





### Respimatic 100



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### US and INDIA IP Protection



#### (19) United States

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(54) VENTILATOR

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- Foreign Application Priority Data

#### Publication Classification

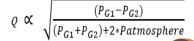
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#### ABSTRACT

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 cmH<sub>2</sub>O wh is of the of a thousand cmH<sub>2</sub>O of pressure. At sea level, Patmosphere is O. Even at an altitude of 15,000 feet, . 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 used a square root. The flow equation can be simplified to the one below.

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

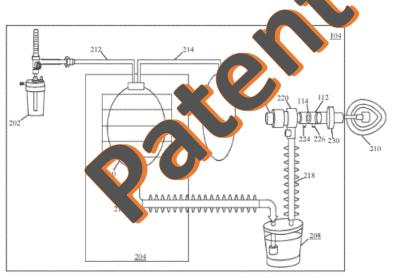
Recalling Equation 2 from the theory section above, this equation can be recast as below given that the orifice characteristics and pressure tap locations are the same for every system.

$$Q = C * \frac{\sqrt{(P_{G1} - P_{G2})}}{\sqrt{(Patmosphere)}}$$
 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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## Setting the Context

The Motivation

The Problem Statement

# RESPIMATIC 100 (Patent Pending)

Is it right for you?

Need adult, non-invasive 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?** 

# The Motivation Serve the Bottom of the Pyramid

Medical Colleges & Specialization

(Tertiary In-patient Care)

**District Hospitals** 

(Secondary In-patient Care)

Subdistrict Health Complex

(Out-patient & In-patient Care)

**Gram Panchayat PHC** 

(Ambulance, Emergency, Clinic)

Village PHC

(Out-patient Care & Referrals)

A robust, portable respiration support system for remote Primary Health Centers in India and other developing countries.

A system that works in a harsh uncontrolled environment and as a travel ventilator without piped compressed air or piped oxygen.

A system that requires minimum training. Fits budget of the bottom of the pyramid.



### 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 - Respiratory Technology Revisited

#### Remote Diagnosis and Monitoring (Telemedicine)

Rural, remote areas do not have skilled specialists
BUT Communication Technologies have come of age

#### Leverage Time-proven Technologies

<u>Simplify</u> design and feature list <u>Simplify</u> Human-Machine Interface Use <u>Off-the-shelf</u> proven components

#### Maintenance Breaths in case of unexpected errors

System <u>must never</u> stop delivering breaths.

Implement <u>Fallback</u> mechanism for each error scenario.



## Respimatic 100 Details

**System Components** 

**Technical Details** 

# 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

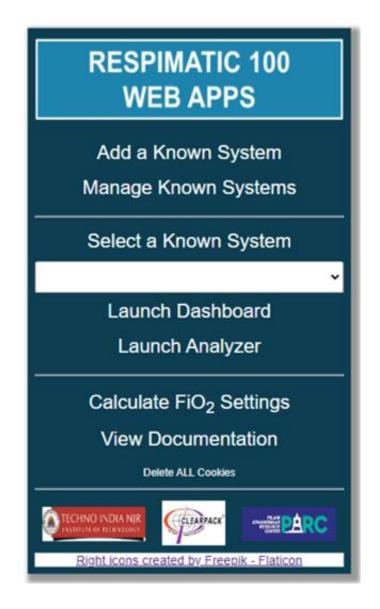
Mandatory &
Spontaneous Breaths
with Full Breath
Synchronization

Complete set of WEB Apps Remote Dashboard Remote Recorder Remote Analyzer FiO<sub>2</sub> Calculator

