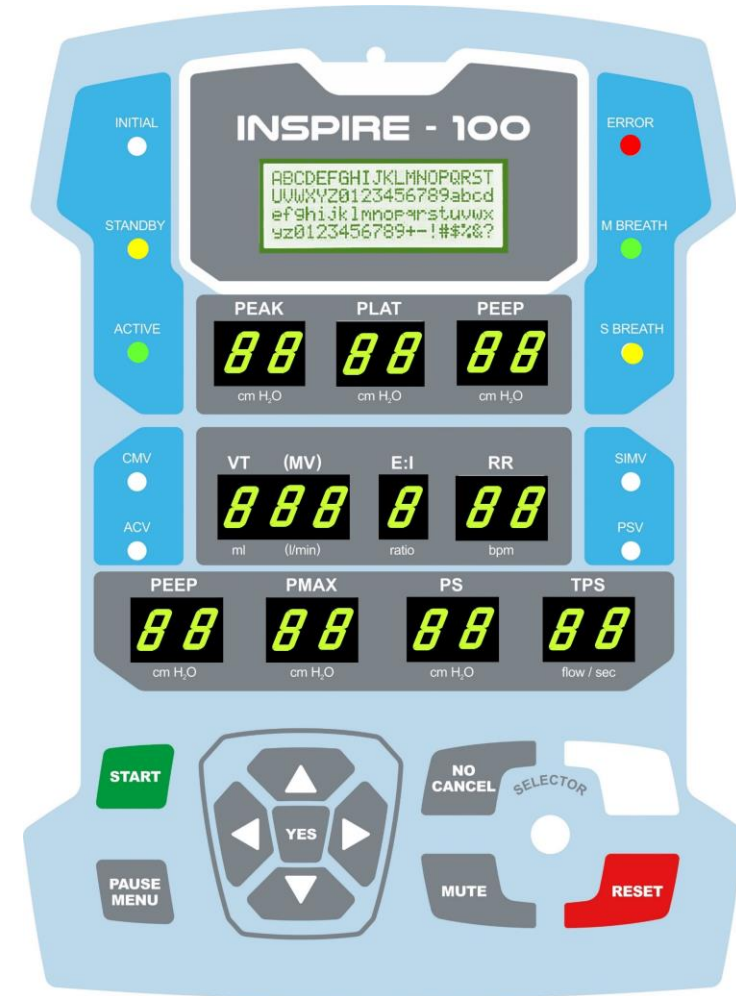**tek**Medika

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

Rs 12 Lakhs ++

Less than Rs 1 Lakh

Less than Rs 50,000

Home Use

Home Use

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

ICU Use

CPAP

BiPAP

Big Hole

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
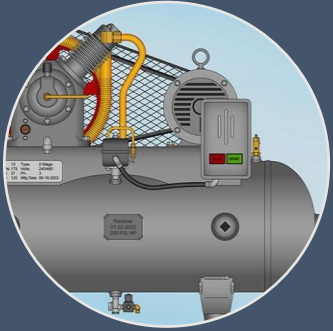
Iron Lung Age

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**

(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

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

(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 actual volume of the gaseous inhalant and iteratively modifies the compression value of the bag valve to attain a desired volume of the gaseous inhalant.
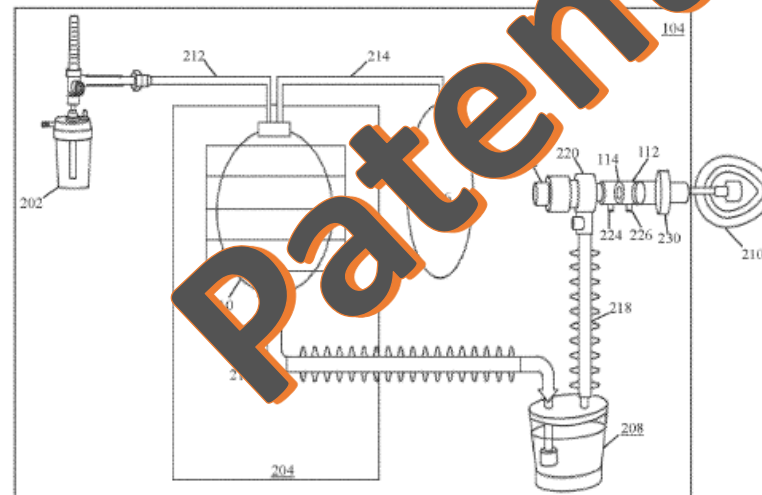
$$Q \propto \sqrt{\frac{(P_{G1} - P_{G2})}{(P_{G1} + P_{G2}) + 2 * Patmosphere}}$$

An important and necessary simplification is that P_{G1} and P_{G2} encountered in our system are of the order of tens of cmH$_2$O while Patmosphere is of the order of a thousand cmH$_2$O of pressure. At sea level, Patmosphere is approximately 1000 cmH$_2$O. Even at an altitude of 15,000 feet, Patmosphere is approximately 600 cmH$_2$O. On the other hand, the P_{G1} and P_{G2} in the system range from 1 to 60 cmH$_2$O.

