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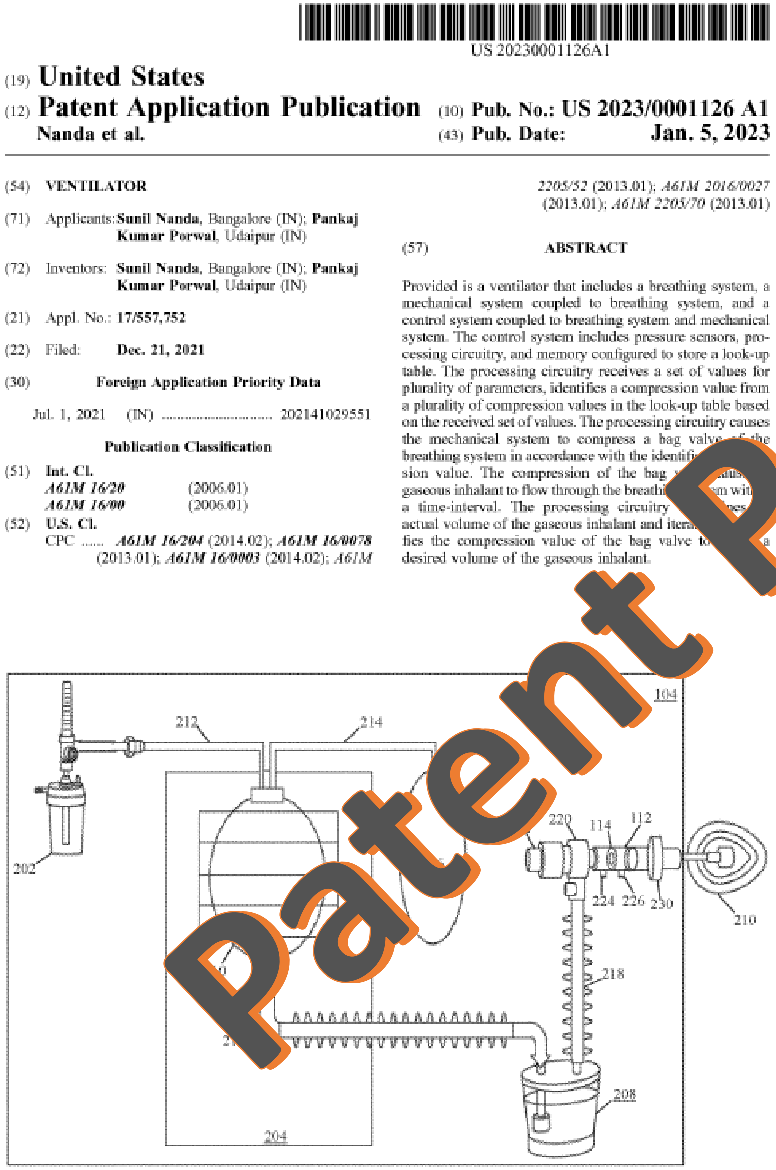
Respimatic 100

Sunil Nanda (PARC)

US and INDIA IP Protection



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(54) **VENTILATOR**

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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 of the breathing system in accordance with the identified compression value. The compression of the bag [illegible] gaseous inhalant to flow through the breathing system with a time-interval. The processing circuitry [illegible] actual volume of the gaseous inhalant and iteratively [illegible] fies the compression value of the bag valve to [illegible] a 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 necessary simplification is that P_{G1} and P_{G2} encountered in our system are of the order of tens of cmH_2O while Patmosphere is of the order of a thousand cmH_2O of pressure. At sea level, Patmosphere is approximately 1000 cmH_2O. Even at an altitude of 15,000 feet, Patmosphere is approximately 600 cmH_2O. On the other hand, the P_{G1} and P_{G2} in the system range from 1 to 60 [illegible]

[illegible] $(P_{G1}+P_{G2})$ term is negligible compared to (2* Patmosphere), even more so since it [illegible] is [illegible]ed 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.

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

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.

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 O_2 Cylinder or Concentrator?

Full range of Respiration parameters?

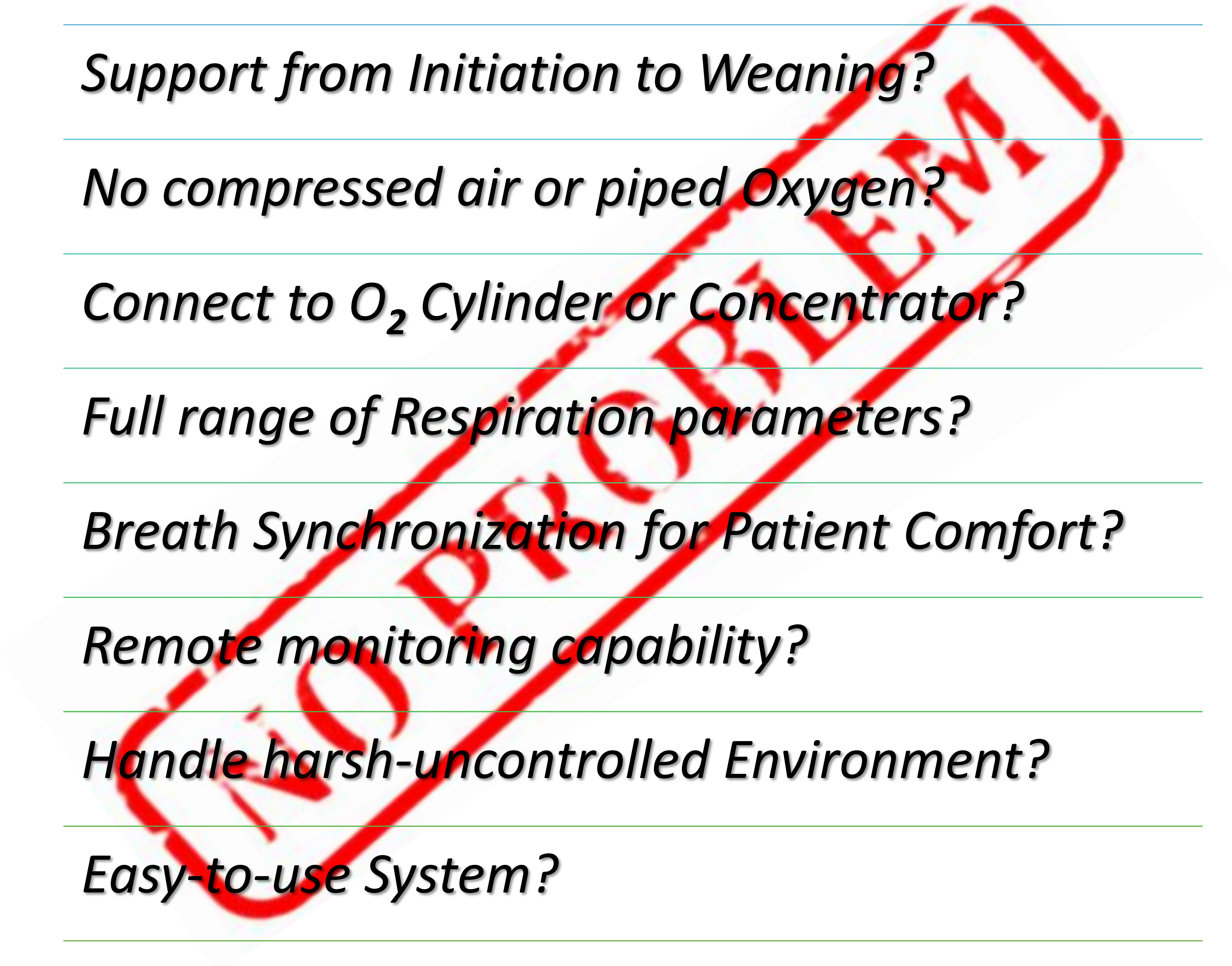
Breath Synchronization for Patient Comfort?