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

Uses secure HTTPS protocol

Field upgradable with new Firmware releases



https://www.respimatic.com

### Dashboard Snapshot View

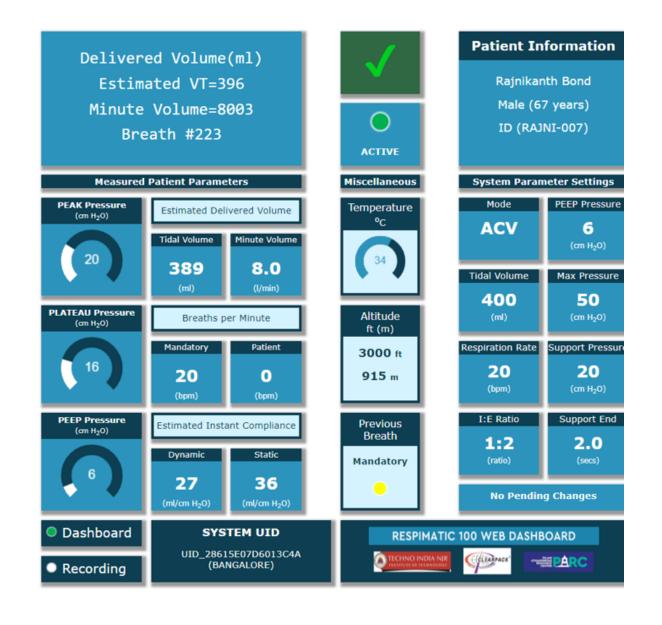
Anyone, anywhere in the world can monitor any patient via the WEB

Multiple specialists can monitor same patient

One specialist can monitor multiple patients

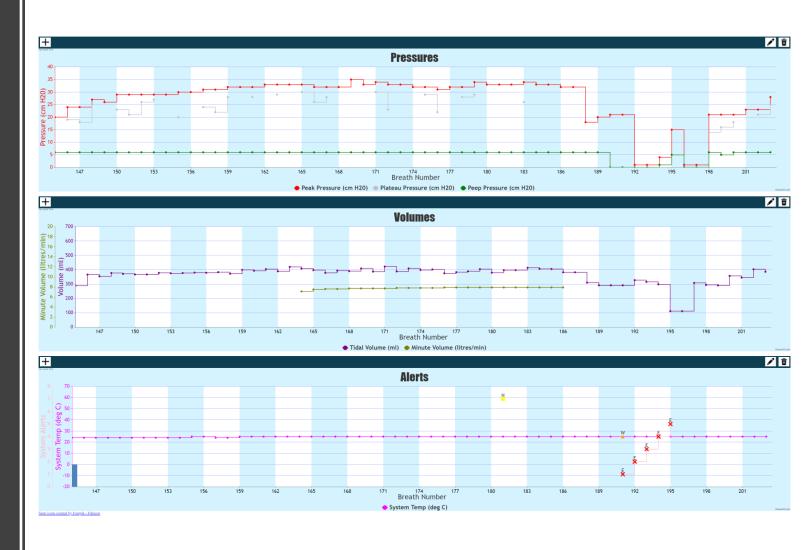
#### 5 Dashboard views

- Snapshots
- Charts
- Statistics
- Breath Shapes
- Alerts



https://www.respimatic.com

## Dashboard Charts View



## Dashboard Statistics View

#### **Parameters Measured**

Parameter	Units	Min	Max	Avg
Peak Pressure	cmH20	1	35	28.1
Plateau Pressure	cmH20	17	33	27.1
PEEP Pressure	cmH20	5	7	6.0
Tidal Volume Delivered	ml	150	412	359.4
Minute Volume Delivered	litres/min	5.6	5.9	5.7
Mandatory BPM	bpm	15	16	15.2
Spontaneous BPM	bpm	0	1	0.7
FIO2	%	50	50	50.0
Instantaneous Static Compliance	ml/cmH20	14	30	18.4
Instantaneous Dynamic Compliance	ml/cmH20	14	22	16.5
System Temperature	degC	29	30	29.2

#### **Miscellaneous Information**

Information	Value
Number of Breaths	73
Number of Mandatory Breaths	56
Number of Spontaneous Breaths	17
Number of Maintenance Breaths	0
Number of Missing Breaths (Comms Failure)	0
Number of Notifications	0
Number of Warnings	2
Number of Errors	17

#### **Static Information**

Patient Name: --

Patient Info: --

System Deployment Altitude: 3000 (915) ft(m)

#### **Parameter Settings Used**

Parameter	Units	Values
Ventilation Mode	mode	ACV,CMV
Tidal Volume	ml	400,300
Respiration Rate	bpm	15,20
I:E Ratio	ratio	1:3,1:2
PEEP Pressure	cmH20	6
Maximum Pressure	cmH20	50
Support Pressure	cmH20	25
Support Pressure Termination	%flow,secs	F20%
FIO2	%	50