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

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

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

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_2 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
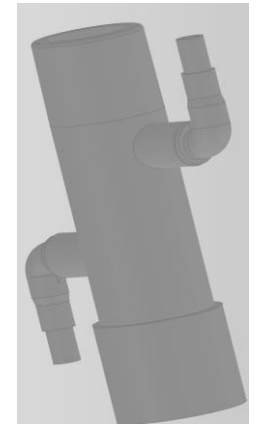- BVM or Ambu Bag with Reservoir
- Pressure sensing lines
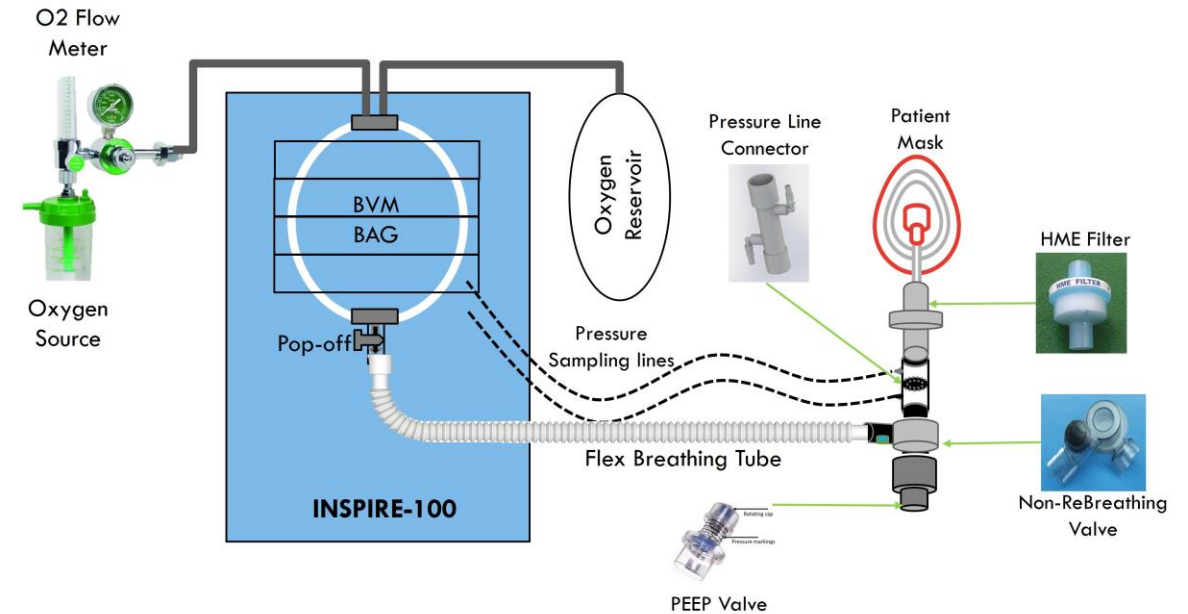- PEEP valve
- HME Filter
- Oxygen Source

