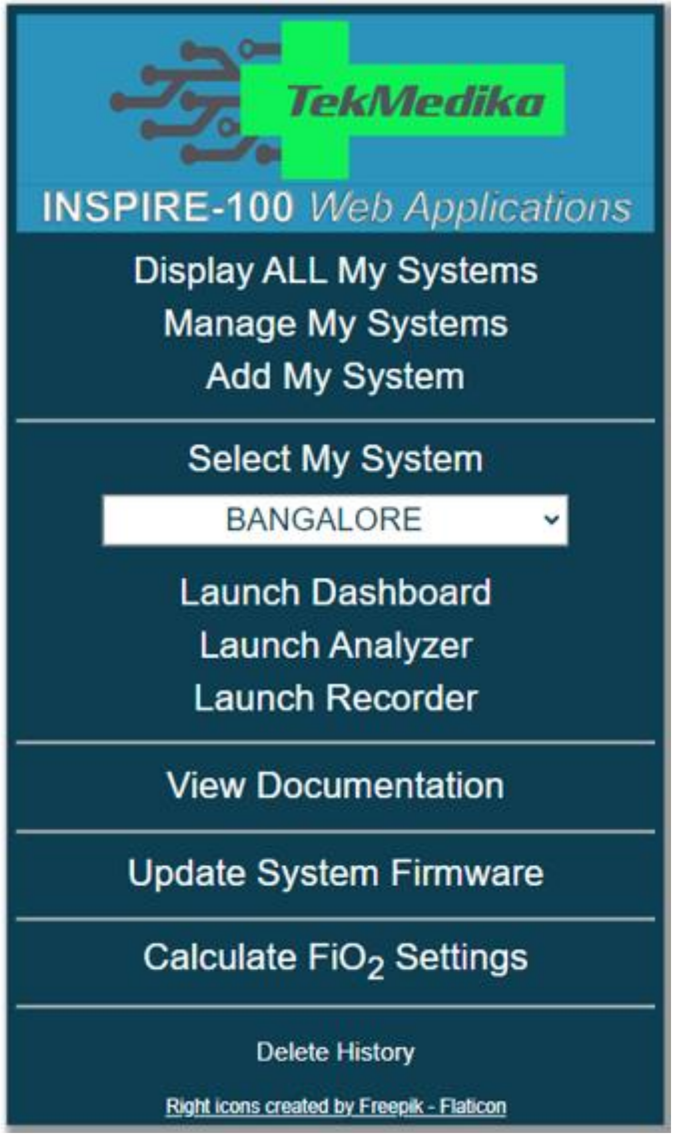
Complete set of WEB Apps
- Remote Dashboard
- Remote Recorder
- Remote Analyzer

Low-speed Wi-Fi sufficient

Phone Hot-spot sufficient

Uses secure HTTPS protocol

Field upgradable with new Firmware releases

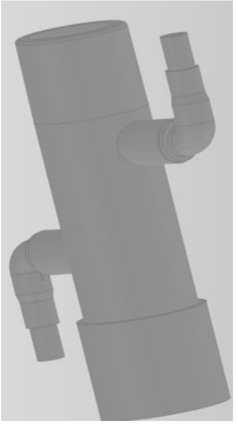


https://www.inspire-100.com

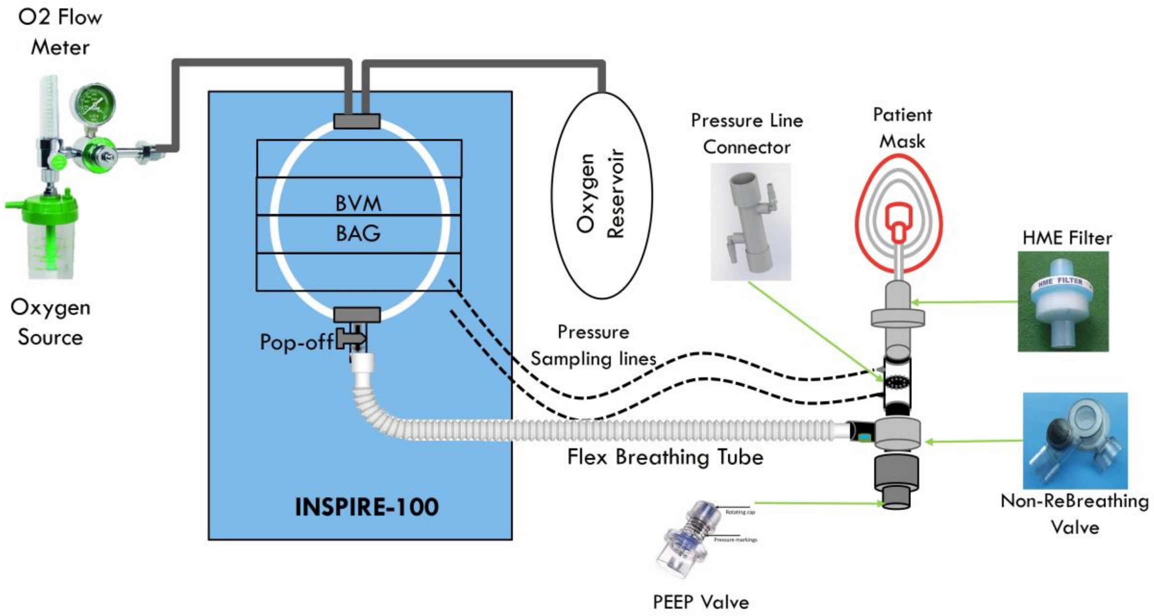
Breathing Circuit

- Proprietary, *patent-pending* 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

Simple Tactile buttons
No delicate touch
screen etc.

