

Introduction

Haemodialysis is a lifesaving intervention. Patients with renal disease undergo a progressive loss in renal function which eventually necessitates dialysis therapy to sustain life. While life sustaining in many circumstances, haemodialysis can be catastrophic if appropriate care is not taken as it is a very complex therapeutic procedure.

Dialysis is a blood purification process which removes waste products resulting from metabolism and food intake. It can also correct electrolyte abnormalities and acid-base balance. Fluid gained in between treatments is also removed during dialysis.

Dialysis machine mimics the operation of kidney using a dialysis fluid, which facilitates the diffusion process. The machine monitors treatment and ensures that the equipment reverts to a “fail safe condition” in the event of malfunction, thereby protecting the patient.

The purpose of this paper is to review the status quo of dialysis machine technology, emerging trends and Tata Elxsi’s approach to answer the dialysis machine market needs from a technological perspective. This paper attempts to encompass the basic blocks of a dialysis machine within the product design framework and aims to align it with our expertise.

Figure 1: Functional blocks of dialysis device
Medical device market drivers and their impact on dialysis machine

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. Dialysis machines 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 dialysis machines. The stringent regulatory and statutory compliance requirements also catalyzed the innovation trend of dialysis machines. It is of great importance to understand the medical device market drivers so as to assess its impact on dialysis machines.
Dialysis machines – architecture overview

The block diagram portrays the complex electromechanical challenges that are addressed in the system design of a typical dialysis machine. The design complexity gets another exponent when patient safety has to be considered. The criticality of the procedure while ensuring safety of the patient with enhanced usability make the design task a challenge for the device designer. But then ships are not made to be barnacle crested but to go out in the rough sea. This is the challenge that the medical device design must be prepared for.

Dialysis machines are medical equipment whose design and manufacture is regulated by the Food and Drug Administration (FDA). They come under FDA device Class II. This means that their design and construction must follow precisely documented processes, and their performance must meet stringent documentation, development testing, production testing, and field maintenance requirements. The equipment also must contain comprehensive self-test and fault-indication capabilities, which require additional circuitry and the use of components that include self-test features. Electrical leakage to the patient is a significant concern. Medical device developers must meet the requirements of the IEC 60601-1 product safety standard for electrical medical equipment. In addition to this the dialysis machine must comply to the standard IEC 60601-2-16 Medical electrical equipment – Part 2-16: Particular requirements for the basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment.

**Figure 2:** Dialysis machine generic block diagram (courtesy: Maxim semiconductors)
Dialysis trends and workflow

As shown in figure 2 clear understanding of the dialysis workflow is important so as to identify the pain areas that the medical device manufacturers are facing. These steps will also help to find solutions that will eventually enhance clinical workflow and result in better quality of life for those undergoing dialysis procedure.

The challenge for future research in the area of dialysis machines technology is to generate controlled clinical studies to support its application. With the impact of financial constraints on healthcare, research will also need to examine the economic issues related to the application of newer modes of mechanical dialysis. Integrating the vital signs monitoring with dialysis in conjunction with other assessment parameters may prove to be useful tools to measure the impact on patients undergoing dialysis. Proliferation of wireless technologies, tech savvy patients, modern sensors have made strong impact on dialysis.

There is a strong drive to enhance quality of life of patients undergoing dialysis. Portable dialysis machine that can be carried in a suitcase is paramount example for this.

![Figure 3: Dialysis workflow](image-url)

The figure 3 represented workflow of pre-dialysis testing, aggregate data, treatment plan, prescription, pre-dialysis patient evaluation, safety checks, post-dialysis patient evaluation, monitoring during treatment, and actual procedure.
Market drivers for dialysis machine

The market drivers for medical devices may be applied to dialysis machine too. Emergence of new generation sensors, single chip solutions and new generation components have impacted the design architectures of dialysis machine. 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 dialysis.

NxStage System One PORTABLE HEMODIALYSIS MACHINE provide the simplicity, flexibility and portability to make home hemodialysis a practical reality, without compromising safety is an excellent example demonstrating product design that answers the demands of dialysis market.

Figure 4: NxStage portable dialysis machine
Tata Elxsi approach for dialysis machine

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

Case study: VOC dialysis machines of future

Tata Elxsi conducted VOC study with leading nephrologists to understand the possible need for the dialysis machines of the future. Below are the highlights:

**Alarm requirements**
- The range and sensitivity of the alarms should be internally set as default.
- Operator should only be able to operate within the set range without being able to alter these settings, especially while HD is in progress.
- Alarms should be visible clearly from at least 2 meters, but also easily audible.
- All blood alarms (air detector, arterial, venous, blood leak, trans membrane pressure, blood pump torque) should automatically shut off the blood pump, clamp the venous return line, and stop UF, thus isolating the patient.

**Safety**
- Equipment should programmed to automatically switch to “safe mode” thus, essentially isolating the patient from the HD machine.
- Usage of heated citric acid as disinfectant is highly recommended.

**Battery Backup**
Battery backup may be provided to the blood pump module.

**New generation sensors and dialysate monitoring**
Introducing pH sensors may improve the safety of patients as uncontrolled pH values have caused fatalities in the past.

