





Respimatic 100



Sunil Nanda (PARC)

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?

Respiration Assist Devices

Categories - Usage and Pricing











BiPAP

Big Hole ICU Ventilator

CPAP v/s BiPAP v/s RESPIMATIC 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	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			Full Breath Synchronization		
No Tidal Volume control			Direct Tidal Volume control		
No Respiration Rate control	No Respiration Rate control No Respiration Rate control		Direct Respiration Rate control		
No Inspiration: Expiration ratio control	o Inspiration:Expiration ratio control No Inspiration:Expiration ratio 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 No display of Peak, Plateau or 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

Respimatic 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

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(21) Appl. No.: 17/557,752

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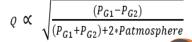
(51) Int. Cl. A61M 16/20 A61M 16/00

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(52) U.S. Cl. A6IM 16/204 (2014.02); A6IM 16/0078 (2013.01); A6IM 16/0003 (2014.02); A6IM 2205/52 (2013.01); A6IM 2016/0027 (2013.01); A6IM 2205/70 (2013.01)

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 cmH₂O wh is of the of a thousand cmH₂O 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.

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

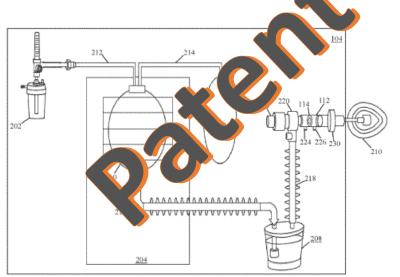
Recalling Equation 2 from the theory section above, this equation can be recast as below given that the orifice characteristics and pressure tap locations are the same for every system.

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



Respimatic 100 - Preliminary and Confidential

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

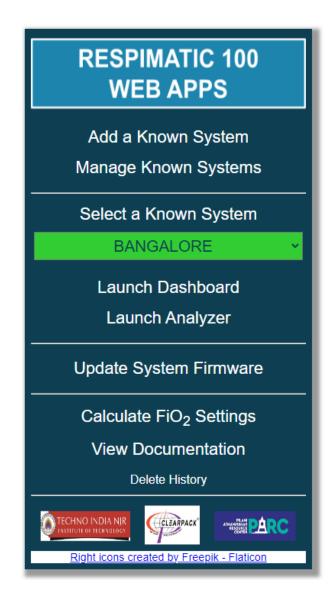
Mandatory &
Spontaneous Breaths
with Full Breath
Synchronization

Complete set of WEB Apps Remote Dashboard Remote Recorder Remote Analyzer FiO₂ Calculator

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

Uses secure HTTPS protocol

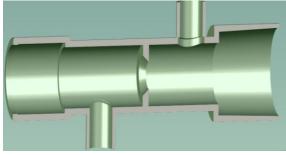
Field upgradable with new Firmware releases

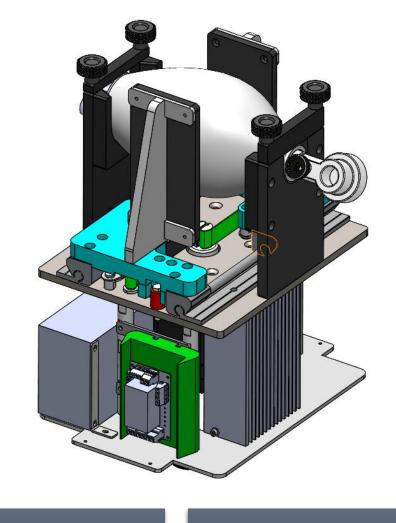


Respimatic 100 Under the hood

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

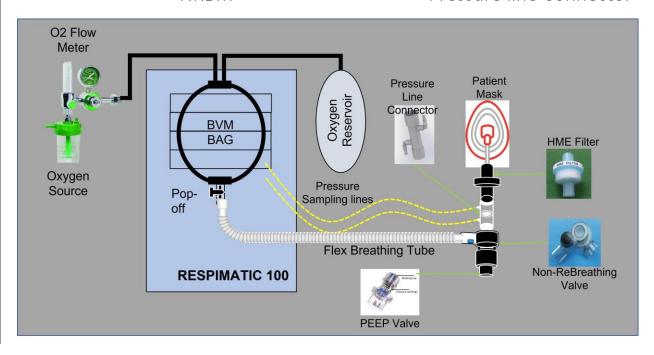




Off-the-Shelf Single limbed Circuit with NRBM



Proprietary Dual
Pressure line Connector



Front Panel The Human-Machine Interface

No delicate touch screen etc.