#### **Sequence of Parameter Combinations**

MODE	VT	RR	I:E	PEEP	PMAX	PS	TPS I	FIO2	# of BREATHS	Before BREATH#
ACV	400	15	1:3	6	50	25	F20%	50	17	0
CMV	300	15	1:2	6	50	25	F20%	50	16	17
ACV	400	15	1:3	6	50	25	F20%	50	21	33
ACV	400	20	1:3	6	50	25	F20%	50	19	54

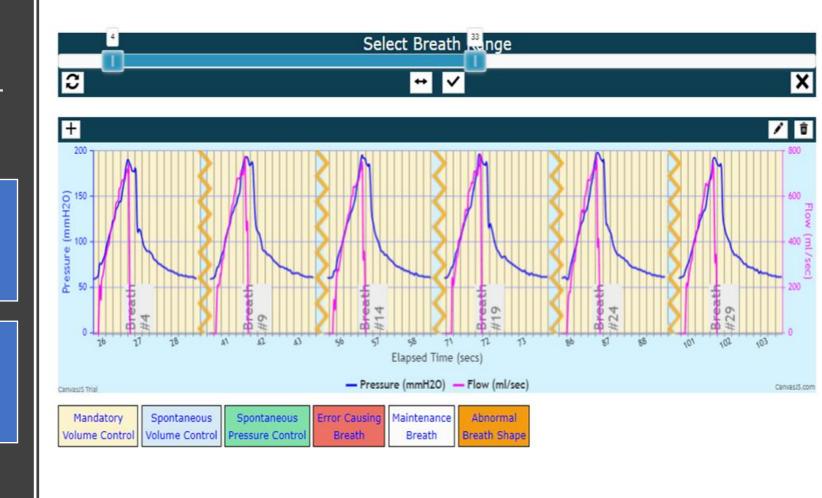
### Dashboard Waveforms View

Pressure and Flow Graphs

For Selected Breaths

Periodic Display

Display on demand



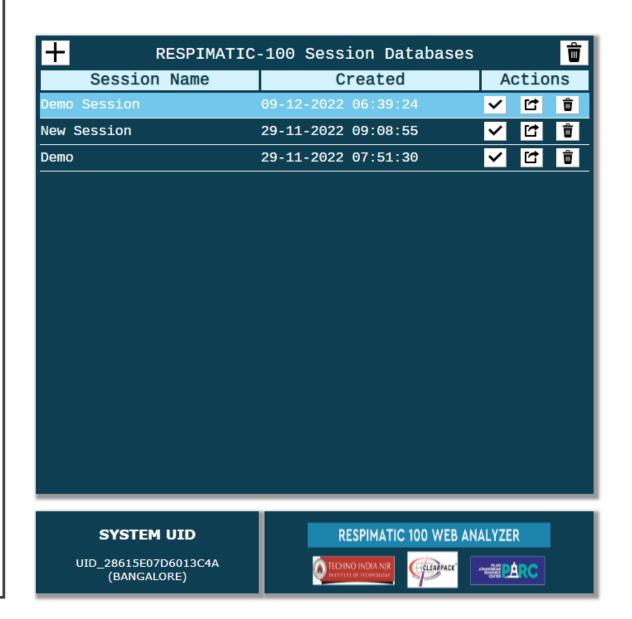
### Dashboard Alerts View



### Analyzer

Any patient Session can be recorded locally or remotely.

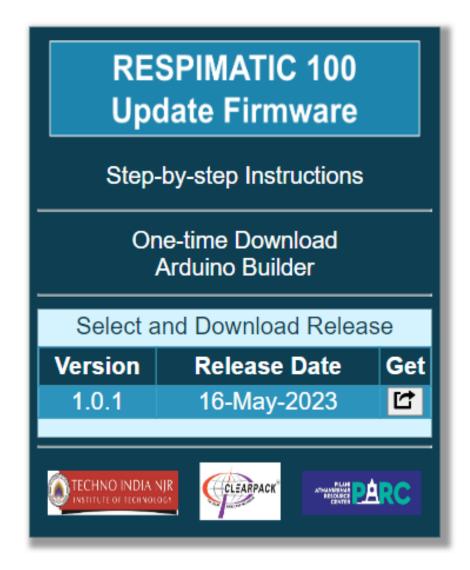
The recorded Session can then be analyzed off-line using the Analyzer.



