

## **Journey of Evolution of an Indigenous Modern ICU Ventilator:**



**Paper Presented by: Sudhir Waghmare, Dr B D Bande.**

## **About Shreeyash Electro Medicals:**

**Shreeyash Electro Medicals is into Manufacturing Life saving devices since last 30 years in Pune, having their own factory in Katraj. The manufacturing activity is carried out in an ISO 13485 certified facility.**

**Shreeyash is the only manufacturer of Neonatal Ventilators in INDIA & only company in the world who makes a Servo Controlled High Frequency Oscillatory Ventilator.**

Shreeyash is manufacturing Neonatal & Paediatric Ventilators since 2004 & supplying the same to all over India with great success. After the success of Neonatal Ventilators, Shreeyash successfully manufactured the First even Servo controlled High Frequency Oscillatory Ventilator (HFOV) in 2006. Model: (Dragonfly)

With this long experience of 16 years in manufacturing Ventilators, Shreeyash ventured into making an Adult & Pediatric Ventilator, **that can be used in ICU as a regular modern ventilator and of course for COVID 19 patients.**

**Shreeyash is a Proprietary organization managed by Dr Sudhir Waghmare.**

### **Achievements of Dr Sudhir Waghmare:**

- 1. Awarded Hon PHD from Camden University Delaware USA for his work in Ventilation of New Born Babies.**
- 2. The only manufacturer who exports his life saving devices to Europe, Australia, Russia, East Africa, South Africa & other Asian countries.**
- 3. Authored a book on Neonatal High Frequency Oscillatory Ventilation. (Manual of High Frequency Ventilation)**
- 4. Dept of Anaesthesiology and Critical care of KEM Hosp Pune, felicitated him as their Hon Student in 2015 for his contribution in the field of Critical Care.**

### **Awards:**

- 1. The Best Small Scale Industry, by Maharashtra State Govt in 1999.**
- 2. The Prestigious Parkhe Award in 2000**
- 3. The Udogshree award by Mumbai Chamber of Commerce in 2001.**
- 4. Rotary club of Midtown has applauded his efforts & have published an article on him along with other 10 entrepreneurs in a book titled as "Akanksha Pudha tithe gagan thengane".**
- 5. Service above Self award by Rotary International, 2013,**  
Recognised for technology and cost innovation in Ventilators by Marico Innovation Foundation; awarded grant of INR 43.5 lacs in 2020

## **What was the need of the Hour?**

During this COVID 19 pandemic, when there was a huge shortage of ventilators due to increased demand across the globe & there was a ban on export of ventilators from European & American continents, it was mandatory to find out an indigenous solution, that will not only reduce the dependency on foreign made ventilators but will also save our country's valuable foreign exchange.

In this scenario, it was an absolute necessity to develop & manufacture an Indian brand of ventilator which can be successfully used in all hospitals to treat the COVID patients.

## **How & why did we develop the Adult Ventilator?**

During the COVID pandemic, when we learned about the non-availability of ventilators, we decided to manufacture an Adult & Paediatric Ventilator which will be a cost-effective life saving device & can be afforded by even a small hospital in rural India and at the same time, can be compared with any imported brand.

While designing & manufacturing the ventilators our focus was on to making a state-of-the-art ventilator which will be very cost effective, easy to operate and will have all the latest modes of ventilation and which can be used from Rural to Corporate Hospitals with great trust.

This innovation also ensured that it will save a lot of valuable foreign exchange, will reduce the dependency on the foreign companies, & more importantly this lifesaving facility can be provided to the grass root level & will be beneficial to the weaker section of the society.

## **How we started manufacturing the Adult & Pediatric Ventilator?**

As mentioned earlier, during the pandemic when we learnt about the worldwide shortage of ventilators, we decided to venture in to manufacturing the same. But it was very difficult to start the manufacturing due to worldwide lock down.

We were in need of manpower, spare parts, finance & few imported components, for which we had to pay 100% advance to the foreign counter part which was not possible for us.

But during these adverse situations, we were motivated by chief scientist Mr Sasikumara from IISER, Pune, Mr Tripathi from Kamal Nayan Bajaj Hosp group, Mr Ayush Prasad IAS, CEO Pune ZP, The Honorable Collector of Pune, Mr Naval Kishor Ram, Deputy collector Mr Avinash Hadgal, & above all Mr Prakash Jee Chhabriya of Finolex Industries, who were instrumental in providing us the necessary permissions to open up our facility, allow our employees to attend the work & start our manufacturing activity.

