

Chapter 10

Nipro Online Hemodiafiltration System: Surdial™ -X

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Abstract The Surdial-X, manufactured by Nipro, is a dialysis machine that can be equipped with one, two, or three pumps. In its HDF configuration, the machine permits double needle online HDF, in pre and post dilution, as well as single needle online HDF in pre and post dilution. All therapies can be carried out with different ultrafiltration, bicarbonate and sodium profiles. A 15 inch touch screen display allows straightforward operations, properly assisting users with full-text guidance. The Surdial-X comes standard with two innovative techniques: Clean Treatment Start (CTS) and Dialysate Infusion Function (DIF). This last one permits the use of the typical online functions even without using the HDF circuit, extending their benefits also to regular HD treatments.

Keywords Clean treatment start (CTS) • Dialysate infusion function (DIF) • Disinfection • Online hemodiafiltration • Predilution • Postdilution • Substitution fluid • Transmembrane pressure

Introduction

The Surdial-X, manufactured by Nipro, is a dialysis machine that can be equipped with one, two, or three pumps. In its HDF configuration, the machine permits double needle online HDF, in pre and post dilution, as well as single needle online HDF in pre and post dilution. All therapies can be carried out with different ultrafiltration, bicarbonate and sodium profiles. A 15 inch touch screen display allows straightforward operations, properly assisting users with full-text guidance. The Surdial-X comes standard with two innovative techniques: Clean Treatment Start (CTS) and

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Fig. 10.1 Dialysis machine



Dialysate Infusion Function (DIF) (see Fig. 10.1). This last one permits the use of the typical online functions even without using the HDF circuit, extending their benefits also to regular HD treatments.

Water Treatment System Required

The water treatment system for hemodialysis and hemodiafiltration shall be designed on knowledge of the feed water characteristics. This system should ensure a water quality at the dialysis machine inlet complying to applicable national standards, as well as the international ISO 13959 standard (Water for haemodialysis and related

therapies). Concentrates must meet the requirements of ISO 13958 (Concentrates for haemodialysis and related therapies), and the produced dialysis fluid those of the ISO 11663 standard (Quality of dialysis fluid for haemodialysis and related therapies).

Short Description and Outline of the HDF Machine

The Surdial-X is a machine used for the treatment of patients with acute or chronic renal failure. In its HDF configuration, the machine has a dedicated substitution pump, assuring the correct fluid flow through a specific bloodline for HDF. To grant the appropriate purity of the dialysate fluid, the machine relies on two endotoxin retention filters (cut filters). The dialysis fluid will pass through the first filter just after its preparation and subsequently through a second filter just prior to infusion into the bloodline, as substituting fluid. The appropriate fluid balance is obtained with the action of two internal chambers. Technical features of the Surdial-X dialysis machine are summarized in Table 10.1.

HDF Prescription Modality

In the HDF settings, the Surdial-X permits double needle online HDF, in pre and post dilution, as well as single needle online HDF in pre and post dilution. In case of the single needle format, the machine must be configured with a third pump, specific for this treatment. All therapies can be carried out with different ultrafiltration, bicarbonate and sodium profiles. The substitution volume can be managed automatically or manually. In this last case, the operator just has to program the desired substitution volume and time.

HDF Modalities

Independent of the type of HDF treatment (pre or post dilution), a specific online screen in the interface permits to manage the online function menu, setting the target fluid replacement volume and rate, as well as the parameters for bolus injection, see Fig. 10.2. The auto-sub function prevents hemo-concentration and clotting: the machine changes the substitution fluid pump flow according to the blood pump flow, permitting automated fluid replacement.

Specificities of Disposables Required

The Surdial-X needs to be equipped with disposables for an accurate dialysis treatment, including blood tubing sets, ultrafilters and hemodialyzers.

Table 10.1 Technical features of the Surdial™-X dialysis machine

Technical features	Surdial™-X (Nipro)
Blood pump flow range (ml/min)	10–600 ml/min
Dialysate flow (ml/min)	100–800 ml/min
Dialysate flow selection mode	Yes (including link with blood flow)
Emergency button	Yes
Substitution mode: manual/automatic	Manual/automatic
Settable parameter(s) in volume control mode	0.00–720.0 L as substitution volume
Substitution fluid flow range	0, 10–500 mL/min
Electrolyte concentration adjustment	Yes, concentration of Na + Electrolyte for conductivity control (0.0, 3.0–20.0 mS/cm)
Substitution fluid delivery options	Postdilution, predilution
Online priming, rinsing, IV bolus	Yes
Stationary ultrafilters	Yes, 2 for HDF (CF-609 N)
Additional ultrafilter	Not needed
Integrity pressure test ultrafilter	Yes
Blood access monitoring	Yes (control to arterial and venous pressure)
Online clearance monitoring	Calculation through Kt/V dose finder
Blood volume monitoring (BVM)	Under development
Blood temperature monitoring	Not available
Other monitoring options	Blood pressure monitoring
Alarm and information signals	Yes, available as visual alarm (3 colors light indicator), audible alarm (five stage setting of sound intensity) and text messages on the touch screen interface
IT connectivity	Yes, export of data to external software with .XML or .HL7 files
Data transfer via patient card	Yes
Standard safety features	Venous pressure monitor, arterial pressure monitor, venous clamp, arterial clamp, blood leak detector, bubble detector, temperature monitor, conductivity monitor, blood pump monitor, UF monitor, TMP monitor, dialysate pressure monitor, close circuit test
Advanced safety features	Leakage sensor for hydraulic parts, leakage sensor for extracorporeal circuit, substitution port connection test
Touchscreen operation and ergonomic design	Yes
Special features	Clean treatment start, dialysate infusion function, single needle HDF in both pre and post dilution mode



