NIKKISO

Haemodialysis System
DBB-EXA

D-FAS

Dialysis Fully-Automated System

Innovations for Human Care.

CE
0123

Concept

User-friendly and cost efficient dialysis monitor providing safe and adequate haemodialysis.

DBB-EXA has been developed for the value-oriented dialysis providers who are committed to high quality and safety standards, looking for a monitor to deliver standard HD treatments and advanced therapies as well.
DBB-EXA is a compact, user-friendly and cost efficient dialysis monitor providing a safe and adequate haemodialysis.
With a variety of configurations and options, DBB-EXA meets the needs of the modern dialysis facility.

Inherited reliability

Reducing costs

For the administrator who manages the dialysis facility, and is seeking a way to reduce the treatment costs, DBB-EXA is the dialysis machine that can reduce the total costs of ownership.

Automation

For the healthcare professional who requires more time for the patient, DBB-EXA is the dialysis machine that can provide more time for patient care by reducing routine dialysis tasks.

Kind to patients

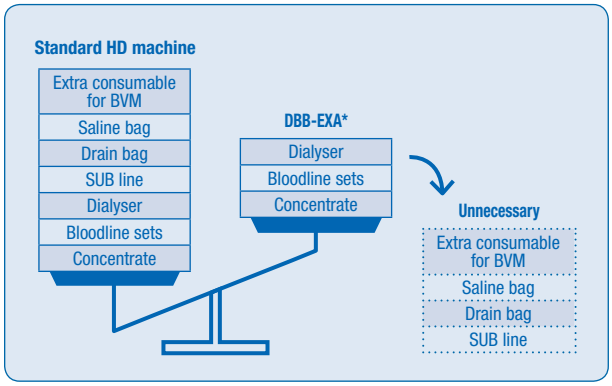
For the dialysis patient, DBB-EXA is the dialysis machine that provides a comfortable treatment environment thanks to its smart, quiet and compact design.

Useful features

For the nephrologist who wants to deliver a safe and effective treatment, DBB-EXA is the dialysis machine that provides accurate and safe monitoring as well as flexible treatment modes.

Reducing costs

Nowadays dialysis facilities face a reduction in reimbursement.
In order to reduce the treatment costs, DBB-EXA is designed to minimise the consumption of consumables. With inherited reliability and time-proven mechanical components of the DBB series, DBB-EXA can minimise maintenance costs with simple preventive maintenance and long MTBF.



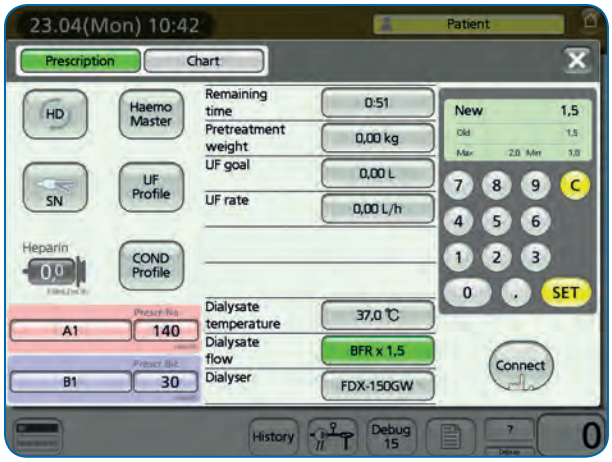
*When using DBB-EXA with D-FAS and BVM option.

- Priming, wash back and emergency bolus can be performed with dialysis fluid to save on saline costs.
- Online priming, wash back and emergency bolus can be performed without substitution line or special adapter, eliminating extra costs.
- Online priming solution and substitution fluid is purified using the integrated reusable double stage endotoxin retentive filter cascade.
- Priming fluid from the extracorporeal circuit can be drained through the drain port to eliminate the need for a drain bag. The drain port can be utilised in priming for both dialysis fluid and saline.
- BVM can be measured with NIKKISO standard bloodline set. No need for extra consumables for BVM.
- Screen motion sensor enabling automatic switch-off / on of screen.

Dialysate Flow Adaption

When the dialysate flow rate equals the blood flow rate, almost 90% of the small molecules clearance is achieved. By setting a factor (e.g. 1,5), the dialysate flow rate increases automatically with an increasing blood flow rate (BFR) thereby ensuring an equal treatment efficiency for all conditions.

This could lead to reduced dialysis fluid consumption and costs in terms of energy, water etc. without compromising Kt / V.



