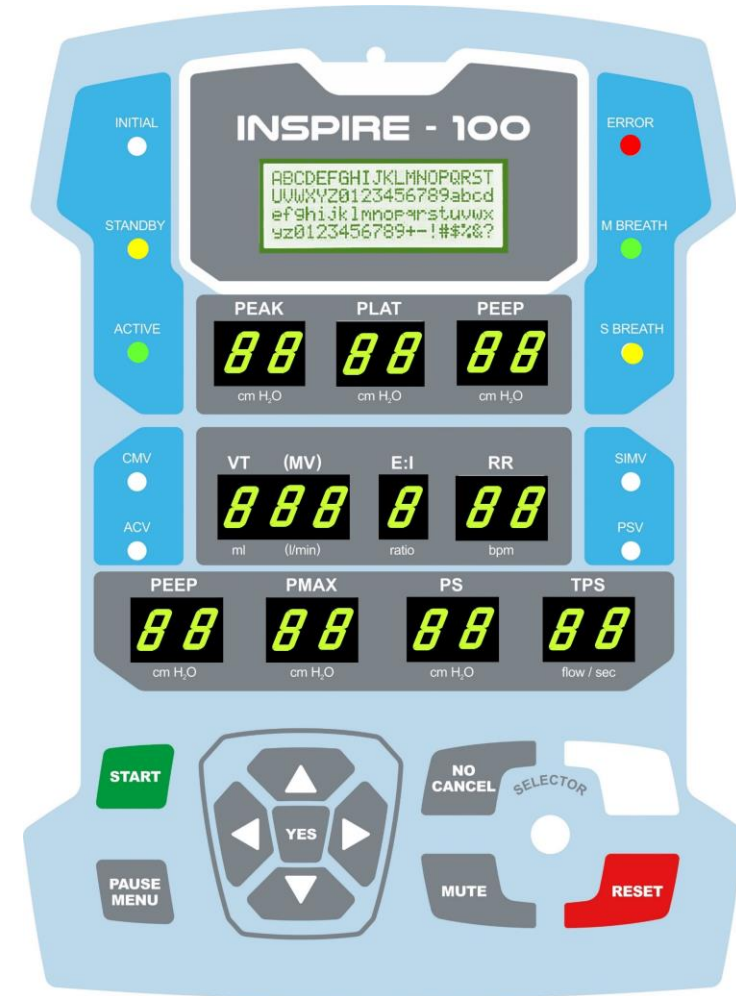


***TekMedika***



# 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<sub>2</sub> 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 ++



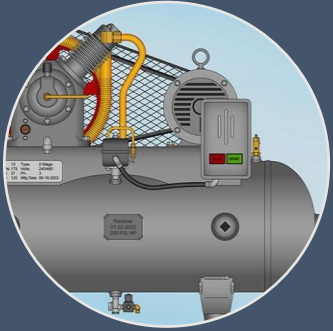
ICU Ventilator

# 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



$\mu$ 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*

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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**

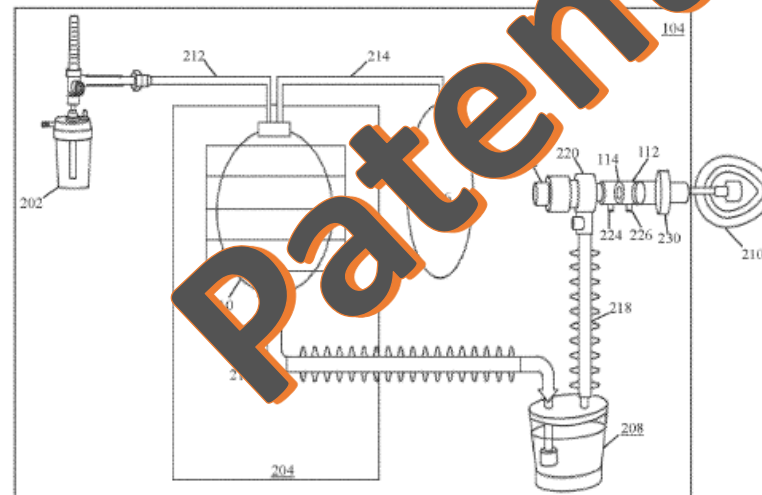
(30) **Foreign Application Priority Data**  
Jul. 1, 2021 (IN) 202141029551

**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 cmH<sub>2</sub>O while  $Patmosphere$  is of the order of a thousand cmH<sub>2</sub>O of pressure. At sea level,  $Patmosphere$  is approximately 1000 cmH<sub>2</sub>O. Even at an altitude of 15,000 feet,  $Patmosphere$  is approximately 600 cmH<sub>2</sub>O. On the other hand, the  $P_{G1}$  and  $P_{G2}$  in the system range from 1 cmH<sub>2</sub>O to 60 cmH<sub>2</sub>O.

