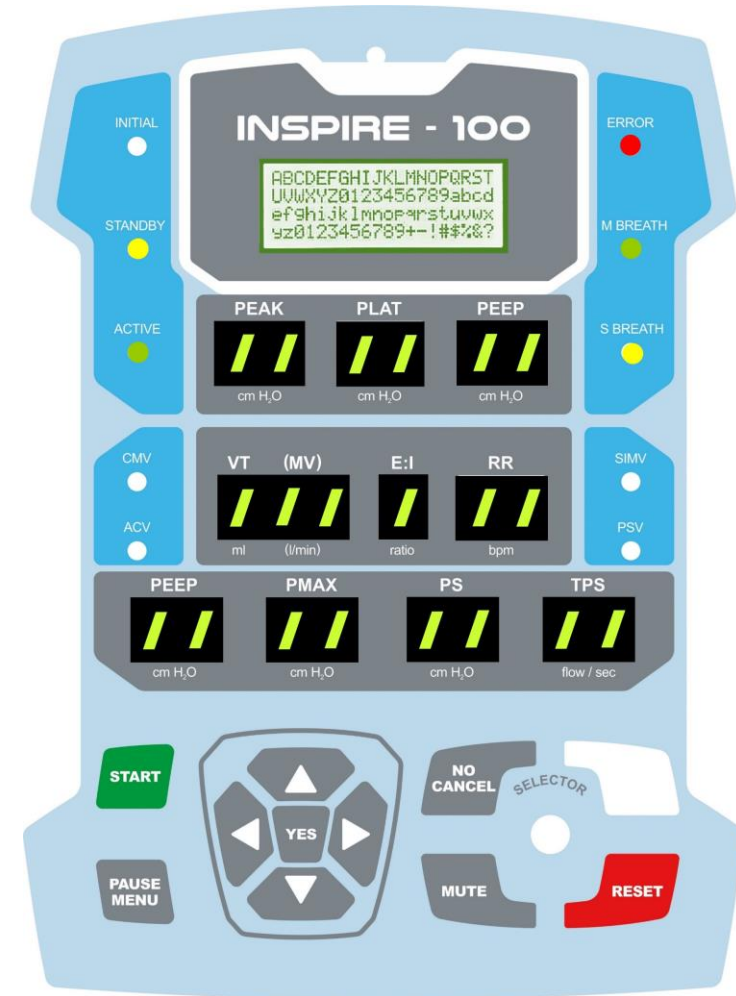




tekMedika



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 O₂ 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

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 ++

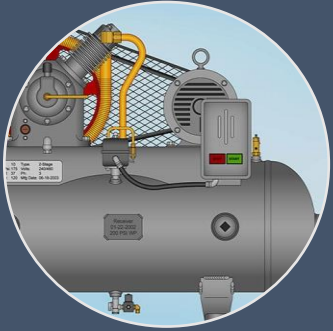


ICU Ventilator

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 (Hypercapnic)	Useful for Hypoxemic and Hypercapnic respiratory failure	Useful for Hypoxemic and Hypercapnic 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



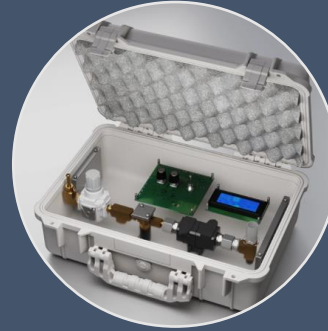
Iron Lung
Age



Pneumatic
Age



μ Controller
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

(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** 2205/52 (2013.01); A61M 2016/0027 (2013.01); A61M 2205/70 (2013.01)

(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**

(22) Filed: **Dec. 21, 2021**

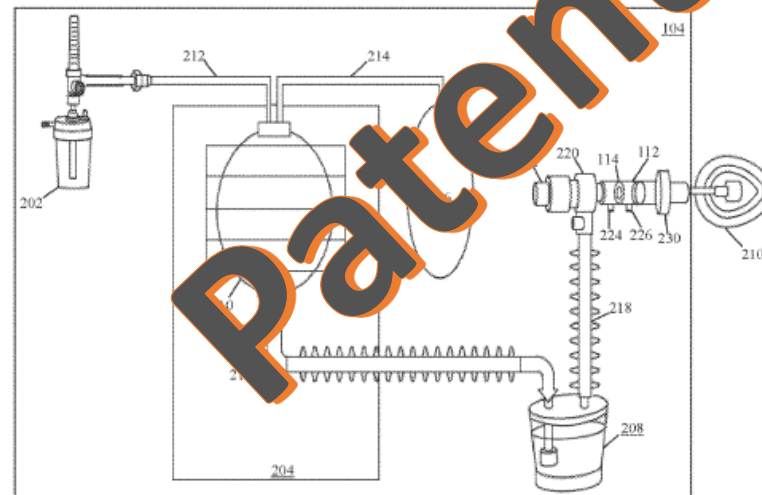
(30) **Foreign Application Priority Data**
Jul. 1, 2021 (IN) 202141029551

Publication Classification

(51) **Int. Cl.**
A61M 16/20 (2006.01)
A61M 16/00 (2006.01)

(52) **U.S. Cl.**
CPC A61M 16/204 (2014.02); A61M 16/0078 (2013.01); A61M 16/0003 (2014.02); A61M

(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 of the breathing system in accordance with the identified compression value. The compression of the bag valve causes gaseous inhalant to flow through the breathing system with a time interval. The processing circuitry determines an actual volume of the gaseous inhalant and iteratively adjusts the compression value of the bag valve to achieve a desired volume of the gaseous inhalant.



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

An important and necessary simplification in the P_{G1} and P_{G2} encountered in our system are of the order of tens of cmH₂O while $Patmosphere$ is of the order of a thousand cmH₂O of pressure. At sea level, $Patmosphere$ is approximately 1000 cmH₂O. Even at an altitude of 15,000 feet, $Patmosphere$ is approximately 600 cmH₂O. On the other hand, the P_{G1} and P_{G2} in the system range from 1 cmH₂O to 60 cmH₂O.

