

Dialysis Device Concepts and Modalities

I. Hemodialysis Overview

Hemodialysis is a medical treatment for renal failure delivered by a dialysis device that removes toxins from the blood through an artificial kidney, called a dialyzer. The dialysis device consists of mechanisms that monitors and controls pressures, flow rates, temperatures and conductivity of the patient's blood and/or dialysate solution. Dialysis machines are used in home, in-center, and acute-care settings.

II. Hemodialysis Therapies

Hemodialysis Therapies include various forms of treatments for chronic and acute renal failure, including:

- Hemodialysis (HD) – dialysis by diffusion performed primarily for chronic and acute renal failure
- Hemofiltration (HF) – dialysis by convection performed primarily for acute renal failure
- Hemodiafiltration (HDF) - dialysis by diffusion and convection for chronic and acute renal failure
- Continuous veno-venous hemofiltration (CVVH) – CRRT HF
- Continuous veno-venous hemodialysis (CVVHD) – CRRT HD
- Continuous veno-venous hemodiafiltration (CVVHDF) – CRRT HDF
- Slow continuous ultrafiltration (SCUF)

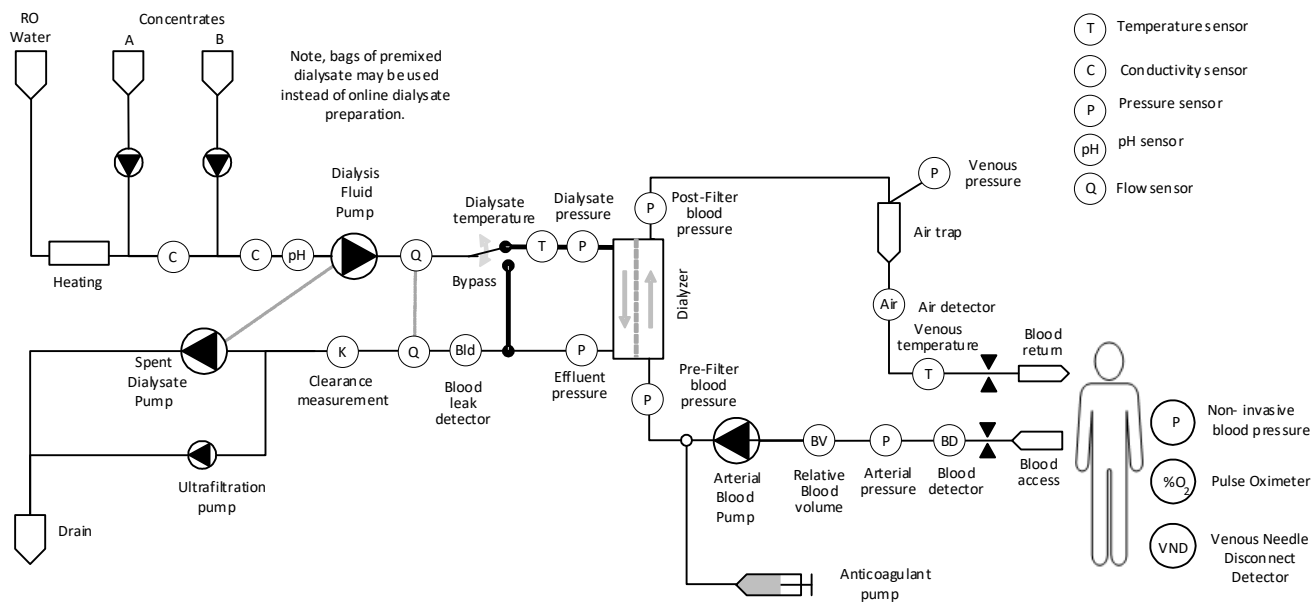
III. Chronic dialysis devices

Chronic renal failure is a condition of the kidney that cannot be cured or reversed. Once End-stage renal disease (ESRD) is reached, medical treatment is required to replace the function of the kidney. The two treatment options for the ESRD patient are dialysis and transplantation. Dialysis options include Hemodialysis and Peritoneal Dialysis. Hemodialysis is the process of filtering the blood through a device using an artificial membrane, or dialyzer, and a solute called dialysate.

