Respimatic 100

Sunil Nanda (PARC)

Setting the Context

The Motivation

The Problem Statement

RESPIMATIC 100
(Patent Pending)

Is it right for you?

Only non-invasive 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?
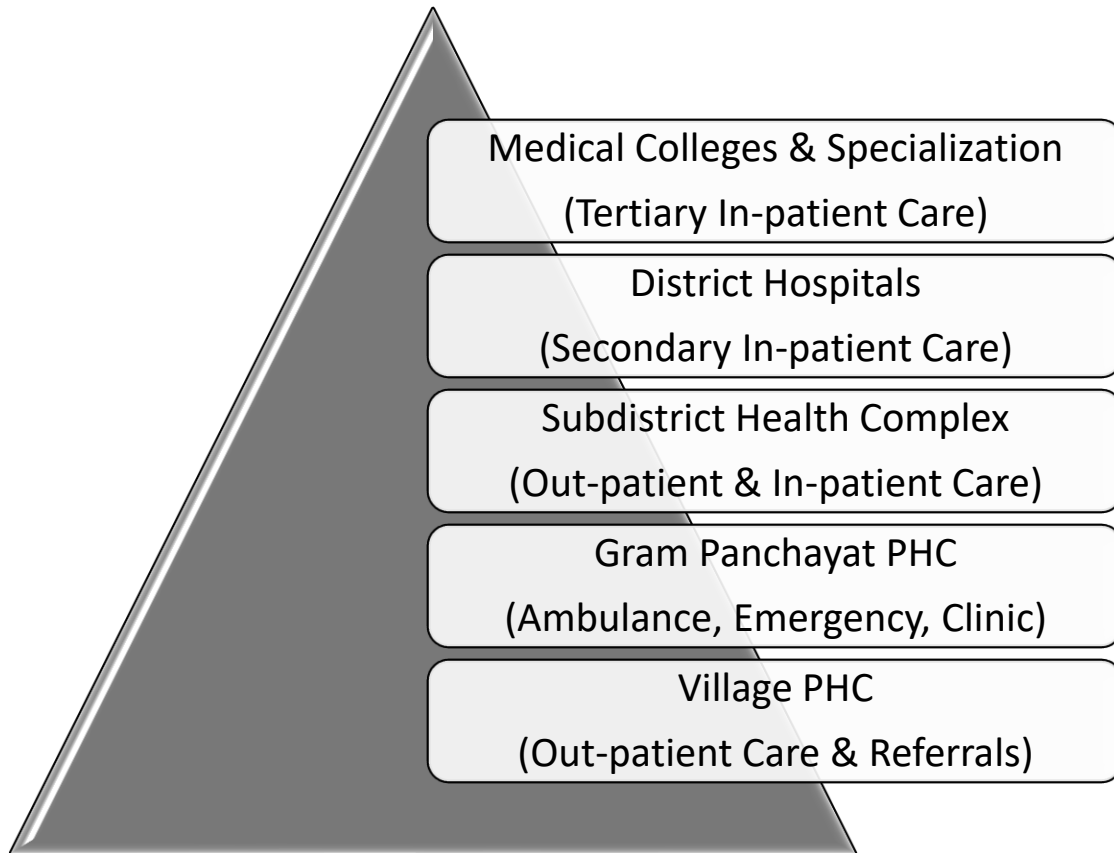
Remote monitoring capability?

Handle harsh-uncontrolled Environment?

Easy-to-use System?

Budget Friendly?

NO PROBLEM

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)

Provide a robust, portable respiration assist system to 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 oxygen
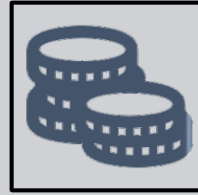
A system that requires minimum training

Within the budget of the bottom of the pyramid
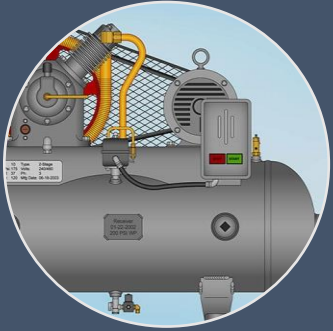
The Problem
2 BIG Challenges

Lack of Affordability leading to Scarcity

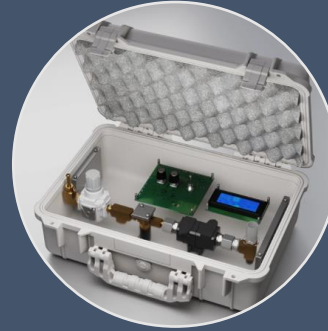Lack of Skilled Practitioners

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 not* stop delivering breaths.

Implement *Fallback* mechanism for each error scenario.

Respimatic 100 System Details

System Components

Technical Details

Our Solution
RESPIMATIC 100

4 Commonly Used Ventilation Modes

CMV, ACV, SIMV, PSV

Respiration Rate, Tidal Volume, PEEP, Support Pressure Controls

Volume Controlled and Pressure Supported Breaths

Mandatory & Spontaneous Breaths with Full Breath Synchronization
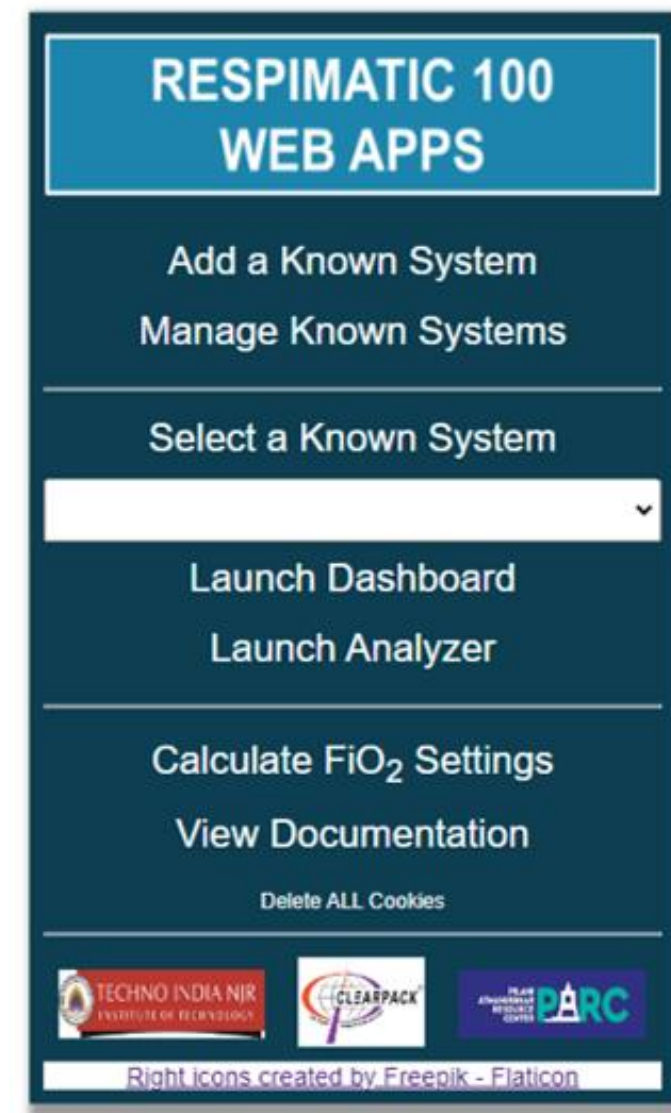
Complete set of WEB Apps