Remote monitoring capability?

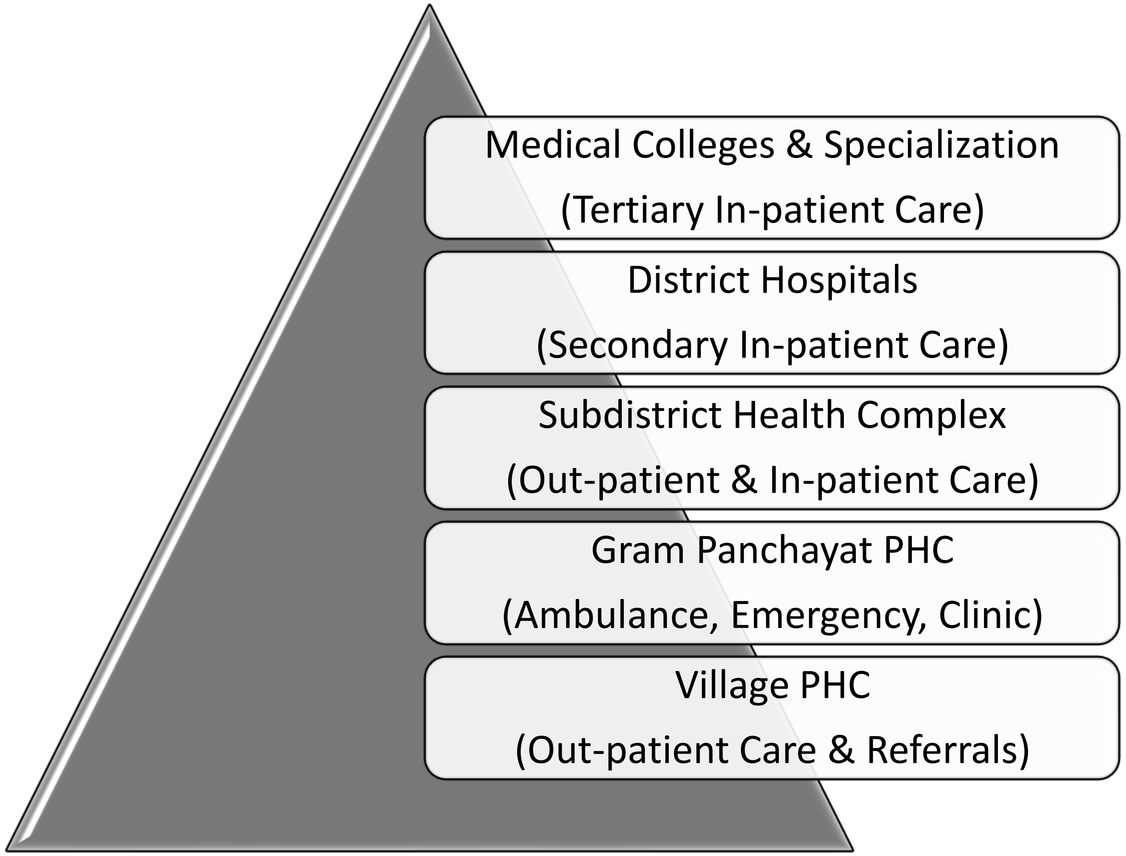
Handle harsh-uncontrolled Environment?

Easy-to-use System?

Budget Friendly?



The Motivation
Serve the Bottom of the Pyramid



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.

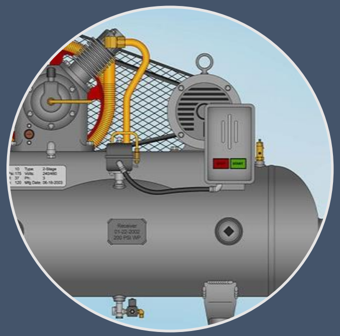
Fits budget of the bottom of the pyramid.

2 BIG Challenges

Lack of Affordability leading to Scarcity

Lack of Skilled Practitioners

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

Simplify design and feature list

Simplify Human-Machine Interface

Use *Off-the-shelf* proven components

Maintenance Breaths in case of unexpected errors

System *must never* stop delivering breaths.

Implement *Fallback* 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

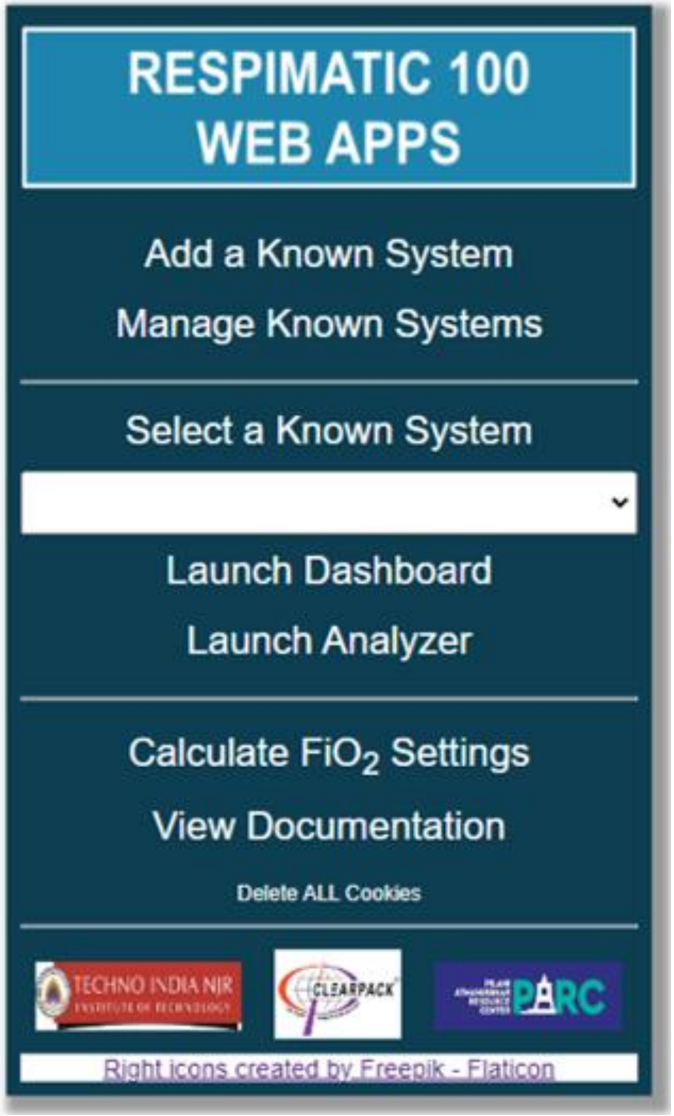
Mandatory & Spontaneous Breaths with Full Breath Synchronization

