Selection and Use of Machine, Dialyzer and Dialysis Fluid for Maintenance
Hemodialysis

The HD machine is used to deliver dialysis in uremic patients. It essentially pumps the dialysate as well as the patient’s blood through a dialyzer. The blood and dialysate are separated from each other by a semipermeable membrane, permitting solute and water transfer as governed by the laws of physics. The operational system of the HD machine represents a complex array of detectors, controllers, monitors, and safety devices to ensure a safe and effective operation. This integrated system allows the operator to control the blood and the dialysate circuits as well as monitor important variables such as ultrafiltration (UF) rate, solute removal, dialysate composition, and circuit pressures.

The recommendations for the selection and use of HD machines and dialyzer units are discussed under five sections as follows:
1. HD machine specifications
2. Dialysis delivery system
3. Safety of dialysis delivery system
4. Dialyzer specifications and
5. Dialysis fluid specifications.

Hemodialysis Machine Specifications

Recommendation for requirements of the hemodialysis machine

We recommend that all equipment used in the delivery and monitoring of HD should have conformance certification by an appropriate authority and are approved to ensure compliance with the relevant safety standards for electrical equipment in clinical use. A new or a refurbished HD machine with a specification of 230 V, 50 Hz, and 15 A earthed supply may be used to deliver dialysis, which fulfills all the mandatory requirements of HD machine, as mentioned below.

We suggest that the optional features of machines be available wherever possible.

Mandatory

- Blood pump to achieve a unidirectional flow of up to 500 ml/min
- Heparin pump
- Arterial line and venous line pressure monitors
- Functional air bubble detector
- Mixing proportion unit with bicarbonate dialysis facility, with the rate of dialysate delivery from 300 to 500 ml/min or more
- Conductivity meter
- Functional blood leak detector
- Dialysate temperature regulator that has a range of temperature from 35°C to 39°C
- UF control
- Safety devices: Functioning alarms and venous blood clamp

Optional

- Online blood volume monitor
- Online urea clearance
- Sodium profiling of dialysate
- Single-needle dialysis facility
- Hemodiafiltration (HDF)

Description

Blood pump consists of two or more spring-loaded rollers and a stator supporting the blood tubing. One of the rollers should occlude the tube at all times to prevent uncontrolled flow in the circuit as well as back leak. The pump should be able to achieve a unidirectional blood flow of up to 500 ml/min, though most of the time, the range used for dialysis delivery is 0 to 400 ml/min.

Modern dialysis machines achieve the desired UF based on flow sensor systems (inflow and outflow) that measure and control the pre- and post-dialyzer flow rates (the difference is the UF rate). By keeping the pumps out of sequence, the dialysate keeps flowing continuously.

The other method is by matching the dialysate inflow and outflow rates using a balancing chamber and controlling valves (a separate pump is available for UF). This is called volumetric controlled UF.

The heparin pump is mostly a syringe pump, although a roller pump may be used. Heparin is infused downstream into the positive-pressure segment of the blood circuit (post-blood pump, pre-dialyzer). If heparin pump is located pre-pump in the negative-pressure segment, the risk of air embolism is enhanced. Air leak detector is an important safety device in HD machine. Infusion of >50 ml of air into the circulation is often lethal, unless rescue measures are applied immediately. It is placed distally in the venous blood line and monitors for and prevents air embolus. The air generally enters the extracorporeal circuit in case of a leak on the negative pressure side and presents as foam with microbubbles. Ultrasound-based sensors are preferred to optical detectors as they have a better sensitivity in detecting air foam, typically detecting air bubbles of 50–100 µl. On detection of air foam, it should induce an audible alarm, clamp the venous line, and stop the blood pump.

Arterial pressure monitors

Arterial pressure monitor measures the pressure between the blood access and the blood pump using a strain gauge sensor. The pressure is negative between the access and the blood pump, but achieves a high-positive range post-blood pump. The pressure transducer signal is amplified and converted to an electrical signal. The alarms may indicate
patient disconnection, separation of blood tubing, or obstruction/kink in the blood circuit. The normal pressure reading in this segment of the blood circuit is negative (subatmospheric).

**Venous pressure monitor**

The venous pressure may build up owing to resistance to venous return anywhere between the venous drip chamber and the venous needle (together with the access pressure). Venous pressure monitors normally read positive pressures. Out-of-range pressures trigger clamping of the blood line, stopping of the blood pump, and activation of appropriate alarms, with shutting off of the venous return.