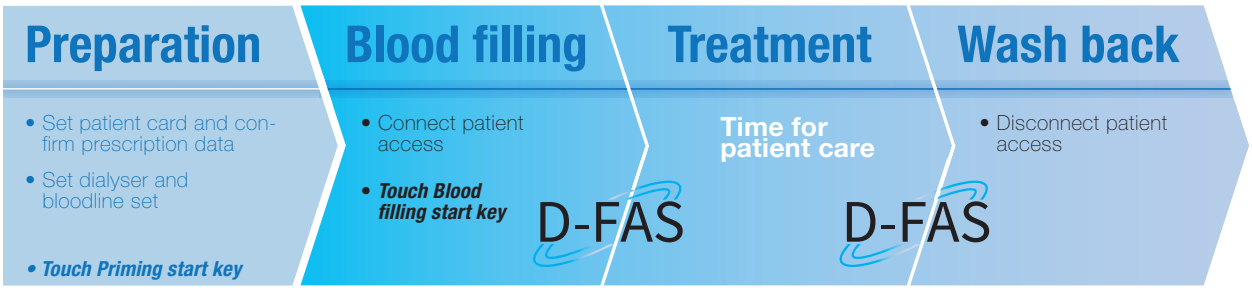
Automation

D-FAS

Dialysis Fully-Automated System

Supporting nursing staff

Healthcare professionals in the dialysis facility have many tasks to complete such as lining, priming, entering prescribed treatment data, blood filling and wash back besides the primary role of patient care.
Dialysis Fully-Automated System (D-FAS) can simplify and automate user operations.
As a result, it may be possible that operator errors and/or the risk of contamination can be significantly reduced.



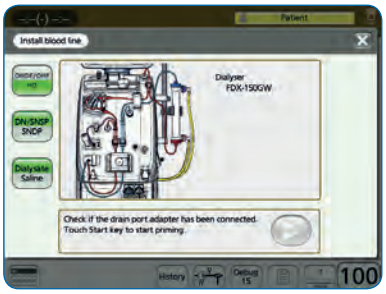
Bringing nursing staff back to patient care.

Advantages

- Reducing standard operational tasks between treatments such as preparation, connecting and disconnecting patients.
- Minimising the number of times the operator has to interact with DBB-EXA.
- Simplifying and automating the tasks to reduce operator errors and risks of contamination.
- Dialysis facility can select automatic priming, wash back and emergency bolus utilising dialysis fluid or saline (based on the facilities policy).
- Automatic wash back solution can be switched from dialysis fluid to saline. The operator can keep the standard wash back procedure even if the power supply is interrupted.
- D-FAS blood filling removes the priming solution automatically through the dialyser. Patient UF removal can be minimised.

D-FAS priming

The operator installs the bloodline set and dialyser, and then starts **D-FAS priming**. D-FAS automatically primes the extracorporeal circuit without operator intervention.



D-FAS blood filling

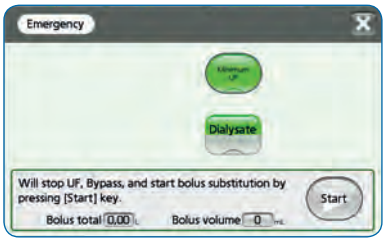
The operator simply connects the arterial and venous patient access and starts **D-FAS blood filling**.
D-FAS blood filling can remove the priming solution automatically through the dialyser, therefore the patients UF removal can be minimised.

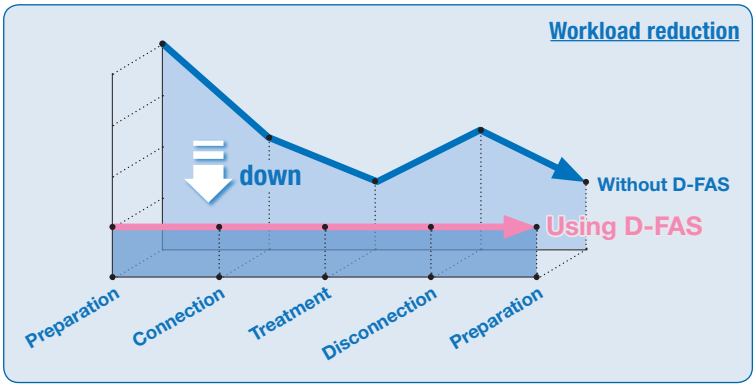
D-FAS wash back

After the completion of the treatment, **D-FAS wash back** returns the blood in the extracorporeal circuit automatically through the arterial and venous patient access without any operator intervention. All the operator needs to do is simply disconnect the patient.

D-FAS emergency bolus

The operator can start the emergency bolus without handling the bloodline set. **D-FAS emergency bolus** can deliver automatically a defined volume of substitution fluid to the patient.