Complete set of WEB Apps
- Remote Dashboard
- Remote Recorder
- Remote Analyzer
- FiO_2 Calculator

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

Uses secure HTTPS protocol

Field upgradable with new Firmware releases



https://www.respimatic.com

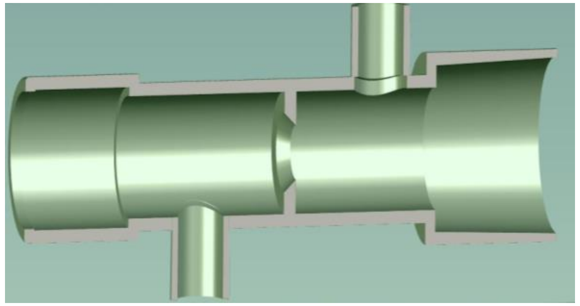
Respimatic 100
Under the hood

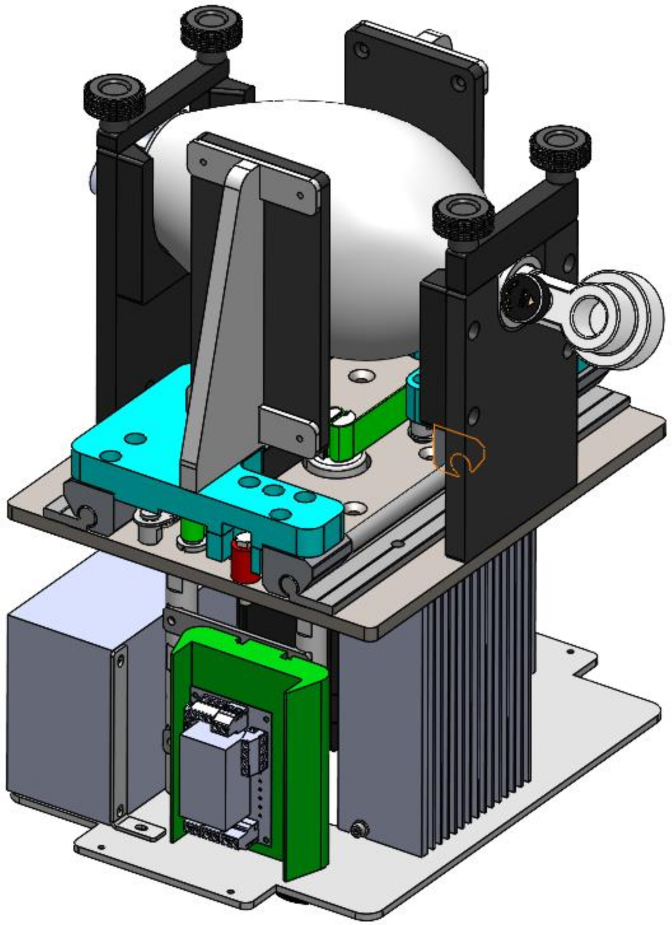
Low Production Cost

Compact and Robust

Intuitive HMI

Simple to operate





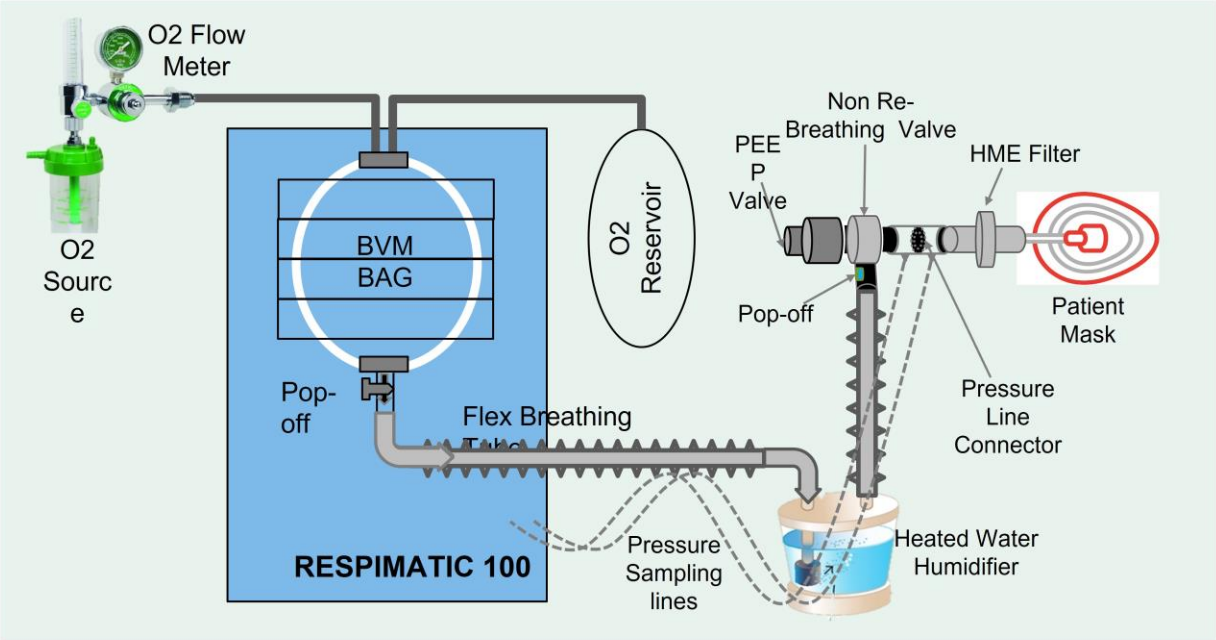
- Simple Electronics COTS components
- Rugged mechanical system
- Complete Parameter monitoring
- Complete set of alarm conditions
- Robust, Suitable for mass production

Breathing Circuit

- Proprietary, ***patent-pending*** 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

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.