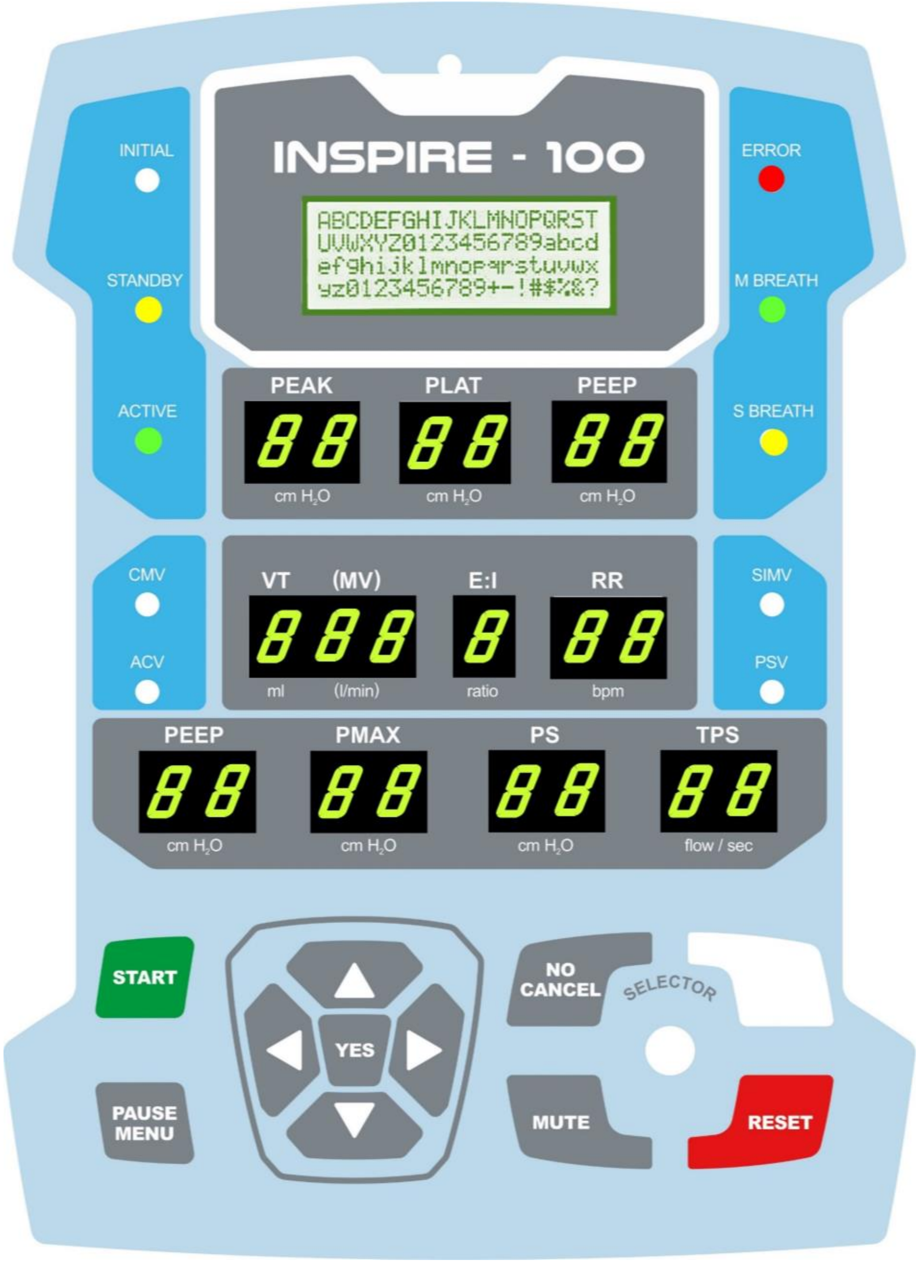
Easy to read 7-seg
LED Parameters
Display