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 & FiO<sub>2</sub> 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

## INSPIRE-100 Web Applications

Add a Known System

Manage Known Systems

Select a Known System

BANGALORE

Launch Dashboard

Launch Analyzer

Launch Recorder

Update System Firmware

Calculate FiO<sub>2</sub> Settings

View Documentation

Delete History

Right icons created by Freepik - Flaticon



**TekMedika**

<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

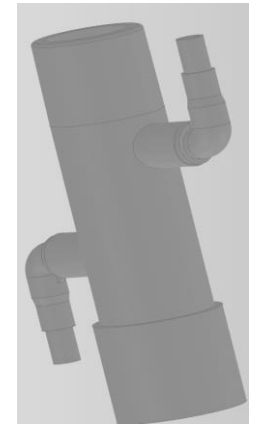
PEEP valve

HME Filter

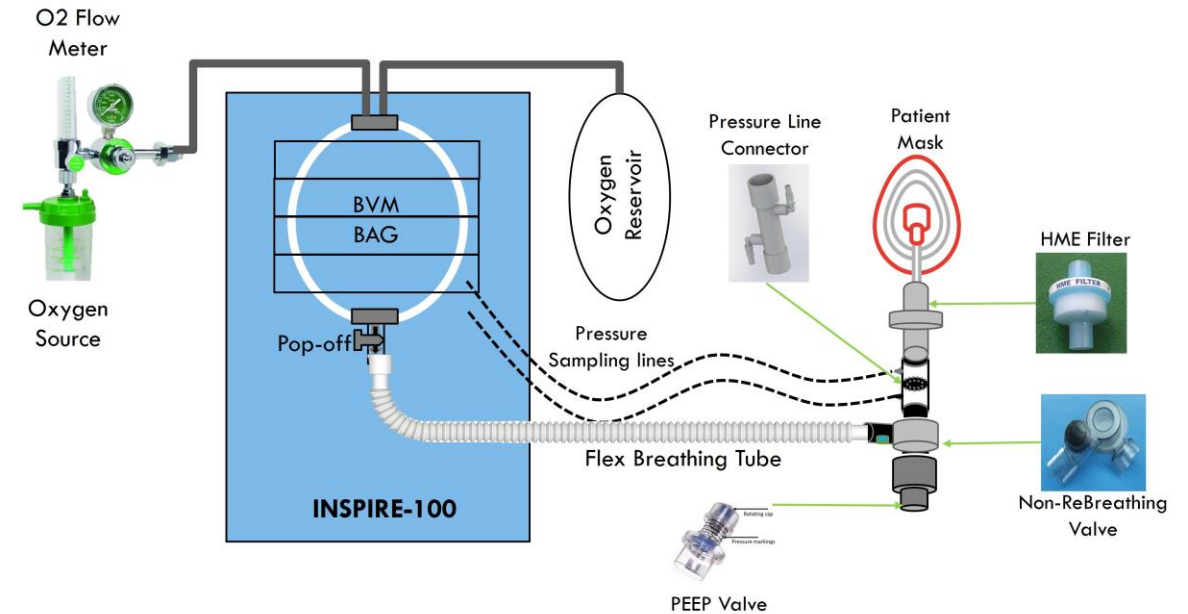
Oxygen Source



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.