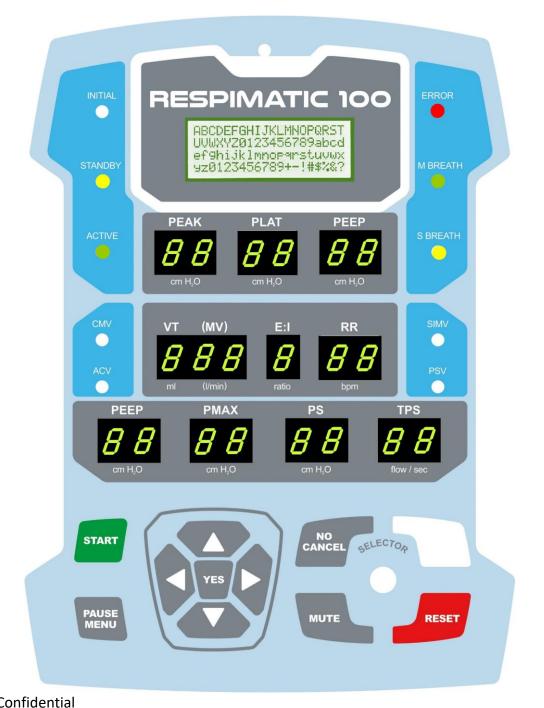
Easy to read 7-seg
LED Parameters
Display

Parameter selection using simple arrow buttons

4-line LCD Display for displaying Messages and Menus

Peak, Plateau, PEEP pressures displayed after each breath

Shows Delivered
Volumes, Lung
Compliances, Breath
types etc.



Dashboard Snapshot View

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

• Must know the UID of the system

One-to-many and many-to-one

5 Dashboard views

- Snapshots
- Charts
- Statistics
- Breath Shapes
- Alerts

Range Selector on every view to display data for different breath number ranges

• For instance, use to compare the statistics for the first hour of ventilation against the second hour.