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

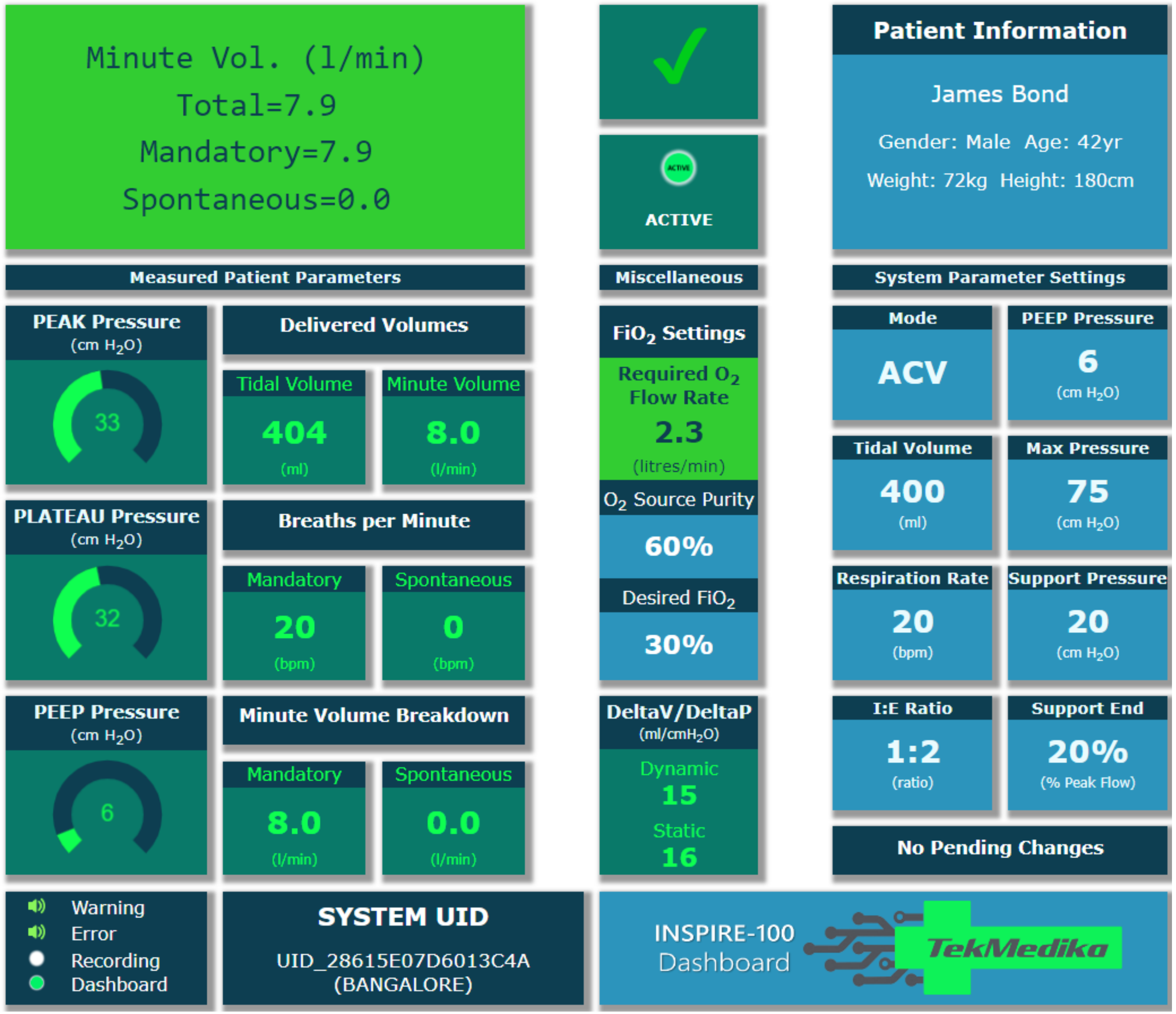
One-to-many and many-to-one monitoring

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.



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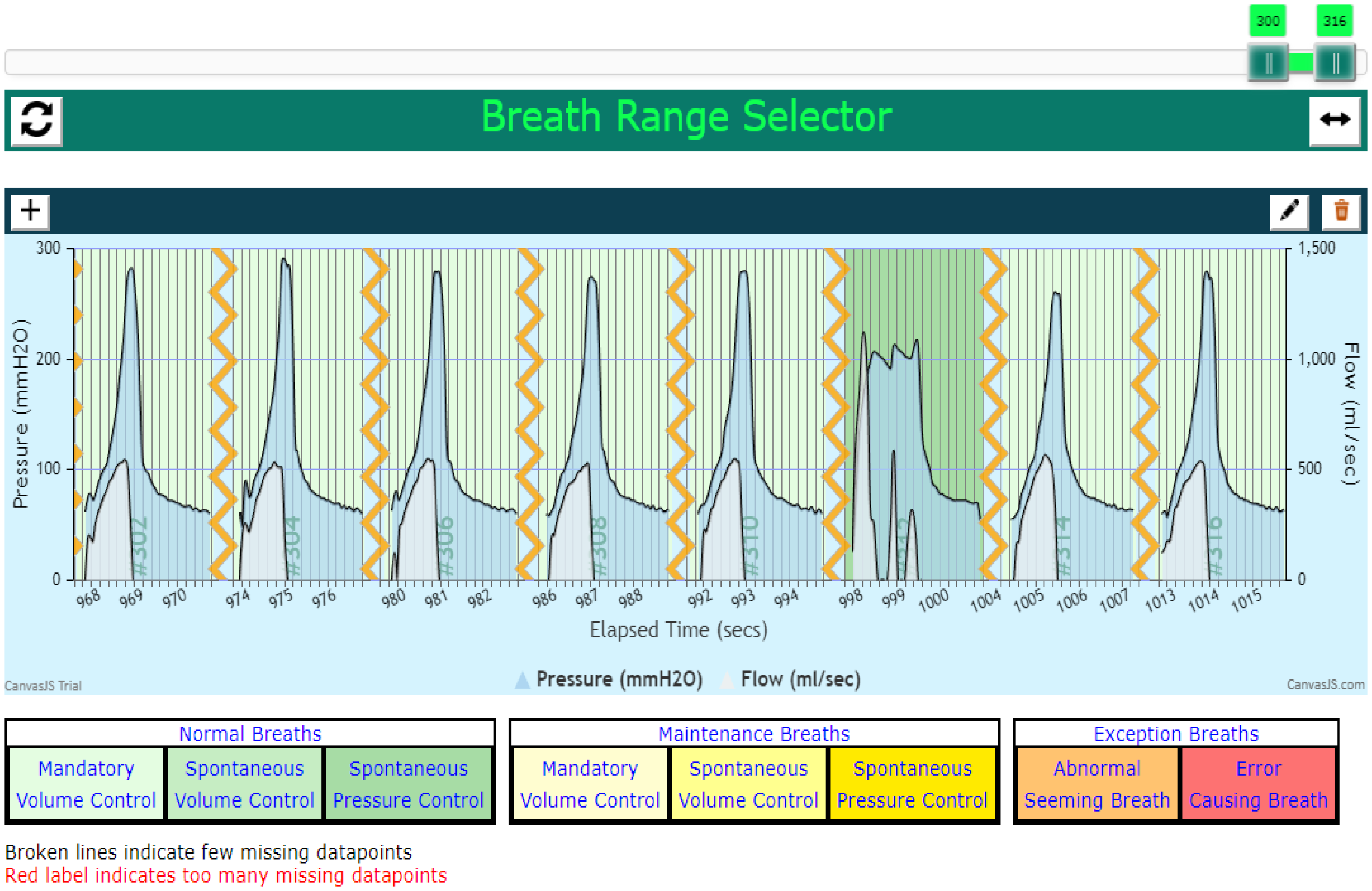
Dashboard Waveforms View