Off-the-Shelf Single limbed Circuit with NRBM

Proprietary Dual Pressure line Connector

Front Panel
The Human-Machine Interface

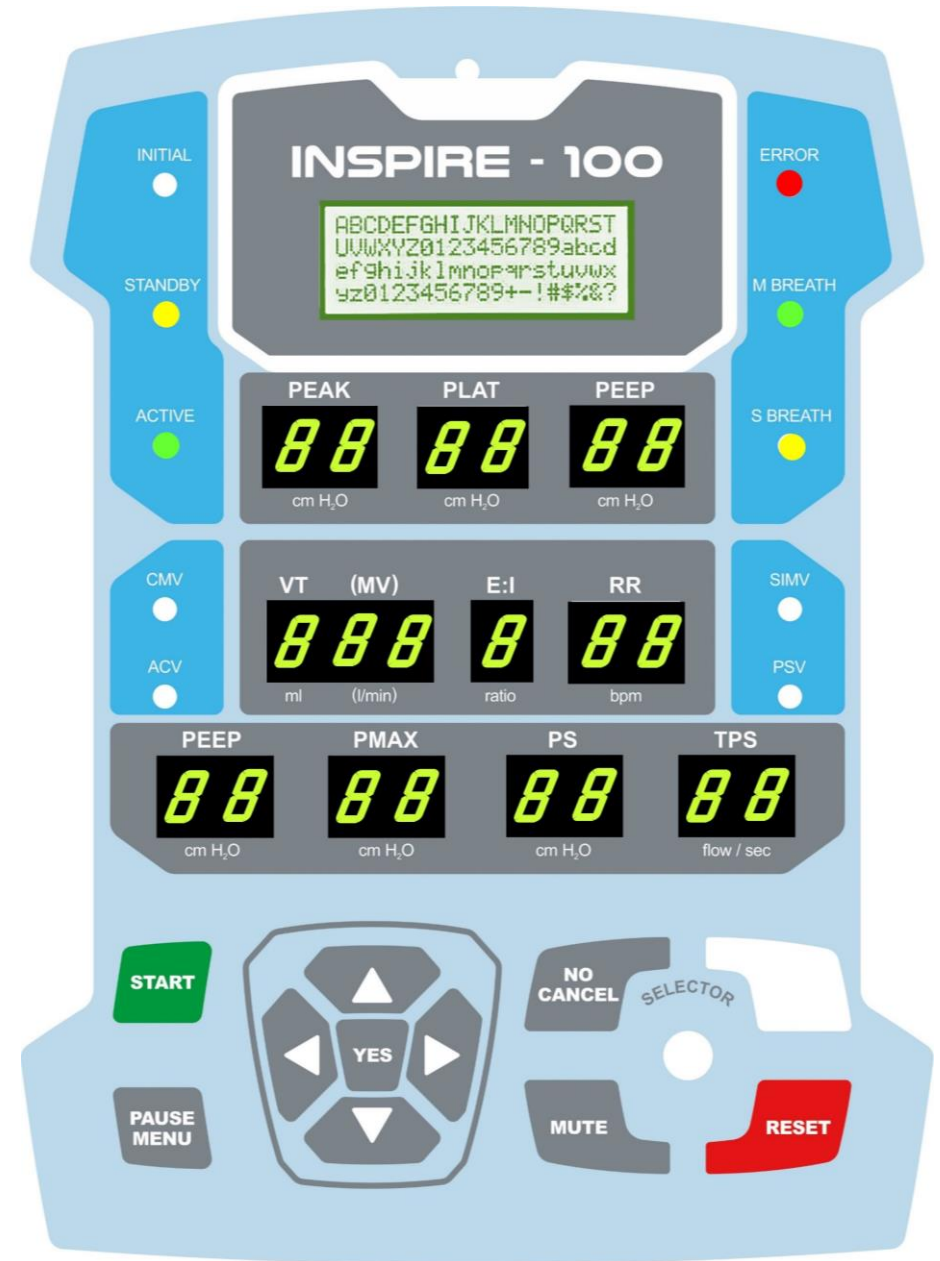Simple Tactile buttons No delicate touch screen etc.