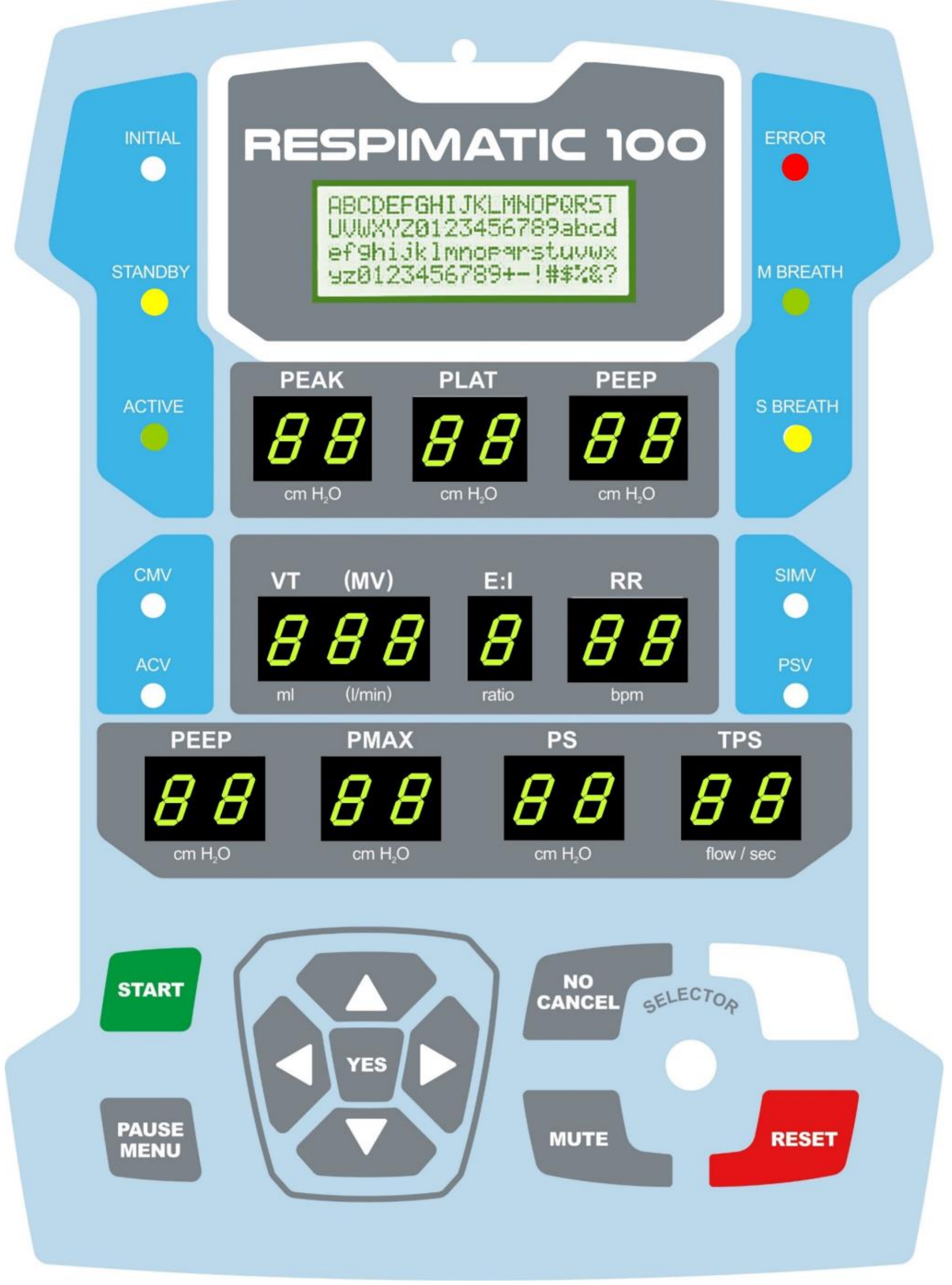
Easy to read 7-seg
LED Parameters
Display

Parameter selection
using 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.



Dashboard Snapshot View

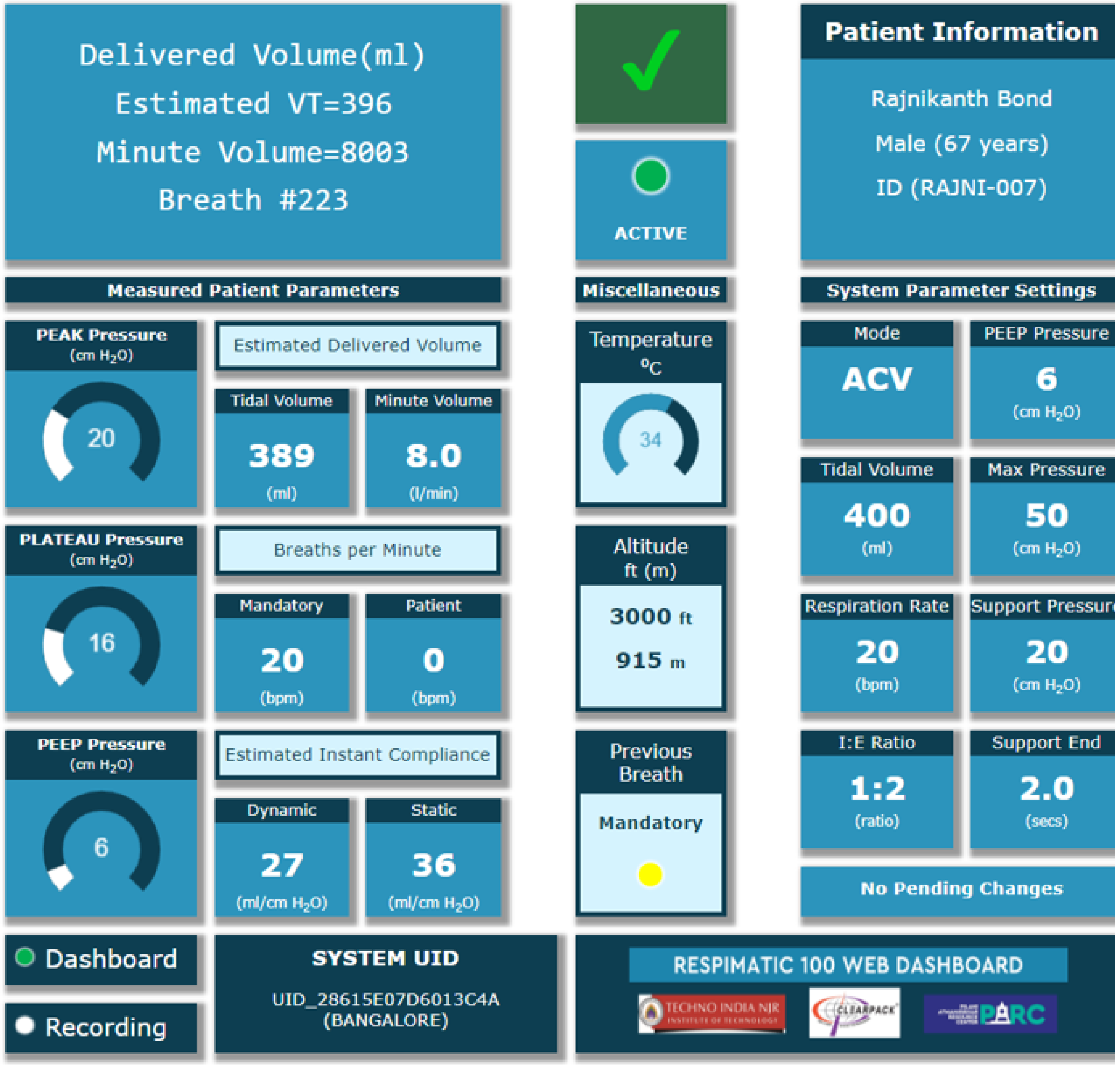
Anyone, anywhere in the world can monitor any patient via the WEB