**It will be very ungrateful on my part if I do not mention the Help & motivation by Mr Prakashjee Chhabriya, MD, Finolex group of Industries, who was in constant touch with me & kept motivating my team to manufacture a state-of-the-art ventilator.**

**I am indebted to Prakashjee Chhabriya along with Dr B D Bande for their immense support, help & motivation.**

## **About our Scientific Advisor Dr Balasaheb B Bande:**

We were very fortunate to know a very sincere, down to earth, a clinical expert & an eminent Anaesthesiologist & Intensivist, Dr B D Bande. He is also a teacher to post graduate students & is a renowned faculty member who is invited all across India to deliver lectures on Anaesthesia & on various Critical care topics for last 25 years.

Dr Bande is very closely associated with Shreeyash since last more than 20 years. **He has provided free advice to Shreeyash** on various occasion & for various products like the Patient warming Blanket, Syringe Pumps, Fluid warming cabinet etc & NOT TO FORGET THE ADULT & PAEDIATRIC VENTILATOR.

## **Credentials of Dr Balasaheb Bande.**

MBBB from BJ Medical college Pune, MD Anaesthesia, Pune University, MD General Medicine, Pune University, EDIC (European Diploma in Intensive Care), FICCM (Fellow of Indian College of Critical care Medicine), Diploma in Consumer Law, ILS Law College Pune, Diploma in Medicolegal Studies, Symbiosis law Institute, Pune.

Senior Consultant, Medicine, Anaesthesiology & Critical care at K E M Hospital Pune since 1994. Post graduate Guide & examiner in Anaesthesiology, Post Graduate Guide & examiner for Diploma & Fellowship in Critical Care, Reviewer, IJA, IJCCM, SQU Med J Oman.

Secretary, Indian College of Critical care Medicine (ICCM),

National Vice President, Indian Society of critical care Medicine (ISCCM) 2006-08,

Member, National Governing Council of Indian Society of Anaesthesiologist

Member of ISA, ISSCM, IMA, API, ISSP, AOA, AORA, ISPEN, CSI Pune.

Guest Speaker at National conferences on topics in: High Risk Anaesthesia, Transplant Anaesthesia, Critical Care, ethical & legal issues,

## How is Shreeyash Ventilator, PC 903 A, at Par with Imported Ventilators?

While designing the ventilator we studied the features & facilities of branded ventilators across the globe, referred various books on ventilation & ventilators regarding all the clinical requirements & the expected performance from the ventilator, in consultation with our Clinical advisor Dr B D Bande & then incorporated the features & facilities in our ventilator.

Following are the few striking features of ventilators which are available only in Imported ventilators that cost above INR 12 Lacs. We have made the same features available in our ventilator which is priced at 70 % less cost.

### A. Regular Features:

**Modes:** ACMV (VC & PC), SIMV (VC & PC) plus PSV, PRVC, PEEP, CPAP plus PSV,

**Alarms:** All essential alarms

**Graphics:** Scalar Graphics

### B. Besides having above regular features, modes etc. we have incorporated following special features.

- 1. ACMV with Auto Mode:** In ACMV mode, if the patient starts breathing at a faster rate than the set rate, the ventilator assists each breathing effort of the patient and leads to hyperventilation with incomplete expiration which may lead to dynamic hyperinflation of the lungs and can result in alveolar rupture leading to Pneumothorax in clinical terms. **To circumvent this issue, Shreeyash developed the Auto Mode for absolute safety of the patient.** When the Auto Mode is activated on Shreeyash ventilator, the ventilator diligently watches the patients breathing pattern. If the breathing rate of the patient is more than a pre decided one, the ventilator sounds an alarm & warns the user regarding the same. This is usually rectified manually. But if there is no clinical intervention & if this happens for 3 consecutive cycles, the ventilator **Automatically shifts** the mode of ventilation to a safer mode of ventilation known as **SIMV Plus Pressure Support & starts ventilating the patient with preset values as set by the clinician.**

The incorporation of Auto Mode ensures absolute safety of the patient & is also a welcome feature for the clinician.

## **2. Auto Mode in CPAP mode:**

CPAP (continuous positive air way pressure) is a weaning mode in which the ventilator provides the required percentage of blended Air & Oxygen flow & the patient breaths spontaneously through the flow provided by the ventilator. The CPAP or PEEP or the CDP (Continuous Distending Pressure) is set by the clinician & is maintained in the patient's lung.

During the CPAP mode, if the patient stops breathing, the ventilator sounds an alarm after the selected Apnea period is lapsed & immediately shifts the mode of ventilation from CPAP to control Ventilation mode & starts providing mechanical ventilation with preset backup values.

This ensures that the patient is not deprived of Ventilation what's so ever the case be. It also ensures absolute safety of the patient.

## **3. HFNO: This was incorporated as a special requirement for COVID 19 patients.**

## **4. Non-Invasive CPAP plus Pressure support mode.**

## **5. Incorporation of Help key:**

When "Help" key is activated, the ventilator screen displays various diseases & the standard ventilator settings required in those diseases. This feature is of great help especially to the paramedical staff when the clinician is not available. With this feature, the semi expert can set the required parameters of ventilator & can immediately start the rescue ventilation which will be of great help in saving lives of the patient.