### Updating Firmware

Firmware releases available on the WEB.

Step-by-step menu driven update procedure



# Front Panel The Human-Machine Interface

No delicate touch screen etc.

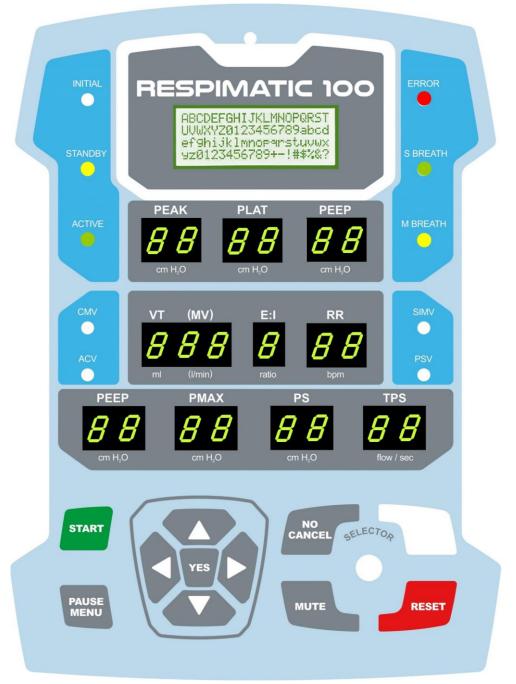
Easy to read 7-seg
LED Parameters
Display

Parameter selection using simple arrow buttons

4-line LCD Display for displaying Messages and Menus

Peak, Plateau, PEEP pressures displayed after each breath

Also shows Delivered Volumes, Lung Compliance, Breath types etc.

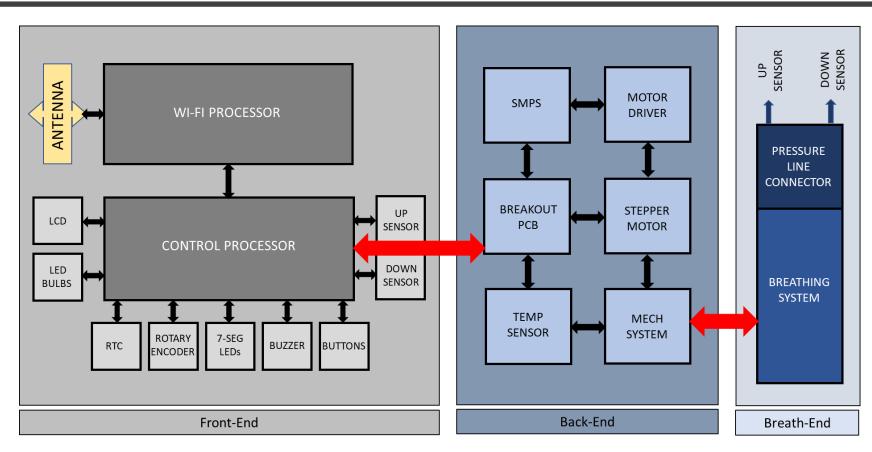


## System Architecture

Clearly separated
Frontend, Backend and
Breathing system

IP is the Frontend design and Algorithms

Backend and Breathing
System can have
multiple avatars

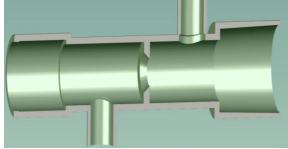


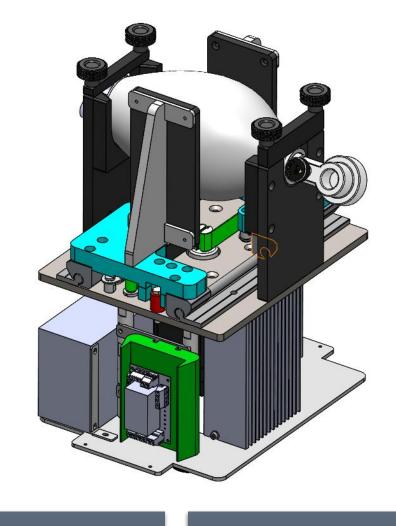
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## Respimatic 100 Under the hood