**Blood leak monitor or detector**

It allows detection of blood leaks and prevention of dialysate contamination by blood downstream of the dialyzer. The monitor (infrared or photodetector) has a “flow-through” configuration (sensor is at the bottom, and therefore, air bubbles do not interfere). Red blood cells present in the dialysate scatter light. The monitor operates by looking for loss of transparency when light is passed through the dialysate column (postdialyzer). Loss of sensitivity may occur owing to biofilm, deposits, or clots. The sensitivity of monitor is 0.25–0.35 mL of blood per liter of dialysate. The monitor triggers visual and audible alarms, immediately deactivating blood pump.

**Dialysis Delivery System**

The dialysis delivery system supplies dialysate to the dialyzer, maintaining proper concentration, temperature, pressures, and flow in the dialysate circuit. The delivery system also monitors various functions related to both dialysate and blood compartments, such as dialysate pressure, UF rate, blood leak into the dialysate, changes in the pressure of the blood circuit, air or air foam in the blood, and other parameters.

**Recommendation for dialysate delivery system**

- We recommend the use of a single-patient, single-pass system or a central delivery system.

**Description**

Dialysate is produced by mixing two solutions namely acid concentrate and bicarbonate concentrate in proportion suitable for dialysis. This is done by two methods: (1) fixed ratio and (2) servo controlled (variable rate). In the fixed-ratio proportioning systems, cylinders of known volumes are used to proportion the dialysate concentrate and treated water in exact amounts and a series of valves control the cyclic filling and emptying of each cylinder. All available fixed-ratio systems incorporate an electrical conductivity sensor to monitor the mixture and to initiate action (e.g., bypass and alarms) if the conductivity of the dialysate is not within preset limits. The servo-controlled systems use a control sensor to monitor the conductivity of the dialysate and regulate the flow of the dialysate concentrate within the specified conductivity limits. The flow can be regulated using variable-speed pumps, often roller pumps, variable-orifice valves, or other mechanisms. The servo systems also employ a second conductivity sensor to monitor the mixture and to initiate action (e.g., bypass and alarms), if conductivity is not within the specified limits.

Single-patient, single-pass systems discharge dialysate to drain after one passage through the dialyzer and are used to deliver dialysate to one patient at a time. Dialysate is produced from proportioning dialysate concentrate and purified water. Normally, single-patient systems, also called “negative pressure systems,” maintain a subatmospheric (negative) dialysate pressure in order to accomplish fluid removal. The central delivery system maintains a single “central dialysate proportioner” which prepares dialysate for a number of bedside consoles or bedside stations.

Both the single-patient/single-pass systems and the multipatient/single-pass systems require a continuous supply of purified water and a continuous source of concentrate. Spent (discarded) dialysate is discarded to the drain after it has made a single pass through the dialyzer.

- We recommend that a check on machine configuration and concentrates being used be made prior to machine preparation, especially in units using multiple concentrates
- We suggest that dialysate cans or lines in the case of a (CDS) Central Distribution System be color coded to match the concentrate connector color coding on the machine (usually red for acid concentrate and blue for bicarbonate.)

**Conductivity meter**

The conductivity meter must be made of high-quality corrosion-resistant material. The ionic constituents of the dialysate determine its conductivity. Conductivity monitoring ensures proper water-to-concentrate ratio of the dialysate. The unit of conductivity is millisiemens (mS) per centimeter. The normal range is 12 to 16 mS/cm; high and low alarm settings should be within ±5% of the set value. External readjustment of the alarm settings by machine operators can lead to extremely risky and dangerous situations. Conductivity can be affected by temperature or acetate:chloride or chloride-to-bicarbonate ratio.

1. We recommend that a machine with a narrow conductivity range be chosen
2. We suggest that machines with individual conductivity probes for acid concentrate, bicarbonate, and final dialysate conductivity are preferred
3. We recommend that conductivity range should be preset and not be adjustable by users
4. We recommend periodic confirmation of conductivity and dialysate sodium by laboratory analysis of the dialysate
5. We recommend that the conductivity be calibrated if a
>5 mEq/L variation in sodium from the set value and
the laboratory value exists.