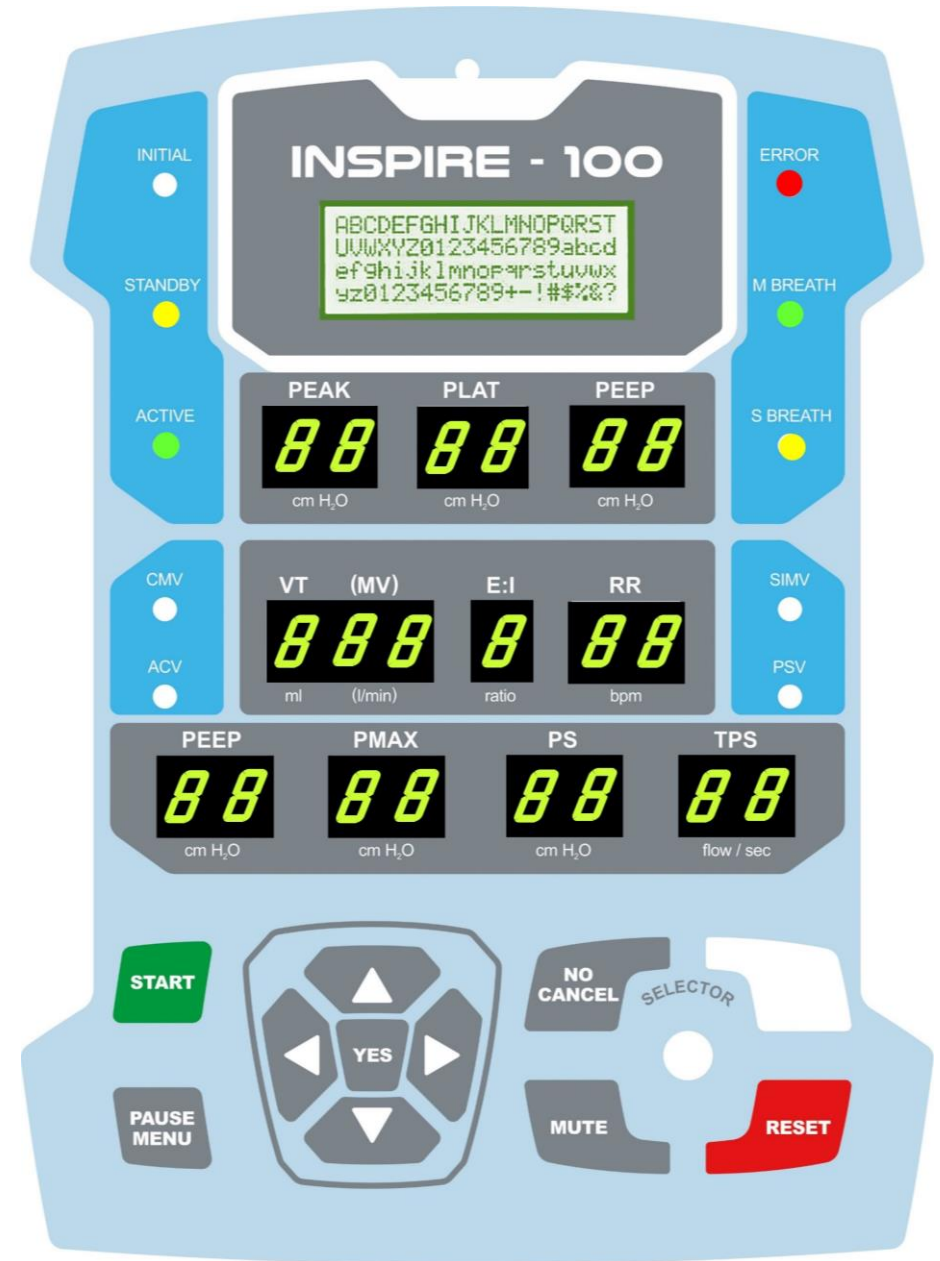
Easy to read 7-seg LED Parameters Display