Low Production Cost
Compact and Robust
Intuitive HMI
Simple to operate







Simple
Electronics
COTS
components

Rugged mechanical system Complete Parameter monitoring Complete set of alarm conditions

Robust, Suitable for mass production

### 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 sensors, PEEP valve

**HME Filter** 

Humidifier

Oxygen Source

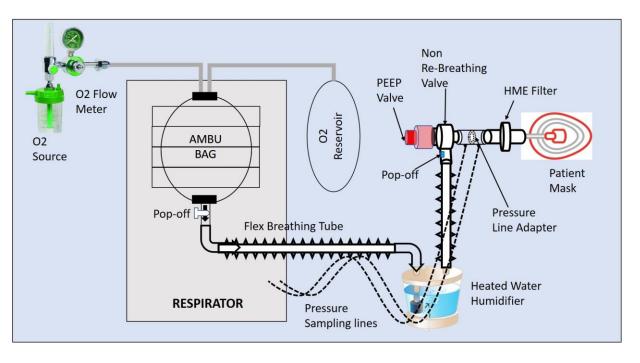








Proprietary Dual
Pressure line Connector



### 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)

20 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 30 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% of peak flow

#### Time dependent

Terminate after 1.0 to 2.5 secs in increments of 0.5 secs

#### **Both ACV and SIMV modes**

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

## Breath Synchronization

### FiO<sub>2</sub> Settings

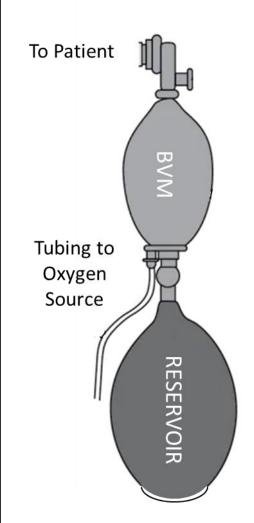
Without the Reservoir bag, FiO<sub>2</sub> delivered is the Atmospheric O<sub>2</sub> content at site

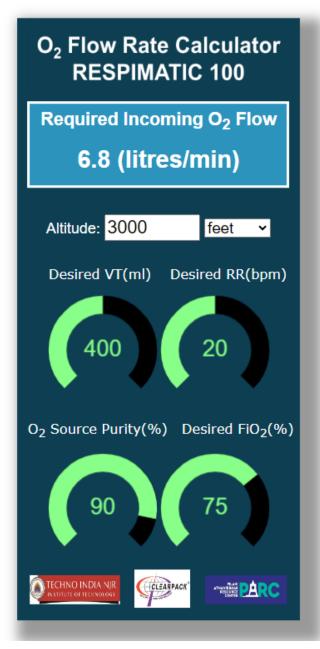
FiO<sub>2</sub> delivery with the Reservoir bag is mathematically modelled, calibrated and verified in the Lab to provide +/- 5% accuracy

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%)

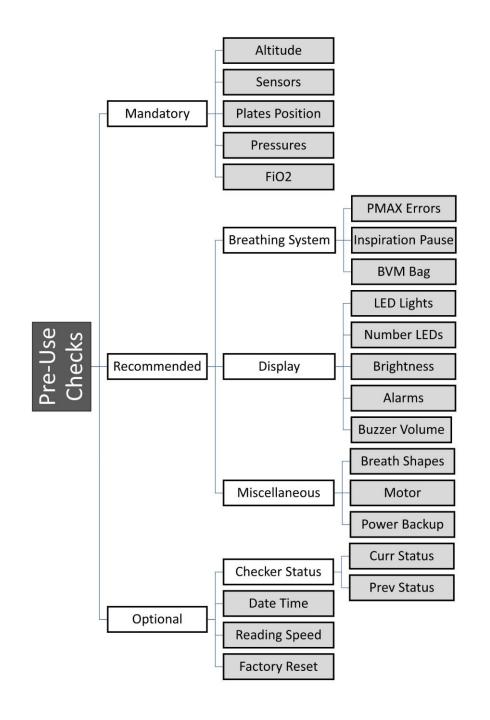
Online Web-accessible FiO<sub>2</sub> calculator is also provided for exploration purposes





# Alarms and Safety Features

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



### **Power Consumption**



An online, sine-wave, external battery UPS recommended to continue operation during power outages



