Chapter 6
Dialog+: B. Braun Hemodiafiltration System

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Abstract B.Braun provides renal care with all modalities of dialysis for >23,000 patients in 24 countries. The hemodialysis system Dialog + was introduced to the market in 2003. It is available in different configurations, e.g. single-pump, double-pump and HDF-online. All machines are suitable for hospital and in-center dialysis.

In the HDF-online machine, the online production of ultra-clean dialysate for autopriming in hemodialysis and for substitution fluid in HF/HDF treatments is performed by a two-stage dialysis fluid filter system to ensure the ultra-pureness of the substitution solution.

Keywords Dialog • Dialyser inlet pressure • Disinfection • Online hemodiafiltration • Predilution • Postdilution • Substitution fluid • Transmembrane pressure

Introduction

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In the HDF-online machine, the online production of ultra-clean dialysate for autopriming in hemodialysis and for substitution fluid in HF/HDF treatments is performed by a two-stage dialysis fluid filter system to ensure the ultra-pureness of the substitution solution, see Fig. 6.1

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Fig. 6.1 Dialog+ HDF-machine

Water Treatment System

A water treatment system for hemodialysis 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 purified water from the RO system enters the machine via a pressure reducer. Degassing of the water is required to improve the treatment and is performed by a degassing pump and chamber. In parallel, the water is heated to a set temperature (usually 37 °C). The water is then collected in a tank ready to be mixed in the dialysate preparation system.

Processed water is mixed with bicarbonate and acid concentrate conductivity controlled. Bicarbonate powder or central concentrate supply can be used optionally. Substitution fluid is produced online from dialysis fluid. The fresh dialysis fluid passes the first ultrafilter and enters the dialysis circuit, whereas the substitution fluid passes a second ultrafilter before it reaches the patient. In HDF treatment mode, the substitution flow (Qs) is split from the dialysate flow (Qd). Thus the dialysate effectively reaching the dialyser is reduced. This is compensated by automatically setting the dialysate flow to 600 ml/min in case HDF is activated, but can be changed according to the physician's prescription.

Fluid balance is ensured by the balance chamber of the machine, consisting of two chambers separated by a flexible membrane allowing to be filled from one side, while an identical volume is emptied from the other side.

The membrane has a magnetic sensor determining the exact membrane position and thereby controlling the dialyzing fluid flow, thus ensuring continuity in the flow of the dialysate. Ultrafiltration removal is carried out by the UF pump which bypasses the balancing chambers.

Technical features of the Dialog+ dialysis machine are summarized in Table 6.1.

HDF Prescription Modality (Manual/Automatic)

Treatment time, net ultrafiltration (UF) and blood flow rate are usually prescribed parameters.

The machine principle is based on volume control, which means that either substitution rate/min or total substitution target volume can be set. The filtration fraction (FF) is calculated and displayed as the ratio between the total UF rate (net UF plus substitution flow rate) and the blood flow rate. Any parameter change immediately adapts the ratio according to the new settings. Individual alarm limits, which can be set in the system configuration mode, monitor the FF within the allowed alarm limit ranges.

Table 6.1 Technical features of the dialog + dialysis machine

Technical features	Dialog+ (B. Braun)
Blood pump flow range (ml/min)	50–600 ml/min
Dialysate flow (ml/min)	300–800 ml/min
Dialysate flow selection mode	Flow profiles in addition to manual setting (free and predefined)
Emergency button	No full automatic button, necessary functions available on main screen
Substitution mode: manual/automatic	Manual setting
Settable parameter(s) in volume control mode	Substitution flow rate (ml/min); substitution volume (L); display of filtration fraction (%) with configurable alarm and warning limits
Substitution fluid flow range	20–400 ml/min
Electrolyte concentration adjustment	Profiles in additions to manual setting
Substitution fluid delivery options	Predilution, postdilution
Online priming, rinsing, IV bolus	Yes
Stationary ultrafilters	Yes, 2, Diacap Ultra
Additional ultrafilter	No additional filter in disposable
Integrity pressure test ultrafilter	Yes
Blood access monitoring	Arterial and venous pressure
Online clearance monitoring	Yes (Adimea)
Blood volume monitoring (BVM)	Not available
Blood temperature monitoring	Not available. Dialysing temperature profiles available
Other monitoring options	Blood pressure measurement (ABPM), Kt/V-monitoring based on measurement of removed uremic substances (Adimea), monitoring of clotting via dialyser inlet pressure
Alarm and information signals	Acoustical and optical alarms and warnings, help function – text display
IT connectivity	Unidirectional (BSL, bed side link), or bidirectional (Nexadia) data transfer and monitoring system between dialysis machine and IT equipment
Data transfer via patient card	Yes
Standard safety features	Complying to international standards
Advanced safety features	Warning for ratio blood flow versus UF rate (FF), dynamic arterial and venous pressure window
Touchscreen operation and ergonomic design	Yes
Special features	Biologic RR comfort: biofeedback system for reduction of hypotensive episodes