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>



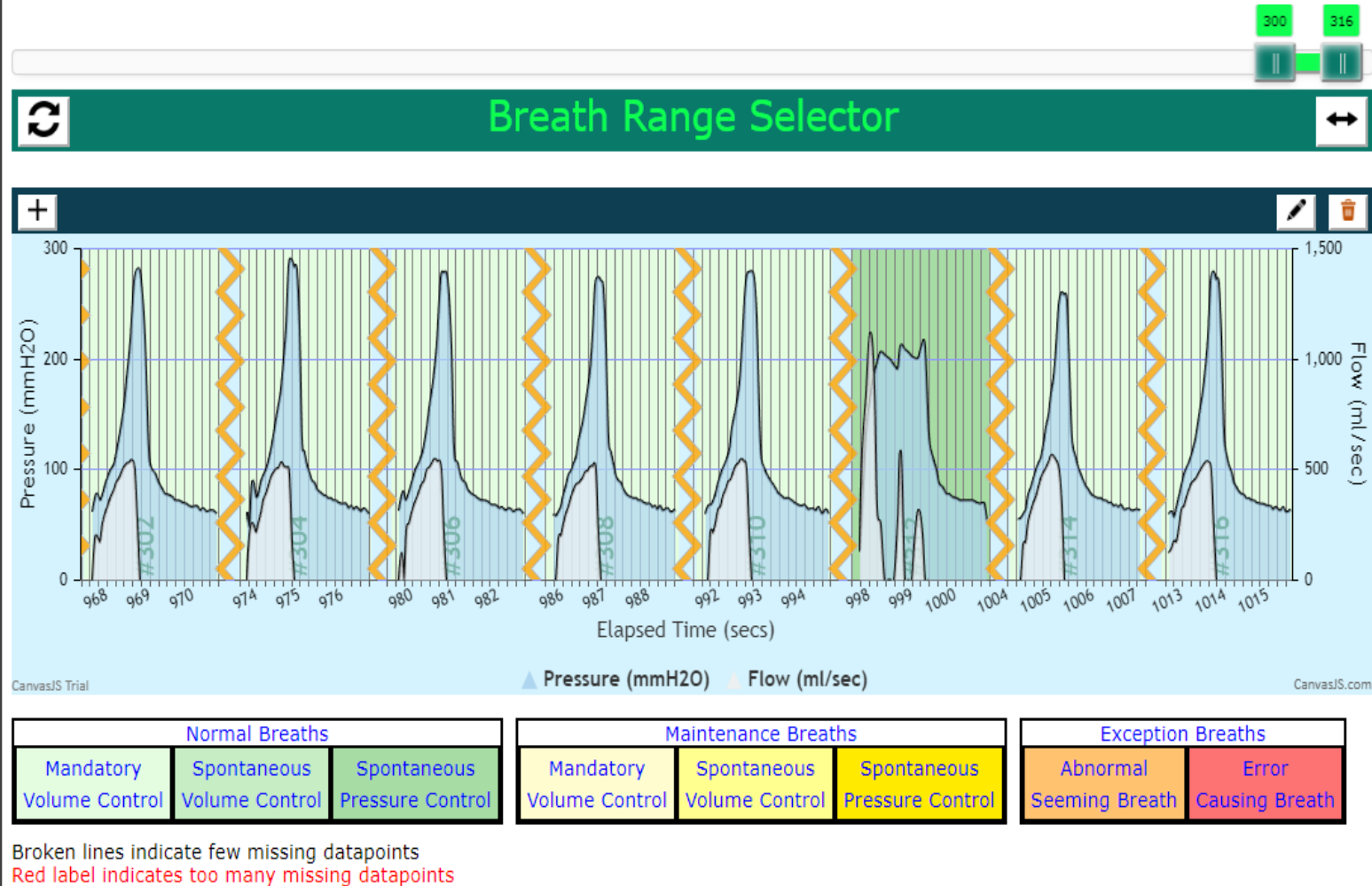
# Dashboard Waveforms View

Pressure and  
Flow Graphs

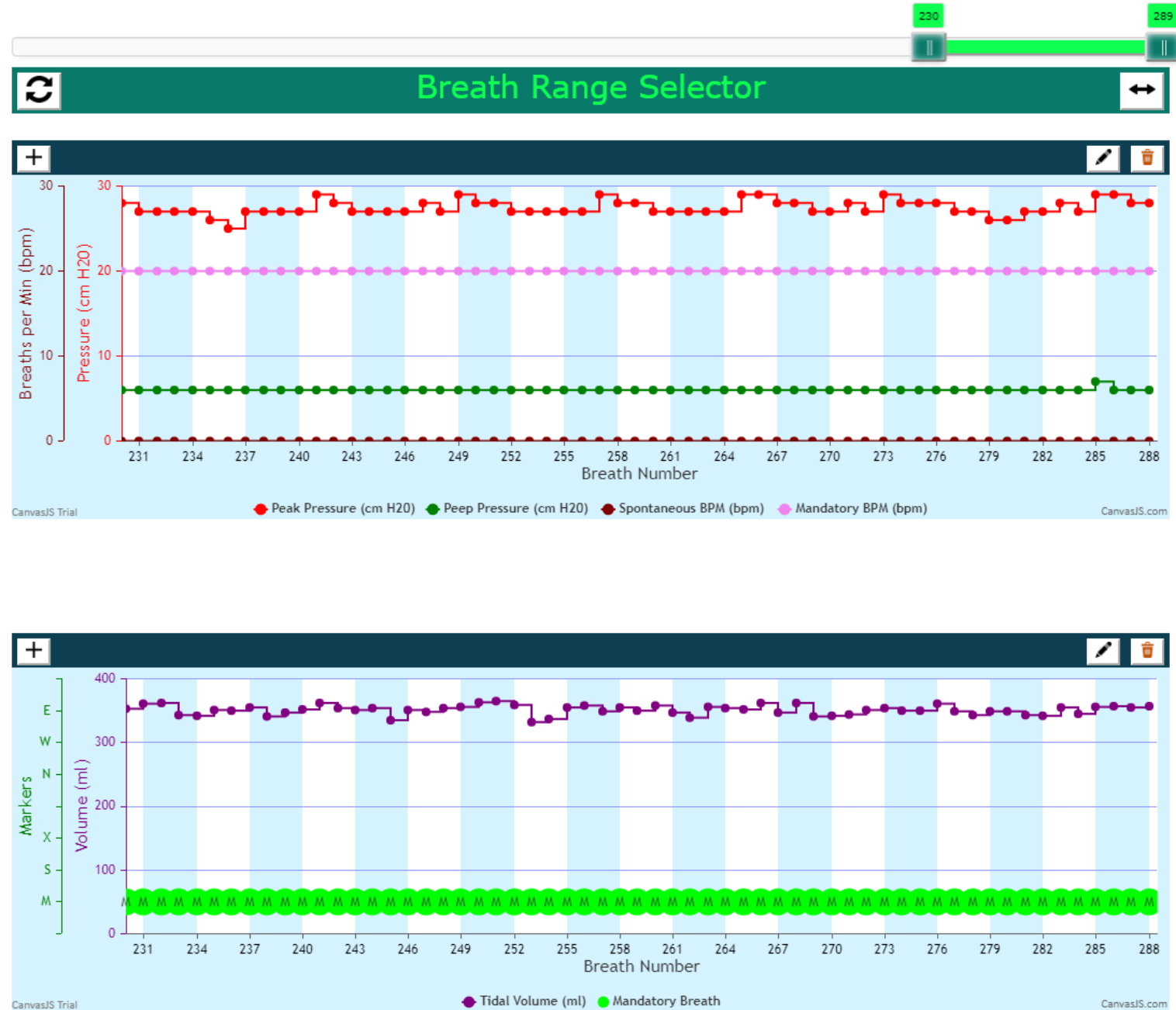
For Selected  
Breaths

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. At the top, a green header bar shows the patient name 'Bugs Bunny' and the timestamp '[08-01-2024 11:09:03]'. Below this, a dark blue header bar contains the title 'INSPIRE-100 Recordings' and a trash icon. The main area features a table with columns 'Recording Name', 'Created', and 'Actions'. A single row is visible for 'Bugs Bunny' with the timestamp '08-01-2024 11:09:03' and three action icons (checkmark, share, and trash). To the left of the table, a sidebar contains two green boxes: 'RECORDED DATA' with values for Breaths (11), Duration (00:00:44), and PriorBreaths (36); and 'ANALYSIS WINDOW' with values for BreathRange (1-11) and Duration (00:00:44). Below these boxes is a 'Select Recording' button. Further down, a dark blue menu lists options: 'View Charts', 'View Waveforms', 'View Statistics', 'View Alerts', and 'View Raw Data'. The bottom of the interface has a footer bar with three sections: 'SYSTEM UID' (UID\_28615E07D6013C4A (BANGALORE)), 'INSPIRE-100 Analyzer' with a green cross icon, and the 'TekMedika' logo.

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

**RECORDED DATA**

- Breaths: 11