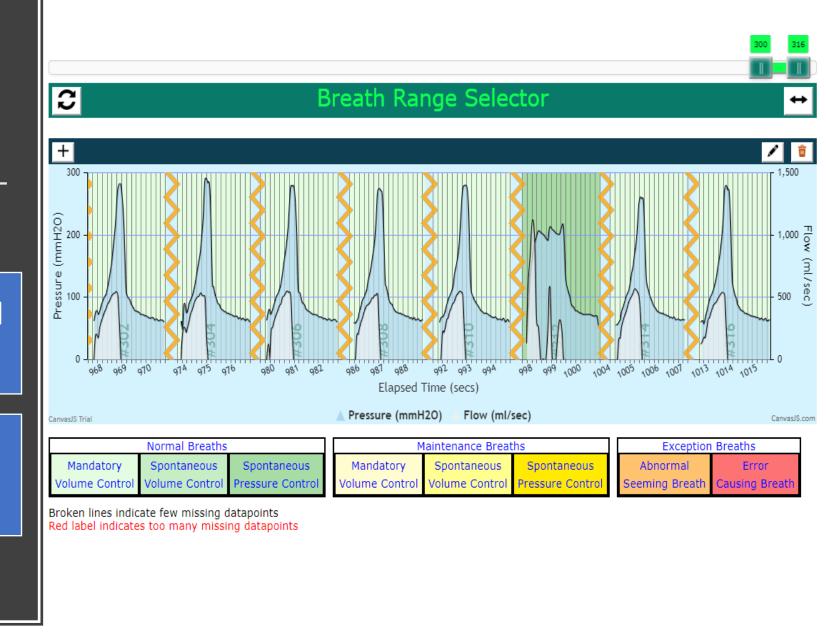
Dashboard Waveforms View

Pressure and Flow Graphs

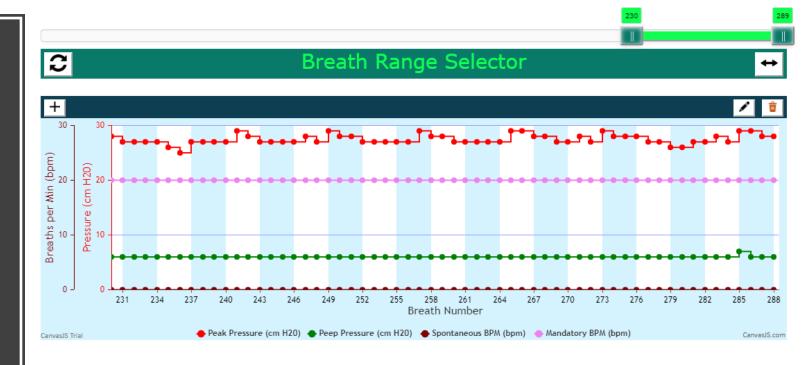
For Selected Breaths

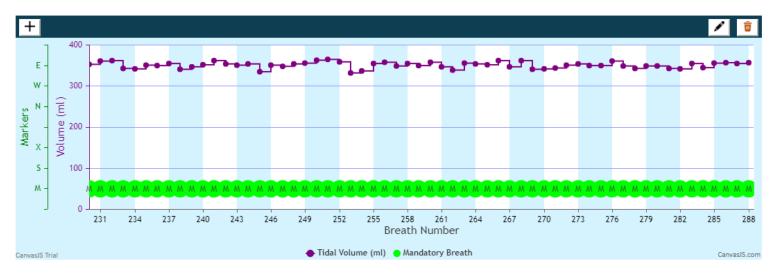
Periodic Display

Display on demand

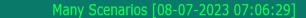


Dashboard Charts View





Dashboard Statistics View



Parameters Measured

Parameter	Units	Min	Max	Avg
Peak Pressure	cmH20	6	39	33.7
Plateau Pressure	cmH20	5	37	32.1
PEEP Pressure	cmH20	6	7	5.9
Tidal Volume Delivered	ml	314	454	347.3
Minute Volume Delivered	litres/min	4.8	7.1	5.7
Mandatory BPM	bpm	15	20	16.5
Spontaneous BPM	bpm	0	3	0.9
FIO2	0/0	60	60	60.0
Instantaneous Static Compliance	ml/cmH20	11	23	13.0
Instantaneous Dynamic Compliance	ml/cmH20	10	304	14.3
System Temperature	degC	24	25	24.1

Miscellaneous Information

Information	Value
Number of Breaths	31
Number of Mandatory Breaths	30
Number of Spontaneous Breaths	
Number of Maintenance Breaths	
Number of CMV-mode Spontaneous Breaths	
Number of Missing Intervals (Packet loss)	4
Number of WiFi or Server Disconnects	
Number of Notifications	
Number of Warnings	
Number of Errors	

Static Information

Patient Name: Elmer Fudd

Patient Info: Male (80 years) [ID: WABBIT]

System Location: Bengaluru Location Altitude: 3000 ft (915 mtrs) Location Atmospheric Oxygen: 19%

Parameter Settings Used

Parameter	Units	Values
Ventilation Mode	mode	SIMV
Tidal Volume	ml	350
Minute Volume	l/min	10
Respiration Rate	bpm	20,15
I:E Ratio	ratio	1:2
PEEP Pressure	cmH20	6
Maximum Pressure	cmH20	55
Support Pressure	cmH20	20
Support Pressure Termination	%flow,secs	1.5
FIO2	%	60

Sequence of Parameter Combinations

MODE	VT/MV	/ RR	I:EF	PEEF	PMAX	PS	TPS	FIO2	# of BREATHS	Before BREATH#
?	?	?	?	?	?	?	?	60	3	0
SIMV	350	20	1:2	6	55	20	1.5	60	82	3
SIMV	350	15	1:2	6	55	20	1.5	60	188	126

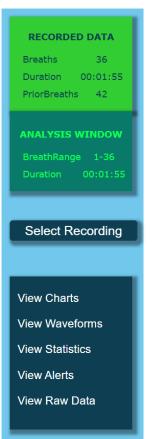
Dashboard Alerts View



Analyzer

Any patient Session can be recorded locally or remotely.

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

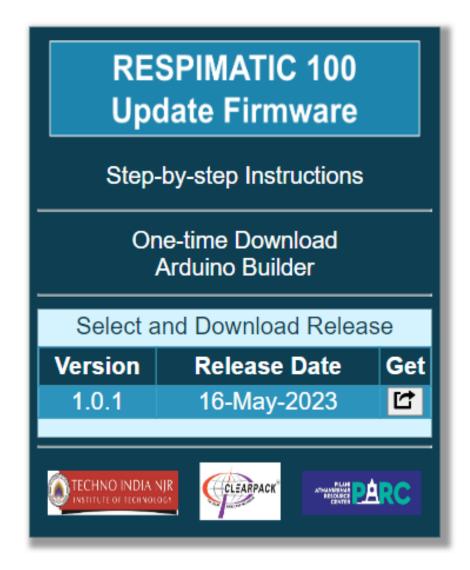




Updating Firmware

Firmware releases available on the WEB.