Pressure and Flow Graphs

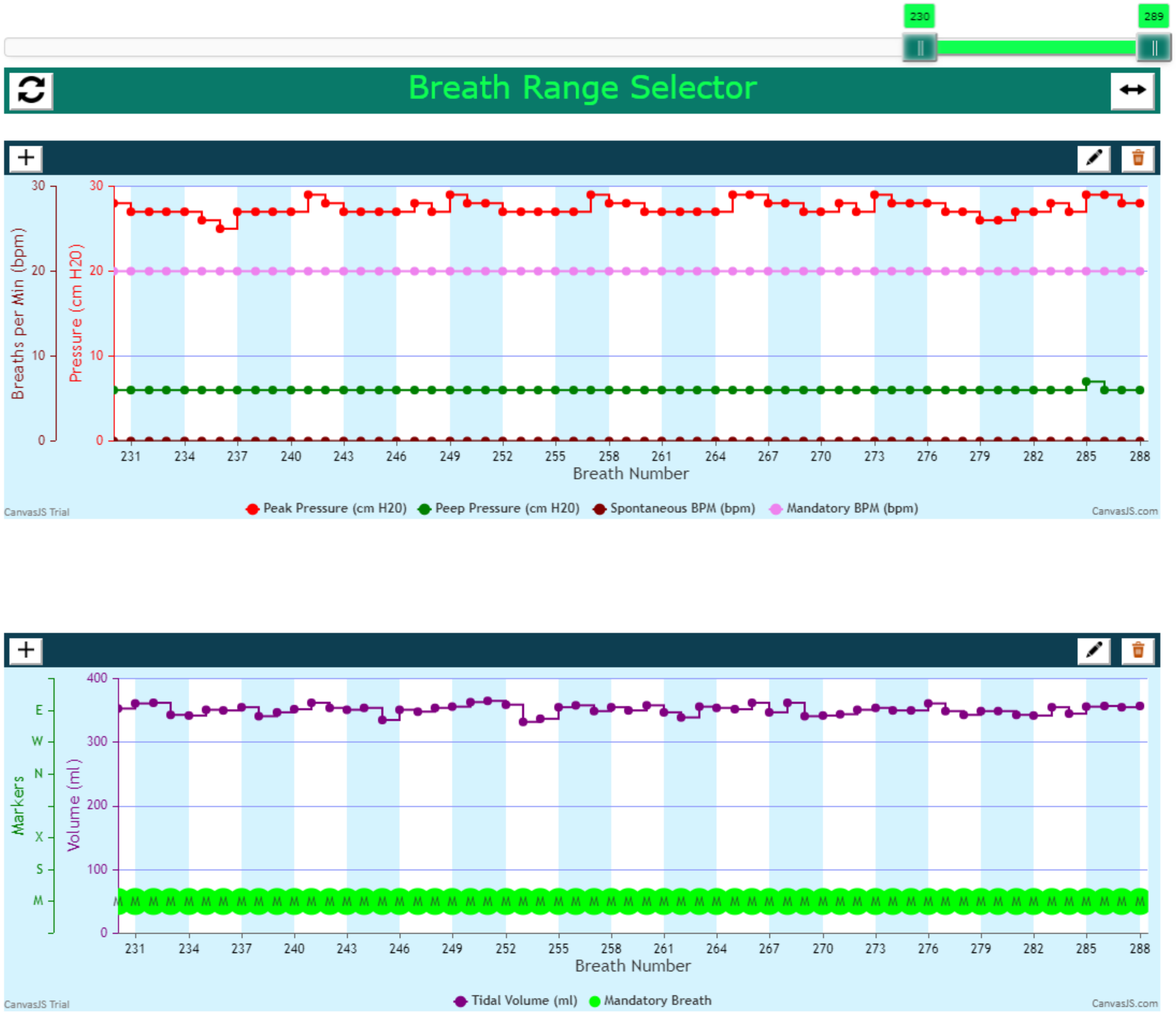
For Selected Breaths

Periodic Display

Display on demand



Dashboard
Charts View



Dashboard Statistics View

Breath Range Selector

Parameters Measured

Parameter	Units	Min	Max	Avg
Peak Pressure	cmH20	27.0	30.0	28.6
Plateau Pressure	cmH20	17.0	29.0	27.1
PEEP Pressure	cmH20	5.0	5.0	5.0
Tidal Volume Delivered	ml	384.0	412.0	399.8
Total Minute Volume	litres/min	8.0	8.1	8.0
Mandatory Minute Volume	litres/min	8.0	8.1	8.0
Spontaneous Minute Volume	litres/min	----	----	----
Mandatory BPM	bpm	20.0	20.0	20.0
Spontaneous BPM	bpm	----	----	----
FIO2	%	21.0	21.0	21.0
Static DeltaV/DeltaP	ml/cmH20	17.0	32.0	18.3
Dynamic DeltaV/DeltaP	ml/cmH20	16.0	18.0	17.0
System Temperature	degC	27.0	27.0	27.0

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	l/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

Session Errors

ERROR #1 Breath#6 [13-02-2024]10:45:36
Some Pressure Leak
Check PEEP valve
Check Patient Mask
Check Breathing tube

ERROR #2 Breath#7 [13-02-2024]10:45:39
Some Pressure Leak
Check PEEP valve
Check Patient Mask
Check Breathing tube

ERROR #3 Breath#8 [13-02-2024]10:45:42
Some Pressure Leak
Check PEEP valve
Check Patient Mask
Check Breathing tube