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

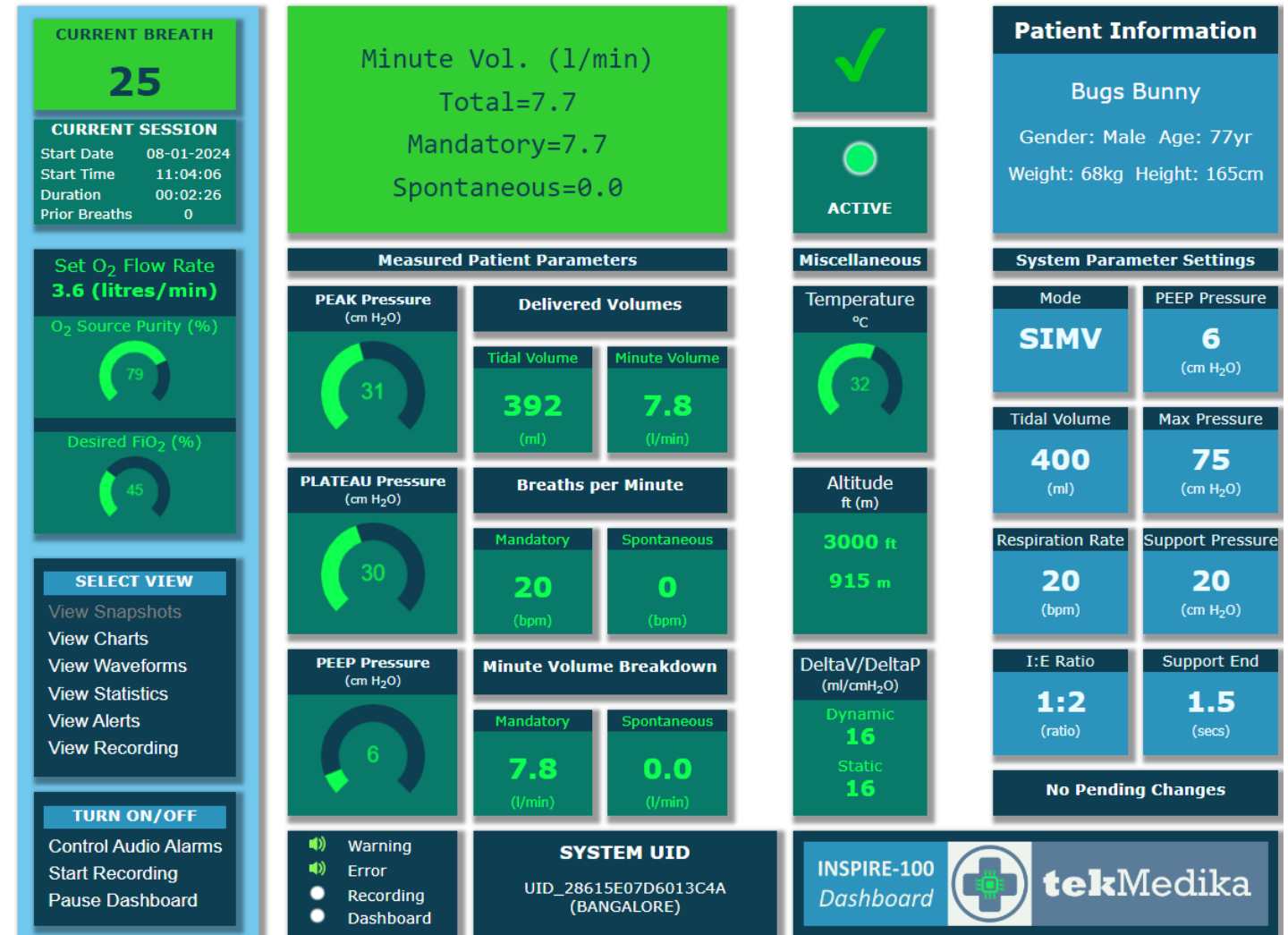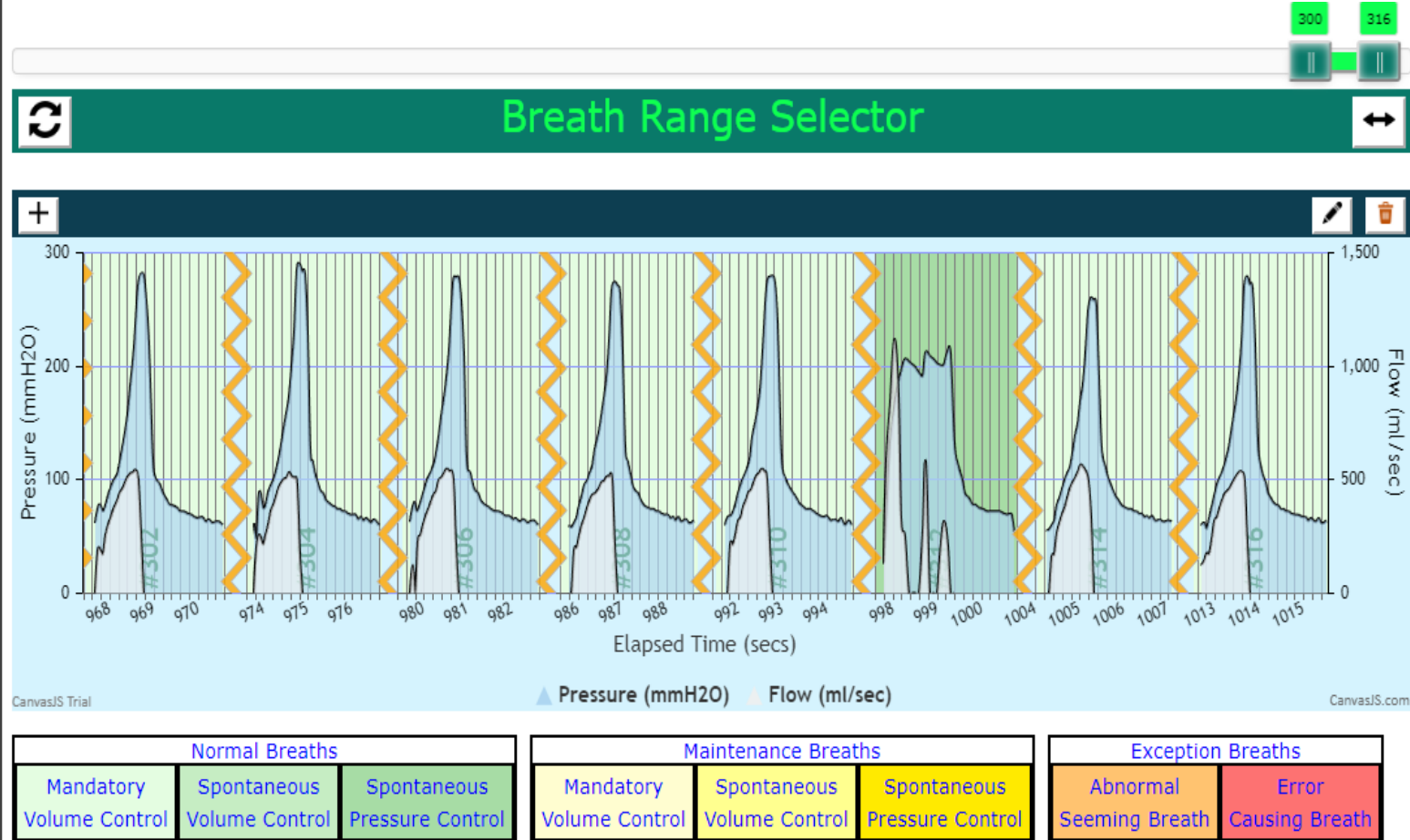Shows Delivered Volumes, Lung Compliances, Breath types etc.