Multiple specialists can monitor same patient

One specialist can monitor multiple patients

5 Dashboard views

- Snapshots
- Charts
- Statistics
- Breath Shapes
- Alerts



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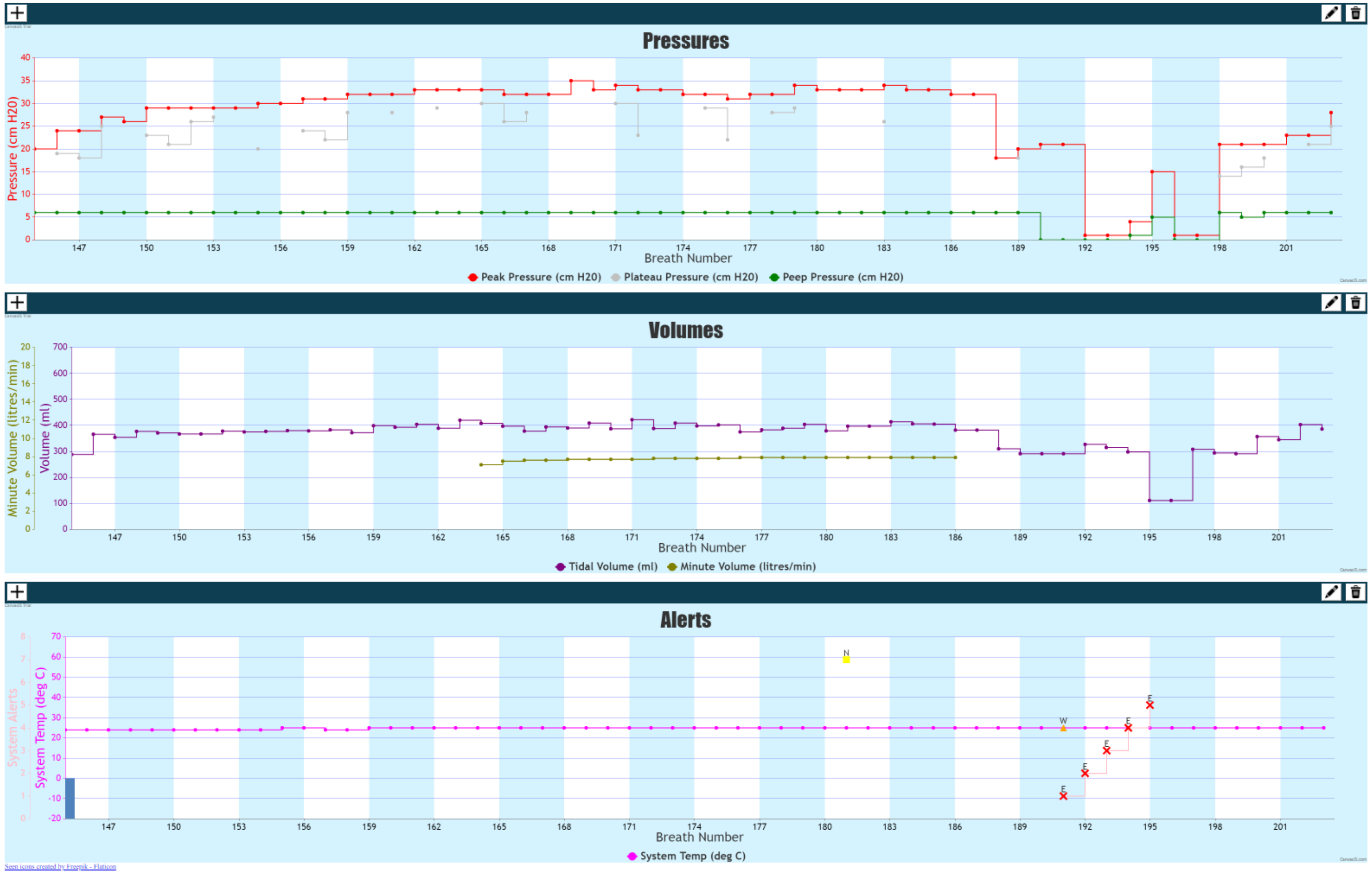
Dashboard Charts View



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	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