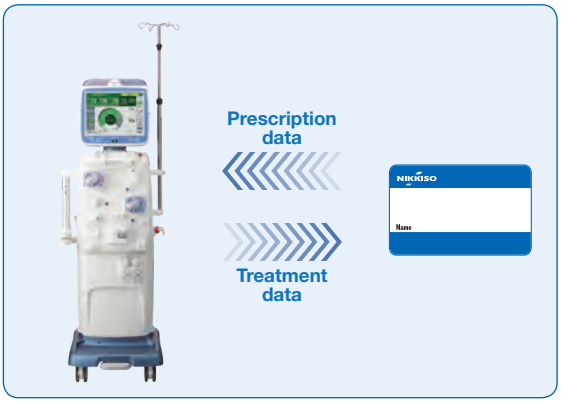


Automation

Bi-directional Patient Card – Stand-alone data management solution

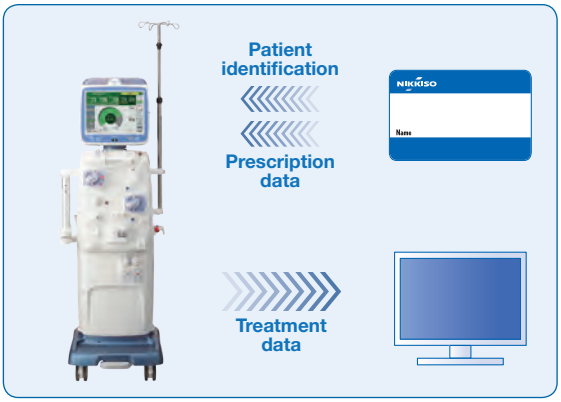
EASY - FAST - FLEXIBLE (without network system)

The prescription data can be imported to the DBB-EXA via the personal patient card, easily and fast, and without any cable connection. At the end of the treatment, the last 3 treatments are available on the contactless (RFID technology) patient card as a data package for export to the data management system.
Not requiring any data cable installation throughout the dialysis centre, this flexible stand-alone solution from NIKKISO offers a simple, fully autonomous and maintenance-free data management.



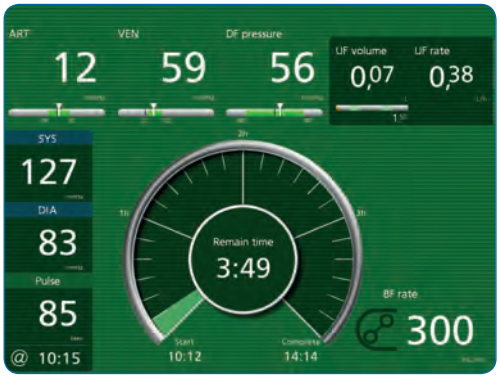
CONVENIENT - ACTUAL - FLEXIBLE (with network system)

By connecting the DBB-EXA to your network with Ethernet cables, up-to-date information about the current treatment parameters are available in your data management system. With the DBB-EXA patient card, and regardless of the used data management system and network connection, the import of the prescription data is fast and safe. Thanks to this newly achieved autonomy in bi-directional data transmission, potential network breakdown has no impact on the daily routine and you remain independent from any binding cooperation with a specific data management system supplier.

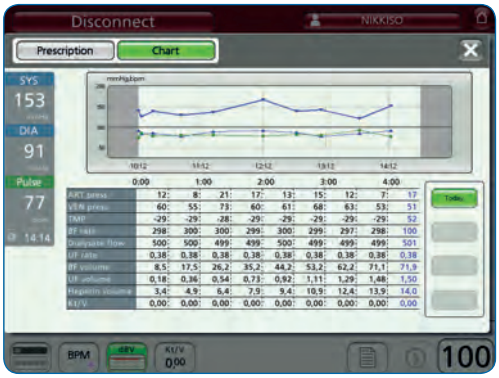


User-friendly interface

The user-friendly interface has operational guidance with intuitive graphical instructions. The interface is designed to simplify the operation. Using D-FAS and patient card, the number of screens and key strokes is minimised. Displayed information can be customised individually to fulfil all the dialysis facilities requirements.

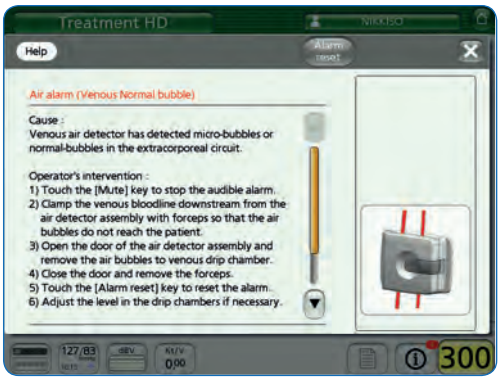


Informative **screensaver**
Improved legibility from a distance.

