Ventilators of the Future

A Tata Elxsi Perspective

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Abstract

Mechanical ventilation is a lifesaving intervention for patients with respiratory failure. Ventilator may also be employed as a diagnostic tool, to get data on the static compliance of the respiratory system and airway resistance.

The clinical scenario and the data obtained from the ventilator allow the respiratory therapist to provide effective and safe mechanical ventilation through manipulation of the ventilator settings.

While life-sustaining in many circumstances, mechanical ventilation may be harmful and should be withdrawn when clinically appropriate. It is of prime importance to wean the patient of the ventilator as early as possible to avoid ventilator related injuries.

The demands of the global ventilator market are changing rapidly and many of the ventilator manufacturers are struggling to cope up with that. This paper attempts to explore the basic functional blocks of a ventilator within the product design and regulatory framework to incorporate changes that are demanded by the global market dynamics.
Introduction

In a wide range of disease conditions such as refractory hypoxemia, respiratory muscle dysfunction, decreased ventilator drive and increased airway obstruction, a patient may require assistance to carry out a normal respiratory function. The ventilator is a device, which either partially or completely supports the patient to carry out a normal respiratory function.

Ventilator performs following functions:

- Ventilator mixes air and oxygen in the required ratio and delivers to patient through special tubing called “breathing circuit”.
- Ventilator moves out CO2 in expired air from patient.
- The ventilator delivers and controls the flow of gas to the patient, based on values set by the clinician.
- Ventilator improves oxygenation and supports lung mechanics, while disease is treated.

Following are some of the common clinical indications for mechanical ventilation:

- Apnea with respiratory arrest
- Acute lung injury
- Respiratory rate >30 breaths per minute
- Chronic obstructive pulmonary disease (COPD)
- Clinical deterioration
- Respiratory muscle fatigue
- Coma
- Hypotension
- Tachypnea or Bradypnea
- Blood gases, showing persistent hypoxemia
- Neuromuscular disease.
Medical device market drivers

Medical device technology is well known for its ability to adapt to other disciplines of knowledge, which is indeed the reason for its enhancement. Developments in aerospace applications, consumer electronics, and semiconductor technologies have all triggered the avalanche of innovation in medical devices.

Miniaturization

Many of the complex circuitries can be integrated into a single chip, which reduces the real estate of PCBs, thereby realizing products with smaller form factors. (For example, the fully-integrated analog front end (AFE) chip which can be used for patient monitoring, portable and high-end electrocardiogram (ECG), and electroencephalogram (EEG) equipment, in a BGA package size of 8mm x 8mm).

Enhanced portability

Miniaturization of the medical device has, in turn, enhanced the portability of the medical device, which will help in monitoring the condition of the patient at any given point of time like during the transportation of the patient from one health care facility to another, shifting the patient from one place to another, ambulatory monitoring etc.

Low power designs

Developments in Bioelectronics and semiconductor technologies have made it possible to design circuits that consume less power. This will also allow for smaller battery size and longer backup time. Smaller battery size will reduce the weight and enhance portability.

Enhanced clinical workflow

Wireless connectivity in medical devices will enhance clinical workflow as the medical device need not be tethered for internet connectivity for an EMR or remote monitoring.

Impact of market drivers on ventilators

Ventilators like many other medical devices have undergone enormous changes thanks to the technological developments. The changing technology, market dynamics, disease patterns have all contributed to the metamorphosis of ventilators. The stringent regulatory and statutory compliance requirements also catalyzed the innovation trend of ventilators. It is of great importance to understand the medical device market drivers so as to assess its impact on ventilators.

Figure 1. Medical device market drivers
Ventilator architecture

As shown in figure 2 a ventilator system consists of two major systems: the pneumatic system and the electrical system. The pneumatic system, under control of the microprocessor in the electrical system, supplies air and oxygen to the patient system external to the ventilator. Air for delivery to the patient and to operate the pneumatic components is provided by an external compressed air supply or by an optional compressor.

Oxygen is provided by an external oxygen source. The pneumatic system consists of two parallel pneumatic gas circuits: one for oxygen and one for air. An important element of the pneumatic system is the solenoid valves which precisely control the flow delivered to the patient. Air and oxygen flow sensors provide feedback, which is used by the microprocessor (CPU) to control the solenoid valves. Thus the ventilator is able to supply air and oxygen to a patient according to ventilator settings defined by the operator on ventilator GUI. The output of mixed air and oxygen passes through the patient circuit system external to the ventilator. The patient exhales the gas through the exhalation valve, which is part of exhalation module.

The electrical / electronic system controls and monitors the gas delivery using the pneumatic system. Power to operate the ventilator comes from AC power and Backup Power Supply unit in the absence of AC power.

Figure 2. Ventilator generic block diagram
Mechanical ventilation trends

The challenge for future research in the area of ventilator technology is to generate controlled clinical studies to support its application. With the impact of financial constraints on health care, research will also need to examine the economic issues related to the application of newer modes of mechanical ventilation. Integrating the vital signs monitoring with ventilation in conjunction with other assessment parameters may prove to be useful tools to measure the impact of interventions such as suctioning, positioning, muscle reconditioning, weaning techniques, and comfort measures on mechanically ventilated patients.

Market drivers for ventilators

The market drivers for medical devices may be applied to ventilators too. Emergence of new generation sensors, single chip solutions and new generation pneumatic components have impacted the design architectures of ventilators. Ventilating infants and newborn babies makes special demands on ventilation technology which cannot be met partially by equipment designed for adults. The specific challenges of neonatal ventilation are smaller inspiratory volumes, faster changes in the gas flow and more particularly protection against too high airway pressures and too large mandatory breath volumes.