Bacterial-retentive filters

We suggest that these be included between the water inlet
and the machine. Most machines are provided with these
filters by the manufacturer.

Ultrafilters

In case of HDF, a sterile pyrogen-free substitution fluid
is achieved by the addition of at least two filters in the
path of dialysate to generate substitution fluid online.
In the first step, the dialysate is made to pass through a
filter (ultrafilter-1) to achieve ultra-pure quality of the
dialysate. In the second step, a part of ultra-pure dialysate
used for HD is diverted to a separate line which passes
through another filter (ultrafilter-2) to ensure that sterile
and pyrogen-free substitution fluid is achieved, which is
delivered into the blood line of the circuit, either before
(predilution) or after (postdilution) the dialyzer. These
ultrafilters exclude particles of size >30–40 kDa and
remove other smaller sized pyrogens by adsorption. The
ultrafilters may be reused for a number of treatment
hours specified by the manufacturers after an adequate
disinfection process after each session of HDF. An
additional filter (ultrafilter-3) may also be used (optional)
in the substitution fluid line, which may be of single-
use, to ensure requisite quality of the substitution fluid
generated online.

The integrity of the ultrafilters is checked by a cyclic
pressure-holding test, and we recommend that this test
should not be skipped.

Recommendations for maintenance of hemodialysis
machines

• We suggest that machines should be replaced after
between 5 and 10 years’ service or after completing
between 15,000 and 40,000 h of use for HD,
depending on an assessment of machine condition and
specifications provided by the manufacturer
• We suggest that routine preventive maintenance of the
machines should be done at an interval of 3 months
or as specified by the manufacturer by the qualified
engineers
• In addition, we suggest that calibration of all machine
functions be done at least annually. These designated
technicians may be located in-house or may be stationed
outside. Records of routine servicing of machines
should be maintained
• To perform HDF, we recommend the use of a machine
which is capable and specified for HDF, which is
able of generating the substitution fluid online and
delivering sterile, pyrogen-free substitution fluids
• There must be a provision for emergency electric
power supply for lifesaving equipment in case of power
failure. An UPS backup of up to 30 min is desirable for
each machine in case of power failure.

Recommendations for disinfection of the hemodialysis
machine

• We recommend that machines be disinfected by heat or
chemical methods or a combination of the two
• We recommend heat disinfection on a daily basis and
chemical disinfection once a week or after an episode
of blood leak into the dialysate or if surveillance
cultures show high colony-forming units (CFU) and/or
derendotoxin levels
• We suggest that heat disinfection be carried out after
each shift, if feasible
• Sodium hypochlorite, citrosteril, or peracetic acid may
be used for the disinfection of HD machines
• We recommend routine cleaning of the machines on
daily basis. It should be accompanied by rinsing of
machine with purified water and acid such as acetic
acid or citric acid or peracetic acid.

Description

Disinfection of the HD machine is mandatory to prevent
the transmission of infections between patients. The
disinfection of the machine may be performed using either
bleach or citrosteril (a combination of citric, malic, and
lactic acids). Disinfection with bleach is recommended
after each blood leak into the dialysate or at a regular
interval of at least 1 week. Disinfection with citrosteril may
be performed after each dialysis session or at least once
daily. With standard disinfectant fitted to the rear of the
machine, bleach must be administered via the pickup stick
(the concentrate connectors) at the front of the machine.
The disinfection procedure is performed by the designated
personnel in the dialysis unit. Gloves and protective glasses
must be worn during the procedure by the operator. The
steps of disinfection of the machines should follow the
guidelines recommended by the manufacturer of the
individual machines.

Heat disinfection

It is performed by circulating water heated to 85°C in
internal fluid pathways of the machine, with an average
length of heat exposure being 30 min. It is critical to allow
proper cooling down of machine before patient use. The
efficiency of the procedure is enhanced by using heated
citric acid instead of water.

Formaldehyde disinfection

It is a highly effective disinfectant which kills all organisms
including mycobacterial species, spores, and viruses. A 4%
formaldehyde concentration is used, and the frequency of
disinfection with formaldehyde is determined by policy
decision of the dialysis unit. Formaldehyde is left in the
machine overnight for effective disinfection. Formaldehyde
gas is irritant and hence, protection gloves must be worn while using the chemical for disinfection. The residual formaldehyde can cause serious patient injury, hence residual testing is mandatory using indicative test strips, which have a sensitivity of 1 ppm. Schiff reagent can also be used, which can detect a concentration of up to 5 ppm.