Step-by-step menu driven update procedure



Ventilation Modes

The 4 most frequently used

Continuous Mandatory Ventilation (CMV)

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)

20 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

Both ACV and SIMV modes

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

Breath Synchronization

FiO₂ Settings

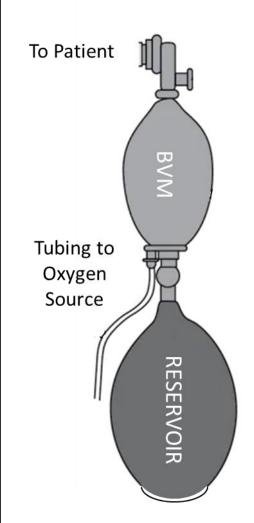
Without the Reservoir bag, FiO₂ delivered is the Atmospheric O₂ content at site

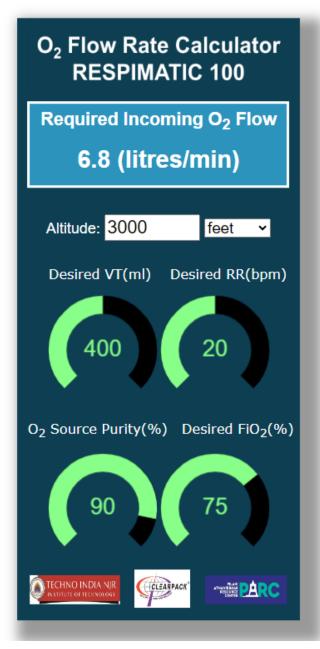
FiO₂ delivery with the Reservoir bag is mathematically modelled, calibrated and verified in the Lab to provide +/- 5% accuracy

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%)

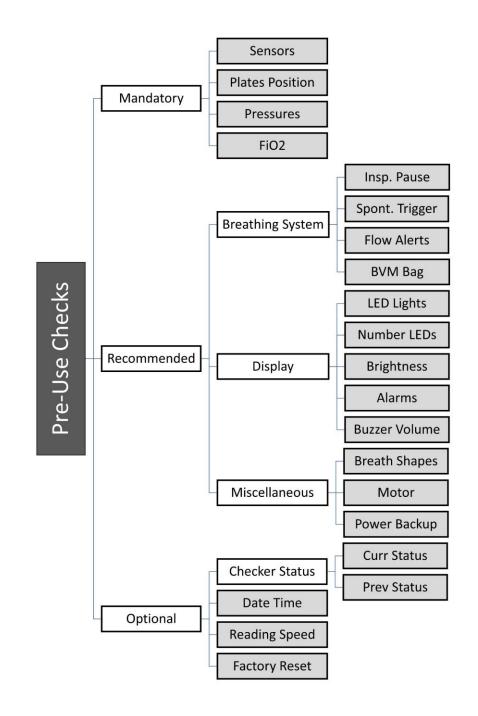
Online Web-accessible FiO₂ calculator is also provided for exploration purposes





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

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

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



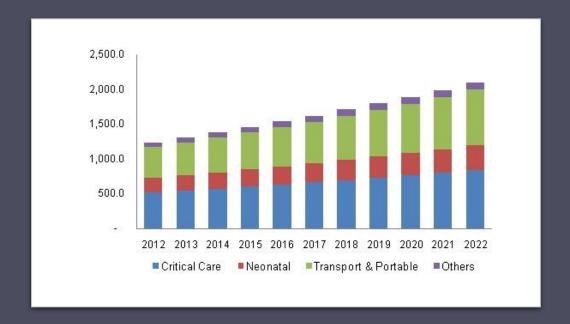
तथा जैसे ही जरूरत पडेगी। वार्ड मे

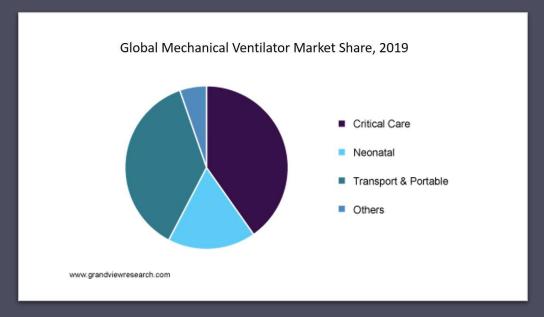
Market Need

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*





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