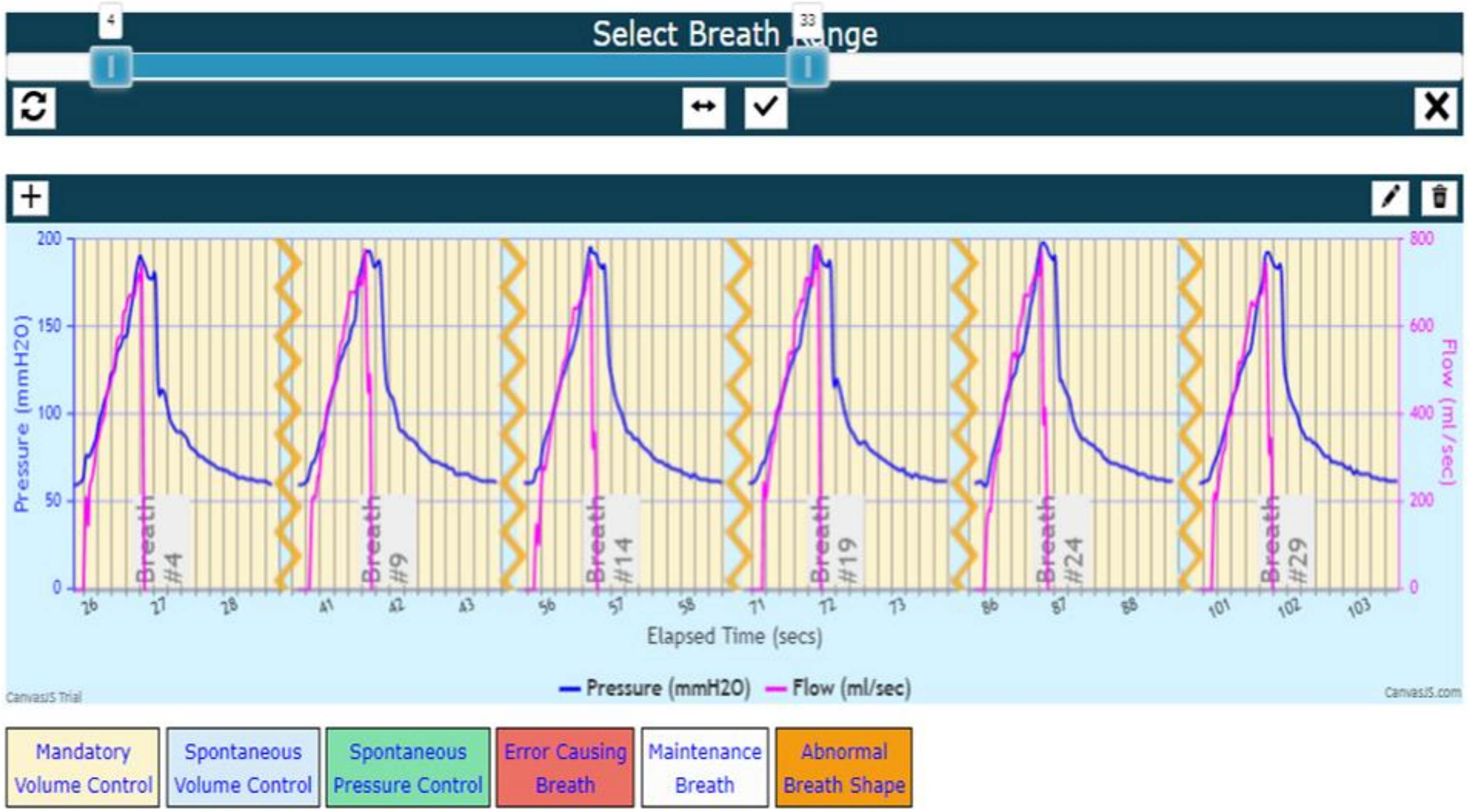
Dashboard Waveforms View

Pressure and Flow Graphs

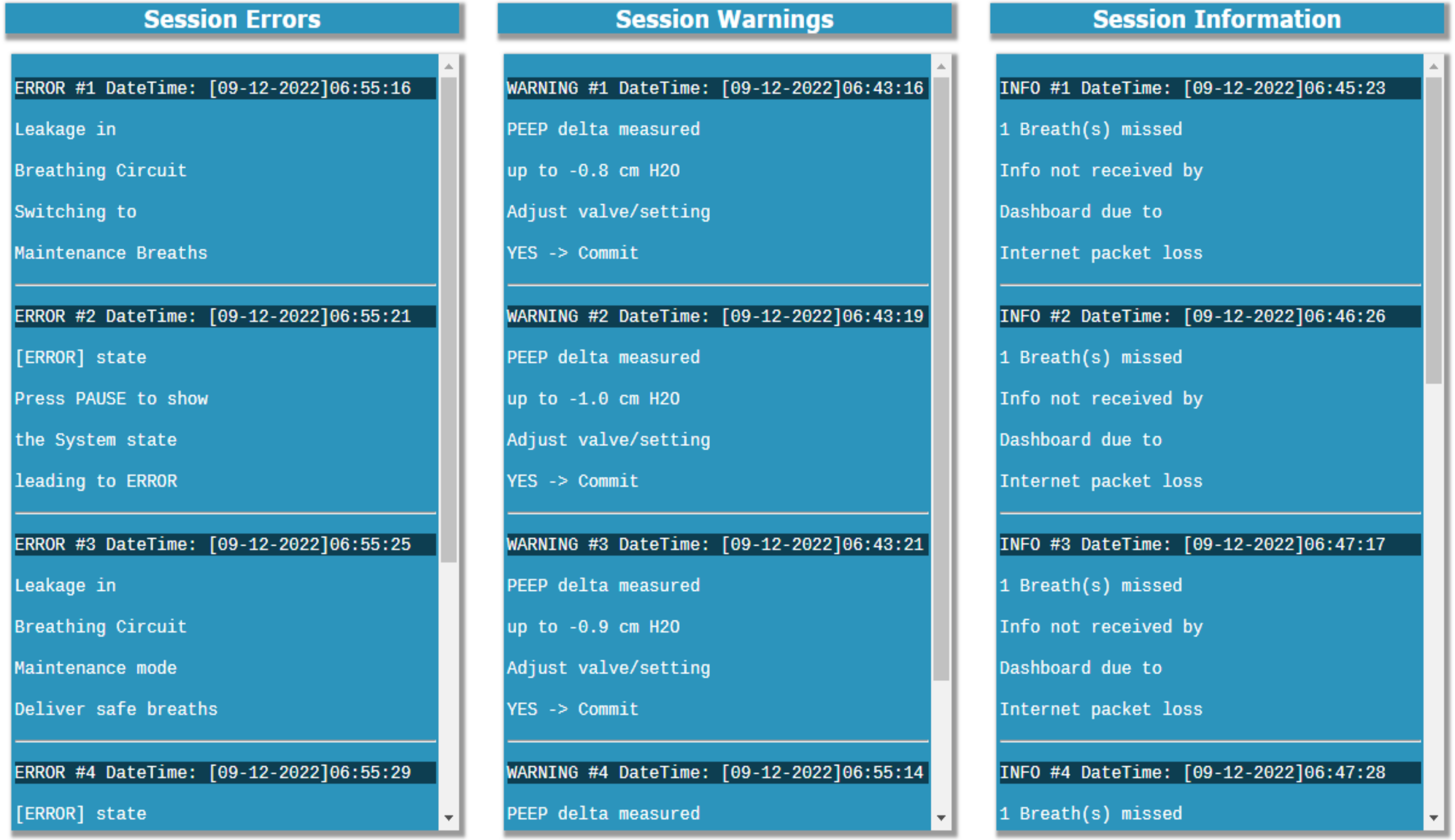
For Selected Breaths

Periodic Display

Display on demand



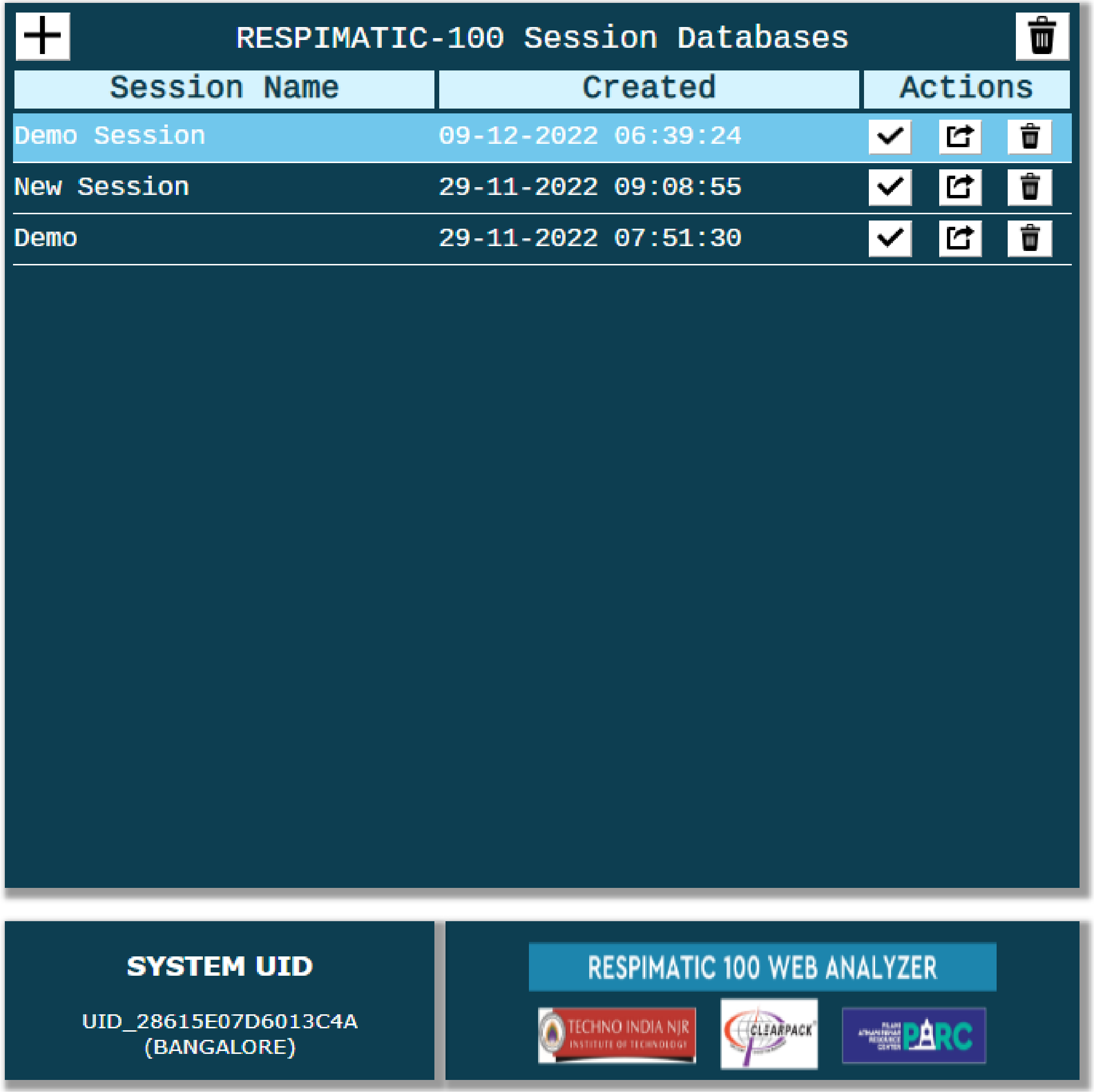
Dashboard Alerts View



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

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)

20 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 30 cmH_2O in increments of 5 cmH_2O

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