## **6. Formula key:**

This key when activated indicates various formulas regarding ventilator settings/parameters & patient related information that can be useful to the clinician.

Example: Formula to calculate Oxygen Index, to calculate new Respiratory Rate for a desired PaCo<sub>2</sub>, to calculate size of ET Tube, to calculate MAP, to calculate ideal body weight, to convert MM Hg to CM H<sub>2</sub>O.

Considering the scarcity of expert paramedical staff in semi urban & rural areas, Shreyash decided to incorporate the above features in the ventilator which can be of great help in those critical conditions.

## Validation, quality assurance, performance and safety of PC 903 A Ventilator:

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**Testing Standards:** This ventilator went through rigorous physical and clinical evaluation, to ensure the quality and endurance.

### 1. Factory Trials:

We tested our ventilator on various artificial test lungs with variable compliance and resistance, including **Fluke meter test lung**, in our factory, for checking the accuracy of set & delivered parameters of the Ventilator.

We also checked all the ventilator parameters like, Pressure including PIP, PEEP, Volume, Flow, Inspiration & Expiration time, Oxygen Concentration etc., using a **Fluke meter\***.

(\***Fluke meter** is a special device manufactured in USA to cross check the ventilator parameters and is used by all the manufacturers across the globe to check the ventilator performance)

### 2. Laboratory Testing

Shreeyash ventilator was tested for following standards from a NABL accredited lab for its performance & safety

- Manufacturing activity carries out in an ISO 13485 organization.
- Ventilator tested from NABL accredited Lab regarding ISO 60601-1
- EN 60601-1:2006 /A1:2013 01, EN 60601-1-2:2015 01
- Electromagnetic radiation disturbance (Radiated Emissions) CISPR 11, Harmonic current Emissions: IEC 61000-3-2
- Voltage changes, voltage fluctuation and flicker
- Emissions: IEC 61000-3-3, Electrostatic Discharge Immunity: IEC 61000-4-2
- Electrical fast transient/burst Immunity: IEC 61000-4-4
- Surge Immunity: IEC 61000-4-5,
- Power frequency magnetic field Immunity: IEC 61000-4-8
- Voltage dips, short interruptions and voltage variations
- Immunity: IEC 61000-4-11
- Radiated RF electromagnetic field Immunity to proximity fields from RF wireless communications, equipment: IEC 61000-4-3
- Immunity to conducted Disturbances induced by RF fields (conducted RF Disturbance Immunity) for single port: IEC 61000-4-6, 3 EN 60601-1-6 0 1, 4 EN 60601-1-8 0 1, 5 ISO 80601-2



### **3. Clinical Trials:**

We manufactured our first Adult & Pediatric Ventilator under the guidance of Dr B D Bande in the last week of March 2020 & provided the same for clinical trials to Dr Kapil Zirpe (Director & HOD, Neuro Trauma unit of Ruby Hall clinic) in the first week of April 2020.

This first prototype of the ventilator was successfully used on a patient suffering from ARDS. (Certificate attached).

By last week of April 2020, we manufactured a second prototype, which had all the essential features required for ventilation of diverse kind of diseases in the ICUs. The features added were, Servo mechanism, Auto mode, Graphics and HFNO mode.

The second model was evaluated by Dr Prachi Sathe, Director, Dept of Critical care, Ruby Hall Clinic, Pune. (Certificate attached)

### **Trials at Nirman Bhavan, Govt of India & Ram Manohar Lohiya Rugnalay (RML) in New Delhi:**

During this manufacturing process, we were approached by one South Indian company, who had an order of 2000 advanced ventilators from Govt of India. It was agreed that Shreeyash will provide them the ventilator under their brand name.

Accordingly, we provided them with the ventilator which was analyzed by panel of 8 Doctors at Nirman Bhavan, Delhi, in regards to the features & functions. The ventilator was critically analyzed for its performance & safety. Our ventilator was validated by this panel & we were further advised to check the ventilator on Fluke meter at RML Hospital.

The Ventilator was put on Fluke meter which has data recording facility. Each mode of ventilator was checked for 8 hours & the set & delivered data was recorded, printed & circulated to the concerned authorities. (Fluke meter data attached)

After successful trials on Fluke meter, the concerned Doctors connected our ventilator on COVID 19 ARDS Patients at RML Hospital. Our ventilator performed satisfactorily during the clinical trials at RML Hospital.

After the RML Trials, we were instructed to demonstrate our two Ventilators at JPIMER, Vizag, where one was tested on Artificial Lung Simulator & second was tested on a COVID 19 ARDS patient.

Our Ventilators passed both the trials with flying colors.

After successful trials at JPIMER Vizag, we were again instructed to provide our ventilator at RML Hospital Delhi for Final Clinical trials.