Remote Dashboard

Remote Recorder

Remote Analyzer

FiO_2 Calculator

Low-speed Wi-Fi sufficient

Phone Hot-spot also sufficient

Uses secure HTTPS protocol

RESPIMATIC 100 WEB APPS

Add a Known System

Manage Known Systems

Select a Known System

Launch Dashboard

Launch Analyzer

Calculate FiO_2 Settings

View Documentation

Delete ALL Cookies

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Right icons created by Freepik - Flaticon

https://www.respimatic.com
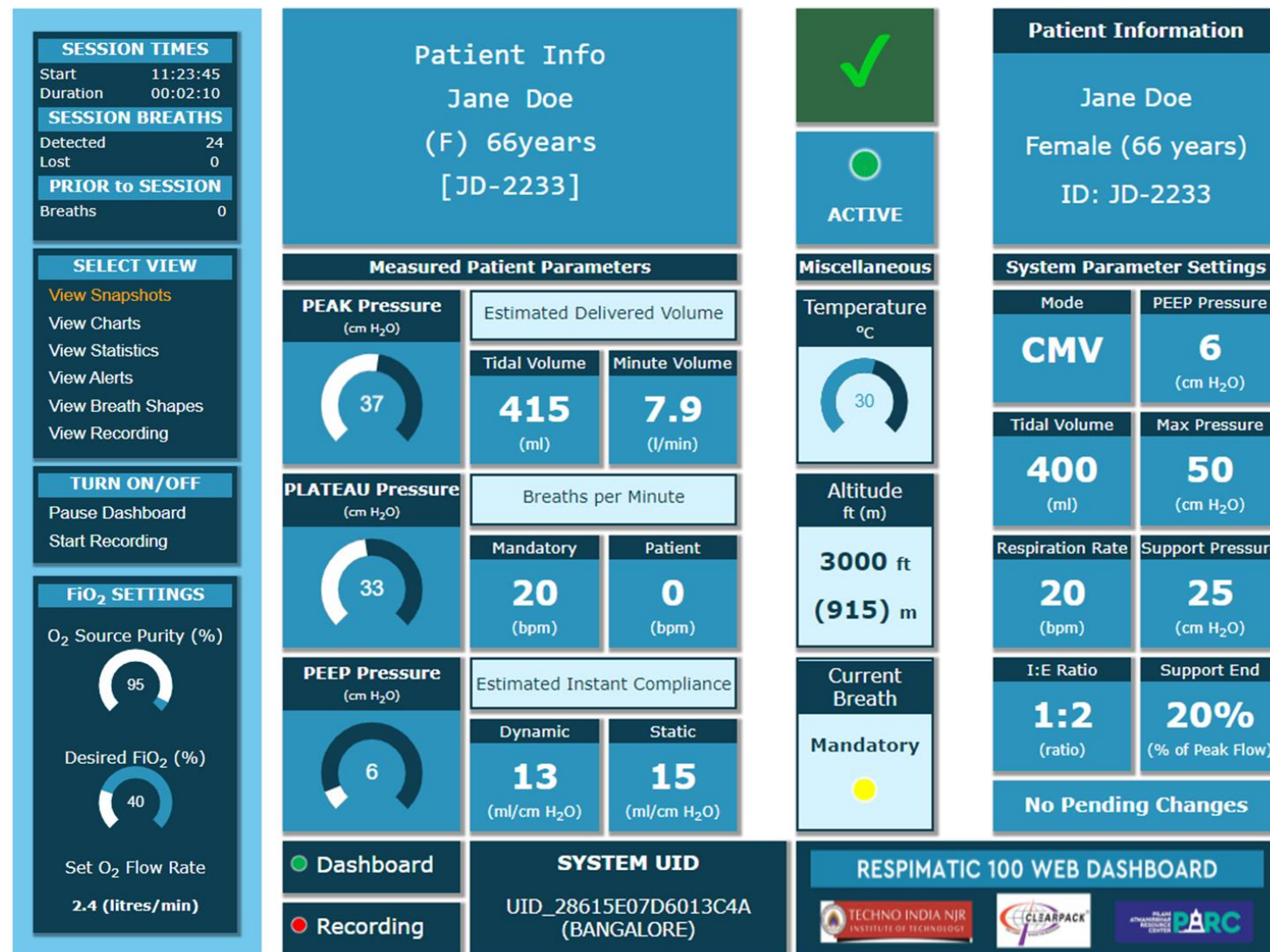
Remote WEB Dashboard Snapshot View

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

Multiple specialists can monitor the same patient

One specialist can monitor multiple patients

5 Dashboard views
- Snapshots
- Charts
- Statistics
- Breath Shapes
- Alerts

SESSION TIMES
Start	11:23:45
Duration	00:02:10

SESSION BREATHS
Detected	24
Lost	0

PRIOR to SESSION
Breaths	0

SELECT VIEW
- View Snapshots
- View Charts
- View Statistics
- View Alerts
- View Breath Shapes
- View Recording

TURN ON/OFF
- Pause Dashboard
- Start Recording

FiO₂ SETTINGS

O₂ Source Purity (%) — 95

Desired FiO₂ (%) — 40

Set O₂ Flow Rate — 2.4 (litres/min)

● Dashboard
● Recording

Patient Info

Jane Doe

(F) 66years

[JD-2233]

Measured Patient Parameters

PEAK Pressure (cm H₂O) — 37

Estimated Delivered Volume	
Tidal Volume	**Minute Volume**
415 (ml)	7.9 (l/min)

PLATEAU Pressure (cm H₂O) — 33

Breaths per Minute	
Mandatory	**Patient**
20 (bpm)	0 (bpm)

PEEP Pressure (cm H₂O) — 6

Estimated Instant Compliance	
Dynamic	**Static**
13 (ml/cm H₂O)	15 (ml/cm H₂O)

SYSTEM UID

UID_28615E07D6013C4A (BANGALORE)

✓

● ACTIVE

Miscellaneous

Temperature °C — 30

Altitude ft (m)

3000 ft (915) m

Current Breath

Mandatory ●

Patient Information

Jane Doe

Female (66 years)

ID: JD-2233

System Parameter Settings

Mode	PEEP Pressure
CMV	6 (cm H₂O)

Tidal Volume	Max Pressure
400 (ml)	50 (cm H₂O)

Respiration Rate	Support Pressure
20 (bpm)	25 (cm H₂O)

I:E Ratio	Support End
1:2 (ratio)	20% (% of Peak Flow)