The term $(P_{G1} - P_{G2})$ is negligible compared to $(2 * Patmosphere)$, even more so since it is divided by 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.

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

The equation needs further simplification to ease the computation burden of the square root computation for an 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

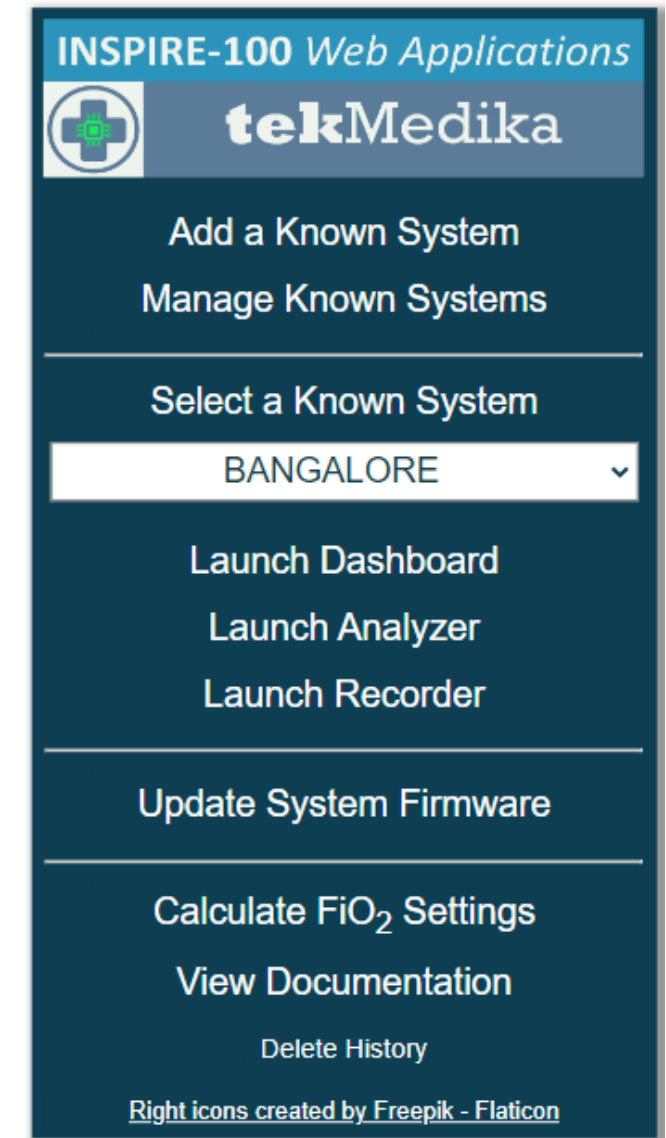
Mandatory &
Spontaneous Breaths
with Full Breath
Synchronization

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

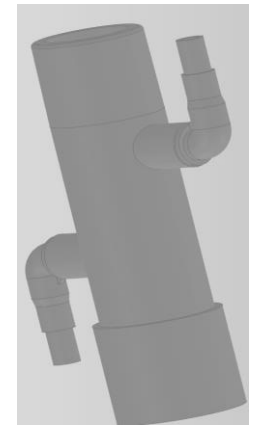
PEEP valve

HME Filter

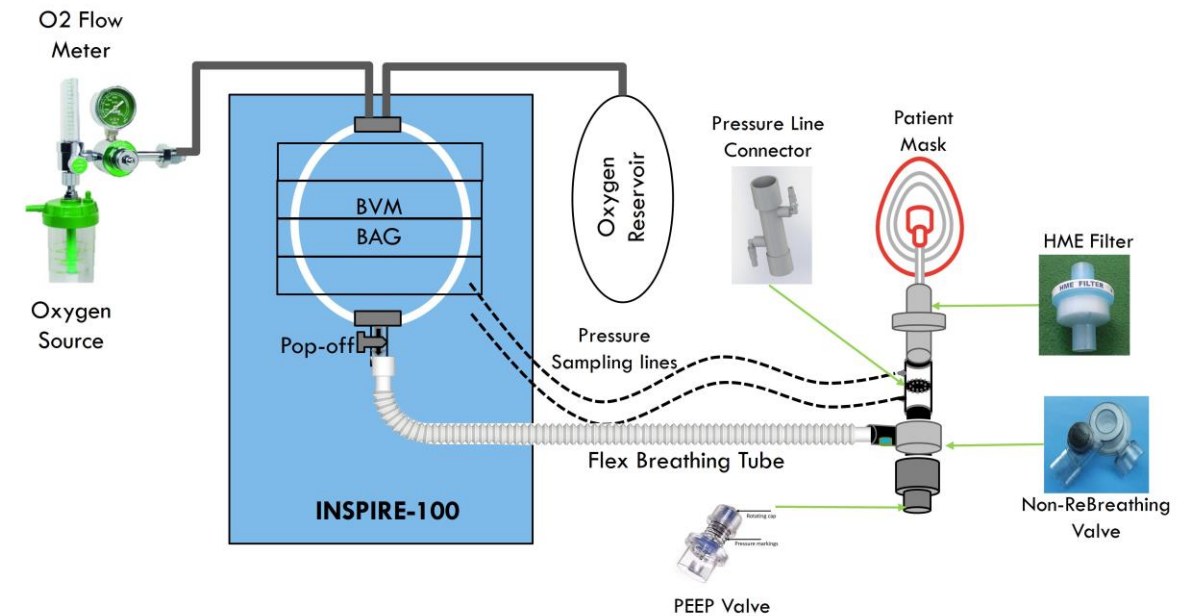
Oxygen Source



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.