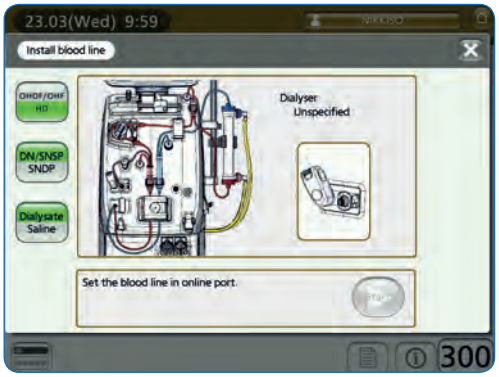


Treatment chart screen for easy documentation.

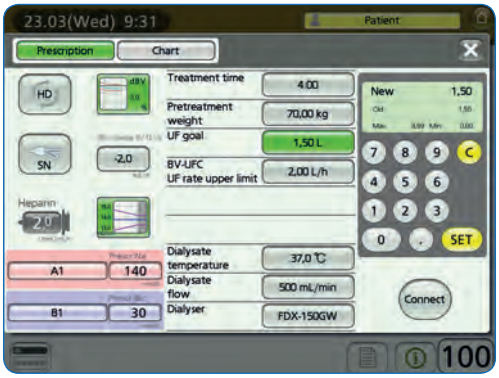
Basic screen during a treatment
Monitors and keys are customizable.



Help screen
Informative troubleshooting guidance,
related monitor and keys appear.



Preparation screen
Intuitive guidance to set up bloodline set.



Prescription screen
Minimum information for simplified operation.

Smart design

The patient is located in the immediate vicinity of the dialysis machine whilst on treatment.
DBB-EXA provides a comfortable treatment environment for the patient through its smart and compact design.

- A curved appearance softens its mechanical impression and is easily integrated into a modern dialysis facility.
- External dimensions which are decreased in depth softens the appearance to the patients.
- Integrated BVM, online port and drain port gives the machine a neat appearance.
- Contactless patient card makes card reader surface smooth.

Connectivity for external alarming device

DBB-EXA NEW feature

DBB-EXA is the first dialysis system complying with IEC PAS 63023 (**P**ublicly **A**vailable **S**pecification).

To minimise the risk to the patient, DBB-EXA triggers an alarm and immediately turns the machine into a safe mode according to the signal from an external alarming device, e. g. a Venous Needle Dislodgement System.

15 inch flat touch screen with wide viewing angle.
4 colored status display on top of the screen visible from any angle.

Smooth curved surfaces allowing for easy cleaning.

Integrated document holder keeping patients area neat and tidy.

The blood pressure monitor cuff holder with detachable flap for ease of cleaning.

A well laid-out extracorporeal circuit minimises patient extracorporeal blood volume and makes it easy to install the bloodline set.

Simple and easy brake pedal, enabling locking of all 4 wheels.

Grip handle with integrated cable hook for ease of maneuverability.

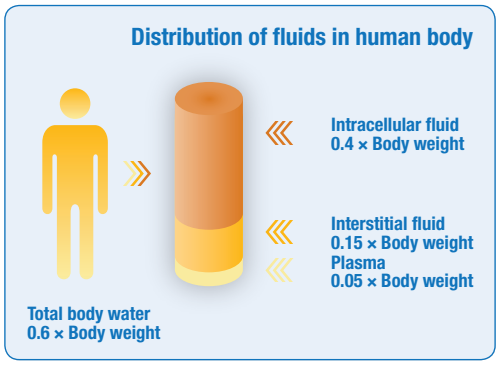
DBB-EXA NEW feature

Interface hub for connecting network and various alarm in- and outputs. Also available is the unique **P**ublicly **A**vailable **S**pecification connection port for external alarming device (IEC PAS 63023).

Useful features

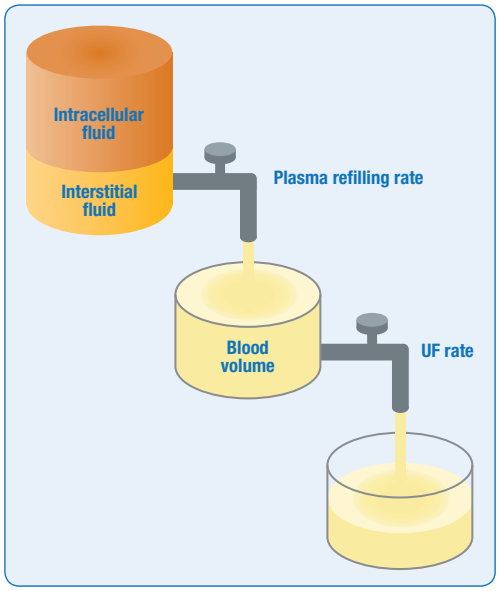
Monitoring patient blood pressure and blood volume

Common complications during haemodialysis are hypotension (20-30% of dialysis sessions), cramps (5-20%), nausea and vomiting (5-15%). Hypotension is related to the plasma volume that is removed during an average dialysis session. Cramps, nausea and vomiting are considered as associated with hypo-tension [1]. Fluid management becomes a key clinical objective.