No Pending Changes

RESPIMATIC 100 WEB DASHBOARD

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https://www.respimatic.com

Remote WEB Dashboard – Charts View

Remote WEB Dashboard – Statistics View

Shape Session [20-12-2022 10:53:21]

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

Remote WEB Dashboard – Breath Shapes View
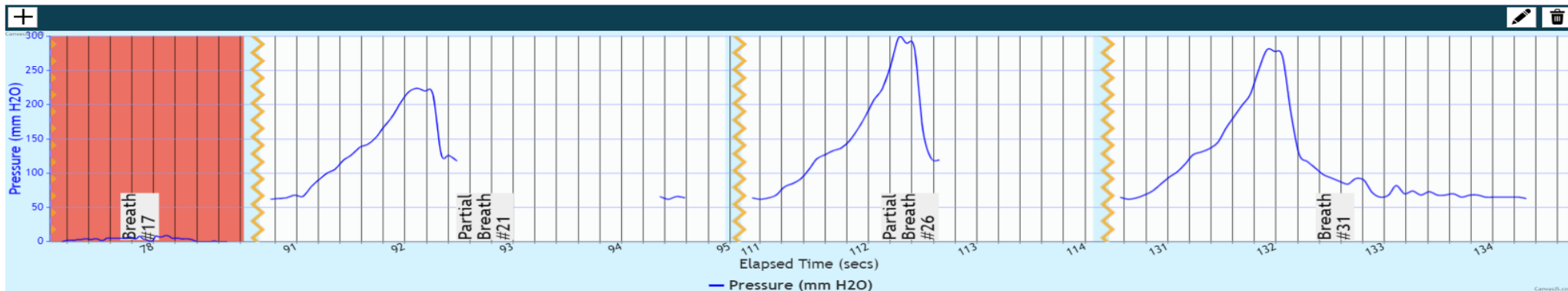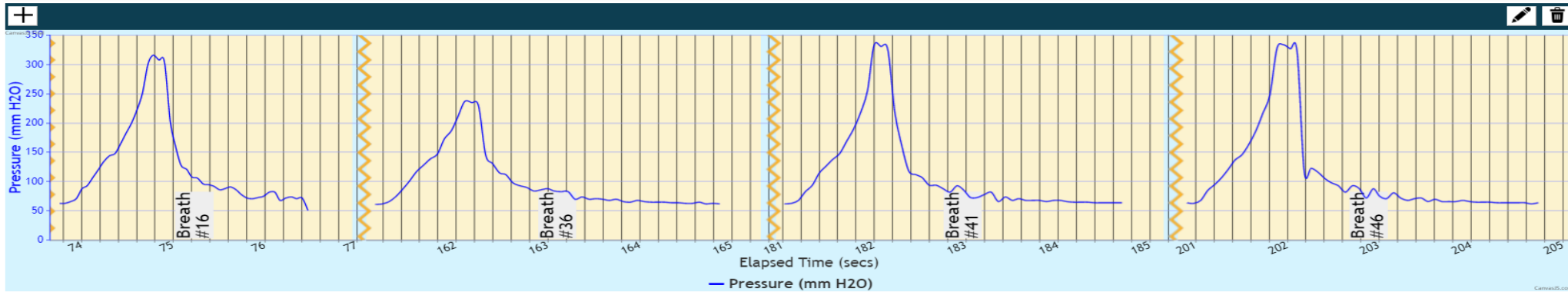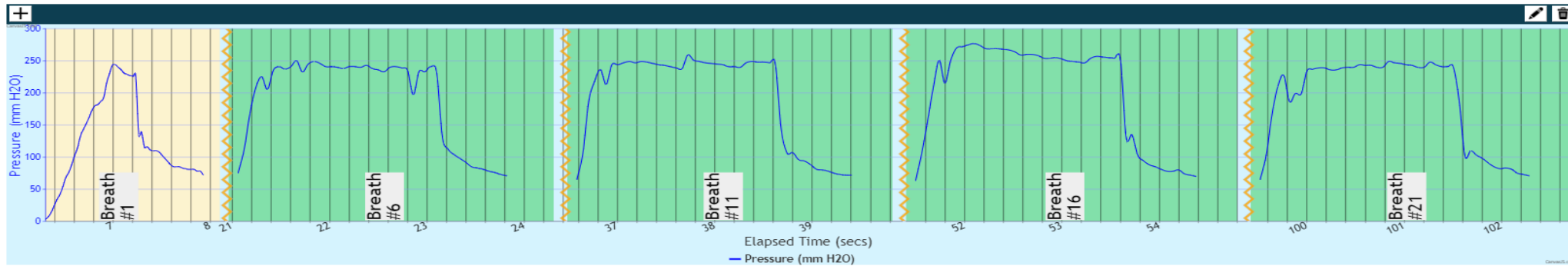
Respimatic 100 - Preliminary and Confidential

Remote WEB Dashboard – Alerts View

1 ──────────────────────────────────── **204**

RESET | Set Breath Range Window for Display ☑ | ✕

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

Remote WEB Analyzer

Any patient Session can be recorded locally or remotely.

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

https://www.respimatic.com

WEB Apps Architecture
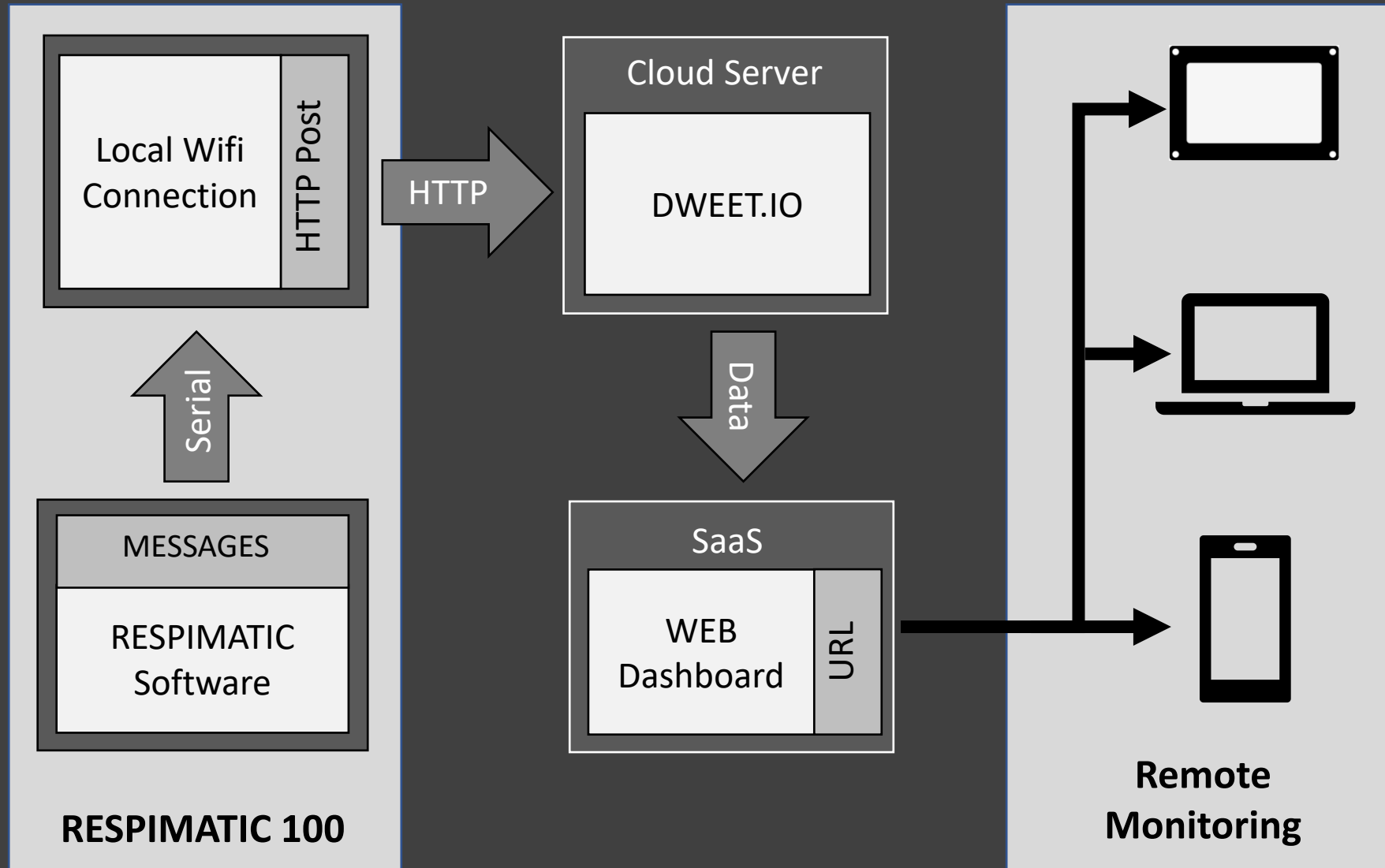
Front Panel
The Human-Machine Interface