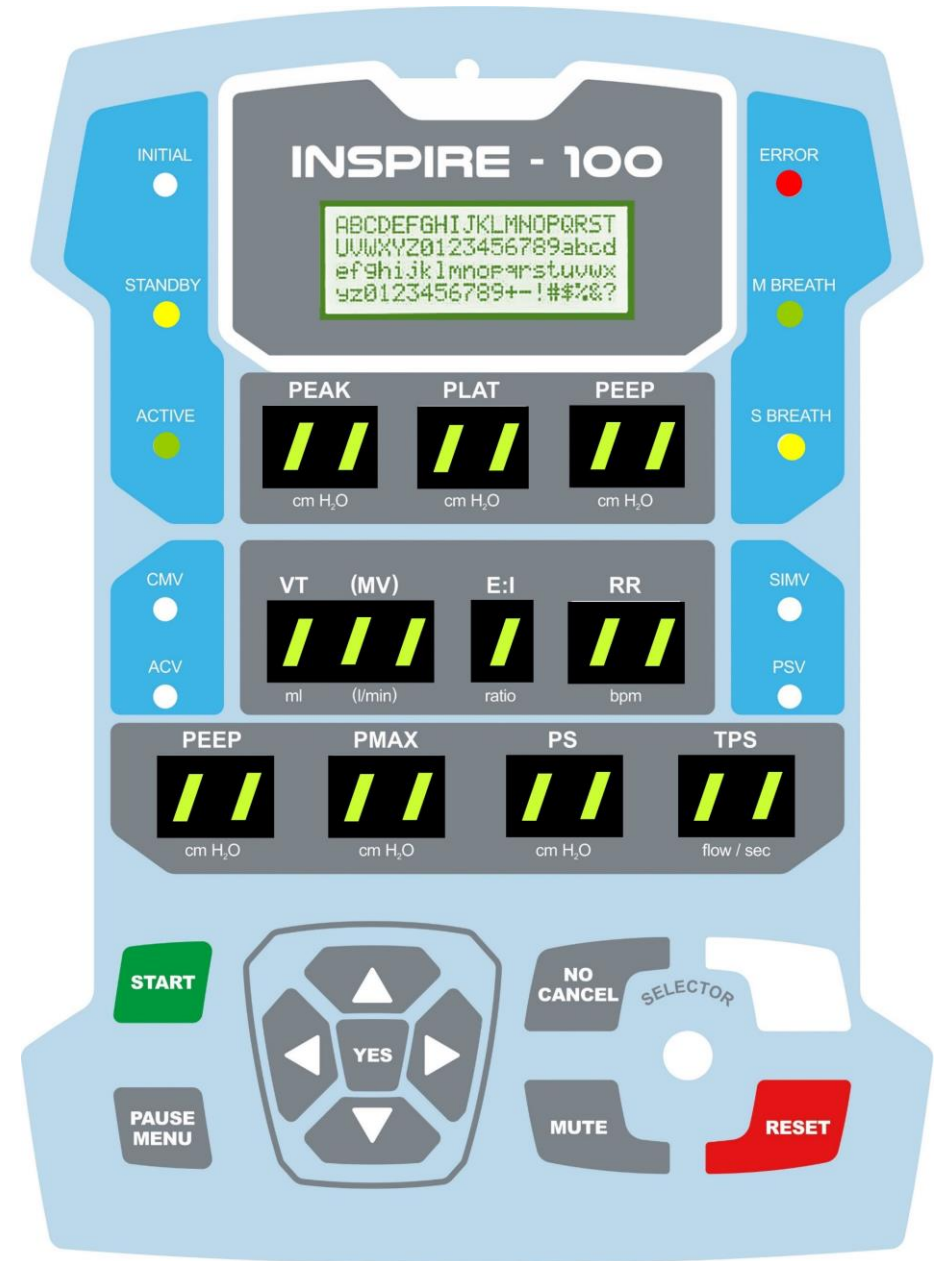
Easy to read 7-seg LED Parameters Display

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.