Body water distribution in the human body

Total body water is distributed between the intracellular fluid (ICF) compartment (2/3) and the extracellular fluid (ECF) compartment (1/3). The ECF compartment is further subdivided into interstitial fluid (3/4 of ECF) and plasma (1/4 of ECF) [2].



UF rate and Plasma refilling rate

UF rate during treatment is exclusively from blood plasma.
Fluid volume reduction of blood initiates plasma refilling from other compartments to recover fluid volume. This refilling rate is called plasma refilling rate (PRR). If UF rate is equal or less than PRR, blood volume is kept the same or recovered. If UF rate is more than PRR, blood volume is reduced. Undesired reduction in blood volume results in a blood pressure drop [3].

BPM

Blood Pressure Monitor (BPM) with UF reduction

DBB-EXA can measure the blood pressure with the integrated BPM. Measurement timing can be selected from manual, auto measurement or continuous.
Results are displayed in graphical form and the UF rate can be reduced automatically when it reaches a preset limit.

Advantages of BPM and Haemo-Master

- Integrated, easy to handle
- No additional costs for disposables
- BPM with automatic UF reduction
- Continuous Blood Volume Monitoring
- Automatic regulation of the UF rate and dialysis fluid conductivity

REFERENCES

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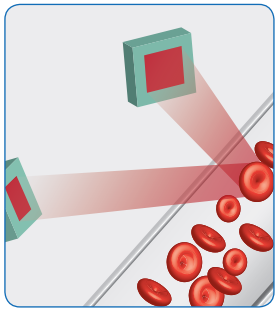
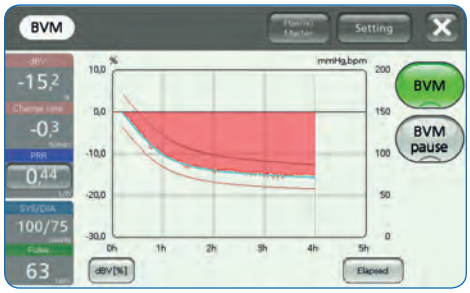
2. Koeppen BM, Stanton BA. Renal Physiology Fifth Edition. Mosby, Maryland Heights, MO: 2012; 1-14
3. Ronco C, Bellomo R, Ricci Z. Hemodynamic Response to Fluid Withdrawal in Overhydrated Patients Treated with Intermittent Ultrafiltration and Slow Continuous Ultrafiltration: Role of Blood Volume Monitoring. Cardiology 2001; 96: 196-201

Haemo-Master

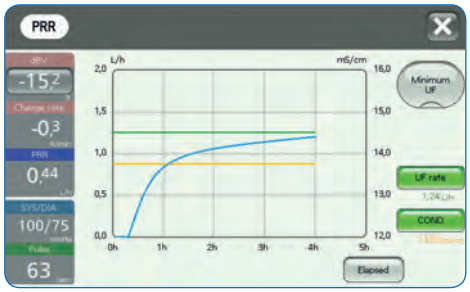
Blood Volume Monitor (BVM) and Plasma Refilling Rate (PRR)



The BVM module transmits light near the infrared spectrum through the bloodline. This light with a specific wavelength is reflected by the red blood cells and the intensity of reflection is measured.
Patient blood volume and blood cell concentration in the arterial bloodline are correlated. Haemo-Master observes the change of reflected light during the treatment and a change of patient blood volume (dBV) can be monitored continuously. Blood volume measurement is considered as a useful tool to help improve tolerance and the haemodynamic response [3]. Estimated patient PRR is calculated from UF rate and dBV trend. Nephrologists can refer to the PRR to help estimate adequate UF rate to stabilise the dBV. The monitored dBV and PRR are displayed in graphical form and clinicians can observe the patient fluid status visually.