Breath Synchronization

Both ACV and SIMV modes

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

FiO_2 Settings

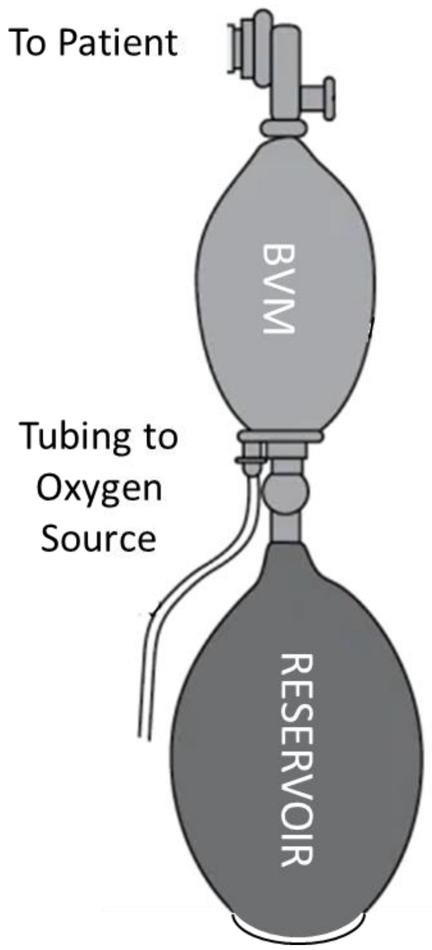
Without the Reservoir bag, FiO_2 delivered is the Atmospheric O_2 content at site

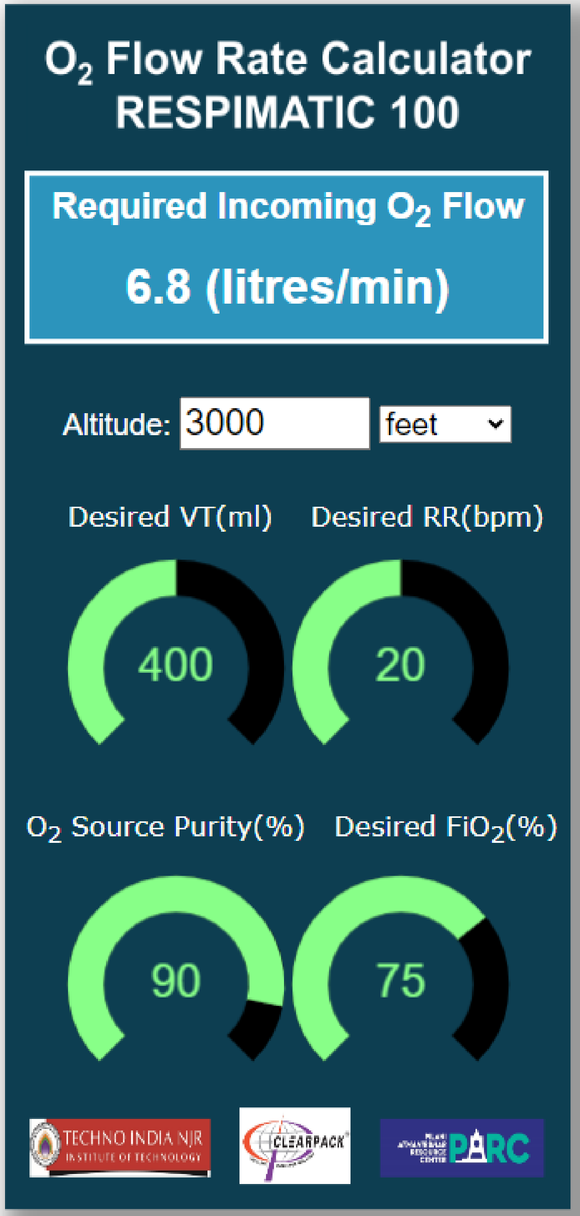
FiO_2 delivery with the Reservoir bag is mathematically modelled, calibrated and verified in the Lab to provide +/- 5% accuracy

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%)

