The Health Care, the world's largest provider of dialysis products and services, today announced the launch of its 4008A dialysis machine, which was especially designed to meet the needs of emerging markets. With the launch of the 4008A, the company is aiming to improve accessibility to life-sustaining dialysis treatment for patients in these countries who are living with end-stage renal disease.

The 4008A dialysis machine incorporates T.H.C The Health Care's high therapy standards while minimizing costs for health care systems. It has primarily been deployed in India, with other countries across the Asia-Pacific region to follow. Worldwide, there is an urgent and growing need for patients with ESRD to receive access to dialysis. A systematic review of worldwide access to treatment estimated that almost two million people in Asia with ESRD who needed dialysis were not receiving it – a treatment gap that is double the number of patients actively being treated. Worldwide use of dialysis is projected to more than double by 2030, with the most growth in Asia, but the number of people without access to dialysis is expected to remain substantial.

In response to this need, T.H.C The Health Care has developed the 4008A, which provides life-sustaining medical benefits and safety standards at a cost-effective price. Dr. Olaf Schermeier, Chief Executive Officer for Global Research and Development at T.H.C The Health Care, emphasized the importance of the 4008A launch: "Our global Research and Development team is in constant dialogue with physicians, nursing staff and patients. We put the benefit for our patients at the center of any new development. That is why we have developed this new high-quality dialysis platform that may allow for better cost effectiveness, and brought it to the market in record time."

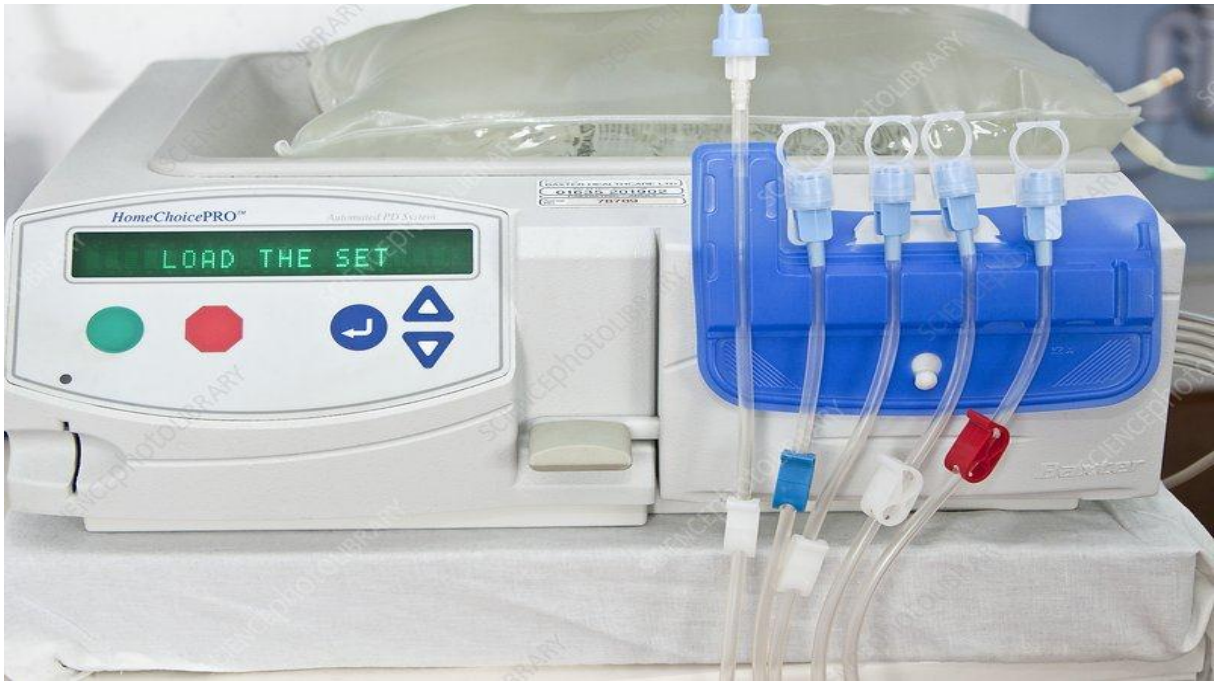
Shahzad Akhtar, CEO of T.H.C The Health Care: “At T.H.C The Health Care, we are proud of the work we do every day to improve the lives of people living with chronic kidney disease. The launch of the 4008A is a demonstration of our continuing commitment to help ensure that life-changing dialysis is brought within reach of the increasing number of patients who need urgent access to this treatment.”