Dashboard Waveforms View

Pressure and Flow Graphs

For Selected Breaths

Periodic Display

Display on demand

Breath Range Selector

Pressure (mmH2O)   Flow (ml/sec)

Normal Breaths

Mandatory Volume Control	Spontaneous Volume Control	Spontaneous Pressure Control

Maintenance Breaths

Mandatory Volume Control	Spontaneous Volume Control	Spontaneous Pressure Control

Exception Breaths

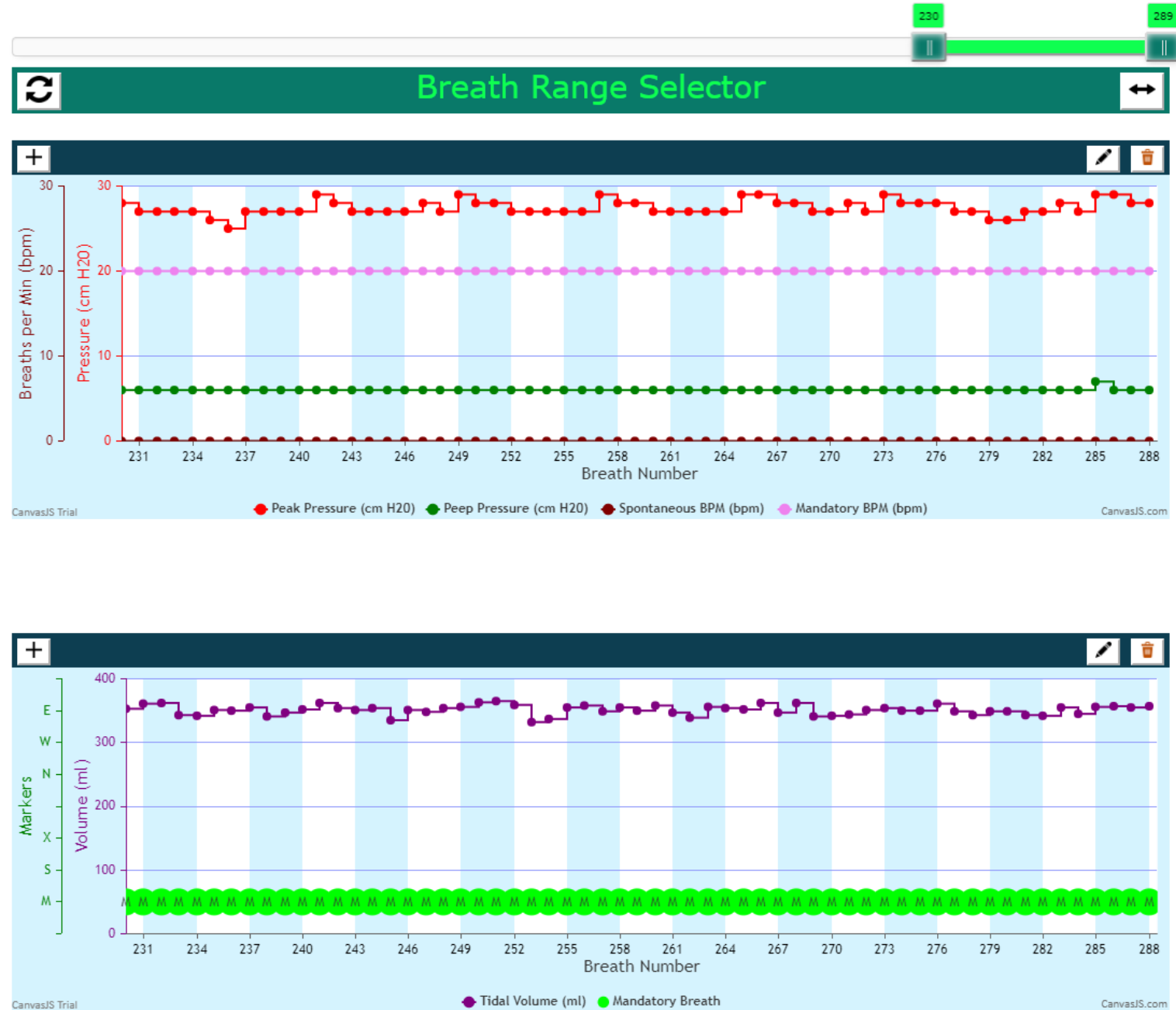| Abnormal Seeming Breath	Error Causing Breath