**Peracetic acid disinfection**

Stable mixture of peracetic acid, hydrogen peroxide, and acetic acid (Renalin) may be used for disinfection. It has an advantage of not leaving any toxic residue. A contact time of 11 h is needed for satisfactory disinfection.

Regardless of the type of cleaning or disinfectant used, a thorough water rinse must be done before adding chemicals and after disinfection. Safety tests must be done after the rinse to confirm the absence of chemical used for disinfection.

**Safety of Dialysis Delivery System**

Patient safety is the most important goal that should never be compromised during HD.

**Alarms**

Various “alarms” built into the HD system can signal the impending or ongoing system malfunction.

**Recommendations for hemodialysis machine alarm system**

- Alarms should never be taken lightly and disarming of alarms should never be practiced
- The range and sensitivity of the alarms should be internally set as default and the 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 m, and also easily audible (70 dB)
- All blood alarms (air detector, arterial monitor, venous monitor, blood leak, transmembrane pressure, and blood pump torque) should automatically shut off the blood pump, clamp the venous return line, and stop UF, thus isolating the patient
- Equipment should be programmed to automatically switch to “safe mode,” thus essentially isolating the patient from the HD machine.

**Monitoring and evaluation of hemodialysis machine**

We recommend that monitoring and evaluation of the HD machine performance at periodic interval should be done to enhance safety and reduce the level of risk of patient injury due to incidents related to malfunction and/or improper use of dialysis delivery systems. The actual numerical reading of each test or the result of a test should be recorded after each test and initials of the person performing the test should be noted.

**Recommendations for evaluation and monitoring on a daily basis**

- Conductivity of the final dialysate being delivered to the dialyzer should be checked before every treatment.

According to the manufacturers’ instructions, the conductivity may be checked with an independent reference meter which is known to be properly calibrated. Conductivity must be within the manufacturer’s stated specifics. In case this is not possible due to the nonavailability of the independent reference meter, a periodic measurement of the dialysate electrolyte composition may be done to confirm that the accuracy of the final dialysis fluid composition is in expected range.

- We recommend confirming machine electrolyte values with the laboratory weekly and calibrating the conductivity and proportioning system when the values differ from the display by >5% [Box 1].

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**Box 1: Dos and Don’ts in monitoring dialysis**

- When used, the pH of bicarbonate dialysate should also be confirmed periodically. If the pH is below 6.5 or above 7.5, dialysis should not be started, even when conductivity is within acceptable limits. The pH can be checked with a pH meter. Temperature should also be within the manufacturer’s specifications. The temperature may be checked with an independent reference meter or with a reference thermometer
- Absence of residual germicide should be verified on all delivery systems connected to a single water treatment “loop” before dialysis begins. Such testing must be performed with an assay known to detect the minimum standard level
- We recommend that the self-test which includes a test of proper functioning of the air/foam detector should be performed before dialysis is initiated. This test should be a direct test of function of the alarm, causing interruption of the blood pump and actuation of the blood line clamp, either by introducing air into the venous-level detector or by removing the tubing so that air is sensed by the detector as recommended by the device manufacturer
- The blood leak detector must be checked for proper armed status according to the method recommended by the manufacturer
- All other alarms must be tested according to the manufacturer’s instructions for use before every treatment including low- and high-conductivity alarm, low- and high-temperature alarm, dialysate pressure alarm, and water pressure alarm. The documentation of that testing should be performed. If the particular delivery system is equipped with a “self-alarm check” mode, it is important that the user understands that, most often, it is a check of the electronic circuitry, and not a confirmation of some of the vital functions of specific alarms
- Observation of dialysate flow should be made while the machine is in a “dialyzing” mode. Absence of dialysate flow should be confirmed when the machine is in “bypass” mode actuated by both manual setting of the machine to bypass and via any of the alarm functions that will cause the machine to enter a bypass mode
- The automatic “self-test” should be performed if this facility is available prior to each HD treatment to confirm proper performance of operative and protective functions of the machine and should never be bypassed
- Do not initiate HD, if the final proportioned dialysate does not conform to the proper chemical concentration (i.e., incorrect conductivity, incorrect pH, and particulate contamination).
Recommendation for once-monthly evaluation and monitoring