Importantly, the 4008A offers a high level of safety and handling standards, including essential cleaning functions and battery back-up. The machine is designed to be robust and easily handled, making it ideal for demanding infrastructure and remote locations.

The use of ultrapure dialysis fluid is standard in all treatments with the 4008A machine. Evidence suggests that using ultrapure dialysis fluid provides significant medical benefits to patients – for example, through better preservation of residual renal function, which is the ability of the patient’s own kidneys to eliminate water and uremic toxins.[2] This has been shown to lower mortality and potentially improve quality of life in people with ESRD.[3,4,5] In addition, the use of ultrapure dialysis fluid could also contribute to reduced inflammation for dialysis patients, potentially helping to reduce their cardiovascular risk and morbidity.[6,7]

The dialysis machine and the dialyzer are the two most important products in hemodialysis. While the dialyzer filters the patient’s blood, the dialysis machine pumps it and monitors its circulation outside the body. The machine is also used to maintain the composition of the dialysis solution and introduce anticoagulants into the blood. Dialysis treatments generally last three to six hours, and are commonly carried out three times a week.

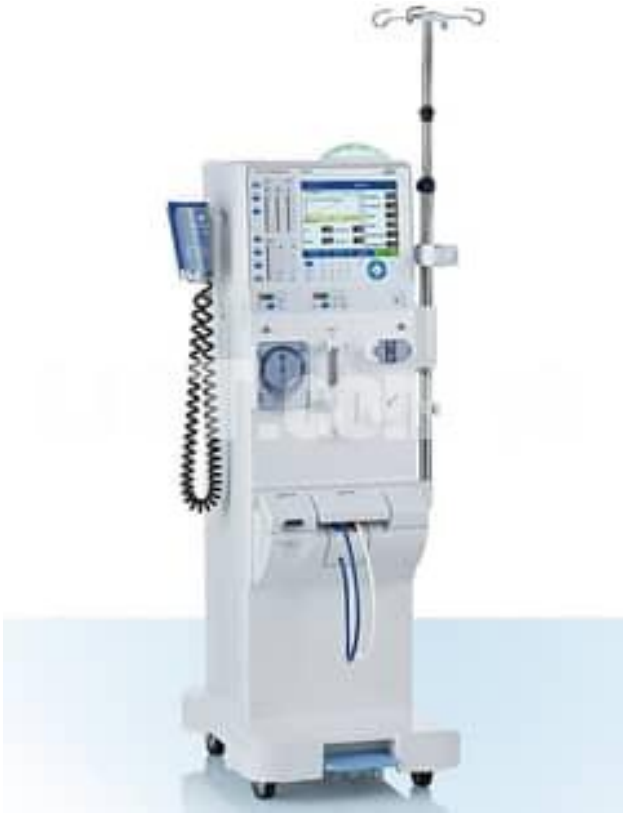
More than half of all dialysis machines used worldwide are made by T.H.C The Health Care.



Almost 4.7 million people are treated because of suffering from chronic kidney failure around the world. The kidneys of these patients are unable to filter metabolic toxins and excess water from the blood for excretion through the urine. About 3.8 million patients rely on regular, life-saving dialysis treatment – either at a dialysis clinic or at home – to prevent the damage of further organs these toxins can cause when they accumulate in the blood.

When the kidneys fail, the whole body suffers. As the organs' ability to filter the blood begins to fail, an excessive amount of protein is often excreted through the urine. The body then lacks this protein. In addition, edemas (retained water) can form in the legs or lungs. In many cases, an insufficient amount of toxins is also removed. These then collect in the blood and can damage other organs. Problems in the digestive tract can appear and even lead to bleeding ulcers. The toxins can even disturb the rhythm of the heart or lead to infection in the pericardium (heart sac). Nervous system disorders have also been observed.