During the said trials, the ventilator was again put on a COVID 19 Patient who was already being treated on an Imported Ventilator. The imported ventilator was disconnected & our ventilator was connected to the patient. The set parameters & delivered parameters were closely observed along with the Blood Gas Reports (ABG). After cross checking the Set Ventilator parameters & ABG reports, we were informed that our ventilator has passed all the required mandatory tests for using it as a Regular Intensive care Ventilator in ICU.

### **Hurdles faced during manufacturing Ventilator during COVID 19 Pandemic.**

Prevailing Lockdown posed a great challenge to organize the manufacturing facility. Shortage of manpower, unavailability of raw material and critical components, inadequate supply of spares from vendors, etc. were the real hurdles to cross. The timely encouragement, facilitation and permissions by various Govt authorities made this uphill task easier.

### **Few of our Ventilator user list:**

1. Army Hospital Lucknow	17 no
2. Army Hospital Delhi	16 no
3. Army Hospital Mumbai	17 no
4. KEM Hospital, Pune	1 no
5. Image Hospital, Hyderabad	6 no
6. Dr Leena Patil, Jalgaon	1 no
7. MMKR Health care, Jalgaon	3 no
8. KM health Care, Pune	1 no
9. Dr Jagtap Hosp, Solapur	2 no
10. Dr Gosavi Hosp, Sangli	1 no
11. Friends Hosp, Kanpur	1 no
12. Dr Niranjan, New Mumbai	1 no
13. Spandan Hosp, Pune	1 no
14. Yash Hosp, Pune	1 no
15. Dr Patankar Hosp, Panvel	1 no
16. Dr Misbah, Nizamabad	1 no
17. Covid Hosp, Pirangut, Pune	1 no
18. Kamal Nayan Bajaj Hosp, Aurangabad	1 no

## Awards & appreciation:

During the pandemic Marico Innovation Foundation (MIF), a not for profit company by Marico Limited, headed by Mr Harsh Mariwala, appealed to one & all manufacturers, innovators from India to come up with Indian make cost-effective solutions to combat COVID 19 & for which they announced a grants of INR 2.5 crores. The grant money was segregated in 2 categories.

- A. For Ventilators and other respiratory solutions &
- B. For Personal Protective Equipment (PPE)

Over 700 small, medium & large companies all over from India applied for this prestigious award.

MIF had a panel of Juries that included eminent Pulmonologists, Anaesthesiologists, Industrialists, Public Health Experts and Bioethicists. This Jury panel was headed by none other than Dr Ragnunath Mashelkar, Recipient of Padma Shri, Padma Bhushan, Padma Vibhushan.

The juries meticulously scrutinised all the applications & short listed **“Shreeyash PC 903 A”** as a winner in the Ventilator category.

After a lot of documentation, clinical evaluation, certifications & interviews via Zoom call, Shreeyash PC 903 A was awarded the innovation award. This Award carried a grant of Rs 43.50 Lacs & was provided to Shreeyash for ramping up the production of Ventilators.

Not only did Marico Innovation Foundation offer the monetary grant for immediate scale and deployment, but also under the Scale-Up Program, supported with building operational efficiencies. Some of the key challenges they helped resolve are perspectives on growth avenues and licensing opportunities, making in-roads for sales with large hospital chains in India, streamline sales pitch and relevant collaterals through strong in-sighting exercise. The hands-on support from MIF as a strategic growth partner has bolstered the growth trajectory for Shreeyash.

## **About “Shreeyash PC 903 A” Ventilator:**

This Ventilator is at par with any imported make of the Ventilator. Imported ventilator costs around INR 12 to 14 lacs, but this Indian made Ventilator will cost 70 % less!

Features like AUTO MODE ensures absolute safety of Patient. CPAP with Pressure Support mode is a boon for the weaning patients.

The various features provided on the Ventilator, ensure that the clinician can treat any type of lung disease on our ventilator.

Various screens provided, not only indicate basic & important ventilator parameters but also provide other vital information like the static & dynamic parameters, RSBI Index, Inspired & Expired Tidal Volumes etc.

Advanced modes like NIV CPAP & HFNC, SIMV Plus PS, CPAP Plus PS, PRVC modes are provided.

It is intended to be used as a regular ICU Ventilator in all hospitals across the globe.

It operates on Compressed Air & Oxygen supply.

Spare parts are easily available at a very economical cost.

Shreeyash conducts annual workshops to train Doctors in the Art of Ventilation which ensures that Shreeyash Ventilator users are always kept updated with recent trends in Ventilation. Shreeyash conducts this workshop Free of Cost each year & only 120 clinicians are invited. The invited clinicians are given Hands on training & are enlightened by eminent Clinicians form all across India. This year too, Shreeyash will conduct the workshop to train the Doctors regarding the Art of ventilation