We recommend that the following tests of dialysate be carried out on at least a monthly basis:

- Microbiological monitoring: Water for production of dialysate and actual dialysate proportioned and exiting the dialyzer should be monitored for bacterial levels on no less than a monthly basis. Microbiological monitoring should be performed to establish the ongoing validation of proper disinfection protocols. The sampling should be done at the termination of dialysis at the point where the dialysate exits the dialyzer. Results for total microbial counts should not exceed 1000 CFU/ml.
- Assessing trends: Pertinent information, i.e., bacterial levels, conductivity, and pH readings, should be logged on a chart across a page so that readings can be examined and compared over an extended period of time. This tool makes it possible to compare the current readings to those taken during the past several days/weeks/months.
- In case HDF is performed in the unit, a stringent microbial and endotoxin monitoring of the dialysate and substitution fluid generated online should be performed, to ensure ultrapure, sterile, and pyrogen-free quality of the fluid, which is defined as dialysate with bacterial level of <0.1 CFU/ml and endotoxin level of <0.03 IU/ml (endotoxin units per milliliter [EU/ml]) and <1 in 10⁶ CFU/ml and 0.03 (EU/ml), respectively. This may be monitored at an interval of 1 month. We recommend that in case endotoxin or bacteriological levels are above the recommended level, more frequent monitoring is carried out.
- We recommend that persistently elevated bacterial counts or endotoxin levels should prompt a search for the source of infection within the machine hydraulics, the water treatment and distribution system, and the concentrate cans or preparation system.
- In case of a CDS, the bicarbonate line is often likely to be the source of contamination and should be more frequently checked.
- We recommend that a thorough disinfection of the contaminated site be carried out once identified and subsequent negative cultures be obtained and recorded.
- Should the source of infection not be identified, we recommend that the entire system including the machine be taken offline and disinfected and only recommissioned after the documentation of negative cultures.

Preventive measures

It is desirable to take measures to prevent HD malfunction so that safety of the HD therapy is ensured.

Recommendations for preventive measures

- All electrical and other equipment used in the facility should be maintained free of defects to prevent potential hazard to the patients or personnel.
- Each manufacturer provides comprehensive directions pertaining to preventative maintenance requirements for the entire dialysis delivery system and these should be followed.
- A master schedule of all preventative maintenance should be developed. Such a master schedule will list every machine by serial number (or other identifier) and identify when preventative maintenance is required.
- Dialysis units should have an established and agreed-upon plan of action for repair and troubleshooting of HD machines.
- Use of mobile phones should be banned or kept to a strict minimum in proximity to dialysis machines as their signals have been shown to disturb the calibration of machines.

Description:

1. Maintenance: We recommend strict adherence to the schedules and procedures established for preventative maintenance. Maximum time intervals either in number of hours of operation of the system or in calendar days between preventative maintenance procedures should also be specified.

2. Recordkeeping: We recommend a history record of all repairs and maintenance for each piece of equipment be maintained in a separate file. This file describes all technical operations performed on the equipment, parts used, actions taken, and tests performed to assure proper functioning before and after maintenance/repair. The dates and the personnel performing maintenance/repair should also be documented. A log of all maintenance and repair work for each piece of equipment should be kept at the front of the “history file.” This log includes a very brief description of the maintenance/repair (e.g., “300 h maintenance” or “adjusted conductivity” or “repaired inoperable blood pump”), date, and person performing action. Such a log provides a trend analysis of any problems related to the delivery system, as well as a quick confirmation of maintenance being performed according to the schedule.

3. Repair and troubleshooting: Despite proper maintenance of the machines, rarely, the entire machine or a component of the system may fail. Although these failures cannot be foreseen and occur very infrequently, when they do occur, it is important that the patient is not put at risk. To counteract these events, dialysis units should have an established and agreed-upon plan of action. This plan should be approved by the medical director and communicated to all facility staff. Repair and maintenance on a delivery system should be
performed by “qualified personnel.” The definition of “qualified personnel” may differ from facility to facility, and that definition is the final responsibility of the medical director.

**Quality assurance for dialysis delivery systems**

It consists of several components such as policies and procedures, staff training and continuing education, and monitoring and evaluation.