HDF Modalities

The Dialog+ system offers the possibility to run HDF treatments either in pre- or post-dilution mode. A change of modes during the treatment is possible but requires a blood pump stop, manual handling and an additional blood tubing accessory for the predilution mode. Screen snapshots are shown in Figs. 6.2 and 6.3.

Specificities of Disposables Required

Hemodiafilters: It is essential that the choice of the dialyser should match the high ultrafiltration volumes of HDF treatment. Therefore a large surface area and a high UF-coefficient (KUF) are needed. High-flux dialyser are recommended in order to keep the transmembrane pressure (TMP) within the allowed range (depending on the substitution flow rate). Since high TMP pressures are common in HDF, a filter with the lowest loss of albumin per session is a preferred choice.

Blood tubing set: B.Braun offers a blood tubing set (HDF-online tubing kit) especially for HDF-online treatments. Standard blood tubing sets together with an additional substitution line can alternatively be used to perform HDF-online treatments.

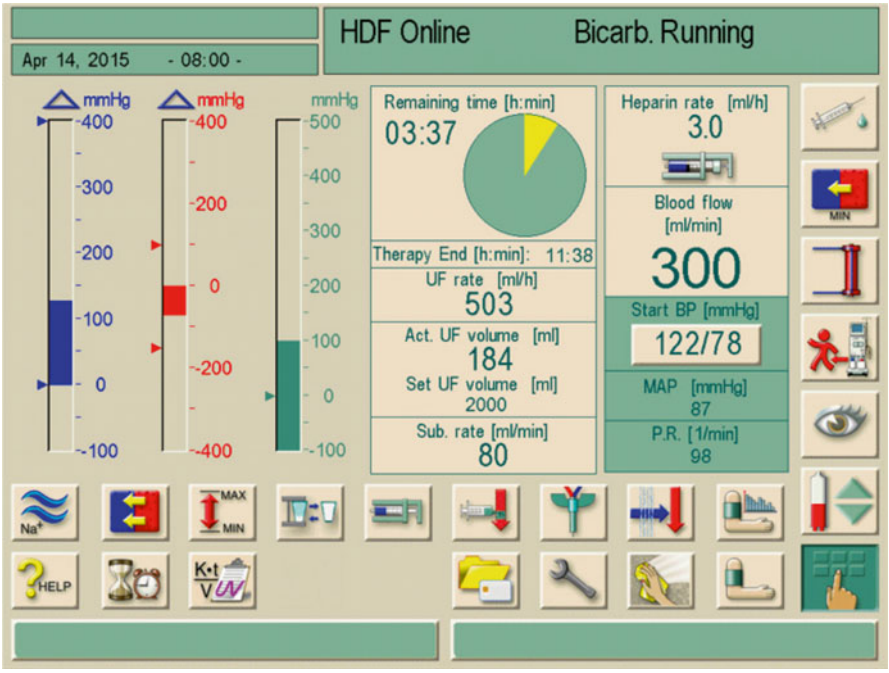

Fig. 6.2 Snapshot screen I

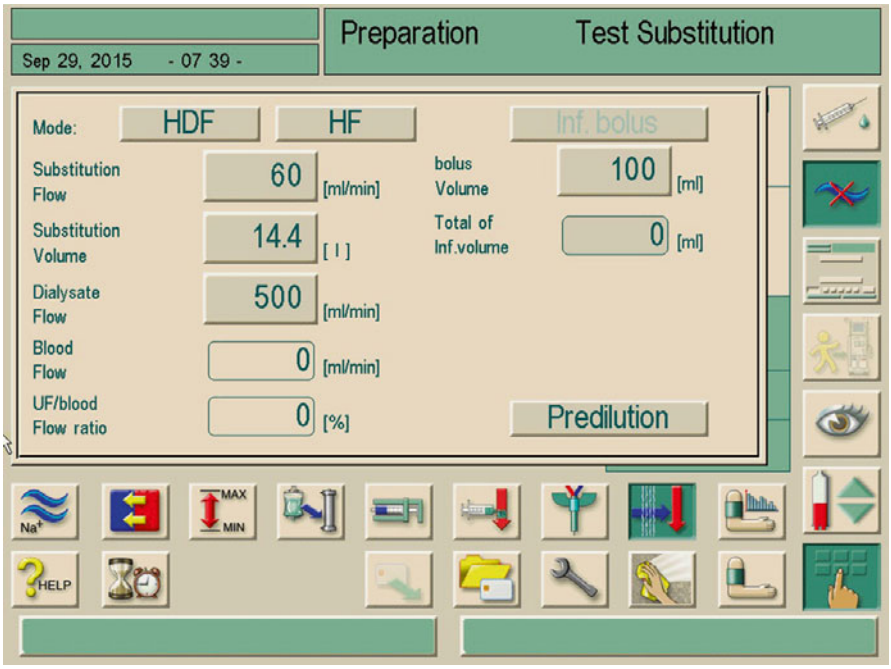

Fig. 6.3 Snapshot screen II

Ultrafilters: The B.Braun Dialog+ system uses two dedicated polysulfone-based ultrafilters (Diacap Ultra) for HDF and HF therapies. The ultrafilters are characterized by long exchange intervals (150 therapies or 900 h of treatment time).

Additional Therapeutic Options

Dialog+ offers to set profiles for particular function parameters such as:

- Dialysate conductivity
- Bicarbonate conductivity
- Dialysate flow
- Dialysate temperature
- Ultrafiltration
- Heparin

Profiles can be combined and set individually.

Additional Monitoring Options

The Dialog+ system offers the following additional monitoring options:

- BioLogic RR Comfort: The biologic RR Comfort option is an automatic blood pressure stabilization system for the prevention of hypotensive episodes. This

system uses actual blood pressure values as well as patient specific blood pressure progressions from past treatments to adjust the UF-control of the machine [1].
- Adimea: A device for continuous monitoring of the delivered dialysis dose (Kt/V). The device uses UV-absorbance measurement to assess the reduction of urinary waste products in the dialysate outlet of the dialysis machine. Due to continuously recorded measurements the Kt/V and the urea reduction ratio (URR) can be determined and displayed online. It can be applied in HD as well as HDF treatments [2].