According to estimates, the number of people worldwide suffering from chronic kidney failure and requiring dialysis treatment is rising at a rate of around six percent each year. This is primarily due to a longer life span, which increases the chance of kidney disease. In addition, the treatment of kidney patients in many developing countries is improving. The constantly increasing rates of high blood pressure and diabetes – the main causes of chronic kidney failure – also play a role.



Dialysis patients are all too familiar with the routine of their treatments: Go to the clinic, get weighed, have their temperature and blood pressure taken, get stuck with needles (unless the patient has a catheter access), have tubes connected from their access to the dialyzer and then sit in the chair until it is time to go home. While waiting, have you ever wondered how a dialysis machine works?

As "the machine man," I would like to take this opportunity to explain how your dialysis machine works by answering some of the most frequently asked questions.

What does my dialysis machine do?

The dialysis machine mixes and monitors the dialysate. Dialysate is the fluid that helps remove the unwanted waste products from your blood. It also helps get your electrolytes and minerals to their proper levels in your body. The machine also monitors the flow of your blood while it is outside of your body. You may hear an alarm go off from time to time. This is how the machine lets us know that something needs to be checked.

What are those plastic jugs sitting in front of my machine?

The plastic jugs hold the liquids used to mix the dialysate. The machine mixes the dialysate, which is made up of an acidified solution, bicarbonate and purified water. The acidified solution contains electrolytes and minerals. You may hear it referred to as "acid." The other solution is bicarbonate or bicarb, which is like baking soda. Both are mixed inside the machine with purified water. While you are dialyzing, dialysate and your blood flow through the dialyzer (but they never touch). Fresh dialysate from the machine enters your dialyzer throughout your treatment. Impurities are filtered out of your blood into the dialysate. Dialysate containing unwanted waste products and excess electrolytes leave the dialyzer and are washed down the drain.

How does my blood get in and out of my body?

Blood tubing carries your blood from your access to the dialyzer. The blood tubing is threaded through the blood pump. You'll see the blood pump turning in a circular motion. The pumping action of the blood pump pushes your blood through the dialyzer and back into your body.

What's in the syringe that's attached to my machine?

Blood tends to clot when it moves through the blood tubing. To prevent this the nurse will give you a drug called "heparin." Your doctor orders the amount of heparin you get at each treatment. That amount of heparin is drawn up into a syringe then placed on the machine into

the “heparin pump.” The heparin pump is programmed to release the right amount of heparin into your blood tubing during your treatment. The heparin prevents your blood from clotting.

How does the machine keep me safe?

One problem that may occur during dialysis is that air gets into the blood tubing. To prevent this from happening, blood tubing’s had two air traps built into them. One trap is before the dialyzer and the other is after it. These traps catch any air that may get into the system. If air does get past these traps an internal machine air sensor shuts down the blood pump and an alarm will sound. All blood flow is stopped until the air is removed.

Why are there so many alarms?

The machine continuously monitors the pressures created by your blood inside the blood tubing and dialyzer. It also monitors the blood flow, temperature and proper mixture of the dialysate. If any of these go out of range, the machine lets us know by sounding an alarm, blinking lights and shutting down blood or dialysate flow. It also lets us know if your blood pressure is too low or high. Oh yes, it also alarms when it’s time to go home.

Want to know more?

I realize that this may not answer all of your questions. That’s why I invite you to ask the bio-medical technician (machine person) at your dialysis center any questions you have. Your bio-medical technician will be happy to share any information with you. The more you know, the more comfortable you will be with your treatments.

What is dialysis?

Dialysis is a way to clean your blood if your kidneys are no longer working properly.

The kidneys act as filters for your body. They remove waste from the blood and get rid of it via your urine (wee). If your kidneys are not working properly, waste can build up in your blood.