<https://www.inspire-100.com>

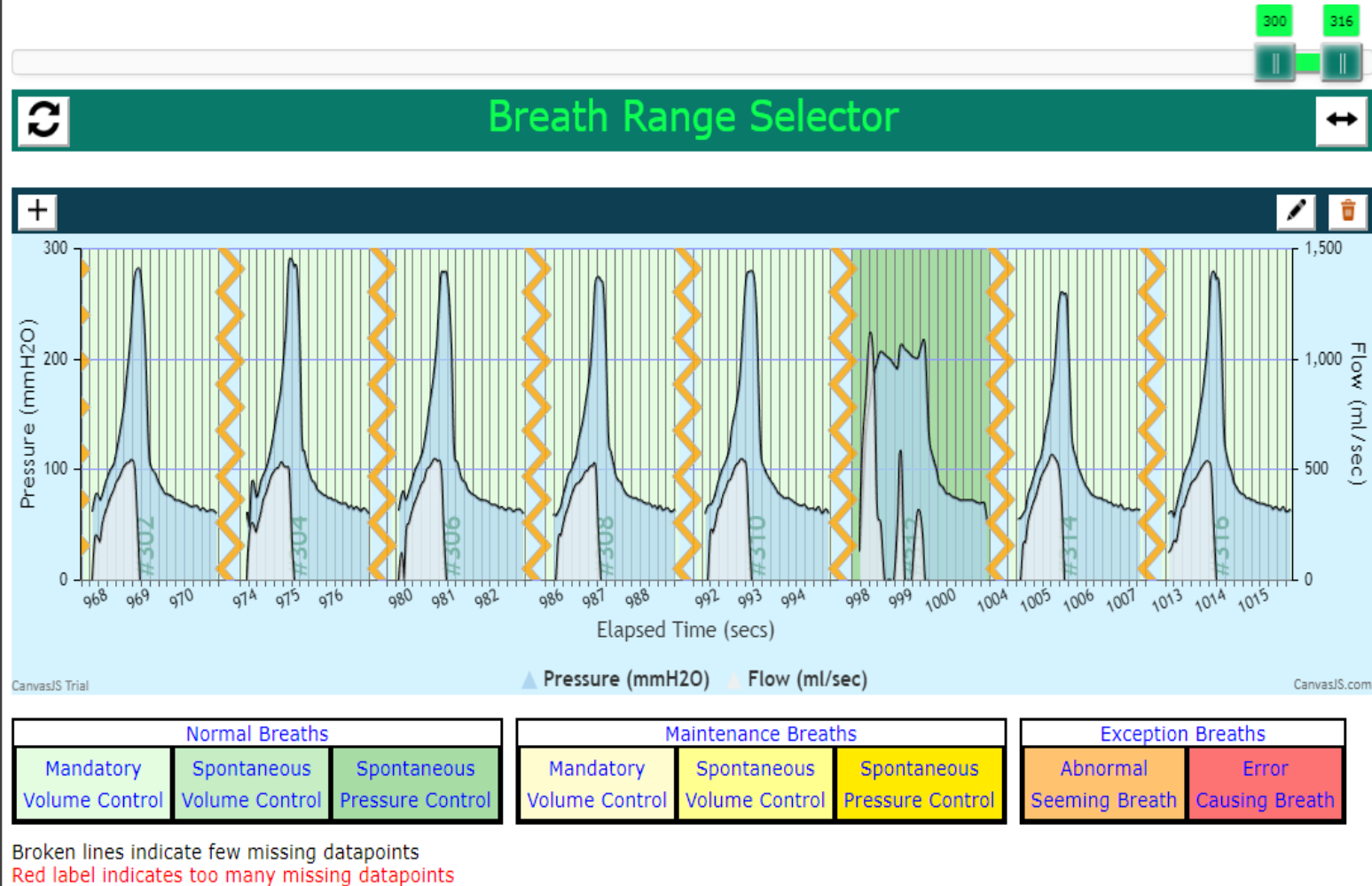
Dashboard Waveforms View

Pressure and
Flow Graphs

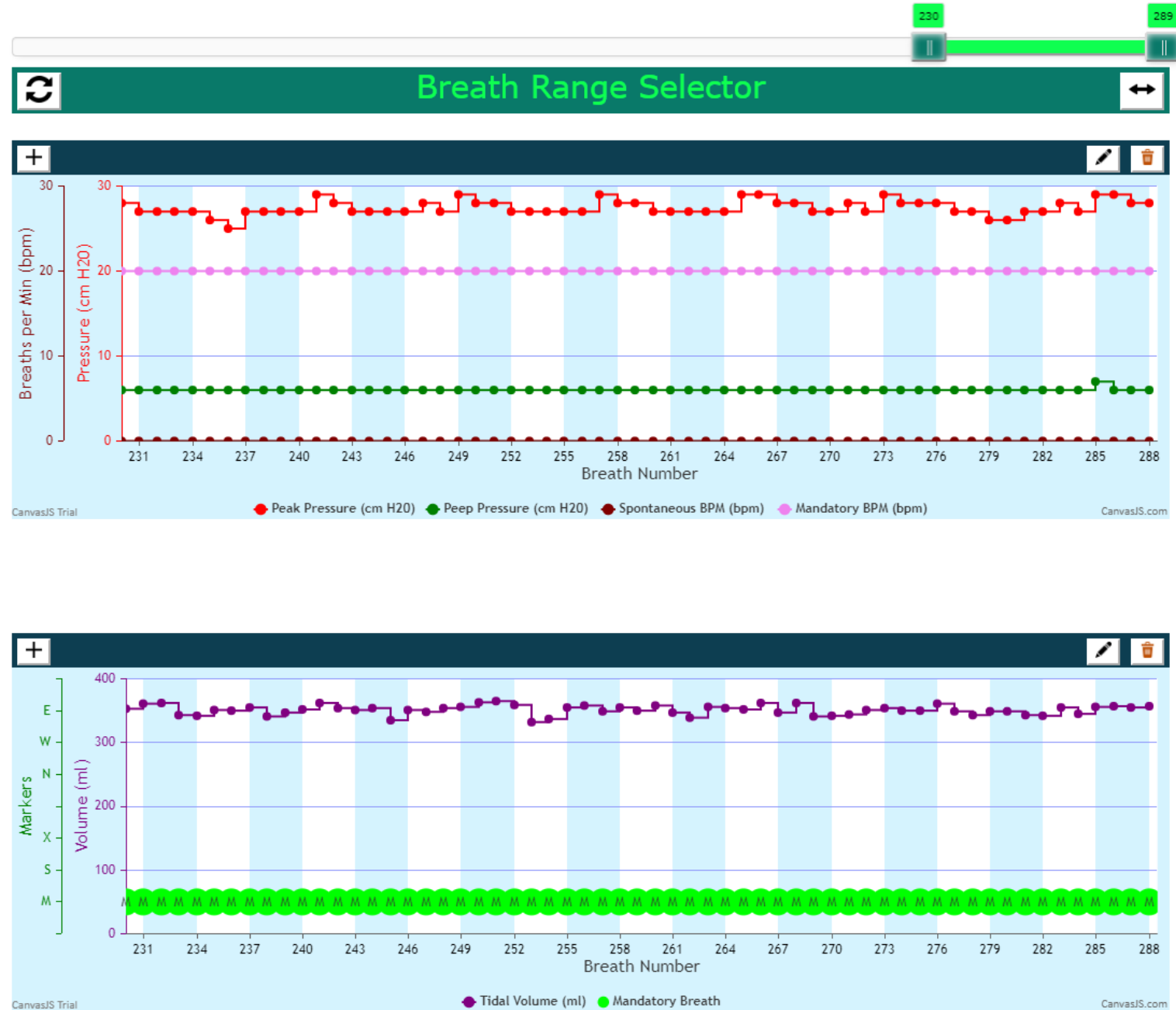
For Selected
Breaths

Periodic
Display

Display on
demand



Dashboard Charts View



Dashboard Statistics View

Breath Range Selector

Parameters Measured

Parameter	Units	Min	Max	Avg
Peak Pressure	cmH2O	27.0	30.0	28.6
Plateau Pressure	cmH2O	17.0	29.0	27.1
PEEP Pressure	cmH2O	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/cmH2O	17.0	32.0	18.3
Dynamic DeltaV/DeltaP	ml/cmH2O	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	cmH2O	5
Maximum Pressure	cmH2O	50
Support Pressure	cmH2O	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 DateTime: [09-12-2022]06:55:16