**Figure 5**: VOC case study - summary
Though dialysis is done under close observation, to assess the dialysis and integrate vital signs is important as integrating vital signs monitoring into the dialysis machines also precious time in the event of any irregularities.

Tata Elxsi visualizes a concept of Encompassed dialysis in which:

- Assessment of dialysis
- Monitoring of dialysate
- Integration of vital parameters
- Dialysis index parameter based on Assessment during dialysis and vital parameters
Emerging market dynamics play a major role in the success of medical device manufacturers. The graphic below clearly depicts the demands of the dialysis market.

About 10 percent of adults in India suffer from kidney disease and almost 200,000 patients develop end-stage disease ever year. Davita, Inc. of Torrance CA has already entered India in the services market. Now Medtronic Inc. of Minnesota will enter the kidney dialysis business in collaboration with India’s Apollo Hospitals Enterprise Ltd.

Medtronic is developing a low-cost, portable approach for patients in the developing world who are less likely to have access to service offered on machines made by Fresenius and Baxter, and need options that don’t require as much water and infrastructure. The challenges are different in emerging economies like reducing the dependency on ultrapure water that’s required by current dialysis machines. There is hardly enough water to nourish human beings and get food on the table in developing nations and designer must find a way to work on constraints.

What this means is that MNCs are ready to experiment with new approaches that could address a large incremental market and these market experiments will be replicated in other emerging economies.

Figure 7. Global dialysis population

<table>
<thead>
<tr>
<th>Region</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>USA</td>
<td>20%</td>
</tr>
<tr>
<td>EUR</td>
<td>15%</td>
</tr>
<tr>
<td>Japan</td>
<td>14%</td>
</tr>
<tr>
<td>ROW</td>
<td>51%</td>
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</tbody>
</table>
Value engineering framework for dialysis machines

Tata Elxsi’s value engineering framework is an excellent methodology to address the demands of dialysis market especially the needs of emerging market.

Figure 8: Tata Elxsi value engineering framework
In addition to the typical value engineering concept, 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.

![Diagram showing Tata Elxsi emerging market design solution suite](image)

**Figure 9:** Tata Elxsi emerging market design solution suite
Conclusion

The global dialysis market is estimated at $61.60 billion in 2013 and is poised to grow at a CAGR of 6.2% from 2013 to 2018, to reach $83.21 billion by 2018.

A number of factors such as the increasing number of end stage renal disease (ESRD) patients and rising prevalence of diabetes and hypertension are stimulating the demand for dialysis treatment.

Furthermore, growth in aging population, low preference of patients for kidney transplantation, technological advancements, and substantial government healthcare expenditure on the treatment of ESRD are propelling the growth of the products and services of Hemodialysis Market & Peritoneal Dialysis Market. Evolution of new dialysis modalities (such as home hemodialysis and nocturnal dialysis) and emerging markets such as China and India represent high growth opportunities for market players.

As of 2013, North America (comprising the U.S. and Canada) holds the largest share of the global Dialysis Market. This large share is attributed to the presence of a large number of dialysis patients in the U.S., high reimbursement rates, and the high adoption rate of new technologies in the North American Dialysis Market.

However, the Asia-Pacific Dialysis Market is expected to witness the highest growth in the forecast period. A number of factors such as the increasing number of independent dialysis centers, increasing awareness about dialysis treatment modalities, and favorable changes in the reimbursement and healthcare insurance policies are propelling the demand for dialysis products and services in the Asia-Pacific region.

The major players in the global Dialysis Market include Fresenius Medical Care AG & Co. KGaA (Germany), DaVita Healthcare Partners, Inc. (U.S.), Gambro AB (Sweden), Baxter International, Inc. (U.S.), B. Braun Melsungen AG (Germany), Nipro Corporation (Japan), Diaverum Deutschland GmbH (Germany), Medical Components, Inc. (U.S.), Covidien (Ireland), and NxStage Medical, Inc. (U.S.)

The gargantuan proportion of the patients needing dialysis is putting enormous pressure on the medical device manufacturers and they have no other choice but to turn to engineering service providers for help which in turn is the raison d’être for that fraternity.

About the author

Vimal Kumar has 23 years of experience in Biomedical design, automated functional testing of Aircraft engines and turbines and also techno commercial business development. He holds an Indian 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 service offerings for the medical device domain.
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 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 devices-engineering services 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.

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 & imaging, ventilator, infusion pump, therapeutic, surgical equipments, point of care, endoscopy, diabetes devices and tele-health solutions.

Contact us

For more information contact: mebu@tataelxsi.co.in

References:

- Prnewswire report Dialysis Market [(Hemodialysis - Machine, Dialyzer, Bloodlines, Concentrates, Services), (Peritoneal Dialysis - Cycler, Catheter, Dialysate, CCPD, CAPD, IPD), (End Users - Hospital, Independent Dialysis Center, Home Dialysis)] - Global Forecast to 2018.

- IEC 60601-2-16 Medical electrical equipment – Part 2-16: Particular requirements for the basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment.