



# Hemodialysis Machine

KIHT Technical Compendium

## **EXECUTIVE SUMMARY**

---

The kidneys are the primary excretory organ of the human body which plays a major role in maintaining homeostasis by excreting by-products in the urine. The processes involved in urine formation include filtration of metabolic waste products (urea and creatinine), balancing the levels of electrolytes (sodium, potassium, calcium, chloride, and bicarbonate) and water, to control the fluid content inside the body. In addition, the kidneys help in maintaining pH, blood volume, blood pressure, blood osmosis, and blood glucose levels. The kidneys also secrete hormones such as calcitriol, erythropoietin, renin, bradykinin, and prostaglandin.

Different diseases related to a renal system like hypertension and diabetes etc. leads to a sudden and severe reduction in the kidney's filtration rate, may lead to acute renal failure. Acute renal failure is reversible over a few days or weeks if it is diagnosed and treated on time. In contrast, chronic renal failure is a progressive, long-standing condition with irreversible impairment of renal functions which develops due to the loss of nephrons over several months.

Different types of renal replacement therapies are prescribed including hemodialysis, intestinal dialysis and peritoneal dialysis based on the condition of the patient and their affordability. Out of three, hemodialysis is most demanding in India because of affordability.

According to a report titled "Global Dialysis Market Analysis (2017-2023)" published by KBV Research, the global dialysis (hemodialysis and peritoneal dialysis) market is expected to attain a market size of \$124 billion United States Dollars (USD) by 2023, growing at a compound annual growth rate (CAGR) of 5.3% during the forecast period<sup>1</sup>. The dialysis market in Asia-Pacific would witness a growth of CAGR of 7.3% during the forecast period, in which Japan held the largest share, whereas, in India, the dialysis market is expected to witness a CAGR of 9% between 2017 and 2023.

The main objective of this technical compendium is to cover the entire spectrum pertaining to a medical equipment called Hemodialysis machine. This report explains the clinical aspects, requirements, and principles to understand the working of the equipment. The detailed technical aspects shed light on the criticality of the product at a component level and provide the information about relevant standards and regulations. In addition, the report is also briefly touching upon the export & import analysis.

---

<sup>1</sup> Global Dialysis Market to Reach a Market Size of \$124 billion by 2023' by KBV Research

## — TABLE OF CONTENTS —

List of Tables .....	iv
List of Figures .....	v
List of Abbreviations.....	vi
Executive Summary.....	vii
1 INTRODUCTION .....	1
1.1 Types of Renal Replacement Therapies .....	4
1.1.1 Hemodialysis.....	4
1.1.2 Continuous Renal Replacement Techniques.....	6
1.1.3 Sustained Low-Efficiency Dialysis.....	7
1.1.4 Peritoneal Dialysis.....	8
1.1.5 Intestinal Dialysis.....	9
1.1.6 Kidney Transplantation.....	9
1.2 Clinical Need .....	9
1.3 Requirements .....	13
1.3.1 Clinical .....	13
1.3.2 Technical.....	13
1.4 Workflow.....	14
2 PRODUCT INFORMATION .....	16
2.1 Working Principles.....	16
2.1.1 Water Treatment System.....	16
2.1.2 Blood Circuit.....	17
2.1.3 Dialysate Circuit.....	17
2.2 Types of Hemodialysis Configurations .....	20
2.3 Typical Specifications.....	24
2.4 Common Features.....	25
2.5 Critical Components .....	25
2.5.1 Blood Pump .....	25

2.5.2	Infusion Pumps .....	29
2.5.3	Blood Leak Detector.....	31
2.5.4	Pressure Monitors.....	31
2.5.5	Air Bubble Detector.....	34
2.5.6	Hemodialyzer.....	35
2.5.7	Ultrafiltration Control System .....	40
2.5.8	Dialysate Proportioning System .....	42
2.5.9	Dialysis Management Software .....	45
2.6	Other Component Information.....	46
3	STATE-OF-ART TECHNOLOGIES.....	49
3.1	Wearable Hemodialysis Machine.....	49
3.2	Implantable Bioartificial Kidney.....	50
3.3	Wearable Artificial Kidney .....	50
4	STANDARDS.....	51
4.1	Types of Standards.....	51
5	REGULATIONS .....	56
5.1	Introduction .....	56
5.2	Life Cycle of a Medical Device .....	56
5.2.1	Pre-market phase.....	56
5.2.2	Post Market Surveillance .....	57
5.3	US FDA Regulation of Medical Devices .....	57
5.3.1	Premarket Notification or the 510(k) Process.....	58
5.3.2	Premarket Approval (PMA) .....	58
5.3.3	<i>De Novo</i> Submissions for new devices.....	59
5.3.4	Device classification methodology under FDA.....	60
5.4	Medical Device Regulations in Europe.....	60
5.4.1	Device classification methodology under EU .....	61
5.4.2	European Union CE Marking / Certifications .....	61

5.5	Medical Device classifications under Indian Regulations .....	62
5.6	Therapeutic Goods Administration (TGA) Medical Device Regulations in Australia 62	
5.7	JAPAN MHLW & PMDA .....	63
5.8	China NMPA (National Medical Products Administration) Medical Device Regulations (CFDA).....	64
5.9	Regulations for Quality Systems.....	65
5.10	Device Classifications.....	65
<b>6</b>	<b>OPERATING INFORMATION .....</b>	<b>66</b>
6.1	General Operating Steps .....	66
6.2	Common Issues Encountered by the Users.....	67
<b>7</b>	<b>MARKET ANALYSIS.....</b>	<b>68</b>
7.1	Global Market Overview .....	68
7.2	Market Segmentation .....	68
7.3	Indian Market.....	68
7.3.1	Indian Hemodialysis Equipment Market Size .....	69
7.3.2	Number of Dialysis Centers.....	69
7.3.3	Hemodialysis Market – By Types.....	70
7.4	Prominent Manufacturers of Hemodialysis - Global.....	71
<b>8</b>	<b>EXPORT-IMPORT INFORMATION.....</b>	<b>72</b>