Patient and operator safety is prime importance which has been regulated by the certifying authorities which has imposed huge challenges for the medical device manufacturers. Better understanding of physiology, anatomy and disease patterns are also triggering a new wave of innovation in mechanical ventilation. Ventilation techniques which ensure automatic adaptation of ventilation to the patient have been developed only recently.

Tata Elxsi approach for ventilators

Tata Elxsi’s proven expertise in interdisciplinary domains such as embedded product design, industrial design, animation, visual effects and systems integration is well backed by an in-depth understanding of technology and mature processes and systems. Tata Elksi is geared to tackle the challenges and pain areas of ventilator manufacturers.

Tata Elxsi concept-encompassed ventilation

Though ventilation is done under close observation, to assess the ventilation and the gas distribution inside the lungs dynamically is a tedious task. EIT (Electrical Impedance tomography) is an excellent tool to assess the lung function during ventilation. It will be of great importance and use if this can be integrated with ventilators. In addition to this integrating vital signs monitoring into the ventilator also saves lot of precious time.

Tata Elxsi visualizes a concept of Encompassed ventilation in which:

- Assessment of the lungs during ventilation
- Integration of vital parameters
- Ventilation index parameter based on Assessment of the lungs during ventilation and vital parameters
Tata Elxsi concept - remote diagnosis and upgrades for ventilators

A typical Remote Diagnosis and upgrades for ventilators will result in:

- Faster call resolution resulting in reduced downtime
- Ability to leverage technical expertise globally
- Minimize on-site repair visits
- The elimination of on-site visits to install base software or software enhancement options
- Software enhancement options can be installed at the customer’s convenience, without interrupting patient care

**Figure 3. Tata Elxsi concept - remote diagnosis and upgrades**
Tata Elxsi service offerings

Tata Elxsi provides design and engineering services to the medical devices industry. We understand the changing trends in this industry and offer services such as concept generation & validation, product development, verification & validation, and sustenance engineering. Our quality process is harmonized with ISO-13485, ISO-14791, US FDA, IEC-60601 series and other equivalent regulations. Our processes can be quickly tailored to cater to specific regulatory requirements. With a unique focus on product design and engineering services, we provide services across the product development lifecycle. We have leveraged our cross functional domain expertise to provide the entire gamut of service offerings for the medical device manufacturers under one roof.

Figure 4. Tata Elxsi service offerings - overview

Figure 5. Tata Elxsi services for new generation ventilators
The medical devices industry is in a state of constant evolution owing to new innovations and regulations. This has led to the development of devices and solutions which have revolutionized patient care. The key trends include miniaturization & portability, connectivity & remote patient monitoring, and reliability & affordability.

Ventilators like many other medical devices have undergone enormous changes thanks to the technological developments. The changing technology, market dynamics, disease patterns have all contributed to the metamorphosis of ventilators. The stringent regulatory and statutory compliance requirements also catalyzed the innovation trend of ventilators. Medical device market drivers such as deep miniaturization, enhanced portability, low power requirements and enhanced clinical workflow have made significant advancements in modern ventilator designs. Since the needs of the emerging markets are different from that of developed different strategies and system engineering paradigms need to be applied.

With a unique focus on product design and engineering services, we provide services across the product development lifecycle. We have leveraged our cross functional domain expertise in the areas of connectivity technologies (Bluetooth, Wi-Fi, wireless), mobility solutions, and industrial design to provide cutting edge solutions to our clients spanning diagnostic devices, surgical devices, point of care devices, telemedicine solutions, and medical imaging solutions.

Tata Elxsi has developed a solution suite that will answer the questions raised by the emerging markets. This solution suite is equipped with tailor made solutions for the emerging market. The requirement of the chosen market may be superimposed on the framework so as to derive the optimum solution.

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Conclusion

The global mechanical ventilators market is expected to grow at a CAGR of 6.6% from 2013 to 2019, to reach an estimated value of USD 4,248.7 million in 2019. It is also important to note that the purchase criteria in the mechanical ventilators market are also changing.

Buyers are placing greater emphasis on service, support and product design instead of prices and brand names. Local vendors in BRIC nations are challenging the larger multinational companies (MNCs).

Customers from developing countries that typically have low awareness and purchasing power – trust local companies to provide better after-sales support which may compel MNCs to scale down prices. These factors are driving the global ventilator market and offer a gold mine of opportunities for engineering service providers and OEMs.

About the author

Vimal Kumar has a Masters in Digital Design, post graduate diploma in International Business and a diploma in French.

He has 23 years of work experience in biomedical and aerospace industries in mission and life critical applications.

He holds a Patent (No: 3035/CHE/2010) for the smallest 3 lead ECG machine.

He leads Tata Elxsi’s medical electronics solution team which plays a pivotal role in conceptualizing and developing solutions for the medical device industry.
About Tata Elxsi

Tata Elxsi is a design company that blends technology, creativity and engineering to help customers transform ideas into world-class products and solutions.

A part of the $100 billion Tata group, Tata Elxsi addresses the communications, consumer products, defence, health care, media & entertainment, semiconductor and transportation sectors. This is supported by a talent pool of over 4000 employees and a network of design studios, development centers and offices worldwide. Key services include embedded product design, industrial design, animation & visual effects and systems integration. Tata Elxsi is a listed company and headquartered in Bangalore, India.

About Tata Elxsi’s medical electronics offerings

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Contact us

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