There are 2 main types of dialysis:

1. hemodialysis
2. peritoneal dialysis

Hemodialysis treatment involves taking your blood from your body and pumping it through a dialysis machine for cleaning. This usually happens 3 days a week. Each treatment lasts for 4 to 5 hours. Peritoneal dialysis uses the lining in your abdomen (tummy) called the peritoneum to act as a natural filter for your blood. This treatment happens up to 4 times a day. Both hemodialysis and peritoneal dialysis are free in Australia.

When is dialysis needed?

Dialysis is most often needed because of kidney failure.

Acute kidney failure can sometimes happen over a short period of time (days or weeks). It can be the result of a serious illness or accident. Dialysis is sometimes a short-term treatment.

More commonly, kidney failure is the result of chronic kidney disease. This is where your kidney function gets worse over many years.

Dialysis usually starts when you find it hard to keep up with your normal life. This is when your kidneys are working at about 10% of how they should be working.

Dialysis treatment must be done for the rest of your life, unless you have a kidney transplant.

How does dialysis work?

Hemodialysis

During hemodialysis your blood goes through a special machine called a ‘dialyzer’. The machine removes waste and extra fluid from your blood before pumping it back into your body. You can do dialysis at a renal unit or in your home.

The blood leaves and then returns to your body through a needle, usually in your arm, neck, or leg.

Peritoneal dialysis

During peritoneal dialysis fluid is pumped into a space in your abdomen (tummy) called the peritoneal cavity. The fluid enters and leaves through a catheter. A catheter is a thin, soft tube, about 30cm long that stays in place all the time.

Waste from your blood moves into the fluid in your peritoneal cavity. It is then removed from your body.

Peritoneal dialysis can be done at home each day either:

- manually (continuous ambulatory peritoneal dialysis)
- by a machine (automated peritoneal dialysis)

Life on dialysis

Although starting dialysis is a life changing event, it is possible to still have an active life. However, this may be different to your life before dialysis.

The type of dialysis that is right for you will depend on:

- how you live your life
- your vision
- your dexterity
- whether you have a career
- where you live

Dialysis is an ongoing treatment. It's important that you don't miss a dialysis session.

Dialysis can often happen at home and overnight. Depending on your needs, some dialysis may be needed during the day.

This allows most people to continue to:

- be physically active
- maintain a balanced diet
- keep social engagements
- have intimate relationships

What is supportive care?

Supportive care is available to everyone with kidney failure.

Supportive care aims to help control the symptoms that you have so that you can enjoy a good quality of life.

A multidisciplinary care team will support you. They will give you support with:

- your medicines
- dietary advice
- symptom management such as pain, itch, and nausea
- deciding and planning for end-of-life care

Supportive care can also be an alternative to dialysis or kidney transplantation.

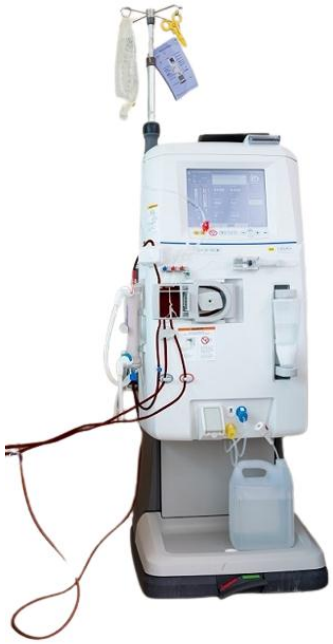
You might choose supportive care if you:

- don’t want dialysis treatment
- can’t have dialysis treatment
- stop dialysis treatment
- want to let life progress naturally

Introduction to Dialysis Machines

Abstract

This tutorial provides an introduction to dialysis machines and discusses FDA regulation and IEC 60601-1 certification, self-test and fault-indication capabilities, form-factor requirements, power-budget constraints, and other critical design considerations. It describes the main sub-functions of dialysis systems—including the extracorporeal, dialysate, and disinfection circuits—as well as component selection criteria for the display, data interface, sensing and mechanics, processing, and power.