The dialysate delivery system prepares and delivers dialysis to the dialyzer. Some systems provide dialysate for a single patient's treatment, such as a pre-bagged solution, or have a capacity to supply several treatment stations simultaneously, such as a central delivery system. In a central delivery system, bicarbonate from a mixing tank and acid from a storage tank are transferred to an overhead holding tank. Gravity feeds the solutions to a solution distribution system which then feeds the patient care area through a series of pipes to each machine station.

Peritoneal dialysis uses the peritoneum in the abdomen as the membrane to exchange fluid and dissolved substances with the blood. It removes excess fluid, corrects electrolyte problems, and removes toxins in person's with kidney failure opting for this dialysis modality. Support for peritoneal dialysis is not included in this standard.

Figure 1 – Typical Chronic Dialysis Machine



IV. Chronic Dialysis Environments

Hemodialysis is provided to the chronic renal failure patient in various environments which may include:

i. In-Center

An “In-Center” Hemodialysis service may be performed in either a free-standing facility or hospital-based out-patient specialty care units. The “In-Center” facility uses the chronic dialysis device to treat more than one ESRD patient throughout a given day. The Hemodialysis treatment is performed by patient care staff including nurses and trained technicians.

ii. Self-care

A “Self-Care” Hemodialysis session is performed in a specialized area of the “In-Center” facility. The “Self-Care” unit allows for certain activities to be performed by the patient, with readily available patient care staff to support the self-care patient. The dialysis device is again used to treat more than one patient throughout a given day.

iii. Nursing homes (SNF – Skilled nursing facilities)

“Nursing Home” chronic care is structured to support the elderly or special care hemodialysis patient. The dialysis treatment may be performed in the patient room or in a specialized location where the patient temporarily transported.

iv. Home Hemodialysis

Home Hemodialysis is an alternative mode of care of the ESRD patient and has been safely performed since the 1960s. Home Hemodialysis programs train patients and their partners in the chronic dialysis facility for approximately six-to-eight weeks. The patient home is also evaluated for the required space for managing the treatment equipment and supplies such as the dialysis machine, water treatment equipment, disposable supplies, dialyzers, tubing and solutions. Home Hemodialysis is recently evolving to be a more common option for the ESRD patient as a result of the health benefits. Home Hemodialysis options include:

- Nocturnal Home Hemodialysis (NHHd) – Patient dialyzes at slower flow rates while they sleep. Remote Monitoring activities may occur through virtual partner monitoring services.
- Conventional Home Hemodialysis – Patient dialyzes at home with same frequency (3 or 4 times per week) and treatment hours (3 to 4 hours per treatment) as “In-Center” Hemodialysis patient.
- Short Daily Dialysis – Home Hemodialysis patients perform daily dialysis treatments (6 or 7 times per week) for shorter treatment time (2 – 3 hours per treatment).

In-Center and Self-Care treatments are provided in a chronic dialysis facility where the dialysis devices are deployed in a treatment area designed and equipped to provide proper and safe care as well as privacy and comfort to the patient. The placement of the dialysis device is called a station and must provide sufficient space to accommodate emergency equipment and staff to move freely to reach the patient. The nursing station is located in an area which provides adequate visual surveillance of the patients during the dialysis treatments. Therefore, the number of devices deployed is dependent on the size of the facility, the patient population and the patient care staffing. The dialysis device commonly moves from one station in the facility to another. A facility will acquire extra devices to support removal of one device from the patient care area for maintenance and replacing the removed device with a spare.