- Duration: 00:00:44
- PriorBreaths: 36

**ANALYSIS WINDOW**

- BreathRange: 1-11
- Duration: 00:00:44

Select Recording

- View Charts
- View Waveforms
- View Statistics
- View Alerts
- View Raw Data

**SYSTEM UID**  
UID\_28615E07D6013C4A  
(BANGALORE)

**INSPIRE-100**  
Analyzer

**TekMedika**

# Updating Firmware

---

Firmware releases available on the WEB.

Step-by-step menu driven update procedure

**INSPIRE-100 Firmware Update**

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	

**TekMedika**

# 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 (cmH<sub>2</sub>O)***

4 to 15 cmH<sub>2</sub>O  
increments of 1 cmH<sub>2</sub>O

### ***Max Pressure (cmH<sub>2</sub>O)***

15 to 50 cmH<sub>2</sub>O  
increments of 5 cmH<sub>2</sub>O

### ***FiO<sub>2</sub> Support***

System Managed  
Externally Controlled  
21% to 100%



# *Pressure Supported Breaths*

*(SIMV & PSV modes)*

## *Support Pressure (PS)*

5 cmH<sub>2</sub>O to 35 cmH<sub>2</sub>O in increments of 5 cmH<sub>2</sub>O

## *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

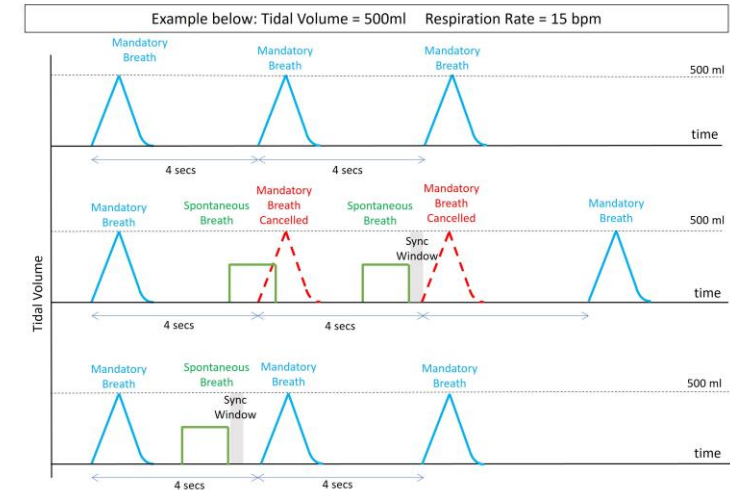
# Breath Synchronization

## Both ACV and SIMV modes

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

### Breath Syncing in SIMV mode

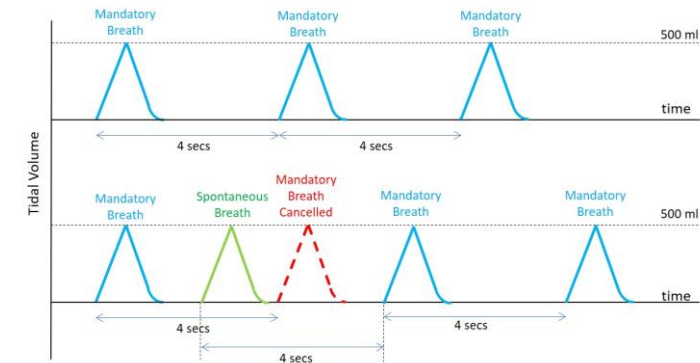
There is a sync-window – the next mandatory breath is rescheduled only if spontaneous breath within the sync-window