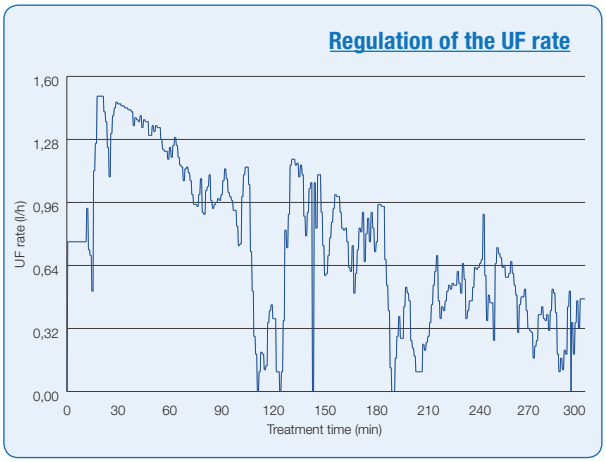


BV-UFC and BV-COC

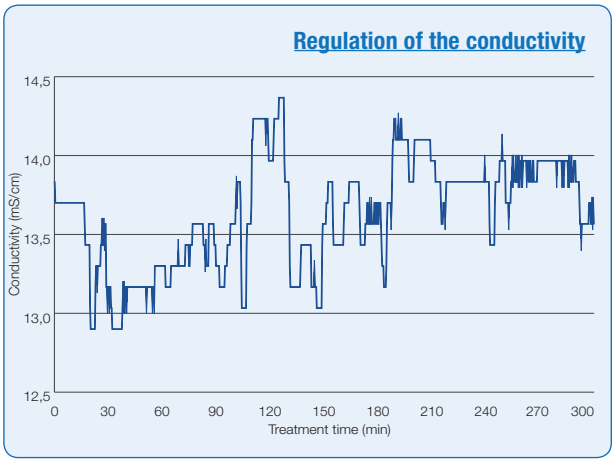


For each patient an individual curve for the ideal blood volume change is established.
DBB-EXA continuously measures dBV during the dialysis treatment. This is the basis for automatic regulation of the UF rate (BV-UFC) and dialysis fluid conductivity (BV-COC) so that patient dBV follows the ideal curve. Some studies show that automatic regulation of the UF rate and dialysis fluid conductivity reduces incidents of hypotensive episodes and the frequency of symptoms during the treatment [4-6].

Regulation of the UF rate



Regulation of the conductivity



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5. Santoro A, Mancini E, Paolini F, et al. Blood Volume Regulation During Hemodialysis. Am J Kidney Dis 1998; 32: 739-748
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Recirculation Measurement System

The vascular access is the link between the patient and the extracorporeal blood circuit. Since the effectiveness of dialysis treatment depends, among other things, on the amount of purified blood, vascular access can be considered as the patient's lifeline, to which special attention should be paid.

Recirculation

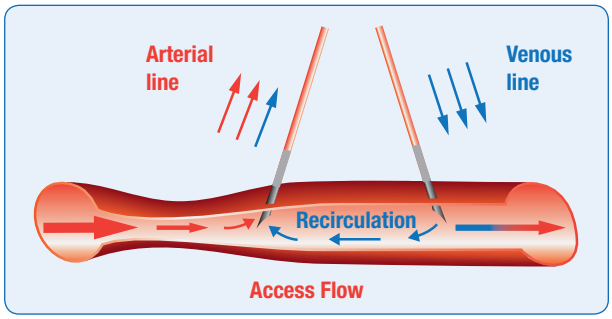
Blood that has already been purified can return to the extracorporeal blood circuit without having previously saturated itself with metabolic end products. This is called recirculation.

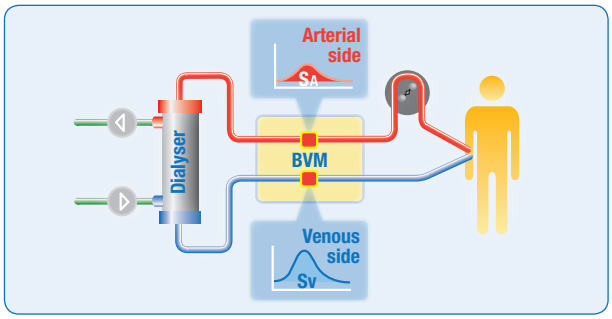
Many factors (invisible for the operator) can influence recirculation in the vascular access. Abnormalities, such as reduced arterial blood flow or obstruction in venous side can result in extracorporeal blood flow being higher than the real vascular access blood flow.

However, there are other factors that can lead to recirculation, such as inadvertent swapping of the blood tubing connections, unfavourable needle positioning, or too short a distance between the needles, to name just a few.

DBB-EXA NEW feature

The NIKKISO RMS option for detection and monitoring of recirculation is an adequate tool to ensure a long-term assessment of vascular access.





Protecting vascular access

The newly developed **R**ecirculation **M**easuring **S**ystem (RMS) is based on the **B**lood **V**olume **M**easurement (BVM) hardware that is used in the DBB-EXA. It is a double measuring system in the arterial and venous bloodline. A blood marker produced by rapid ultrafiltration as a mass of concentrated blood in the extracorporeal venous line occurs in the arterial line, if access recirculation exists. The rate of vascular access recirculation is calculated by the ratio of the integration of the arterial variation (S_A) to that of the venous (S_V) using the equation:

Vascular access recirculation rate (%) = $S_A / S_V \times 100$

Up to five automated measurements per treatment can be scheduled. Manual initiation of the measurement is also possible.

Due to the special measurement method, recirculation measurement in the treatment modalities HD, HDF, HF and ISO-UF is possible without any blood dilution or infusion. This also applies when using double-lumen catheters.