Broken lines indicate few missing datapoints
Red label indicates too many missing datapoints

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

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)	Respiratory Rate (bpm)	Inspiration/Expiration Ratio (I:E)
200 to 600 ml increments of 50 ml	10 to 30 bpm increments of 1 bpm	1:1 1:2 1:3
PEEP (cmH$_2$O)	Max Pressure (cmH$_2$O)	FiO$_2$ Support
4 to 15 cmH$_2$O increments of 1 cmH$_2$O	15 to 50 cmH$_2$O increments of 5 cmH$_2$O	System Managed Externally Controlled 21% to 100%

Pressure Supported Breaths

(SIMV & PSV modes)

Support Pressure (PS)

5 cmH$_2$O to 35 cmH$_2$O in increments of 5 cmH$_2$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

Example below: Tidal Volume = 500ml   Respiration Rate = 15 bpm
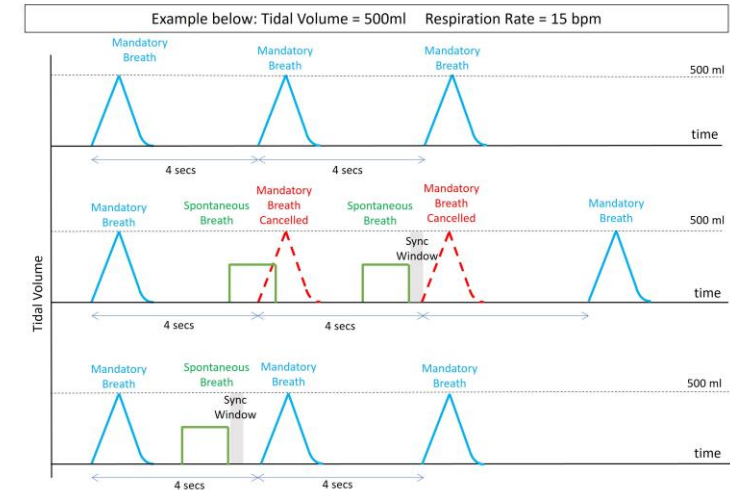
Breath Syncing in Synchronized AC Mode
There is no sync-window – the next mandatory breath is always rescheduled after a spontaneous breath

Example below: Tidal Volume = 500ml   Respiration Rate = 15 bpm
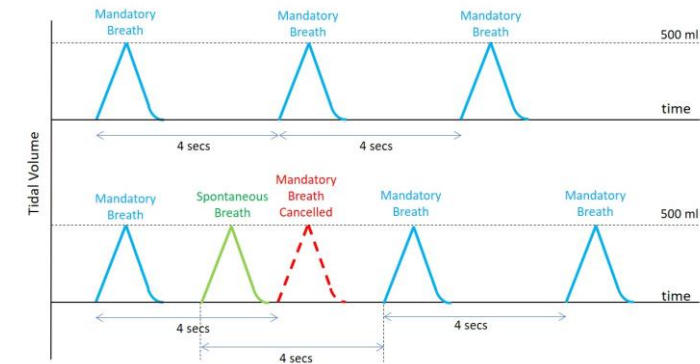
FiO$_2$ Settings

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

To Patient

BVM

Tubing to Oxygen Source

RESERVOIR
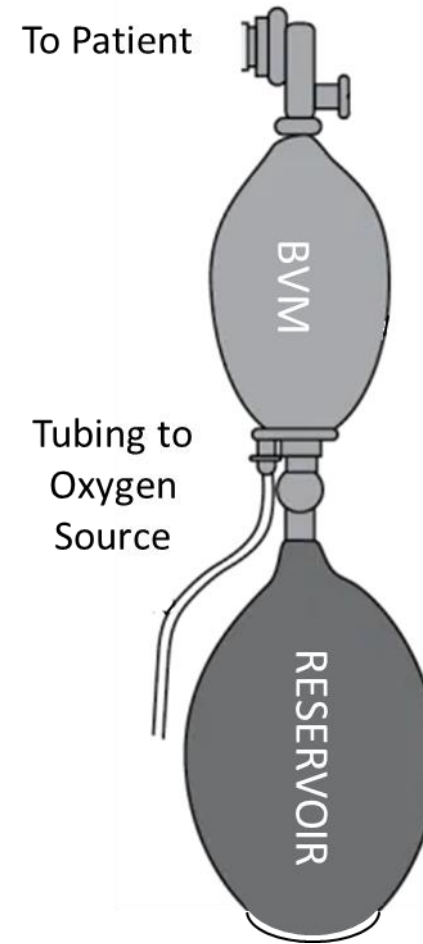
INSPIRE-100 *FiO2 Calculator*

Required Incoming O$_2$ Flow

0.0 (litres/min)