### 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

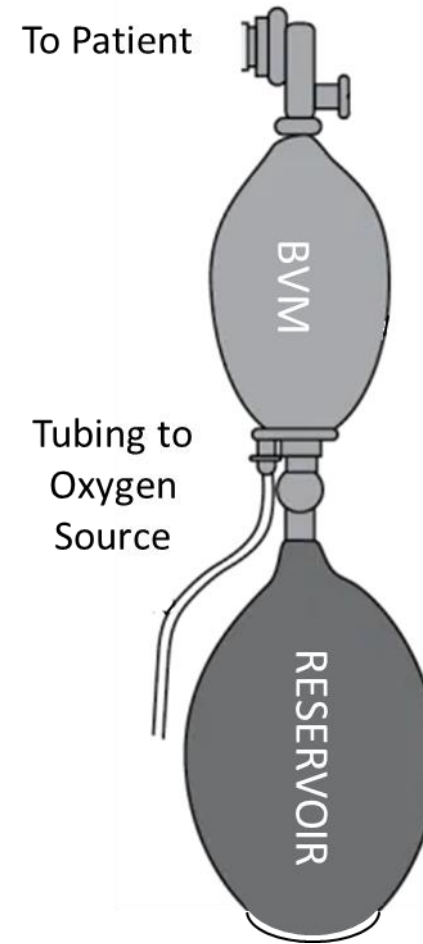
Without the Reservoir bag,  $FiO_2$  delivered is the Atmospheric  $O_2$  content at site

$FiO_2$  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



**INSPIRE-100  $FiO_2$  Calculator**

Required Incoming  $O_2$  Flow

0.0 (litres/min)