The original NIKKISO blood tubing lines of the AV18 series are specially designed for BVM and RMS.

DDM

Advantages of the Dialysis Dose Monitor

- Real-time monitoring
- Recognise treatment inconsistencies
- Easy handling
- No additional costs for disposables

Dialysis Dose Monitor

Positive long-term prognosis & higher quality of life for your patients!

Several studies have proven that a positive long-term prognosis and improved quality of life (QOL) of patients depends on the actual delivery of dialysis dose. Adequate dialysis dose may improve QOL [7-9].

Insufficient clearance performance can have various reasons:

- No counter flow of blood and dialysis fluid due to incorrect connection
- Vascular access recirculation (NIKKISO's Recirculation Measurement System (RMS) can help monitor recirculation).
- Secondary membrane formation and / or dialyser clotting
- Frequent alarms of dialysis machine which shortens effective treatment time
- Reduced effective blood flow etc.

Reaching treatment goals

Reaching the individual treatment goals for your patients can only be achieved by always knowing the actual status.

At the same time, necessary adaption of treatment parameters must be considered.

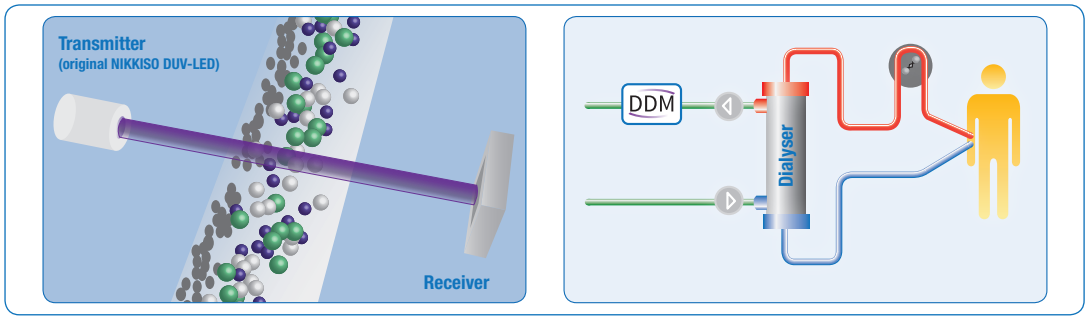
By using the Dialysis Dose Monitor, measured Kt/V is displayed in graphic form with a projection line. You can see deviations from the treatment goal at an early stage, and react accordingly.

DBB-EXA NEW feature DBB-EXA

By pressing the key A, the values K, Kt, Kt/V and eKt/V can be numerically displayed. The graph always shows the Kt/V.

Measurement principle of the DDM

A sensor located directly in the spent dialysis fluid measures the absorbance at a wavelength which directly correlates with patient blood urea nitrogen (BUN) concentration. The continuously measured values are inserted in the formulas for single pool Kt/V (spKt/V) and urea reduction ratio (URR) and the results are immediately displayed.



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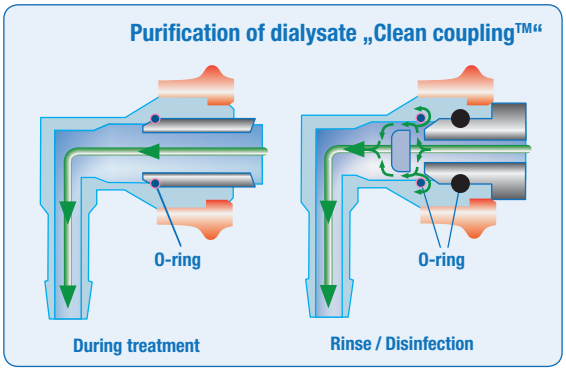
Hygiene

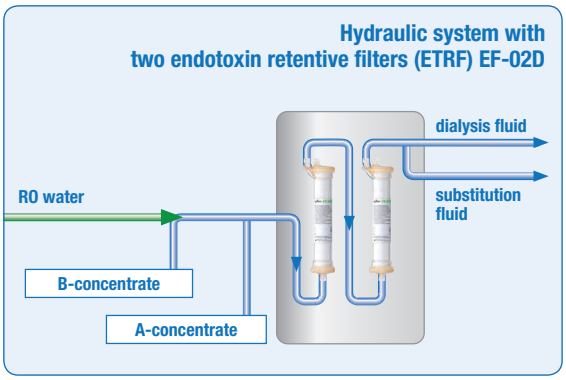
Dialysis fluid and substitution fluid is purified using the integrated reusable double stage endotoxin retentive filter cascade. Dialyser Clean couplings and online port are designed so that all dialysis fluid contact areas are disinfected to help prevent contamination.