Water treatment in a chronic care facility must be adequate in volume and pressure. Water used for dialysis is analyzed for bacteriological quality at least monthly. Chemical quality is measured at least quarterly and treated as necessary to maintain a continuous supply at acceptable levels. Water used to prepare dialysate must not contain concentrations of elements or organisms in excess of AAMI (Association for the Advancement of Medical Instrumentation) specified limits.

Skilled Nursing Facilities which perform treatments in the patient's private room require similar set-up as the Home Hemodialysis sessions. This environment provides a dedicated device to the patient as well as a stand-alone water treatment device.

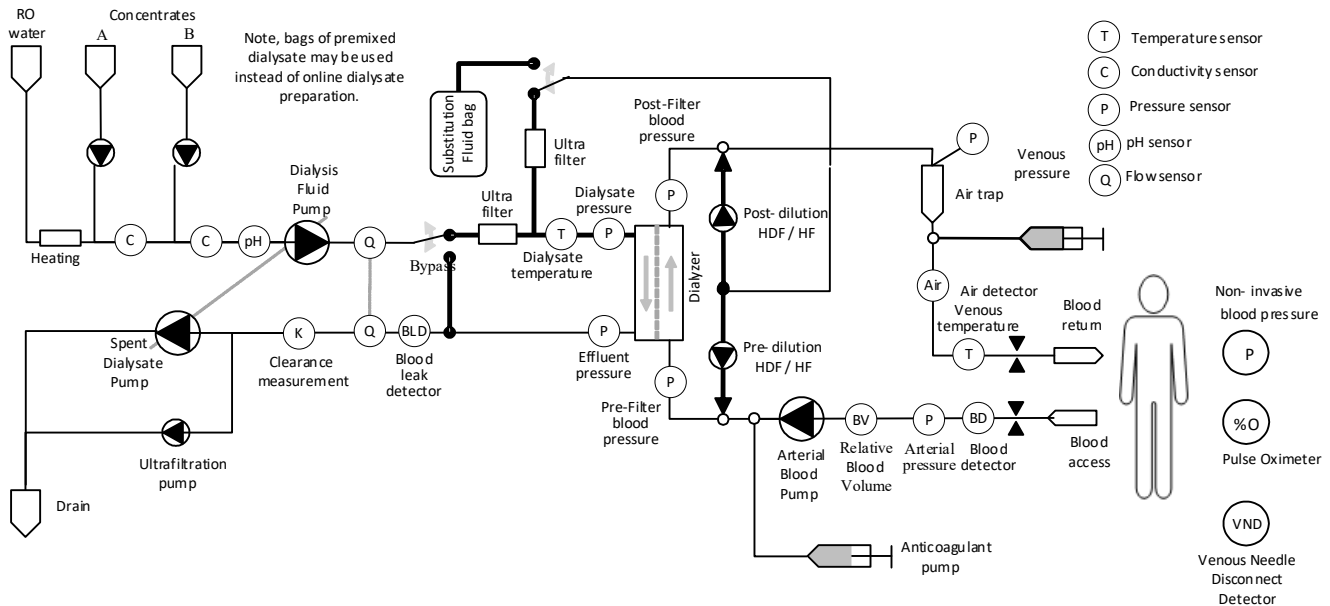
V. Acute dialysis devices

Acute Renal Failure (ARF) occurs in approximately 3 out of every 10,000 people admitted to the hospital. There are multiple indirect causes of Acute Renal Failure (ARF) such as trauma from an accident, burns or surgery; alcohol abuse, crush injury including direct injury to the kidney, infections, urinary tract obstructions, malignant hypertension, and disorders associated with childbirth, such as postpartum renal failure.

Generally, kidneys recover from acute renal failure, depending on the cause. However, an incident of acute renal failure can be 'the final blow' of a long-term debilitating condition such as alcoholism or hypertension (high blood pressure). This may result in the patient requiring chronic treatment, which are, regularly scheduled, life-long dialysis therapy for the kidneys that will never regain function effectively.