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.

System Architecture

Clearly separated Frontend, Backend and Breathing system

IP is in the Frontend design and Algorithms

Backend and Breathing System can have multiple avatars

REAL TIME CLOCK

MICROCONTROLLER

HMI PCB

ROTARY ENCODER

LCD

LEDs

7-Seg LEDs

BUTTONS

Front-End

MOTOR DRIVER

STEPPER MOTOR

TEMP SENSOR

POSITION SENSOR

MECH SYSTEM

Back-End

PRESSURE SENSORS

BREATHING SYSTEM

Breath-End
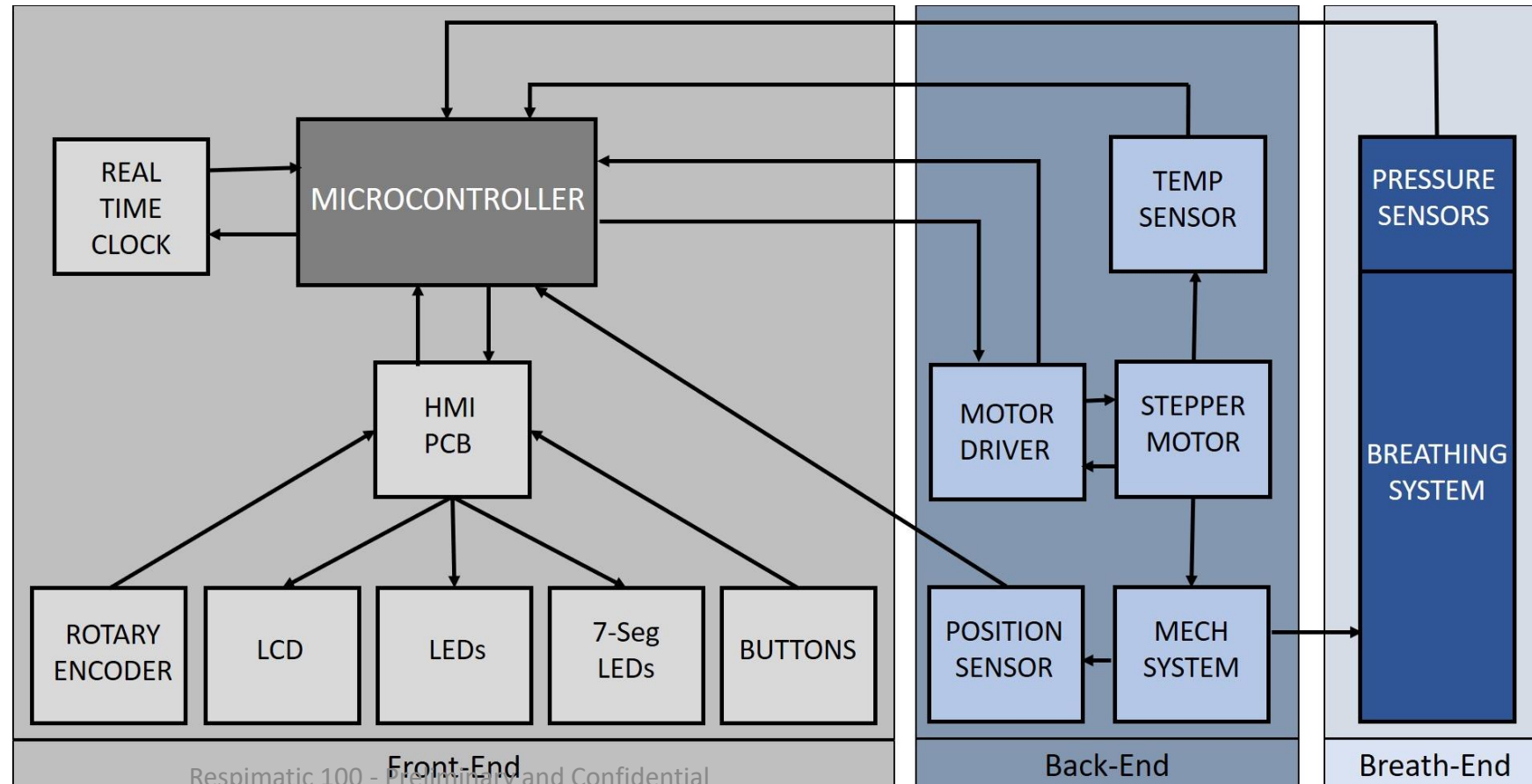
Respimatic 100 Under the hood

Production Cost Rs. 50,000

Potentially lower with bulk negotiations

Compact, Lightweight, and Robust

Usable in harsh environments

Intuitive HMI - Simple to operate

Front Control Panel & Remote Monitoring
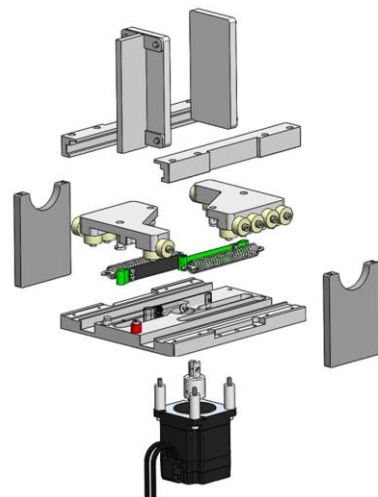
So, $(P_{G1} - P_{G2})$ can be replaced by $E*(P_{G1} - P_{G2})$ for an appropriate transforms to the one below.