Altitude: 0   feet

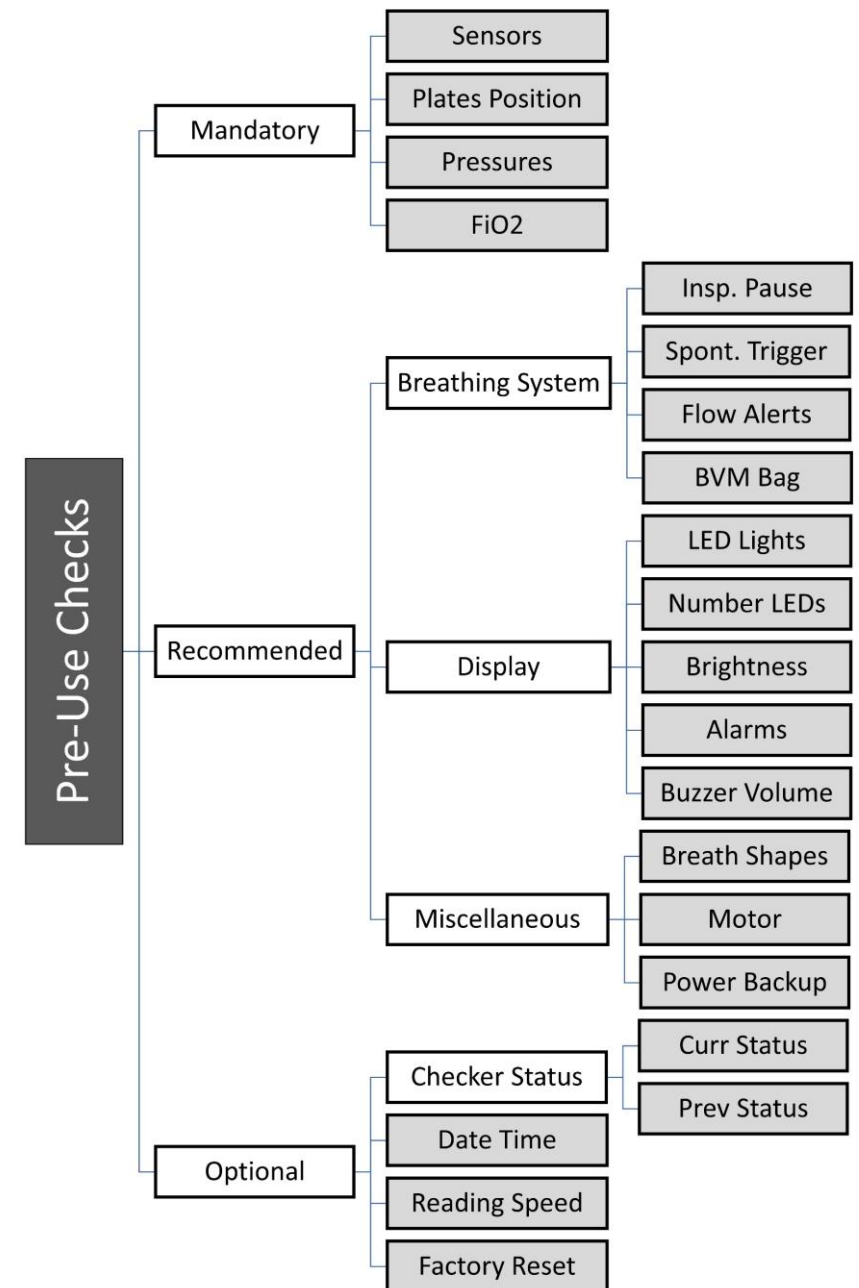Desired VT (ml)   Desired RR (bpm)