When patients with ARF are hospitalized, one method that waste products are removed is through a process called Continuous Renal Replacement Therapy (CRRT). With CRRT, the body's blood is pumped through a filter called a dialyzer, which cleanses the blood with a dialysate solution containing electrolytes such as potassium, sodium and calcium. Excess fluid is also removed from the body. CRRT takes over the functions of the kidneys until the kidneys recover from the injury, trauma, or other cause for their temporary failure.

Figure 2 – Typical Acute Dialysis Machine



VI. Acute Dialysis Environments

Hemodialysis is provided to the acute renal failure patient in various hospital care units which may include:

- ICU
- MCU
- In-Center (w/Acute Patient)

CRRT (continuous renal replacement therapy) is generally done in an Intensive Care Unit (ICU) of a hospital where a nurse is in constant attendance and every aspect of the therapy, including blood pressure, urine output and blood samples are monitored.

VII. Filter (Dialyzer) Overview

The typical dialyzer, or filter, is a bundle of hollow tubes (approx. 5,000 – 15,000) made of a biocompatible, semi-permeable membranes. The inner diameter of each tube is about 200 microns with a membrane thickness of 7 – 45 microns. While the dialysate bathes the outside of the tubes, the blood travels the length of the tube. As it does, metabolic waste and excess fluid are transferred from the blood to the dialysate due to the mechanisms of diffusion and osmosis.

VIII. Device Logical Architecture

i. The Blood Circuit:

Hemodialysis involves accessing either a vein or an artery to remove blood from the patient, anticoagulating the blood, passing the blood through a filtration membrane and returning the blood to the patient via a large vein. Often, a femoral vein and artery or the bilateral femoral veins are used. The arteriovenous set-up uses the patient's own blood pressure to move the blood. Since a major artery is cannulated, the patient must be monitored for ischemia in the accessed extremity. A pump is used to move the blood through the system and an air detector must be on line.

The blood circuit is comprised of three components; the Blood Tubing Set, the Blood Pump, and the Dialyzer.

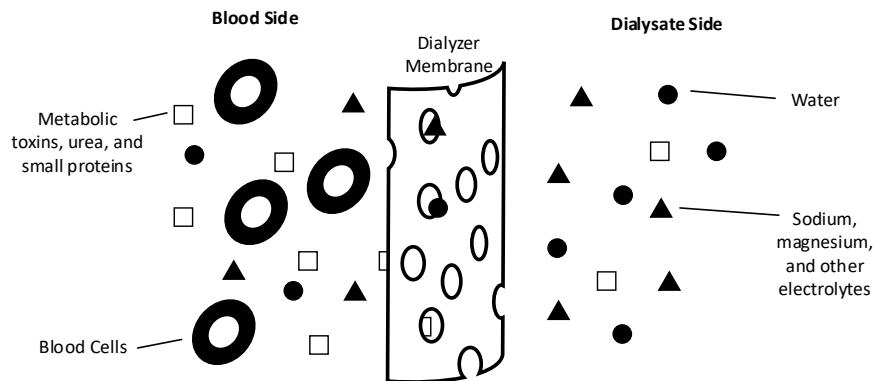
The blood is drawn into the blood tubing set through the patient's access, either a catheter or through a needle inserted into a vascular access. The blood tubing set can be divided into two primary components, the tubing from the patient

to the dialyzer, or the arterial section, and the tubing from the dialyzer to the patient, or the venous section. Usually, each section has a drip chamber where the blood flows and air rises. The blood drains from the drip chamber into the blood tube and continues to flow to the dialyzer. The arterial and venous pressures are monitored with the dialysis device providing an audible alarm notification and an automated stop of the blood pump if the pressure values go outside the defined ranges. The blood returns to the patient through the venous section where a level detector monitors the blood level. If too much air is present, the blood level drops below a pre-defined level, an audible alarm sounds, the pump stops, and the blood tubing is clamped to prevent air from being introduced to the patient.