$$Q = K * \sqrt{E * (P_{G1} - P_{G2})}$$

where $K = \dfrac{C}{\sqrt{Patmoshpere} * \sqrt{E}}$

or $K = \dfrac{f(Re)}{\sqrt{Patmoshpere} * \sqrt{E}}$ where Re is the Reynold

Rewriting for every sample interval time ℓ, the equation is as below.

$$Q(t) = K * \sqrt{E * (P_{G1}(t) - P_{G2}(t))}$$
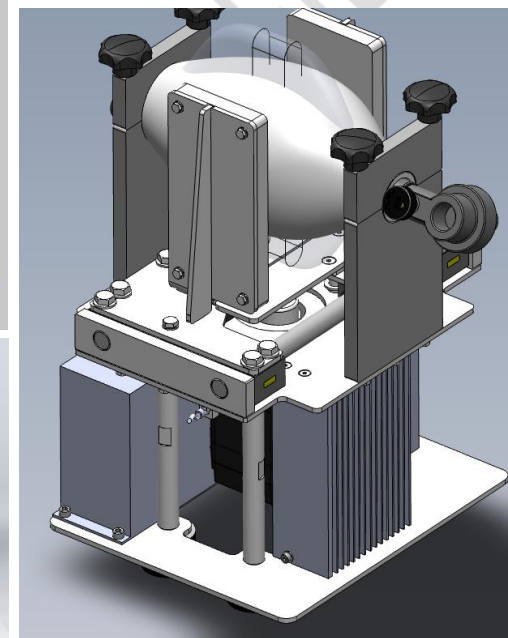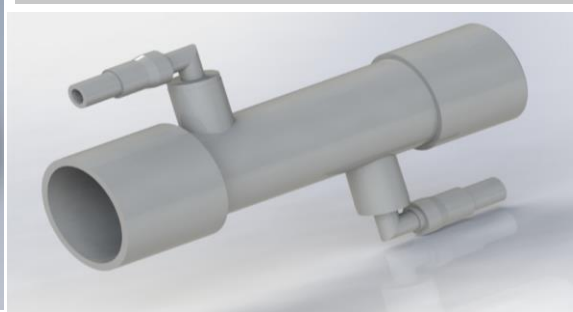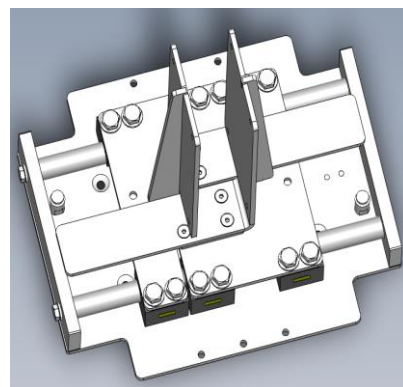
Simple electronics with time proven COTS components	**Rugged mechanical system – various alternatives possible**	**Essential Parameter monitoring and carefully vetted alarm conditions**	**Robust and easy to clean enclosure surfaces**	**Suitable for mass production**

Breathing Circuit

One proprietary, **patent-pending** Dual Pressure line connector with Orifice plate

Off-the-shelf single-limb Breathing Circuit with NRBV

BVM or Ambu Bag with Reservoir

Pressure sensors, PEEP valve

HME Filter

Humidifier

Oxygen Source

Off-the-Shelf Single limbed Circuit with NRBM

Patent-pending Dual Pressure line Connector
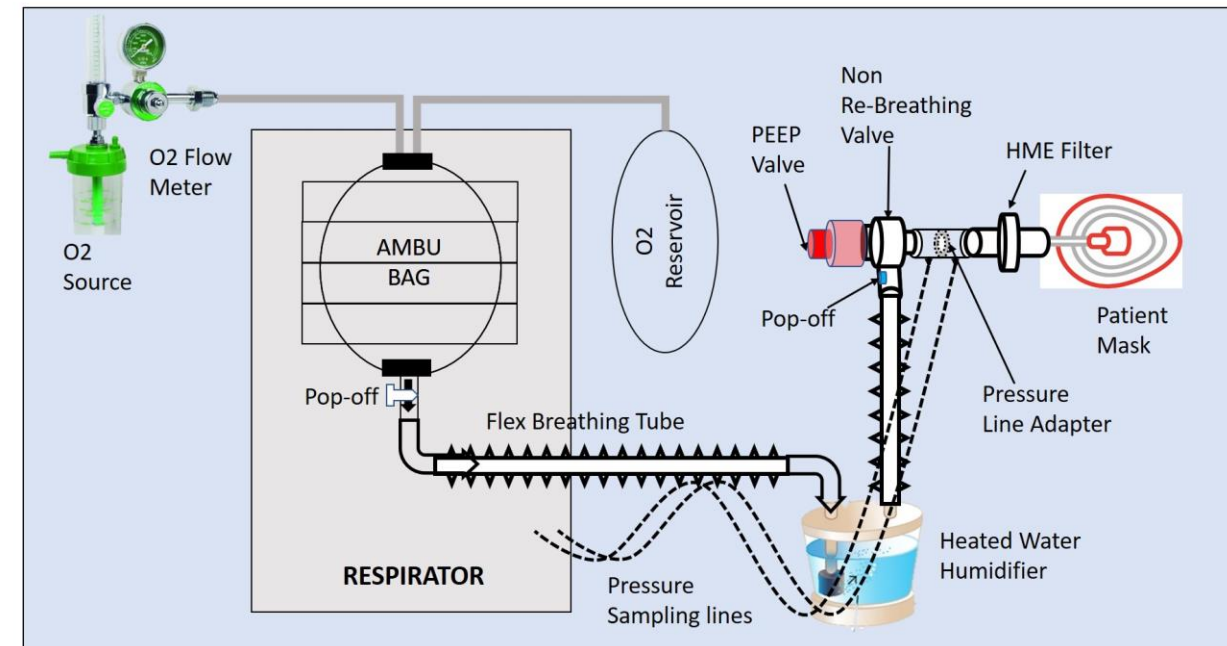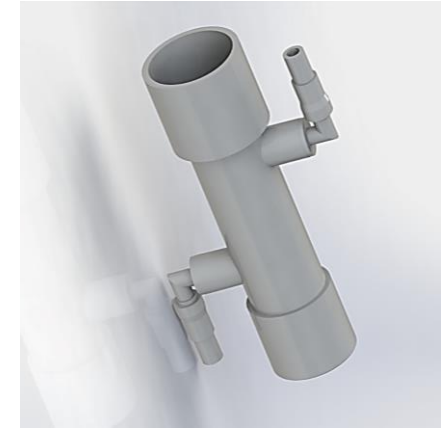
Ventilation Modes
The 4 most frequently used