400   15

O$_2$ Purity (%)   Desired FiO$_2$ (%)
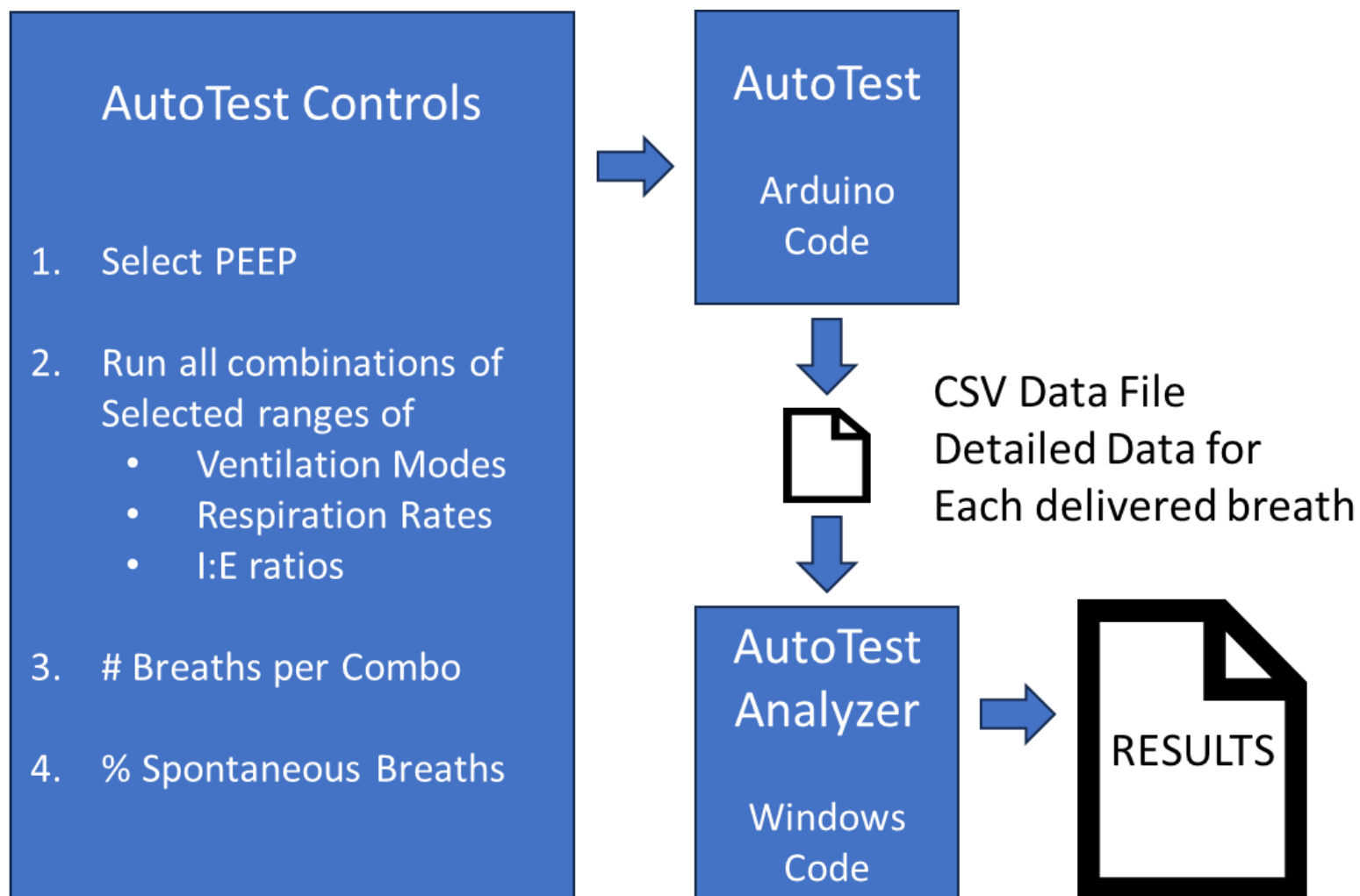
21   21

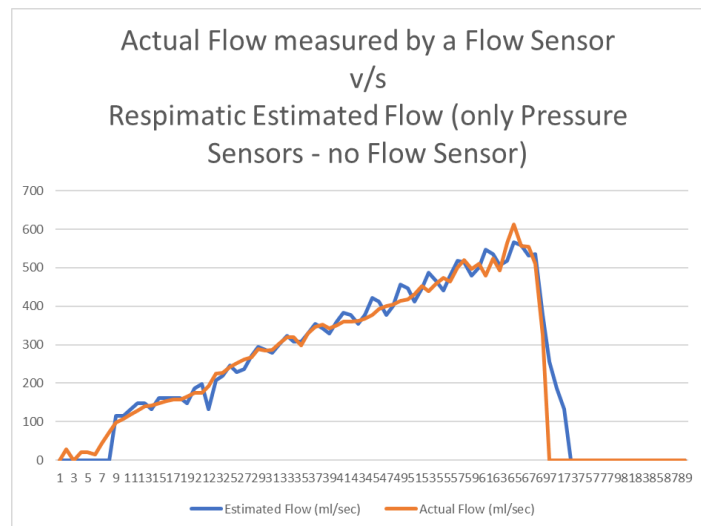**tek**Medika

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 ...

Pre-Use Checks

- Mandatory
  - Sensors
  - Plates Position
  - Pressures
  - FiO2

- Recommended
  - Breathing System
    - Insp. Pause
    - Spont. Trigger
    - Flow Alerts
    - BVM Bag
  - Display
    - LED Lights
    - Number LEDs
    - Brightness
    - Alarms
    - Buzzer Volume
  - Miscellaneous
    - Breath Shapes
    - Motor
    - Power Backup

- Optional
  - Checker Status
    - Curr Status
    - Prev Status
  - Date Time
  - Reading Speed
  - Factory Reset

Some Results

Actual Flow measured by a Flow Sensor
v/s
Respimatic Estimated Flow (only Pressure Sensors - no Flow Sensor)

— Estimated Flow (ml/sec)   — Actual Flow (ml/sec)

VT Titration for VT = 200, 300 and 400ml

— Tidal Volume (ml)

A Mix of VC and PS Breaths

▲ Pressure (mmH2O)   ▲ Flow (ml/sec)

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