**Recommendations for quality assurance for dialysis delivery systems**

- We recommend that each dialysis unit should have “policies and procedures” for dialysis delivery system, which should be developed as per the need, implemented, and evaluated periodically.
- Staff training and education should include operation and proper use and monitoring of dialysis delivery system.

**Description**

**Policies and procedures**

We recommend that each unit develop a quality assurance program for policies and procedures which address safe and effective operation of the delivery system.

Policies and procedures must include the following factors:
1. Basic technical operation
2. Setup and use of equipment and related components
3. Safety checks
4. Preventative maintenance
5. Cleaning and disinfection
6. Troubleshooting and repair
7. Record keeping and
8. Patient monitoring.

**Staff training and continuing education**

We recommend that the responsibilities for operation and use of the delivery system including preventative maintenance, troubleshooting and repairs, daily or pretreatment safety and other system checks, and recordkeeping should be clearly defined. Each responsibility should stem from a specific policy or procedure. Staff training should be a well-defined and organized program.

**Dialyzer (Filter) and Ancillary Device Specifications**

**Dialyzer**

The hollow fiber dialyzer forms the central component of dialysis deliver system, wherein the actual process of transfer of solutes and water occurs across a semi-permeable membrane. A large array of dialyzers is available for clinical use with several permutations and combinations based on biocompatibility, flux, and surface area of the dialyzer. Patients may have specific needs and may require change in the dialyzer specifications. Hence, dialyzers with specifications other than that generally used in the dialysis unit may also be routinely stocked or should be made available at a short notice, when the need arises.

**Recommendations for dialyzer use in hemodialysis**

- Dialyzers and ancillary devices such as blood tubings, used for HD, are classified as medical devices and should carry conformance certificate by the appropriate authority.
- We recommend that biocompatible, synthetic (e.g., polysulfone, polyacrylonitrile, and polymethylmethacrylate), or modified cellulose membrane (e.g., cellulose acetate) should be preferred over unmodified cellulose membranes (e.g., cuprophane). Cuprophane membranes should be used only when other more biocompatible membranes are not available or patient is intolerant to all others.
- We suggest the use of either low-flux or high-flux biocompatible membrane for regular HD.
- We suggest that high-flux dialyzers may be preferred over low-flux dialyzers to provide HD under specific situations such as (1) incident patients, who have lower serum albumin concentrations (<40 g/L) or have diabetes mellitus and (2) prevalent patients, who have been on HD for >4 years or have dialysis-related amyloidosis.
- We recommend that high-flux dialyzer should be used only in facilities where a very high quality of dialysate is ensured at all times.
- We recommend that surface area of the dialyzers should be chosen based on the required dialysis dose and the body size of the patient.
- We recommend that large surface area dialyzers should be avoided in pediatric patients and adult patients with small body size.
- An allergic reaction to a specific dialyzer is rarely encountered in some patients. In such situation, the particular dialyzer should be avoided and this should be specifically written in bold letters on the dialysis folder of the patient to prevent its inadvertent use.
- We suggest that the use of dialyzers sterilized with ethylene oxide (EtO) should be avoided.
- Angiotensin-converting enzyme (ACE) inhibitors should be avoided in patients, when AN 69 membrane is used for HD, for fear of precipitation of allergic reaction.

**Ancillary devices**

**The blood tubing**

The blood tubings serve as a conduit through which blood is circulated from the patient through the dialyzer and back to the patient. The blood tubing consists of two segments:
The blood tubing sets have several components which serve specific purposes and are described below:

**The connectors**
These include (a) patient connectors, which connect the blood tubing to the vascular access of the patient and they may be simple luer or luer locking connectors; (b) dialyzer connectors, which connect the arterial and venous blood tubings to the dialyzer; and (c) other connectors attached to the blood tubings to heparin line, pressure monitoring line, solution administration lines, etc.

**The access ports (injection sites)**
They comprise a sleeve around the blood tubing or a small similar port attached to a component of blood tubing such as bubble trap chamber. A needle can easily be inserted into these ports either to draw the blood sample or to administer the medications or fluids.