Rotating rollers that compress the blood tubing at the blood pump sweep the blood forward at a defined rate. The rotation speed and diameter of the blood tubing determine the Blood Flow Rate. The standard range for the Blood Flow Rate is between 200 and 500 ml/min in adults. Inability to process the blood at the defined blood flow rate may be the result of patient access complications and cause outlying values for the arterial and/or venous pressures, thus stopping the pump rotation.

The dialyzer, or artificial kidney, has two compartments separated by a semi-permeable membrane. The blood flows through the one side and a solution called dialysate circulates on the other side. The movement of the blood and dialysate through the dialyzer follows three processes called diffusion, osmosis and ultrafiltration. When two liquids of different concentration are separated by a semi-permeable membrane, the particles from the higher concentration move to the lower concentration until the two solutions are of equal concentration. This process is called diffusion. In dialysis, diffusion is performed by the dialysate flowing through the dialyzer while the blood's waste products move toward it until a large amount of waste products are cleansed from the blood. Excess fluid is also removed from the blood through a similar process called osmosis. Ultrafiltration is the method in which pressure is applied on the dialysate side to remove fluid from the blood. Adjusting the pressure controls how much fluid is removed during the dialysis treatment.

Figure 3 – Diffusion across dialyzer membrane



An anticoagulant maybe introduced to the blood extracted from the patient to reduce the probability of clotting prior to entry to the dialyzer.

Blood Circuit Components:

- **Blood pump** – In addition to maintaining a preset speed, the blood pump is closely tied to the machines safety systems. In the case of a dialysate alarm, the blood pump is stopped to keep blood from coming in contact with questionable dialysate. Pressure readings associated with the arterial and venous needle will also stop the blood pump.
- **Air detection** – There is a blood chamber in the tubing set just before the blood is returned to the patient. A level of blood is maintained, and the blood pump is stopped should the level drop too low. This is to protect the patient from a potential bolus of air being returned through the tubing. There is also a system that monitors for air bubbles in the blood tubing just prior to the venous needle return. An alarm in either of these systems will cause the blood pump to stop and the venous tubing clamp to close.
- **Venous tubing clamp** – As a last defense mechanism, a clamp is positioned on the tubing just prior to its return to the patient. Most alarms that cause the blood pump to stop also cause the clamp to close. The default condition of this clamp is closed, in order to protect in the case of control system failures

- Optional: Anticoagulation to help keep dialyzer from clogging.

ii. The Hydraulic Circuit:

The primary components of the hydraulic circuitry are the blending and provision of the dialysate to the dialyzer, monitoring the dialysate quality, and the control and monitoring of the ultrafiltration from the patient. The hydraulic circuitry can be separated into four sub-systems which include 1) water preparation system, 2) proportioning system, 3) ultrafiltration controller, and 4) monitors and detectors. Note that the need for the water preparation and proportioning systems can be eliminated when pre-mixed dialysate is used.

The water preparation system receives the treated water. The water is heated to an appropriate temperature (34 – 39°C) by a heater and de-aerated. The water is then transported to the proportioning system.

The initial step in the proportioning system is to mix the dialysate concentrate with the treated water, then pump the solution to the dialyzer. Electrical conductivity is used to monitor the appropriate proportioning of the concentrate and water. Dialysate at the acceptable conductivity level is pumped to the dialyzer. If the conductivity is out of range, the dialysate is pumped to the bypass loop. This requires separate and independent sensors monitoring and controlling the proportioning units.

The dialysate passes through a volume-balancing device before it goes to the dialyzer. This device monitors and controls the rate of ultrafiltration. Another component of the ultrafiltration controller is the dialysate pressure controller. The transmembrane pressure is the pressure on the dialyzer membrane, or the sum of pressure on the blood and the dialysate. This pressure controls the ultrafiltration rate. The volume to be removed from the patient during the dialysis treatment is determined by the patient's weight.