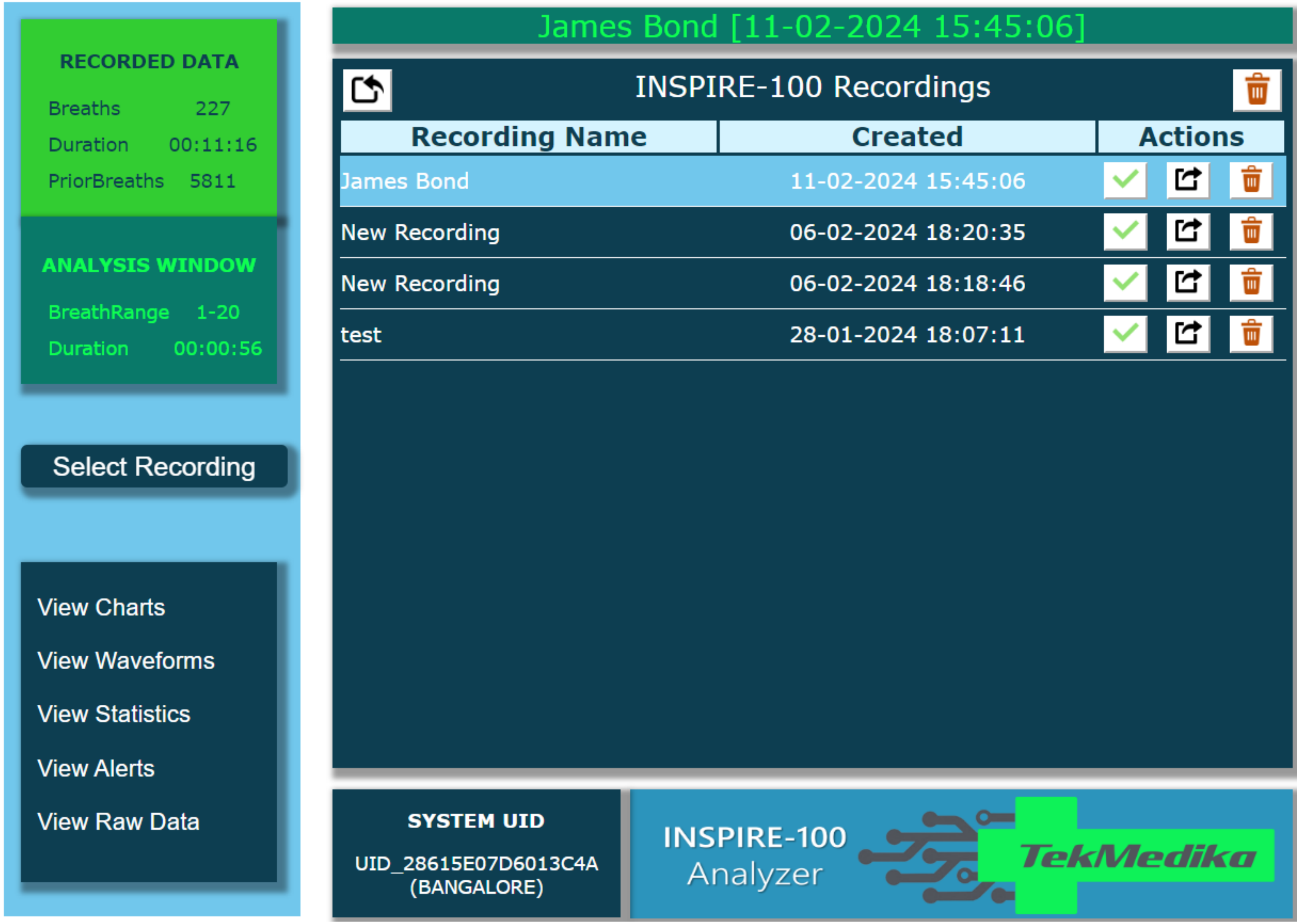
Session Warnings

Session Information

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)	***Synchronized Assist Control Ventilation (Sync ACV)***	***Synchronized Intermittent Mandatory Ventilation (SIMV)***	***Pressure Support Ventilation (PSV)***
Volume Controlled Mandatory Breaths Ignore spontaneous breaths	Volume Controlled Mandatory Breaths Volume controlled breaths in response to spontaneous breaths Breath Synchronization	Volume Controlled Mandatory Breaths Pressure supported breaths in response to spontaneous breaths Breath Synchronization	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 (cmH_2O)

4 to 15 cmH_2O
increments of 1 cmH_2O

Max Pressure (cmH_2O)

15 to 50 cmH_2O
increments of 5 cmH_2O

FiO_2 Support

System Managed
Externally Controlled
21% to 100%

Pressure Supported Breaths

(SIMV & PSV modes)

Support Pressure (PS)

5 cmH_2O to 35 cmH_2O in increments of 5 cmH_2O

Support Pressure Termination (TPS)

Flow-dependent

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

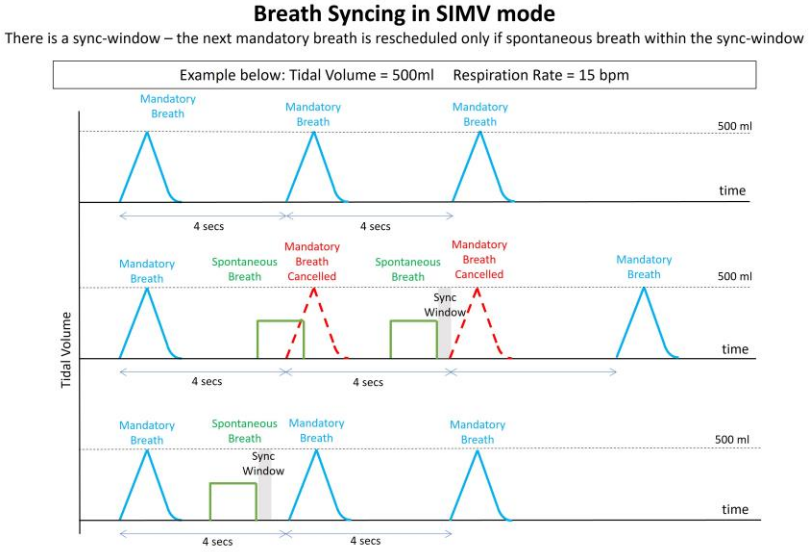
Time dependent

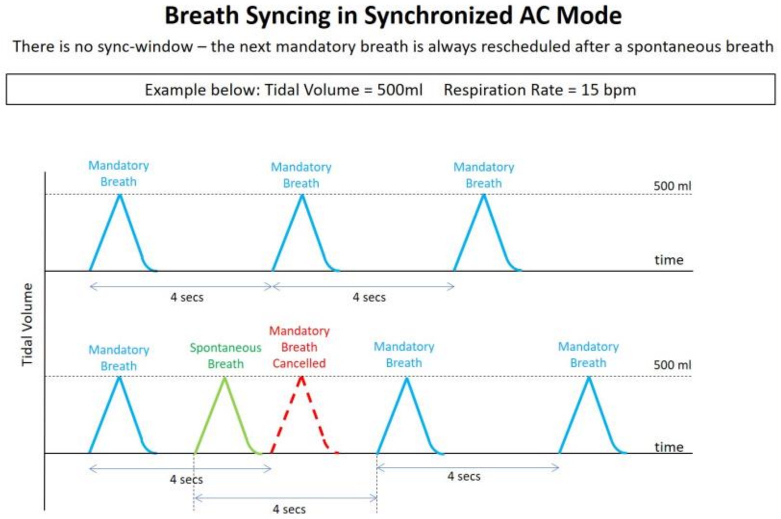
- Terminate after 1.0 to 2.5 secs in increments of 0.5 secs