Leakage in
Breathing Circuit
Switching to
Maintenance Breaths

ERROR #2 DateTime: [09-12-2022]06:55:21

[ERROR] state
Press PAUSE to show
the System state
leading to ERROR

ERROR #3 DateTime: [09-12-2022]06:55:25

Leakage in
Breathing Circuit
Maintenance mode
Deliver safe breaths

ERROR #4 DateTime: [09-12-2022]06:55:29

[ERROR] state

Session Warnings

WARNING #1 DateTime: [09-12-2022]06:43:16

PEEP delta measured
up to -0.8 cm H2O
Adjust valve/setting
YES -> Commit

WARNING #2 DateTime: [09-12-2022]06:43:19

PEEP delta measured
up to -1.0 cm H2O
Adjust valve/setting
YES -> Commit

WARNING #3 DateTime: [09-12-2022]06:43:21

PEEP delta measured
up to -0.9 cm H2O
Adjust valve/setting
YES -> Commit

WARNING #4 DateTime: [09-12-2022]06:55:14

PEEP delta measured

Session Information

INFO #1 DateTime: [09-12-2022]06:45:23

1 Breath(s) missed
Info not received by
Dashboard due to
Internet packet loss

INFO #2 DateTime: [09-12-2022]06:46:26

1 Breath(s) missed
Info not received by
Dashboard due to
Internet packet loss

INFO #3 DateTime: [09-12-2022]06:47:17

1 Breath(s) missed
Info not received by
Dashboard due to
Internet packet loss

INFO #4 DateTime: [09-12-2022]06:47:28

1 Breath(s) missed

Analyzer

Any patient Session can be recorded locally or remotely.

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

The screenshot displays the INSPIRE-100 Analyzer interface. On the left, a sidebar contains sections for 'RECORDED DATA' (Breaths, Duration, PriorBreaths) and 'ANALYSIS WINDOW' (BreathRange, Duration). Below these is a 'Select Recording' button and a menu with options: 'View Charts', 'View Waveforms', 'View Statistics', 'View Alerts', and 'View Raw Data'. The main area shows a table of recordings with the header 'INSPIRE-100 Recordings'. A red banner at the top of the table area says 'No Selected Recording'. The table has columns for 'Recording Name', 'Created', and 'Actions'. One recording is listed: 'Bugs Bunny' created on '08-01-2024 11:09:03'. The bottom of the interface features a footer with 'SYSTEM UID' (UID_28615E07D6013C4A (BANGALORE)), the 'INSPIRE-100 Analyzer' logo, and the 'tekMedika' logo.


Recording Name	Created	Actions
Bugs Bunny	08-01-2024 11:09:03	

Updating Firmware

Firmware releases available on the WEB.

Step-by-step menu driven update procedure




INSPIRE-100Firmware

tekMedika

Step-by-step Instructions

Arduino Builder
One-time Download

Select and Download Release

Version	Release Date	Get
3.1.1	13-Dec-2023	
1.1.1	16-Oct-2023	
1.0.1	16-May-2023	

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

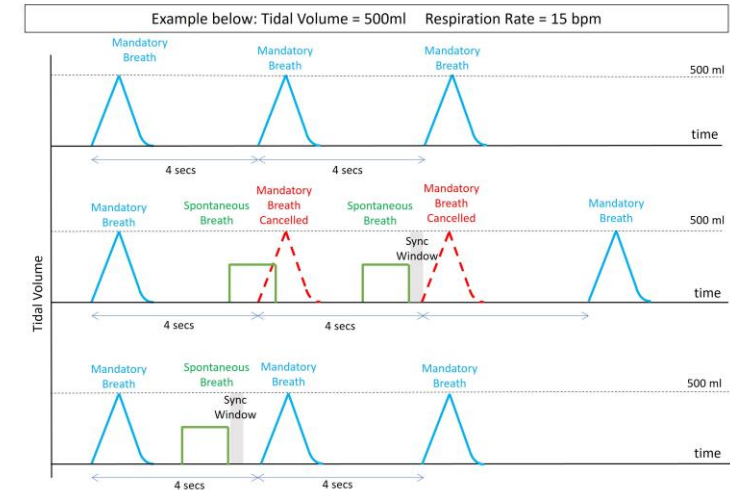
Breath Synchronization

Both ACV and SIMV modes

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

Breath Syncing in SIMV mode

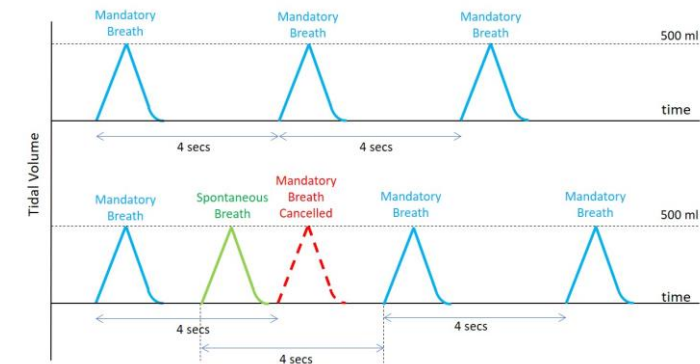
There is a sync-window – the next mandatory breath is rescheduled only if spontaneous breath within the sync-window