**The bubble traps (drip chamber)**
These components are used to remove any air that would have inadvertently entered the blood circuit. The venous drip chamber serves several functions, as follows: (a) air bubbles contained in the incoming blood flow are forced by their buoyancy and reduction in velocity to rise to the air space of the chamber and the blood flow out of the chamber is thereby degassed; (b) pressure in the circuit can be measured via a pressure monitor tube communicating through the chamber top into the air space; (c) air and/or foam is also prevented from exiting the chamber by an ultrasonic air/foam detector attached to the outside of the drip chamber or the outside of the tubing just below the venous chamber. The detector stops the blood pump and causes a clamp to close below the venous chamber. The pump occlusion diameter is manifested by the tubing being sucked or drawn forward with each rotation of the roller.

**Transducer protector**
The purpose of these devices is to isolate the interior of the blood tubing and protect the pressure sensor unit of the dialysis delivery system from blood contamination. The transducer protector device lets the air to pass through while preventing blood from passing through.

We recommend that the transducer protector should not be reused, but specifically discarded at the time of disconnection of the patient from the machine.

**Dialysis Fluid Specifications**
Dialysate, or dialysis fluid, is a nonsterile aqueous solution with an electrolyte composition near that of normal extracellular fluid. Its electrolyte composition is designed to correct the metabolic imbalance that occurs as a result of uremia. Dialysate concentrates are manufactured commercially in liquid or powder form. The chemicals present in the dialysate have access, via the dialyzer, to the bloodstream of patients undergoing dialysis. Hence, the proper concentration of all of these chemicals as well as the quality of the concentrate and the water used to dilute the concentrate is critical.

**Recommendations for dialysis fluid use in hemodialysis**

- Commercially produced concentrates are classified as medical devices and should be approved for clinical use by appropriate authority
- We recommend that the dialysate should contain bicarbonate as the buffer, and acetate as a buffer may be used only when bicarbonate-based dialysate is not available
- We recommend that the final diluted dialysate should be analyzed every 6 months, with every new batch of dialysate and after each major servicing/repair of dialysis machine
- Water used to prepare the dialysate must have a bacteriological colony count of <100/mL
- Electrolyte content of dialysate includes sodium, potassium, chloride, magnesium, calcium, glucose (optional), and bicarbonate (or acetate) as a buffer
- The concentration of HD solutions should be such that after dilution to the stated volume, the final concentrations of the ions expressed as mmol/L are usually in the following ranges: sodium 135–145, potassium 0–4, calcium 1.0–2.0, magnesium 0.25–1.0,
bicarbonate (acetate equivalent of bicarbonate) 32–40, and chloride 95–110
• We recommend that sodium concentration may be adjusted to levels outside the range of 135–140 mmol/L by HD machines with variable sodium capabilities, only when prescribed by physician in charge
• We recommend that bacteriological analysis of the dialysate shall be carried out at least monthly, preferably every 15 days
• We recommend that the colony count in dialysate samples collected at the termination of dialysis (a) in a single-pass system or (b) in a re-circulating single-pass system at the periphery of the recirculating chamber containing the dialyzer shall be <200 CFU/mL
• We suggest that dialysate containing glucose at 100–200 mg/dL concentration is preferable to glucose-free solution

Description
1. Producing bicarbonate dialysate requires mixing a bicarbonate concentrate (part B) and acid concentrate (part A) with purified water. The acid concentrate contains either lactic acid or acetic acid and all divalent cations such as Ca and Mg.
2. We suggest that the substitution of acetic acid with citric acid as an acidifying agent in the acid concentrate is optional. Citric acid part A is commercially available as powder form. Proposed advantages of citric acid are: (a) more effective correction of chronic metabolic acidosis, (b) lower requirement of anticoagulation resulting from citrate’s anticoagulant effect, and c) improved membrane life.
3. The sodium concentration of dialysate varies from 135 to 140 mmol/L in routine HD. However, a wide range (130–155 mmol/L) of sodium concentration in dialysis fluid may be achieved in modern HD machine. Sodium concentration may vary in certain circumstances depending on serum sodium level, cardiovascular instability, and need for higher UF. An option of variable dialysate sodium concentration during a single HD session (sodium modeling) is available in most modern machines, which may be used in patients with cardiovascular instability who need larger UF.
4. Glucose-free dialysate is associated with an increased risk of hypoglycemia, especially in diabetics, cachectic, and septic patients, and increased catabolism. We recommend isoglycemic (100 mg/dL) or mildly hyperglycemic (200 mg/dL) dialysis fluid for HD.
5. Routine use of acetate as a buffer should be avoided. However, in an emergency situation when bicarbonate buffer is not available, acetate buffer may be used for HD. The conversion of acetate to bicarbonate is limited, especially in patients with low muscle mass. Acetate dialysis is associated with increased risk of hypotension, cardiac dysfunction, hypoxemia, nausea, headache, and fatigue.
6. A standard potassium concentrate of 2 mmol/L is recommended for routine HD to keep predialysis serum potassium below 6 mmol/L. However, dialysate potassium concentration varying from 0 to 4 may be used depending on the patient need.
7. We suggest that potassium concentrate of 0 may be avoided, which can result in rapid decline in serum potassium concentration which can induce arrhythmias. When the dialysis fluid of potassium is other than standard one, a label indicating the concentration should be displayed.
8. The physician in charge shall be responsible for arranging for the analysis of the dialysate. Its chemical composition shall be clearly labeled. The results of analysis, bearing the name of the center and officer analyzing the dialysate, should be made available on request as and when required.