Altitude: 0 feet

Desired VT (ml) 400

Desired RR (bpm) 15

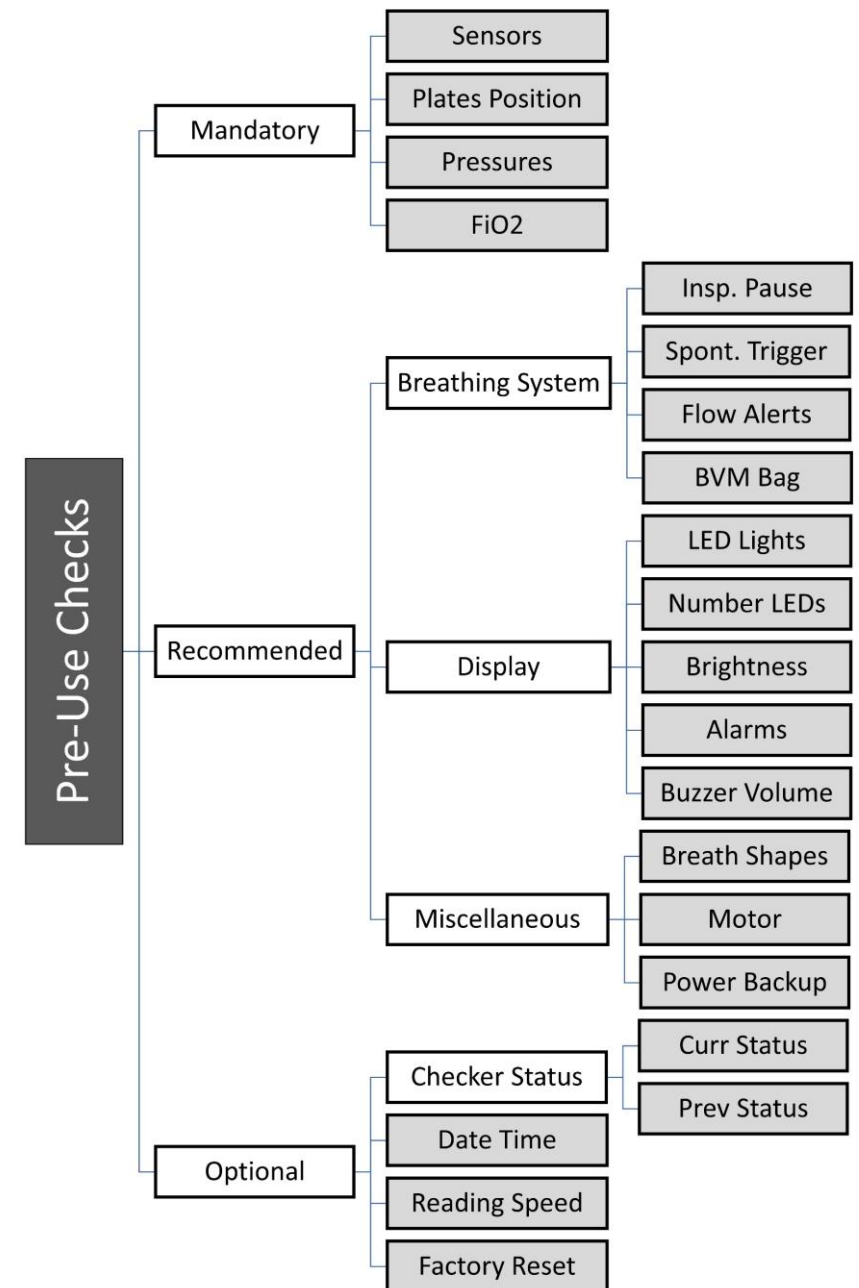
$O_2$  Purity (%) 21

Desired  $FiO_2$  (%) 21

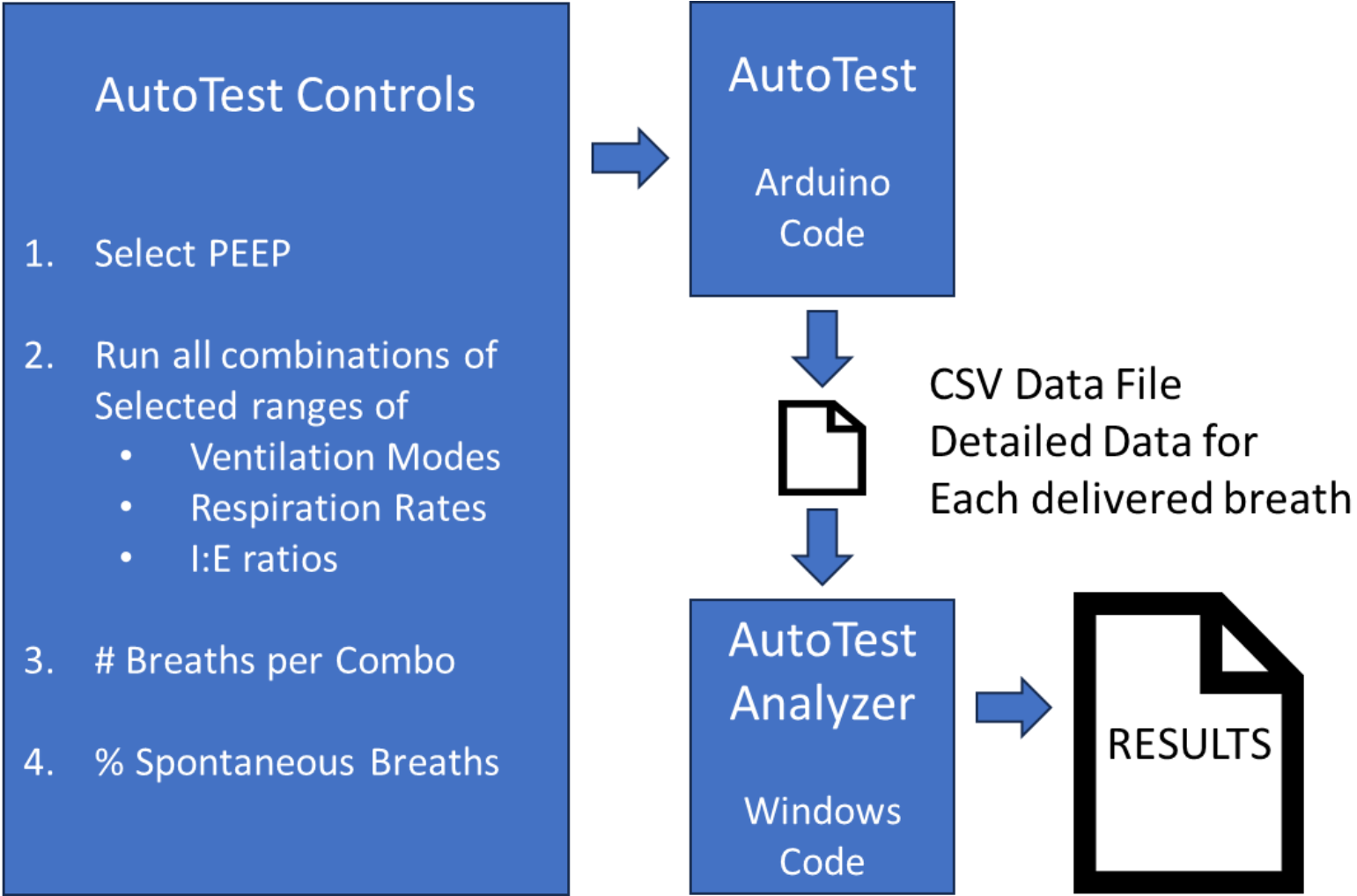
 **TekMedika**

# Alarms and Safety Features

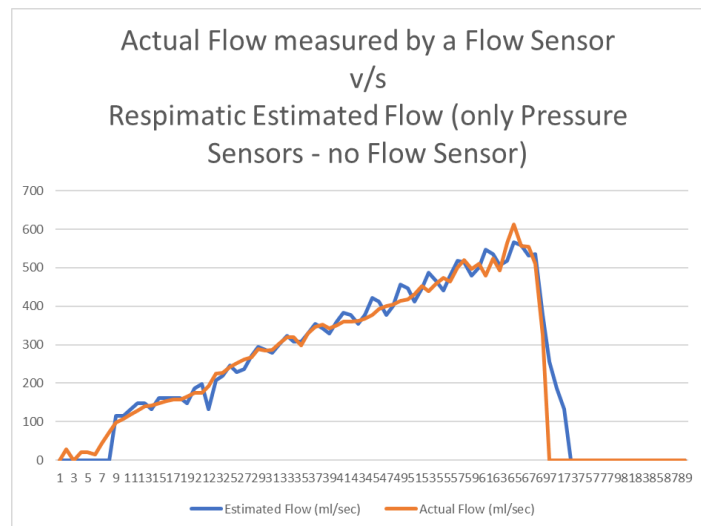
- **Enforcement of Pre-use checks**
- **Alarms, Warnings and Notifications**
- **Maintenance Breaths till Alarm situation rectified**