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



FiO_2 Settings

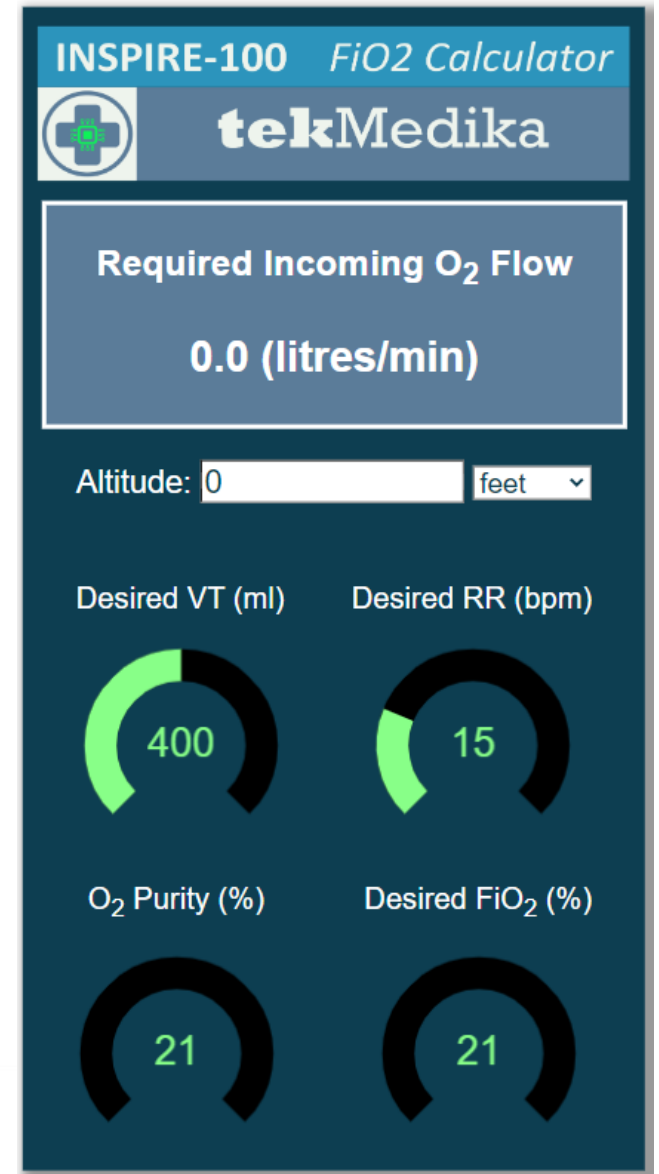
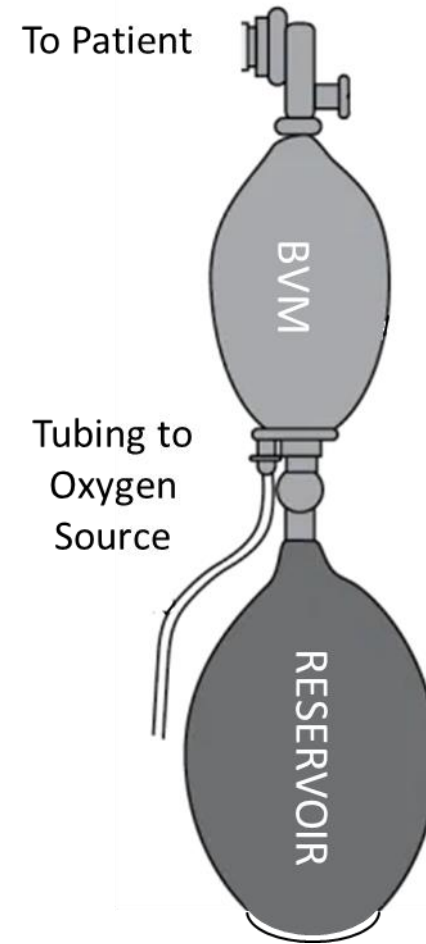
Without the Reservoir bag, FiO_2 delivered is the Atmospheric O_2 content at site