Fig. 10.2 Snapshot screen I

The use of Surdial-X is not limited to Nipro dialyzers, which makes it a very flexible system. However, should the user prefer to couple the machine with Nipro's dialyzers, the offer includes two families of products: ELISIO™ and SUREFLUX™. The ELISIO™ is a synthetic, Polynephron™ based membrane. It is a membrane that can be used for all modern techniques like HF, HD and HDF, during which it gives good clearance levels of small, middle and high molecular weight molecules keeping the amount of albumin leaching within acceptable limits [1]. The SUREFLUX™ dialyzer has a natural based membrane made of cellulose triacetate, making it one of the preferred membranes for sensitive and allergic patients. The use of cellulose triacetate membranes has become increasingly important due to the rising numbers of patients having an allergic response against synthetic membranes [2–4].

All Nipro dialyzers are di(2-ethylhexyl)phthalate (DEHP) free and additionally bisphenol A (BPA) free. If BPA is present in the dialyzers, either in fiber and/or housing, it has been shown to leach from them [5]. BPA is a known endocrine disruptor, which is associated with increased prevalence of albumin leakage in urine [6] and cardiovascular complications [7] in humans.

Bloodlines are specifically designed for the Surdial-X, allowing functions like the machine-assisted insertion of the pump segments or the automatic selection of the treatment mode. The HDF treatments rely on specific bloodline components including tubes for the pre and post dilution. Nipro offers HDF lines for either standard or single needle treatments. The Nipro portfolio also includes endotoxins retention filters for ultra-pure dialysate fluid.

Additional Programs and Options

The Surdial-X comes standard with two innovative techniques: Clean Treatment Start (CTS) and Dialysate Infusion Function (DIF).

- Clean treatment Start (CTS): permits the patient connection to the dialysis machine without infusing the priming solution into the patient; moreover, there is no need for an external drain bag, because the Surdial-X itself is used as a drain port to safely discard the fluid present in the blood lines after the priming. This is beneficial to patients with high blood pressure or high weight gain in the intra-dialytic period, as well as to nurses (avoiding the use of drain bags and the risks related to possible contact with blood) and administrators (escaping the cost of drain bags and related waste management).
- Dialysate Infusion Function (DIF) is a Surdial-X feature that allows the use of the typical online functions (machine priming, bolus administration and patient reinfusion) even without using the HDF circuit. Consequently, the advantages and the benefits of these functions are extended also to regular HD treatments.

Furthermore, in addition to the standard functionalities, extra options can be added. A second screen snapshot is shown in Fig. 10.3.



Fig. 10.3 Snapshot screen II

Additional Monitoring Options

The Surdial-X can integrate an advanced system for Blood Pressure Monitoring (BPM). The system keeps monitored the blood pressure parameters of the patient (Systolic, Diasystolic, MAP, Pulse) at intervals that can be customized by the user. Furthermore, the patient himself can activate, by remote control, extra measurements in case of need.

BPM function permits to set alarm ranges for the above mentioned blood pressure parameters. In case the value of BPM goes out of a preset range, the system alarms and, thanks to an internal feed-back, treatment's Ultra Filtration Rate and Blood Flow turn into pre-set values automatically.

Cleaning and Disinfection

Before each online HDF treatment, the unit has to be heat-disinfected with citric acid, or a chemical disinfection with sodium hypochlorite has to be done. Concentrations of the disinfection solution are properly specified on the unit's instruction manual, as well as all important technicalities related to cleaning and disinfection. The compact design of the hydraulics of the Surdial-X permits an extremely limited disinfection time: for example, a minimum of 29 minutes is required for hot citric cycle in HD.

Risk Management System

The Surdial-X is classified as class IIb according to 93/42/EEC Medical Device Directive and is equipped with all necessary safety features required for the performance and patient security. Safety features include arterial/venous pressure monitoring, arterial/venous clamps, bubble and blood leakage detectors, temperature monitoring, conductivity monitoring. A blood pump monitor acts as a protective system in case of blood coagulation in the blood line, triggering an alarm to assure patient safety. An alarm buzzer and a three-color light indicator promptly inform the user in case of malfunctioning. The safety control can be limited up to once every 24 months; maintenance every 24 months.

Display of Settings and Connection to Hospital Information System

All the settings of the Surdial-X are visualized on the touch screen, showing all parameters related to the operating mode, treatment and reinfusion processes, cleaning and disinfection, management of alarms. Regarding the connection to hospital

information system, the Surdial-X has networking capability, permitting the transmission of treatment data from the machine to the network. Export of data to an external software can be done with .XML or .HL7 files.

Cost Assessment

In terms of costs, the Surdial-X in HDF configuration requires the presence of two cut filters to assure the needed purity of the dialysis fluid, as previously implied. Besides this, specific bloodlines for HDF are required when the machine is used in such modality. The online functionality, however, permits to avoid the use of external saline solution; on the Surdial-X this possibility is not reserved to HDF configuration, but also feasible on HD versions thanks to the standard DIF function. For these reasons, a specific cost analysis is recommendable on a case-by-case basis, according to the system's configuration and the treatments planned by the clinic.

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