50 AH Car battery is sufficient to run the system for 5+ hours





100 AH Tubular battery is sufficient to run the system for 10+ hours

Input Voltage	180-250 V
Power Consumption	< 100 Watts

### Respimatic Testing Process

Timing, Flow and Pressure Checks for all combinations of various settings



Automated Testing for all combinations of VT, RR, IE, PEEP, PS with randomized spontaneous breath triggers



Automated testing of full day runs checked for timing within 1% of theoretical expectations



All testing so far with a simple test lung Next step needs a more sophisticated test lung

CPAP	BiPAP	Respimatic-100	ICU Ventilator
Continuous Positive Airway Pressure	Continuous Bi-Level Airway Positive Pressure	· · ·	Mechanical Ventilation with sophisticated ventilation modes and controls
Non-invasive	Non-invasive	Non-invasive	Non-invasive / Invasive
High Flow + PEEP	Inspiratory Pressure + PEEP	VT + PS + PEEP	VT + PS + PEEP
Useful for Type 1 respiratory Failure (Hypoxemic)	Useful for Type 2 respiratory Failure (Hypercopnic)		Useful for Type 1 and Type 2 respiratory Failure
Continuous flow at a constant pressure. Increases mean airway pressure to recruit collapsed alveoli.	Continuous flow at a constant pressure during inspiration and a different constant pressure during expiration	·	Independent control over the volume, the respiration rate and the pressure as required.
Useful only when patient can breathe on their own	Useful only when patient can breathe on their own	·	Useful when patient can or cannot breathe on their own
Only Spontaneous breaths that are patient triggered.	Only Spontaneous breaths that are patient triggered.		Spontaneous breaths PLUS Mandatory breaths controlled by RR and I:E
External FiO2 control	External FiO2 control	External FiO2 control	Direct Internal FiO2 control
Breath Syncing N/A	Breath Syncing N/A	Full Breath Syncing	Full Breath Syncing
No VT control	Indirect VT control (IPAP-EPAP)	Direct VT control	Direct VT control
No RR control	No RR control	Direct RR control	Direct RR control
No I:E control	No I:E control	Direct I:E control	Direct I:E control
External Humidity control	External Humidity control	External Humidity control	Direct Humidity control
No monitoring of Peak, Plateau or PEEP pressures	No monitoring of Peak, Plateau or PEEP pressures	_	Direct monitoring of Peak, Plateau and PEEP pressures
Minimal alarm signals	Minimal alarm signals	Full set of Alarm signals	Full set of Alarm signals

### Compare & Contrast Various Systems

## Thank you

# Backup

Market Analysis

Sample Waveforms







# The Problem Scarcity & Affordability

- India has amongst the lowest per capita ICU beds in the World\*
- 1.46 beds / 1000 people\*
- 3.65 ICU beds / Lakh people\*
- Only half of ICU beds are equipped with Ventilators
- A meagre 1.8 Ventilators for one lakh people\*
- ICU ventilators are expensive equipment
- Unaffordable in remote clinics
- Ventilator Ambulances are
- Either non-existent except in few major urban centres,
- Or beyond the reach of majority of population

<sup>\*</sup> As per April 2020 Study by Center for Disease Dynamics, Economics & Policy at Princeton University, USA

### The Problem Skilled Practitioners

ICU Ventilators require highly skilled manpower to operate and monitor

#### Ventilators lie unutilised due to shortage of doctors

Jaisalmer: 11 vernment has given 17 ventilators, including 12 to Jaisalmer and five to Pokhran government hospitals. However, they were lying unutilised due to lack of doctors. The serious patients are being referred to Jodhpur and a large number of corona patients have died while undergoing treatment in Jodhpur.

On Tuesday, there were 42 fresh cases of Covid-19 in Jaisalmer district. On Sunday, 54 cases were reported. The condition of some patients is serious as they are being referred to Jodhpur which is a five hours jour-



sion. The main reason behind referring serious patients to Jodhpur is non-availability of ventilator facility and posts of main doctors are lying vacant.