Cleaning and Disinfection

Disinfection of the machine should be performed to reduce to minimum the bacterial level. Dialog+ offers three types of disinfection:

1. Chemical disinfection
2. Thermal disinfection
3. Citro-thermal disinfection

During disinfection the disinfectant reaches all parts of the hydraulic circuit. Temperature and duration of disinfection depend on the disinfectant used. After the disinfection phase a rinsing phase removes any residual disinfectant. The machine performs the disinfection/rinsing phase automatically. Disinfection cycles can be programmed to be performed automatically.

Risk Management System

Additional to the safety features required by international standards, the system offers the following:

– Warning for too high ratio blood flow rate versus UF-rate (filtration fraction; essential to avoid excess hemoconcentration in post-dilution mode)
– Monitoring of blood side dialyser inlet pressure as an indicator for secondary membrane built-up or clotting
– Dynamic adjustment of alarm limits for arterial- and venous pressures (PA and PV)

Display of Settings and Connection to Hospital Information System

Connectivity to internet and/or hospital information system: B.Braun offers the Nexadia system for bidirectional connection to a central database. With Nexadia, individual settings for the dialysis treatment are automatically transferred to the dialysis machine. In the other direction, Nexadia automatically collects all relevant treatment and patient data from the machine. A unidirectional interface of the Dialog+ systems to several databases is possible. Patient therapy prescription is supported by using the patient card.

Cost Assessment

Recent prospective trials suggest that on-line hemodiafiltration (HDF) improves survival, if high convective volumes are reached [3–5]. However, these results await confirmation. In general, HDF treatments are characterized by slightly higher costs mainly due to extra disposable costs and higher water consumption. Higher costs might be compensated when considering patient quality of life or reduced EPO usage [6]. Further studies are necessary to answer this question.

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