Breath Synchronization

Both ACV and SIMV modes

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





FiO_2 Settings

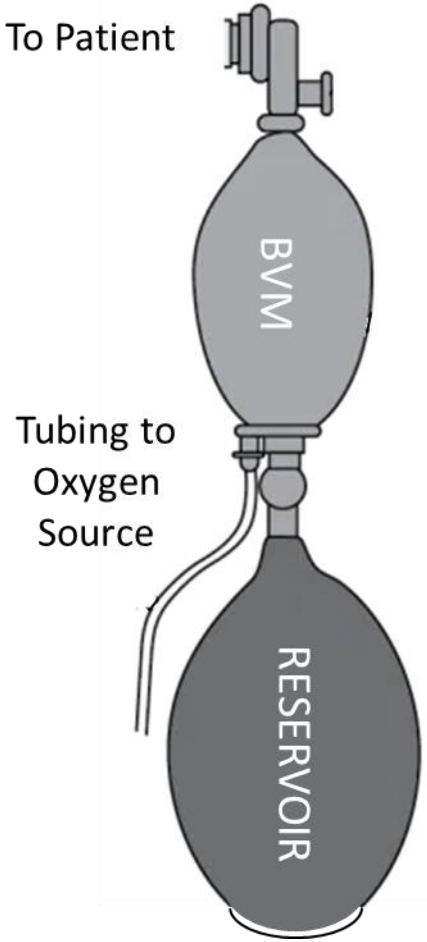
Without the Reservoir bag, FiO_2 delivered is the Atmospheric O_2 content at site

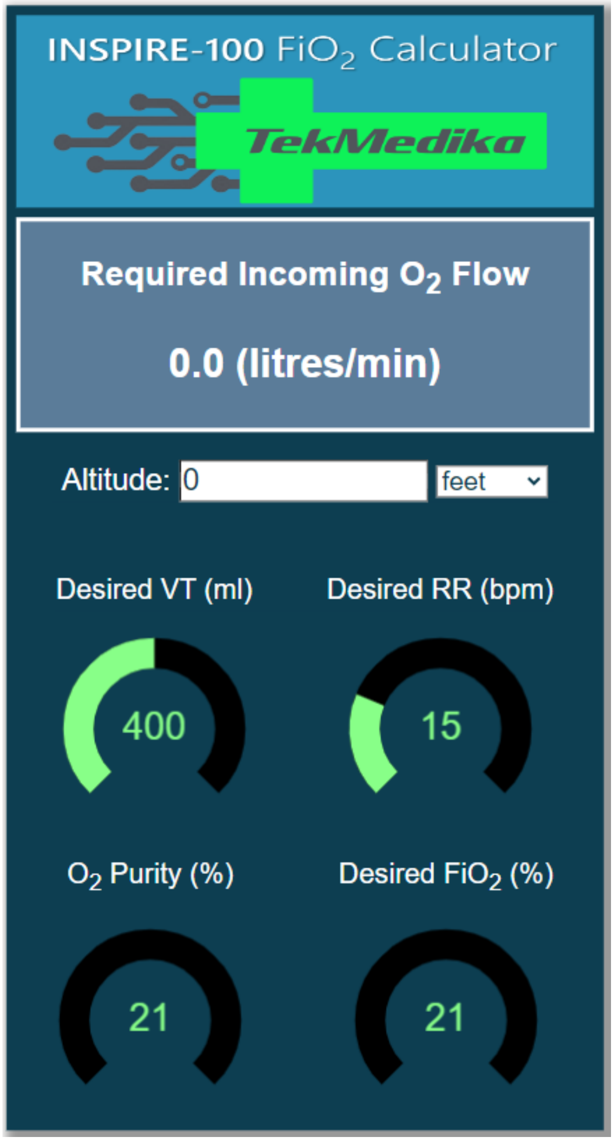
FiO_2 delivery with the Reservoir bag is mathematically modelled, calibrated and verified in the Lab to provide +/- 5% accuracy

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%)