Recommendations for storing and mixing dialysis concentrates
• Store and dispense dialysate concentrates as though they were drugs
• Ensure that all personnel in your unit are aware of the types of dialysate concentrates available, even if you currently use only one type
• Develop a policy, management, and storage system that will effectively control the mixing and dispensing of all concentrates. Storing concentrates according to type, composition, and proportioning ratios should reduce the risk of mismatching concentrates. Prohibit access to storage areas and allow only authorized, specially trained personnel to mix and dispense concentrates
• Doublecheck and record concentrate formulas on the patient’s record. Consider a procedure for countersigning patient and storage records
• Do not dispense concentrates from large containers into smaller ones without a “keyed” dispensing system
• If concentrates are mixed in a large mixing container and then transferred to smaller jugs, each small jug should be labeled with the following information: (a) concentrate A and concentrate B, (b) proportioning ratio, (c) time of mixing and dispensing the solution, (d) any additives inserted in the concentrate (potassium and calcium), and (e) initials of person performing the procedure

We recommend color coding the concentrate jugs to match the concentrate connectors on the machine, i.e., red for acid concentrate and blue for bicarbonate
• Follow a validated procedure for rinsing, sanitization, and periodic disinfection of large mixing tank and individual concentrate containers
• Always dispose concentrates remaining from the previous treatment. Do not pour the remaining concentrate into another container or use in the next treatment. Replace empty or partially full containers with full ones
Whenever possible, standardize the equipment so that only one bicarbonate concentrate system is used.

**Description**

1. Bicarbonate dialysis requires mixing two concentrates, acid and bicarbonate, with treated water. Bicarbonate concentrate is typically supplied in powder form, to be mixed with treated water immediately preceding dialysis. Acid concentrate, containing an electrolyte composition similar to that of acetate concentrates but at a lower pH, is supplied in liquid or powder form. The availability of acid/bicarbonate concentrates with varying ionic contents and proportioning ratios increases the probability of an inappropriate dialysate. The problem is further compounded by the availability of two types of HD machines with different proportioning systems: fixed ratio and servo controlled (variable rate).

2. We recommend that the bicarbonate concentrate should be prepared first and dispensed. The bicarbonate should not be allowed to stand in concentrate preparation machines.

3. Risks and hazards related to dialysate: Approximately 50% of patient complications related to dialysis concentrate are related to the quality of water used for preparing dialysate and the concentrate when delivered from the manufacturer. The remaining 50% are related to user error or machine malfunctions.

4. We recommend that the concentrate-preparing machines should be disinfected twice daily before starting and after the final shift and bacterial counts of these machines checked and monitored in tandem with the water and dialysate.

Briefly, the problems related to manufacturers include the following:

- a) Minimal bacterial growth in liquid bicarbonate concentrate
- b) Actual electrolyte content of the concentrate is different than described on the label
- c) Foreign matter in liquid bicarbonate concentrate
- d) High levels of aluminum contaminating acetate concentrate.

Incidents related to user error, or machine malfunction include:

- a) Improper sodium concentrations due to miscalibration of or improper proportioning by the dialysis delivery systems
- b) Use of wrong concentrates or improper mixing of concentrates due to staff misreading labels
- c) Bacterial problems related to improper disinfection of storage containers or use of water containing excess bacteria.