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

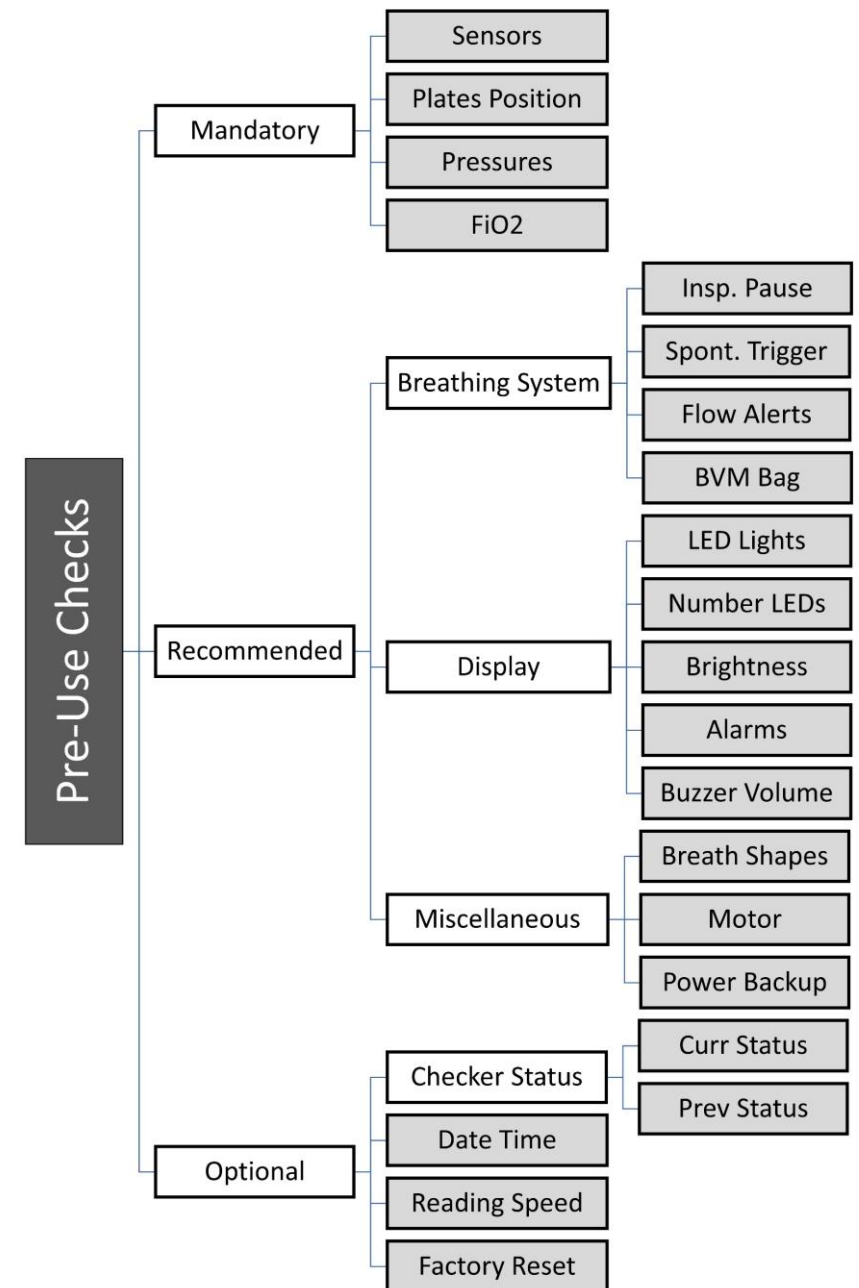
The mathematical model provides for a possible O_2 concentrator as an O_2 source (purity < 100%)