There are only two phy-

three physicians, cardiolo

Jaisalmer collector Ashish Modi said that all the 17 ventilators in the district are in operational condition and oxygen and other resources are available. He said that posts of cardiologist, physician are lying vacant due to which ventilators cannot be used for corona patients. Serious patients are referred to Jodhpur on time and Jodhpur divisional commissioner Dr Samit Sharma is sicians in the Jaisalmer he said. Jaisalmer governhospital of which duty of ment hospital PMO Dr VK one of the doctors is to take Verma said that ventilator.

व्यवस्थाओं को कोरोना: सरकार ने दिए वेंटीलेटर, आधे से अधिक इंस्टाल नहीं किए

#### कहीं पर्याप्त प्रशिक्षित द्राफ ही नहीं

रोना वायरस के संक्रमण लेटर की कमी होने पर बीलेटर उपलब्ध करा सते जहां चरू नहीं होने से परेशानी आ रही है तथा



सात वेंटीलेटर मेल वार्ड में लगा दिए हैं। तीन को भी एक-दो दिन में इंस्टॉल करवा दिया जाएगा। भरतिया अस्पताल के पास जो वेंटीलेटर हैं. उन्हें जरूरत के हिसाब से इंस्टॉल कर दिया जाएगा। मेडिकल टीम को डेमो देकर प्रशिक्षित किया जाता है।

डॉ. हनमान जयपाल. एसोसिएट प्रोफेसर, मेडिकल कॉलेज, चरू

दरअसल. वेंटीलेटर का सरकार ने जिला अस्पतालों को संचालन प्रशिक्षित स्टाफ ही कर वेंटीलेटर उपलब्ध करा दिए सकता है। वह भी उस स्थिति में लेकिन चलाने के लिए यहां पर निश्चेतना विशेषज्ञ मॉनिटरिंग पर्याप्त प्रशिक्षित स्टाफ नहीं होने से रहा हो। कोविड-19 के चलते परेशानी आ रही है।

कोटा. कोटा मेडिकल कॉलेज के बढ़ने के बाद 23 नए वेंटीलेटर और

कोविड अस्पताल में 52 वेंटीलेटर हैं आए हैं। इंस्टॉल होना बाकी है। और सभी चालु हैं। वहीं, कोरोना के संचालन के लिए पर्याप्त कार्मिक हैं।

#### 25 वेंटीलेटर इंस्टाल स्टोर की बढ़ा रहे शोभा

चित्तौडगढ के जिला अस्पताल मे कोरोना से पूर्व पांच वेंटीलेटर थे, जो बढ़कर 42 हो गए हैं। इनमें से कुछ फोल्डिंग वेंटीलेटर है। वेंटीलेटर पर मरीज को रखने के लिए आईसीय का प्रशिक्षित स्टाफ चाहिए और निश्चेतन के चिकित्सक चाहिए।यहां आईसीयु का प्रक्षिक्षित स्टाफ करीब आधा दर्जन का ही है जो आईसीयू में है। यहां कुल 42 वेंटीलेटर में से अभी भी पांच



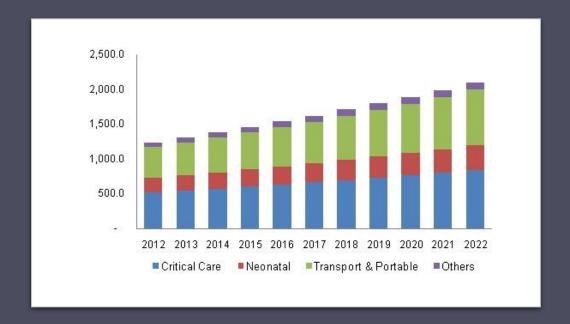
तथा जैसे ही जरूरत पडेगी। वार्ड मे

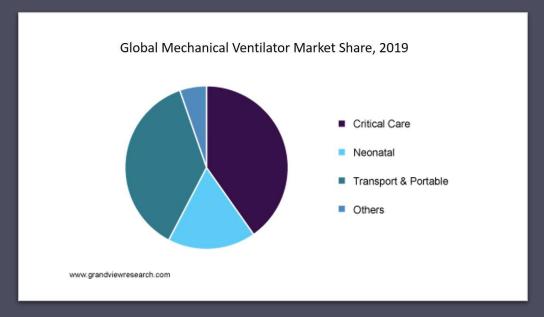
### Market Need

25 to 50 ventilators per lakh people in developed countries

1.8 ventilators per lakh people\* (India)

Even less for lower income developing and underdeveloped countries\*





<sup>\*</sup> As per April 2020 Study by Center for Disease Dynamics, Economics & Policy at Princeton University, USA

### Breath Synchronization in ACV Mode

Tidal volume is delivered at regular intervals  $T_i$ .