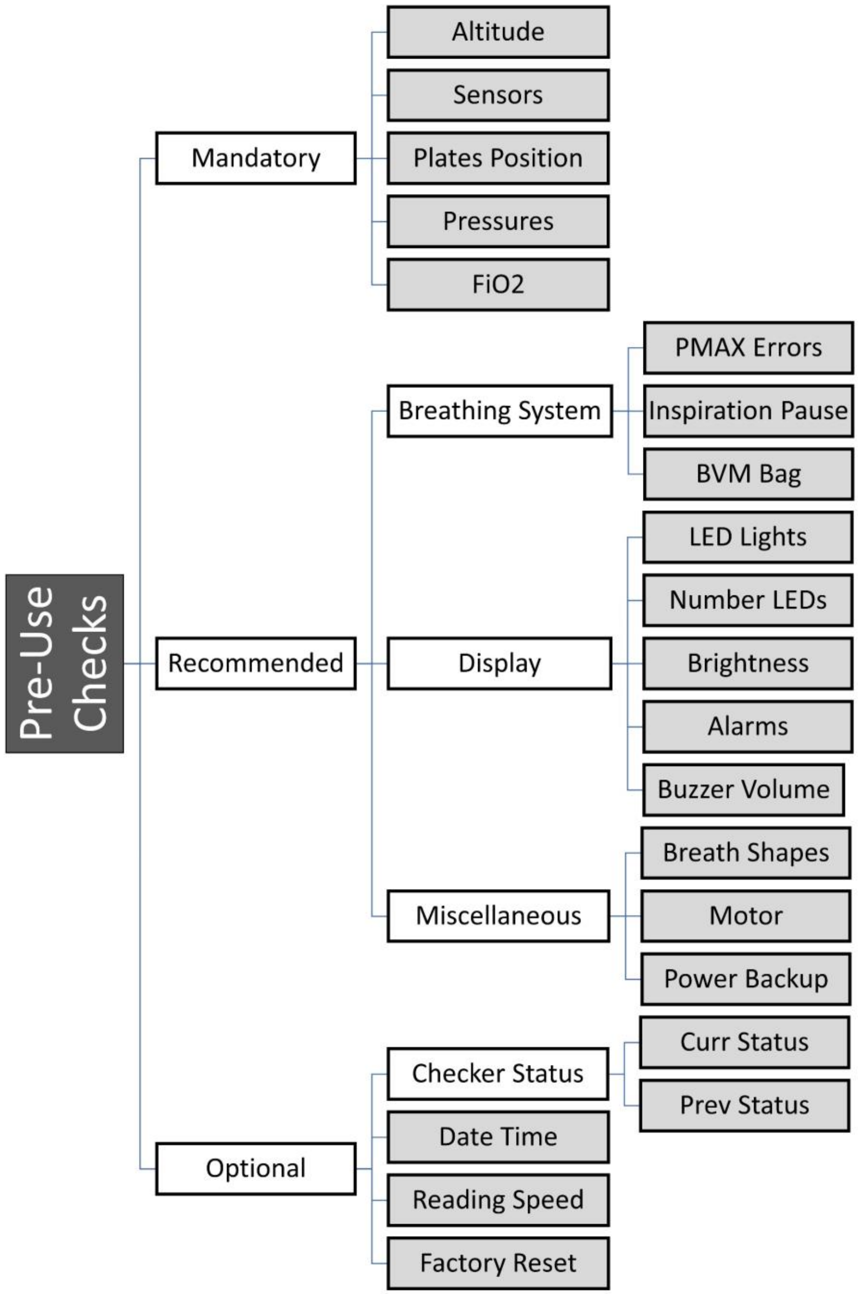
Online Web-accessible FiO_2 calculator is also provided for exploration purposes





Alarms and Safety Features

- **Enforcement of Pre-use checks**
- **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 4 frequently used ventilation modes and controls	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	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.	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	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	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	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

** 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

Times News Network

Jaisalmer: The state government 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 journey from Jaisalmer.

TOI

MUCH TO IMPROVE

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 physicians in the Jaisalmer hospital of which duty of one of the doctors is to take tional doctor to run the ventilator whereas there is need of minimum two to three physicians, cardiologists etc.

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 monitoring the situation, he said. Jaisalmer government hospital PMO Dr VK Verma said that ventilator.

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

प्रदेश में मरीजों की सांसें उखड़ रहीं, यहां स्टोर में 'शो-पीस' बने वेंटीलेटर

कहीं पर्याप्त प्रशिक्षित स्टाफ ही नहीं

पत्रिका न्यूज़ नेटवर्क

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चूरू/चित्तौड़गढ़. प्रदेश में लगातार बढ़ रहे कोरोना वायरस के संक्रमण के बीच वेंटीलेटर की कमी होने पर सरकार ने वेंटीलेटर उपलब्ध करा दिए, लेकिन अस्पताल प्रशासन की लापरवाही के चलते जहां चूरू में आधे वेंटीलेटर अभी तक स्टोर में ही हैं। वहीं, चित्तौड़गढ़ के जिला अस्पताल में पर्याप्त प्रशिक्षित स्टाफ नहीं होने से परेशानी आ रही है तथा यहां भी 25 वेंटीलेटर इंस्टाल ही नहीं किए गए।

चूरू स्थित डेडराज भरतिया अस्पताल में कोरोनाकाल से पहले 12 वेंटीलेटर ही थे। बाद में प्रधानमंत्री राहत कोष के तहत तीन चरणों में 30 नए वेंटीलेटर भेजे गए थे। वर्तमान में यहां 27 वेंटीलेटर उपयोग लिए जा रहे हैं। शेष 15 इंस्टॉल तक नहीं कराए गए।

चूरू स्थित भरतिया अस्पताल के स्टोर में रखे वेंटीलेटर।

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. हनुमान जयपाल, एसोसिएट प्रोफेसर, मेडिकल कॉलेज, चूरू

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

23 वेंटीलेटर को इंस्टाल होने का इंतजार

कोटा. कोटा मेडिकल कॉलेज के कोविड अस्पताल में 52 वेंटीलेटर हैं और सभी चालू हैं। वहीं, कोरोना के बढ़ने के बाद 23 नए वेंटीलेटर और आए हैं। इंस्टॉल होना बाकी है। संचालन के लिए पर्याप्त कार्मिक हैं।

25 वेंटीलेटर इंस्टाल ही नहीं किए गए

चित्तौड़गढ़ के जिला अस्पताल में 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 आईसीयू का प्रशिक्षित स्टाफ चाहिए और निश्चेतन के चिकित्सक की निगरानी की व्यवस्था होनी चाहिए। यहां आईसीयू का प्रक्षिक्षित स्टाफ करीब आधा दर्जन का ही है जो आईसीयू में है। यहां कुल 42 वेंटीलेटर में से अभी भी पांच पुराने एवं सात नए वेंटीलेटर ही काम में आ रहे है। 25 तो इंस्टाल नहीं किए गए।

स्टोर की बढ़ा रहे शोभा

कुचेरा (नागौर). स्थानीय सांसद हनुमान बेनीवाल की अनुशंसा पर शहर के राजकीय सामुदायिक स्वास्थ्य केन्द्र को मिले पोर्टेबल वेंटीलेटर को सीएचसी के स्टोर में रख दिया गया है। चिकित्साकर्मियों ने बताया कि पोर्टेबल वेंटीलेटर वर्किंग मोड में है तथा जैसे ही जरूरत पड़ेगी। वार्ड में लेकर काम में ले लिया जाएगा।

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*

** As per April 2020 Study by Center for Disease Dynamics, Economics & Policy at Princeton University, USA*