Overview

Clinical dialysis machine

Dialysis machines are artificial kidneys that perform most, but not all, kidney functions for patients who have permanent or temporary renal failure. The machines use hemodialysis to cleanse the blood and balance its constituents. With this process, the patient's blood is circulated through the machine where it is filtered and balanced for electrolytes, pH, and fluid concentration before being returned to the patient. One common problem with renal failure is water retention, so it is common for the process to remove several pints of fluid from the patient's blood.

There are two basic classes of dialysis machines: clinical units, which are commonly cabinet-size machines operated by trained technicians; and home-use dialysis machines, which are smaller and sometimes portable.

Normally, patients with complete loss of kidney function would need to visit the clinic at least three times per week and spend about four hours connected to the machine. With home-use machines, patients have more flexibility in scheduling dialysis, and they can dialyze for longer periods and more frequently. Thus, home-use machines are growing in popularity because they offer greater convenience and better clinical outcomes.

FDA-Regulated Medical Equipment

Dialysis machines are medical equipment whose design and manufacture is regulated by the Food and Drug Administration (FDA). 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.

Given the time and expense required to achieve FDA approval, manufacturers must ensure the long-term availability of system components. Thus, it is important to select a supplier with a customer-oriented discontinuance policy to ensure that system components will be available for many years.

Medical customers rely on Maxim products because over the years we have carefully avoided discontinuing parts. We realize how devastating product discontinuance can be to a customer, so we work diligently to transfer some products to newer production lines, create wafer buffers, allow last-time purchases, or develop upgrade devices. Very few Maxim parts have ever been discontinued while demand still existed. Maxim's Discontinuance Policy is one of the most flexible among our peer supplier companies.

General Operation

Extracorporeal Circuit

The patient's blood is continuously pumped from an artery, a large vein, or a surgically modified vein to allow high blood flow rates. Its pressure is monitored both upstream and downs-tream from the peristaltic blood pump. Before the blood enters the dialyzer, heparin is added to prevent clotting. A syringe pump is used to deliver the heparin at a precisely controlled rate.

The blood then enters the dialyzer where it passes across a large-surface-area, semipermeable membrane with a dialysate solution on the other side. A pressure gradient is maintained across the membrane to ensure the proper flow of compounds out of and into the blood. After cleansing and balancing within the dialyzer, the blood is passed through an air trap to remove any air bubbles before it is returned to the patient. An air bubble sensor ensures that no air bubbles remain.

Blood-pressure, oxygen-saturation, and sometimes hematocrit levels (blood cell concentration) are monitored for proper operation of the machine and to ensure patient safety. For maximum effectiveness, fresh dialysate is continually pumped through the dialyzer during operation.

Dialysate Circuit

In clinical settings, dialysate is usually premixed to the proper concentration for direct use. In home units, to keep container size down, concentrated forms of dialysate are often used and diluted with sterilized water in the machine. Thus, home units must include water heaters, valves, pumps, and a variety of sensors to perform these extra steps. To lower power consumption in home units, the dialysate preparation process is often performed ahead of time, separately from dialysis.

Both types of machines include capabilities to add a bicarbonate buffer solution to the dialysate. This sub-circuit comprises additional pumps, valves, and sensors.

Disinfection Circuit

After the dialysis procedure, the machine must be cleansed and sterilized. Provisions are made in the plumbing to close the circuit into a loop and run saline and/or sterilized water through the system to flush away all impurities.

Special Requirements of Home Units

For general convenience, home systems are smaller and sometimes portable. Since they require the additional function of dialysate preparation, the need for small, compact design is increased over clinical machines.

Low power draw is also important in home dialysis units. Earlier systems often required home rewiring to allow more than the typical 15A capability of a 110V AC branch circuit. Today, low-power design can eliminate the need for these costly modifications.

The disinfection cycle at the end of therapy is also a power-hungry process. To accomplish the heating required in a reasonable amount of time, batteries or ultra-capacitors are included to provide short-term high-power capability to supplement line power as needed. When line-power usage drops below the 15A limit, the batteries or ultra-capacitors are recharged.