If spontaneous breath occurs during this interval at time  $T_s$ , the set tidal volume is delivered in response, and the next mandatory breath is set for  $(T_s + T_i)$ .

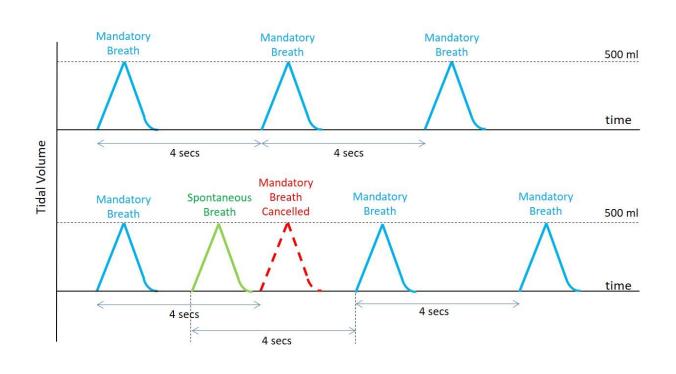


Again, if another spontaneous breath is detected before  $T_s + T_i$ , a mandatory breath scheduled  $T_i$  time in future.

#### **Breath Syncing in Synchronized AC Mode**

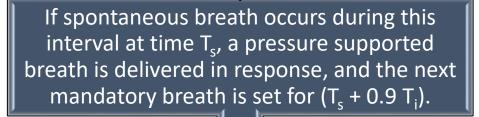
There is no sync-window – the next mandatory breath is always rescheduled after a spontaneous breath

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



### Breath Synchronization in SIMV Mode

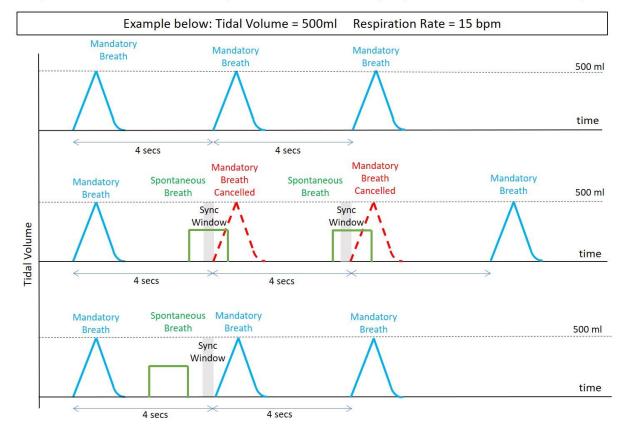
Tidal volume is delivered at regular intervals  $T_i$ .



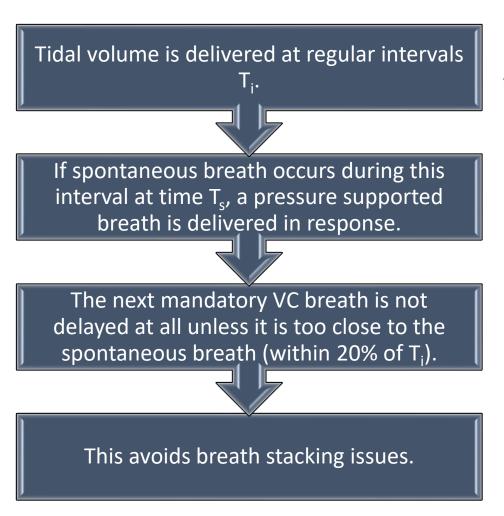
This is to allow more spontaneous breaths but to trigger a mandatory VC breath if spontaneous breath is not detected within 90% of the mandatory breath interval.

#### **Breath Syncing in SIMV mode**

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



### Exceptional Mandatory Breath in PSV Mode



#### Mandatory Breath (Warning) in PSV mode

There is a quiet-window – the next mandatory breath is delivered only if no spontaneous breath within the quiet-window