When the UF pump is part of the circuit during the dialysis treatment, the effluent pump is regulated to make the flow rate equal to the dialysate flow rate. This balance is a very important part of the UF system as it guarantees that the only fluid removed from the patient is equal to what is pulled by the UF pump.

In clinical practice, the term ultrafiltration is often used by clinicians to describe the net ultrafiltration (volume of fluid removed from the patient) during a dialysis session. IEC 60601-2-16 states that “In HF or HDF treatment, ULTRAFILTRATION must not be confused with the reduction in the PATIENT's weight (NET FLUID REMOVAL)”. In order to avoid confusion, NET UF and TOTAL must be clearly defined. NET UF is the change in patient weight at the end of a treatment. For example, if NET UF is 0, the patient should weigh the same at the end of the treatment as they did at the beginning. For an HD treatment with no infusion and a NET UF of 0, the TOTAL UF would be the amount of fluid put on the patient as a result of the priming of the cartridge. For HF and HDF therapies, the TOTAL UF would also include the amount of substitution fluid infused to the patient during the treatment.

$$\text{Total UF Rate} = \text{Net UF Rate} + \text{Substitution Fluid Rate} + \text{Anticoagulant Rate}$$

For example, a treatment that has a NET UF Rate of 150 ml/hr, a Substitution Fluid Rate of 50 ml/hr, and no Anticoagulant, would have a Total UF Rate of 200 ml/hr.

Hydraulic Circuit Components:

- Temperature control – The temperature of the dialysate has a direct effect on the blood temperature. Above 43 °C will lead to the death of red blood cells. Too low, and the patient will be chilled. The setpoint is often kept slightly below body temperature. This causes the blood vessels to constrict, which keeps the blood pressure from dropping as excess fluid is removed from the blood stream.
- Concentration control – Typically, acute dialysis involves premixed dialysate in bags. Chronic dialysis mixes the dialysate as needed using concentrate and treated water. This allows the system to vary some of the electrolyte constituents during a treatment. Sodium is sometimes elevated at the beginning of a treatment to expedite fluid removal from tissue into the blood stream. It can then be reduced toward the end to avoid having the patient leave the treatment thirsty.

- Dialysate (pump) – Careful control of dialysate pressure is necessary to provide controlled removal of excess fluid and to avoid back filtration of dialysate constituents into the blood.
- Ultrafiltrate (pump) – This is also an important component of dialysate pressure and, ultimately, is responsible for the actual removal of excess fluid from the blood stream.
- Effluent (pump) – To maintain dialysate pressure, the effluent pump must match the dialysate pump.
- Safety: In addition to carefully monitoring dialysate pressures, conductivity, and temperature, the effluent dialysate is monitored for the presence of blood.

IX. Device Component Overview

- i. Categorization of the primary dialysis device components include:
 - Pumps
 - Valves
 - Ultrafiltration controller mechanism
 - Detector systems (e.g. air, blood leaks)
 - Heat exchangers
 - Other safety features
- ii. Dialysis device features include variables with pre-set, allowable ranges and default values. These features encompass the following:
 - Flow rates that each pump can deliver; i.e. blood pump, heparin pump,
 - Arterial pressure
 - Venous pressure
 - Transmembrane pressure
 - Ultrafiltration rate
 - Dialysate temperature
 - Dialysate conductivity
- iii. Alarm notifications are safety features included in the dialysis device. The alarm features may be visual and/or audible notifiers. Alarm status may result in automated operations by the dialysis device. Common device alarms include:
 - Arterial pressure alarm
 - Venous pressure alarm
 - Transmembrane pressure alarm
 - Blood pressure alarm
 - Blood leak alarm
 - Blood pump alarm
 - Level (or air) detector alarm
 - Dialysate temperature alarm
 - Conductivity alarm
- iv. A dialysis device also incorporates operational features that provide fail-safe responses and associated alarm actions. These features may include the following:
 - Disinfection, cleaning and/or reprocessing methods
 - Dialysis conductivity and temperature monitors
 - pH sensor
 - Ultrafiltration controller
 - Air and blood leak detectors
 - Power failure fail-safe design
- v. Dialysis devices use various dialysate options. These include dialysate prepared on-line or pre-mixed. The dialysate concentrate may also be wet or dry solutions.
- vi. Different accessory systems may be incorporated into the dialysis device; such as patient data card, network interface, non-invasive blood pressure monitor, etc.