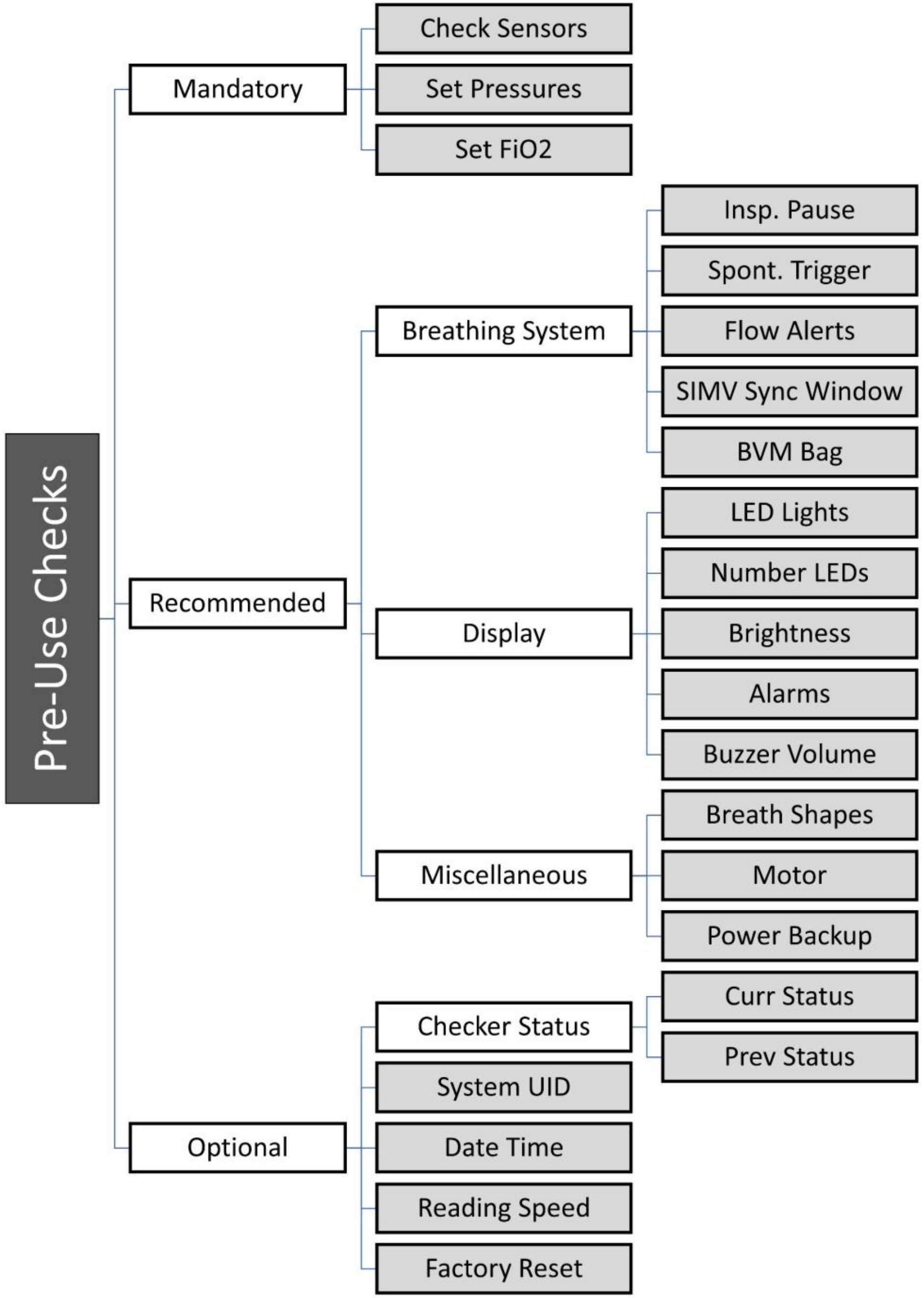
Online Web-accessible FiO_2 calculator is also provided for exploration purposes