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 Careful Monitoring of Minute Volume No Mandatory breaths except when in dire need

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	1:1, 1:2, 1:3

PEEP (cmH2O)	Max Pressure (cmH2O)	FiO$_2$ Support
4 to 15 cmH2O increments of 1 cmH2O	20 to 50 cmH2O increments of 5 cmH2O	System Managed Externally Controlled 21% to 100%

Pressure Supported Breaths

(SIMV & PSV modes)

Support Pressure (PS)

5 cmH$_2$O to 30 cmH$_2$O in increments of 5 cmH$_2$O

Support Pressure Termination (TPS)

Flow-dependent
  Terminate when flow falls below 10%, 20% or 30% of peak flow

Time dependent
  Terminate after 1.0 secs 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$_2$ Settings

Without the Reservoir bag, FiO$_2$ delivered is 21% which is normal Atmospheric O$_2$ content

FiO$_2$ delivery with the Reservoir bag is mathematically modelled, calibrated and verified in the Lab to provide +/- 5% accuracy

Front-panel HMI guides the user in setting the appropriate input O$_2$ flow rate on the connected 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
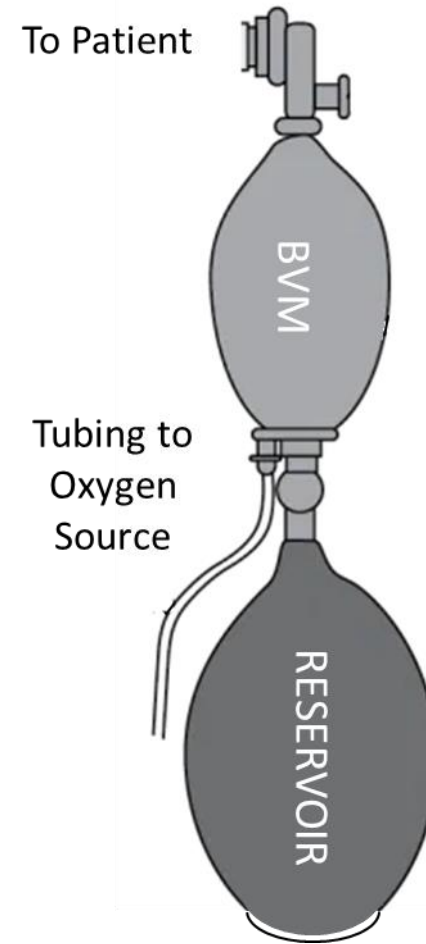
O$_2$ Flow Rate Calculator
RESPIMATIC 100

Required Incoming O$_2$ Flow

6.8 (litres/min)

Altitude: 3000   feet

Desired VT(ml)   Desired RR(bpm)

400   20

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

90   75

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Alarms and Safety Features

- **Enforcement of Pre-use checks**

- **Distinction between 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 fits
  - Inconsistent input parameters
  - And many more …
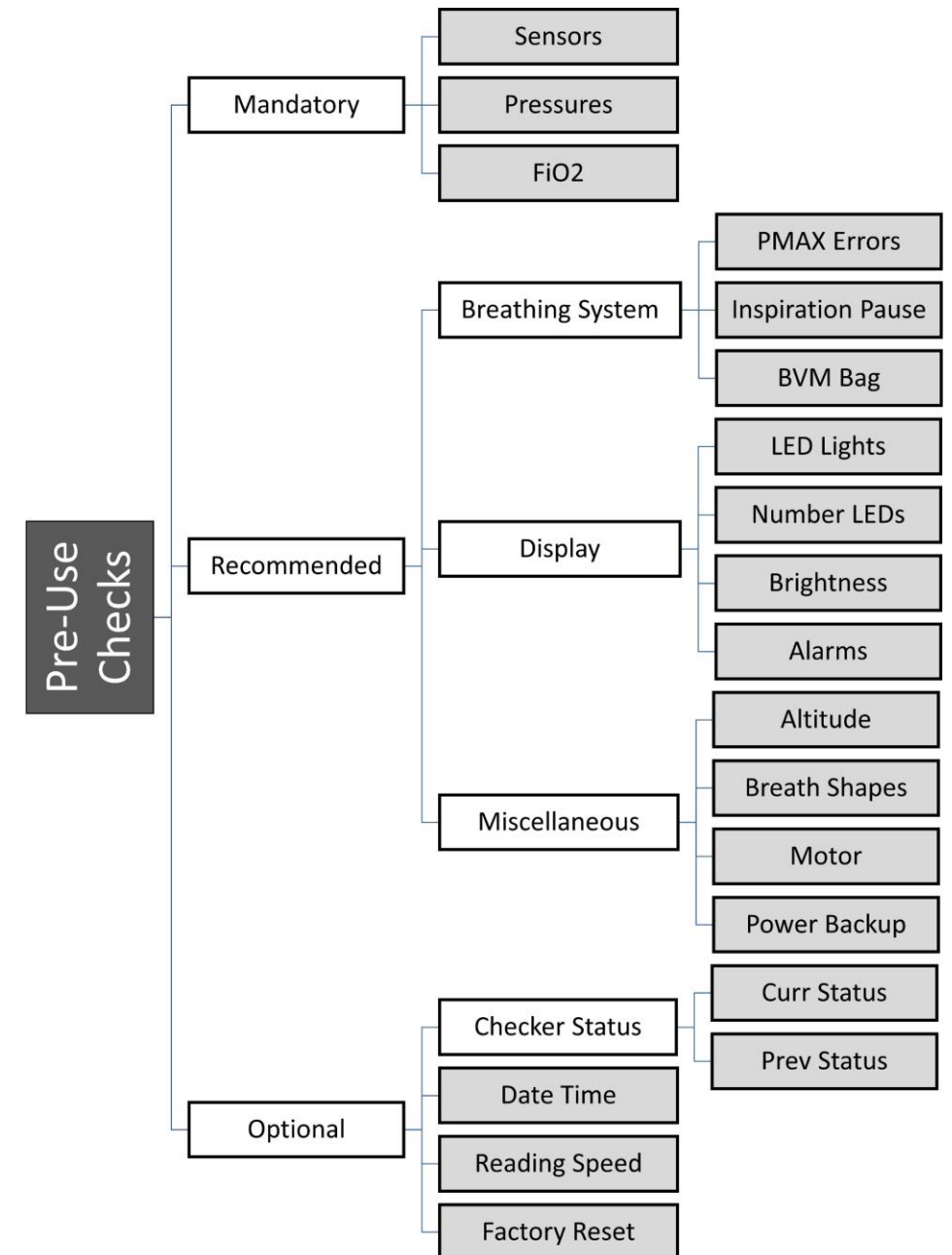
Power Consumption

An online, sine-wave, external battery UPS recommended to continue operation during power outages
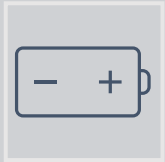
50 AH Car battery is sufficient to run the system for 5+ hours