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

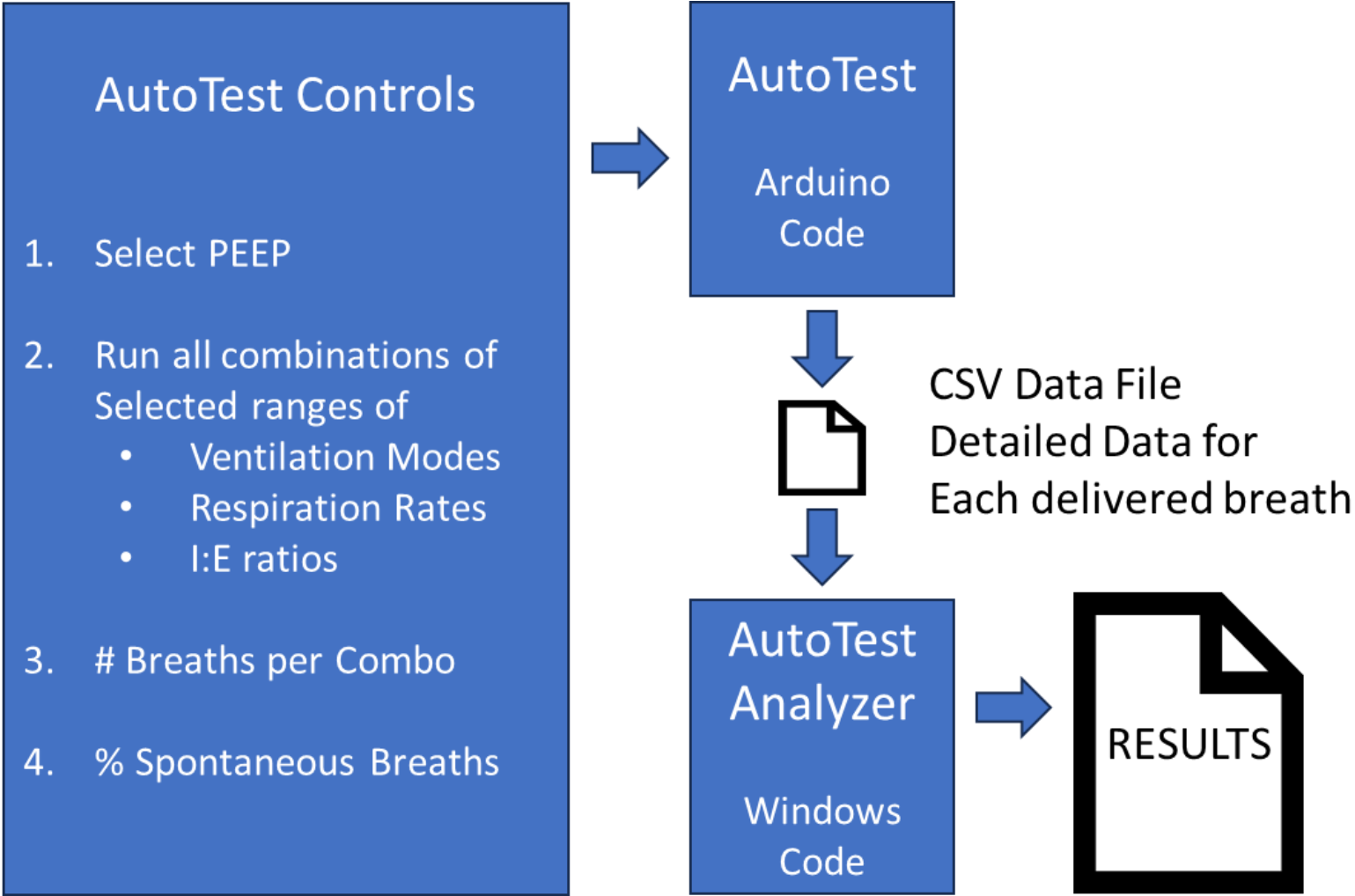


Alarms and Safety Features

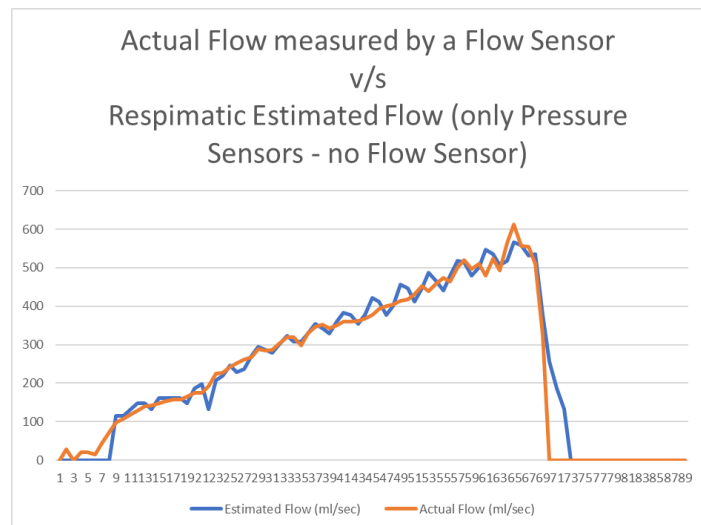
- Enforcement of Pre-use checks
- Alarms, Warnings and Notifications
- Maintenance Breaths till Alarm situation rectified
 - Max Pressure Alarm
 - Pressure Leak Alarm
 - Mask OFF Alarm
 - System Temperature Alarm
 - Sensor failure Alarm
 - Breathing Circuit Failure Alarm
 - Detect coughing/hiccuping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



Automated Testing

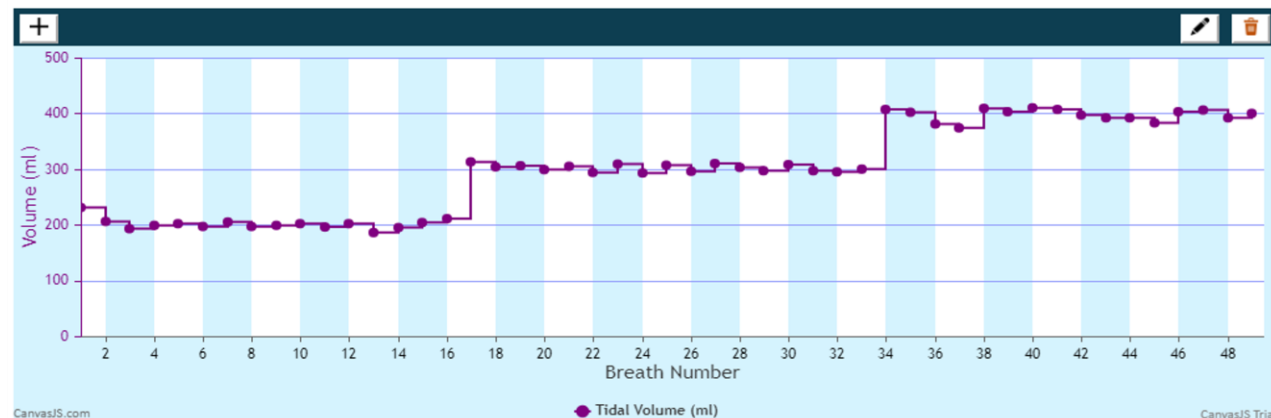


Some Results

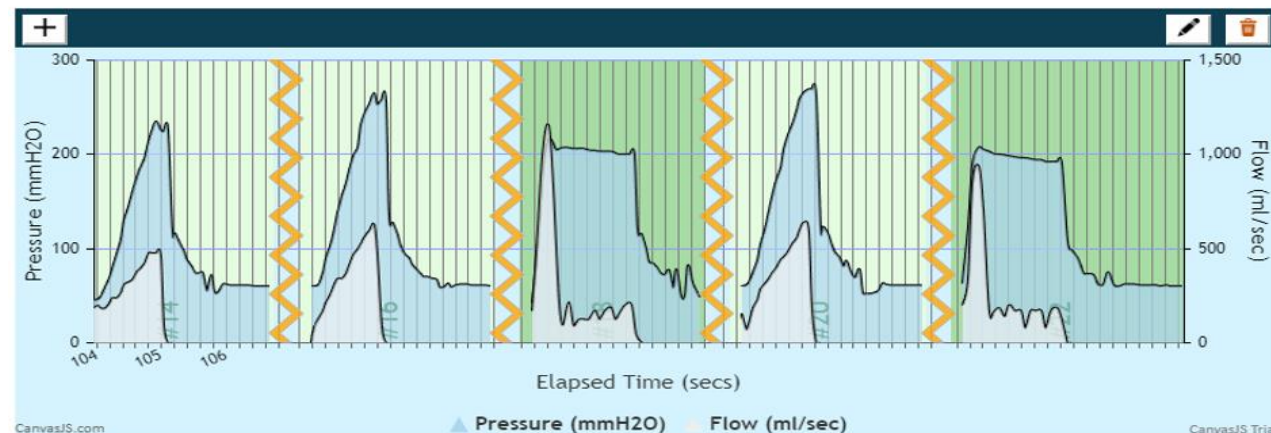


Sample FiO2 Data					
PEEP=6, EI=2			Measured	Calculated	ERROR
VT	RR	O2 (l/min)	FiO2(%)	FiO2(%)	%
400	20	2	40.5	39	4%
400	20	2.5	45.5	43.5	4%
400	20	3	49	48	2%
400	20	3.5	54	53.5	1%
400	20	4	59.8	57	5%
400	20	4.5	63.5	61.5	3%
400	20	5	67.5	66	2%
400	30	2	33	33	0%
400	30	2.5	36.5	36	1%
400	30	3	38.5	39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

VT Titration for VT = 200, 300 and 400ml



A Mix of VC and PS Breaths



Thank you