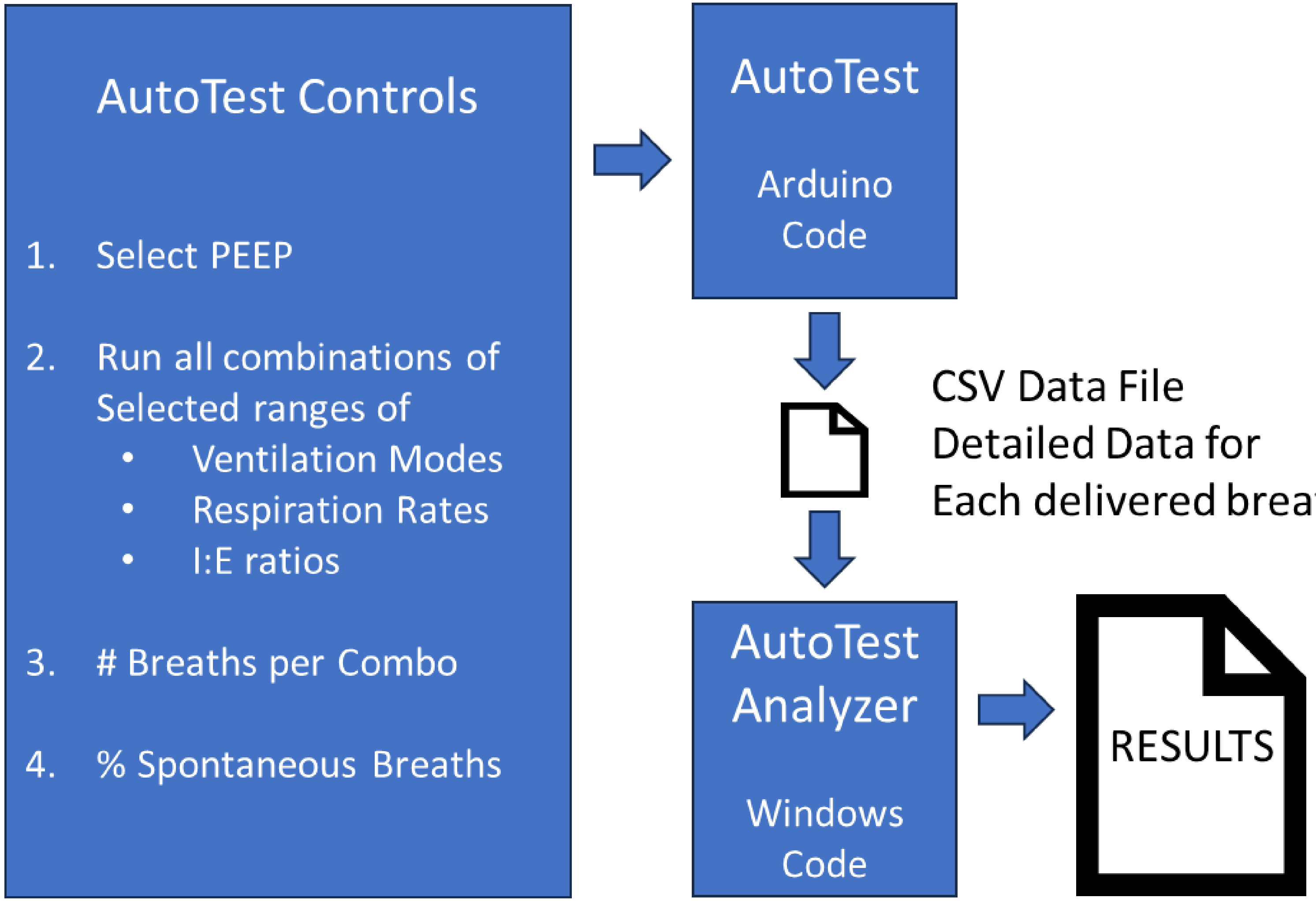


Alarms and Safety Features

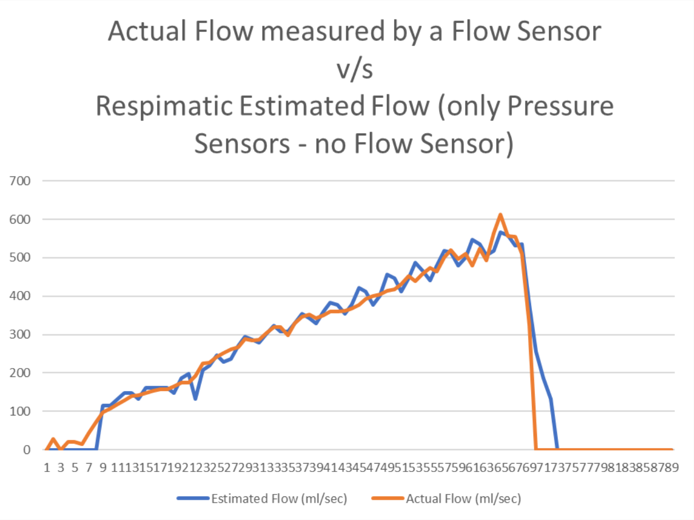
- **Enforcement of Pre-use checks**
- **Maintenance Breaths till Alarm situation rectified**
- **Alarms, Warnings and Notifications**
  - Max Pressure Alarm
  - Pressure Leak Alarm
  - Pressure Loss Alarm
  - Airway Blockage Alarm
  - System Temperature Alarm
  - Sensor Failure Alarm
  - Breathing Circuit Failure Alarm
  - Detect coughing/hiccupping fits
  - Inconsistent input parameters
  - Extreme parameter combination warnings
  - And many more …



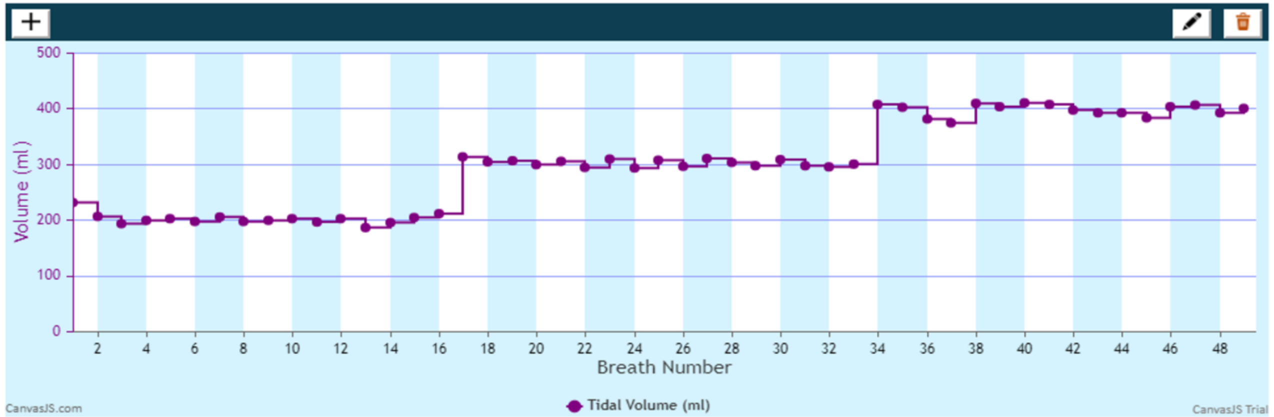
Automated Testing



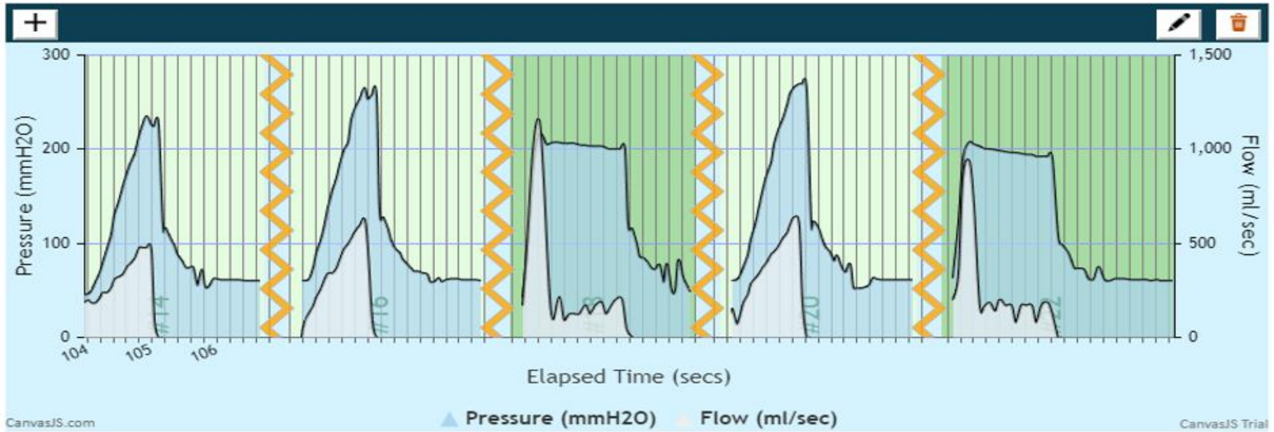
Some Results



VT Titration for VT = 200, 300 and 400ml



A Mix of VC and PS Breaths



Sample FiO2 Data

PEEP=6,EI=2			Measured	Calculated	ERROR
VT	RR	O2 (l/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	20	5	67.5	66	2%
400	30	2	33	33	0%
400	30	2.5	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%

Thank you