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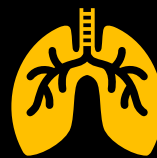
All testing so far with a simple test lung Next step needs a more sophisticated test lung

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

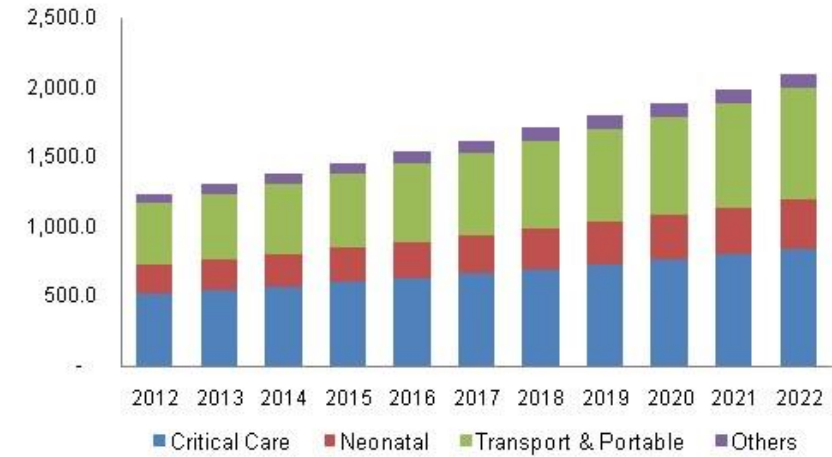ICU Ventilators require highly skilled manpower to operate and monitor

Market Need

25 to 50 ventilators per lakh people in developed countries
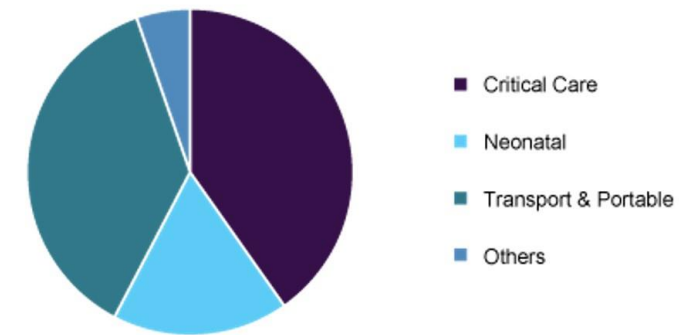
1.8 ventilators per lakh people* (India)

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
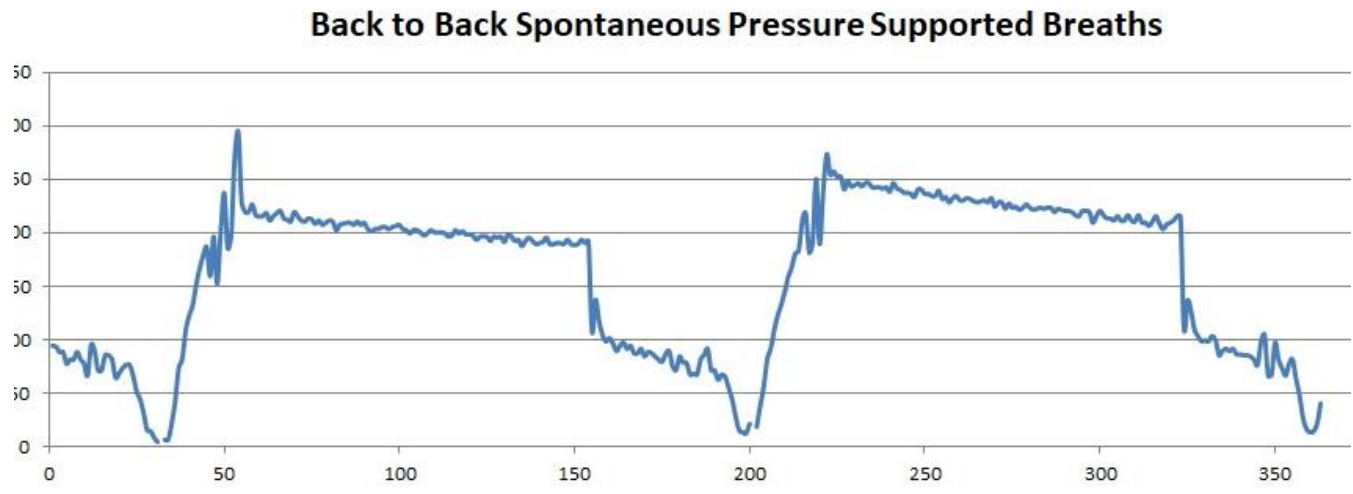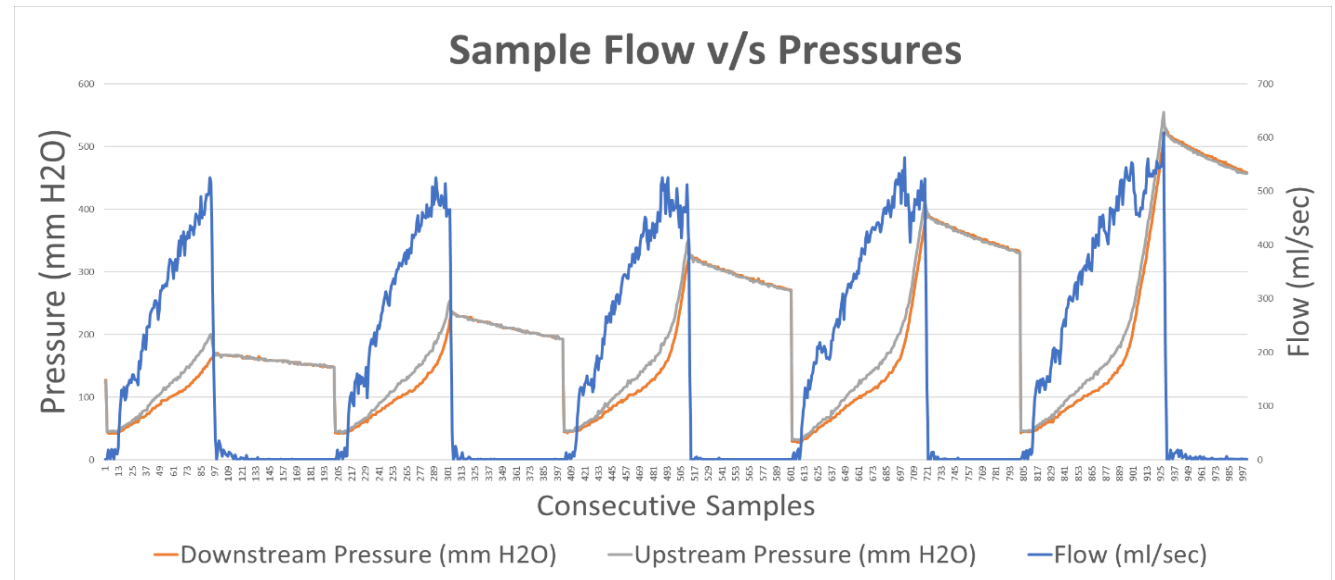