  - Max Pressure Alarm
  - Pressure Leak Alarm
  - Mask OFF Alarm
  - System Temperature Alarm
  - Sensor failure Alarm
  - Breathing Circuit Failure Alarm
  - Detect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



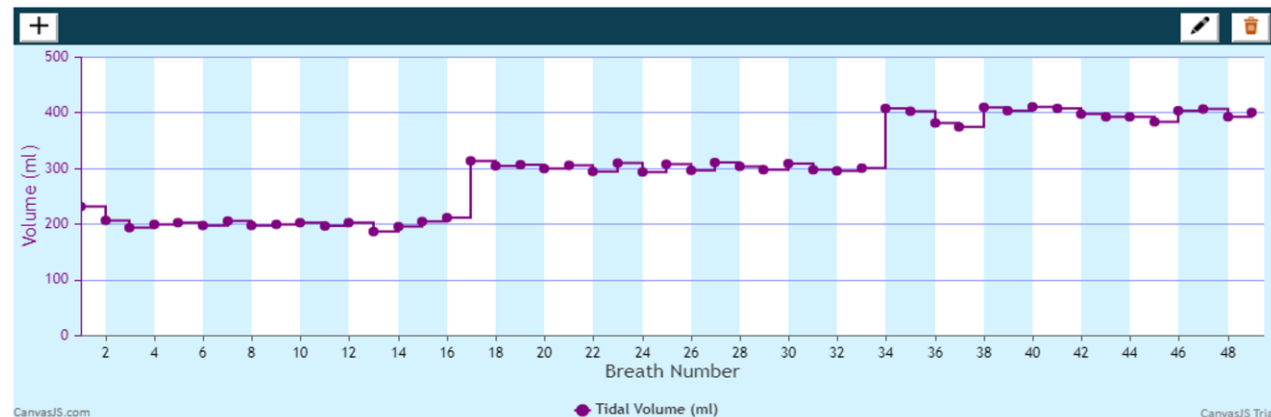
# Automated Testing



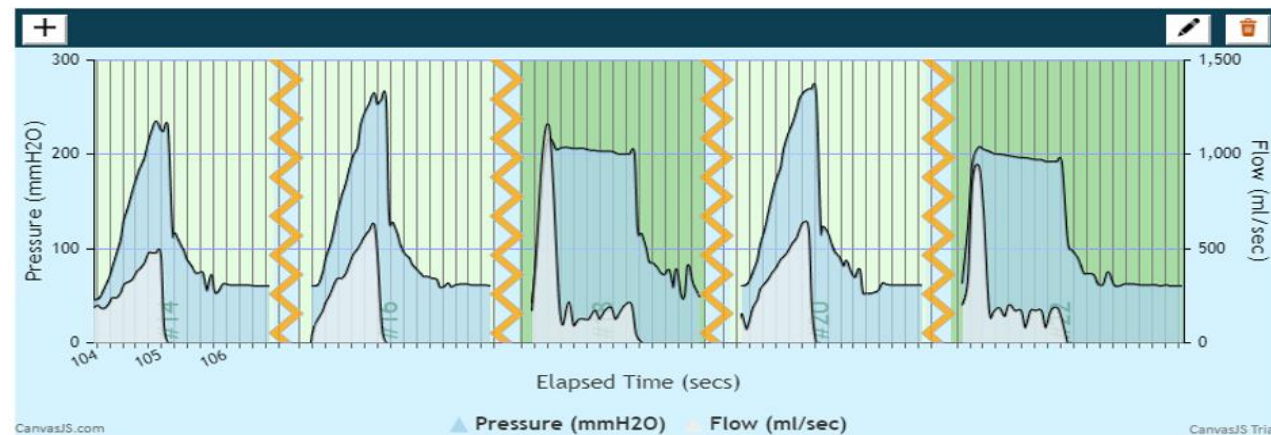
# Some Results



## 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*

---