- vii. Dialysis devices have varying tubing systems, from the complex multi-pump option to unique configurations specific to the device.
- viii. Prescription profiling features, such as sodium, ultrafiltration and dialysate, may be used to automatically adjust the treatment parameters during the Hemodialysis session.

X. Typical Device Operations

i. Start-up

Start-up of a dialysis device consists of the following steps:

1. Operator turns the power switch to the “On” position.
2. The control unit performs an initialization test to check the system electronics.
3. When the initialization test is successfully completed, the device is ready for operation.

ii. Operating Modes

In the course of performing a treatment, the device passes through four normal operating modes: Setup, Standby, Run, and End. Following is a description of each of these operating modes.

iii. Setup Mode

The dialysis device is ready to enter the Setup mode after successful completion of the initialization test. Setup mode enables the operator to dress the machine with the therapy set (e.g. dialyzer and blood line), prepare and connect needed solutions, and prime the set.

The operator performs the following sequential actions:

1. Optionally identifies the patient to be treated (new patient or same patient as in the previous treatment)
2. Optionally, enter on the machine an identification of the patient and the current weight for the patient.
3. Choose the therapy desired.
4. Position the desired set onto the dialysis device.
5. Prepare solutions; connect fluid bags and priming solution bag.
6. If the syringe is used, install the syringe.
7. Prime the set. Priming takes about 5-10 minutes, depending on factors like the therapy/set selected and the priming strategy adopted by the machine and/or the operator
8. Perform the prime test. The dialysis device performs multiple self-tests lasting some minutes (depending on the therapy selected). During the prime test, the following are tested: pumps, blood leak detector, all pressure sensors and sensors, return pressure port/sensor; return line clamp, pumps, both pinch valves, air bubble detector, and switch.
9. If needed, adjust flow rates and syringe pump settings. Set the patient fluid removal rate, if desired.
10. Start the therapy.

iv. Standby Mode

The dialysis device automatically goes into Standby mode after the operator completes all Setup procedures.

The operator can now carry out all the operation needed to connect the patient to the primed set and re-adjust the machine settings.

v. Run Mode

The dialysis device enters Run mode after the operator connects the patient to the primed set starts the dialysis. During Run mode, all appropriate alarms are enabled. Run mode allows the operator to perform the following actions:

1. Administer the treatment to the patient. The fluid pumps operate according to default settings or those entered by the operator.
2. Adjust flow rates, syringe pump settings, and the patient fluid removal rate, as needed.
3. Change the syringe as needed.
4. Change fluid bags at any time through the Change Bags/Containers function.
5. Do any of the following:
View instruction screens, perform a periodic self-test, enter or modify the value for patient weight, reset (re-normalize) the sensitivity of the blood leak detector.
6. View/download history data.
7. Temporarily stop the patient’s treatment.

vi. End Mode

The dialysis device enters End mode when the operator stops the dialysis.

End mode allows the operator to perform the following procedures:

1. *Change Set* - Remove the present set, with or without returning blood to the patient, and load a new set.
2. *End Treatment* - Terminate the present treatment, with or without returning blood to the patient; view/download history data if desired.
3. *Recirculate* - Return blood to the patient; temporarily disconnect patient and recirculate saline through the blood lines. When ready, re-prime the set; reconnect patient and resume treatment.