Global Mechanical Ventilator Market Share, 2019

www.grandviewresearch.com

Respimatic Sample Waveforms

Pressure , Flow and Spontaneous Breaths

Sample Flow v/s Pressures

Back to Back Spontaneous Pressure Supported Breaths

Breath Synchronization in ACV Mode

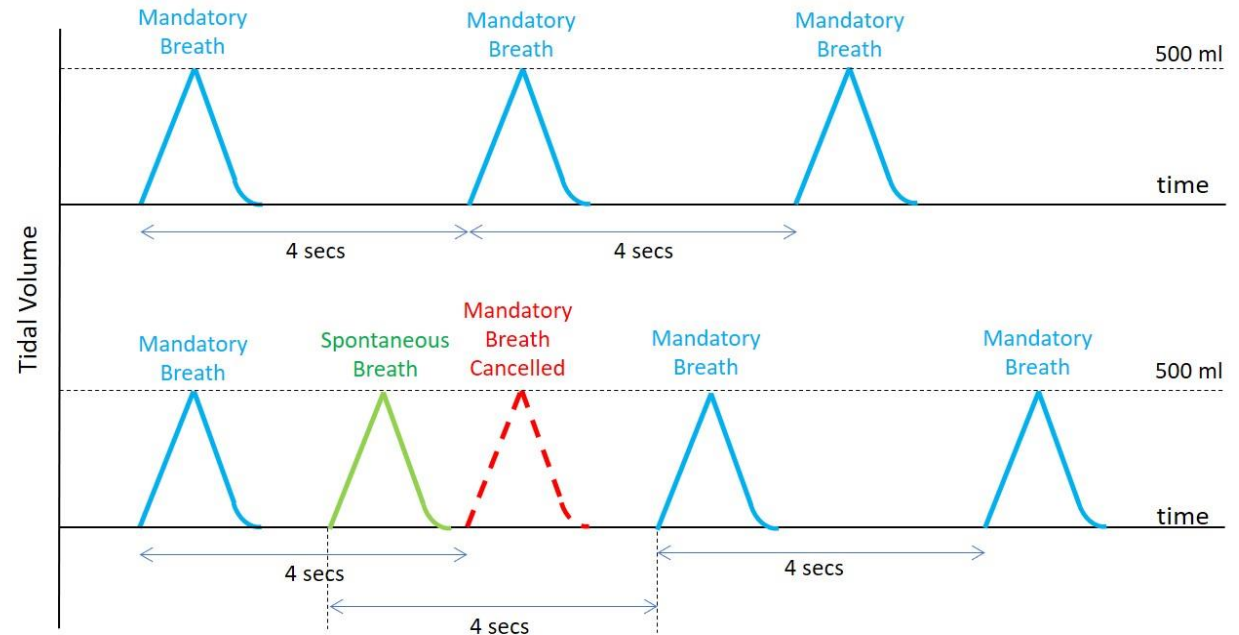Tidal volume is delivered at regular intervals T_i.

⬇

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
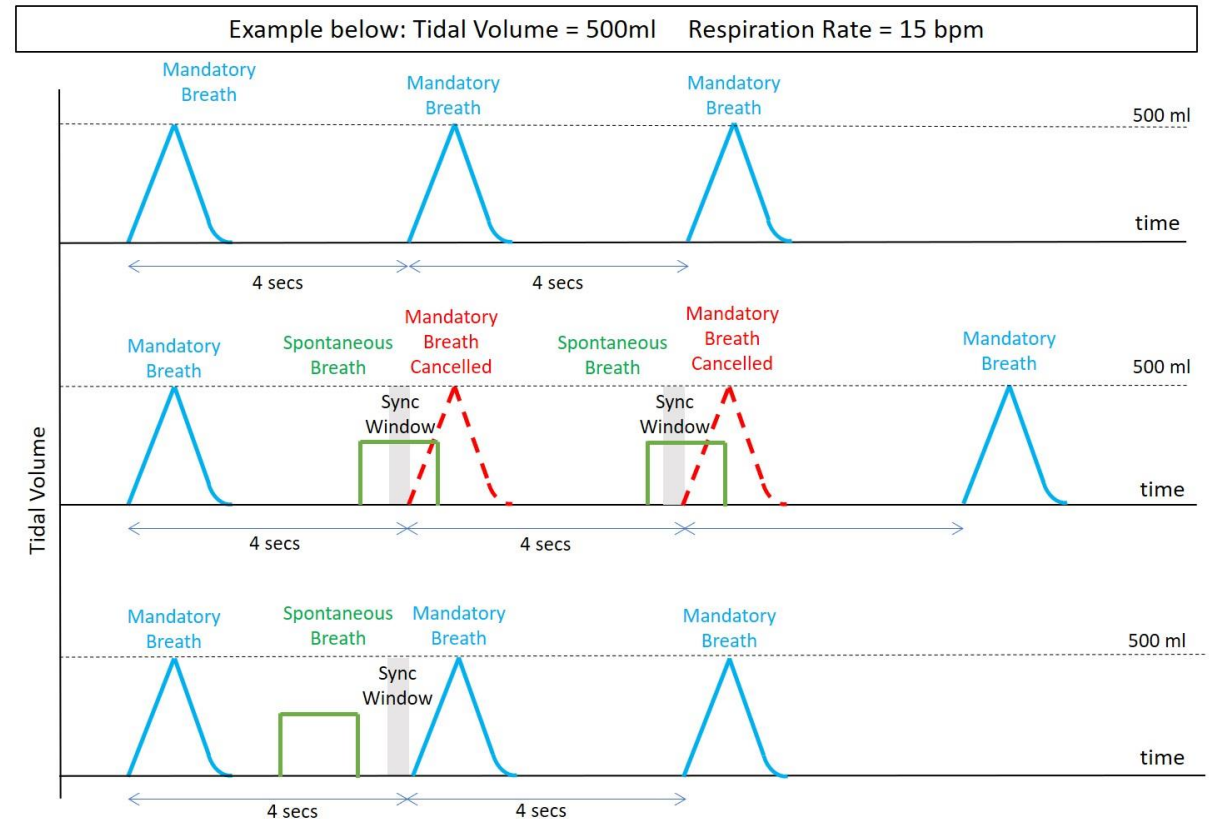
Breath Synchronization in SIMV Mode

Tidal volume is delivered at regular intervals T_i.

If spontaneous breath occurs during this interval at time T_s, a pressure supported breath is delivered in response, and the next mandatory breath is set for $(T_s + 0.9\,T_i)$.

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

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

Exceptional Mandatory Breath in PSV Mode

Tidal volume is delivered at regular intervals T_i.

If spontaneous breath occurs during this interval at time T_s, a pressure supported breath is delivered in response.

The next mandatory VC breath is not delayed at all unless it is too close to the spontaneous breath (within 20% of T_i).

This avoids breath stacking issues.

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

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