Online HDF

Haemodiafiltration (HDF) has an improved clearance of low molecular weight protein compared with haemodialysis (HD), and is considered as a treatment mode with higher dialysis efficiency. Recently several prospective studies which compare HDF with HD have been conducted in large scale [10-13]. The ESHOL study reported that post dilution online HDF with high convection volume reduces all-cause mortality [14].

DBB-EXA is a flexible dialysis machine which can perform different treatment methods such as post or pre-dilution HDF, HF, HD and isolated UF.
DBB-EXA can optimise substitution rate based on the set ratio with blood flow rate. Also substitution rate can be controlled automatically within set TMP limits to help prevent high blood concentration and TMP alarms.



TMP-SUB control

With the TMP-SUB control function, the TMP will be regulated within selected TMP limits to achieve the highest possible filtration rate.

Filtration Fraction

The Filtration Fraction function can optimise the convective volume for improved therapy outcome. The calculation of the optimal substitution volume is based on the patient's individual blood parameters.

The TMP-SUB control and Filtration Fraction functions avoid excessive haemoconcentration and TMP alarms while optimising substitution volume.

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Specifications*

General data

Dimensions	161 x 43 x 46 (H x W x D in cm) Base: 51 x 74 (W x D in cm)
Weight	Approx. 90 kg (incl. all options)
Water supply	Pressure: 1 to 7 bar at minimum 800 mL/min at maximum 3000 mL/min Temp.: 5 to 30 °C
Drain	Minimum drain capacity: 800 mL/min average Height: 50 cm maximum Temp.: 90 °C maximum
Concentrate supply	Pressure: 0 to 0.5 bar 2 central acid concentrates
Power supply	220 to 240 VAC ±10 %, 50 to 60 Hz ±1 Hz (≈10 A)
Battery	Ni-MH battery 24 V/3200 mAh
External connection port	External output (Staff call) External input 1 External input 2 Nurse call switch LAN/Network (RJ-45) Serial interface (RS-232) BPM start switch USB CF card type I
PAS	Input interface for external alarming device (IEC PAS 63023) to stop extracorporeal and/or fluid circuit
Monitor	15 inch LCD

Extracorporeal circuit

Arterial pressure monitoring	Measurement range: -300 to +500 mmHg Measurement accuracy: ±10 mmHg
Venous pressure monitoring	Measurement range: -300 to +500 mmHg Measurement accuracy: ±10 mmHg
Dialyser inlet blood pressure monitoring	Measurement range: -300 to +735 mmHg Measurement accuracy: ±10 mmHg
Single needle pressure	Measurement range: -200 to +600 mmHg Measurement accuracy: ±10 mmHg
Air detector	Method: Ultrasonic waves Sensitivity: 0.02 mL (Normal air bubbles) (At Blood flow rate: 250 mL/min) 0.0003 mL (microbubbles: blood/air mixture) (At Blood flow rate: 250 mL/min)
Arterial blood pump (PUMP1)	Setting range: 40 to 600 mL/min Flow rate accuracy: Set value ±10 % (inlet Pressure -150 mmHg ≦ P ≦ +150 mmHg) Set value -20 to 0 % (inlet Pressure -200 mmHg ≦ P < -150 mmHg)
Heparin pump	Setting range: 0.0 to 9.9 mL/h Output rate accuracy: Set value ±10 % Syringe type: 30 mL or 20 mL, 20 mL or 10 mL (optional) Bolus volume: 0.0 to 9.9 mL
Venous blood pump / Substitution fluid pump (PUMP2)	Setting range: 40 to 600 mL/min Flow rate accuracy: Set value ±10 % (inlet Pressure -150 mmHg ≦ P ≦ +150 mmHg) Set value -20 to 0 % (inlet Pressure -200 mmHg ≦ P < -150 mmHg)
Blood Pressure Monitor (BPM)	Pressure display range: 10 to 300 mmHg Pressure display accuracy: Less than ±3 mmHg Measurement range (adults): Systolic blood pressure (SYS): 60 to 250 mmHg Mean arterial pressure (MAP): 45 to 235 mmHg Diastolic blood pressure (DIA): 40 to 200 mmHg Pulse rate: 40 to 200 beats per minute
Blood Volume Monitor (BVM)	Measurement principle : Near-infrared reflection method Applicable blood flow rate range: 40 to 600 mL/min Applicable hematocrit range: 15 to 50 % Accuracy: ±2.3 dBV % (Double needle)

Hydraulic circuit

Dialysis fluid flow rate	Setting range: Single ETRF 300 to 800 mL/min Double ETRF 300 to 700 mL/min
Dialysis fluid temperature	Setting range: 34.0 to 40.0 °C
Dialysis fluid conductivity	Bicarbonate dialysis Bicarbonate conductivity setting range: 2.3 to 7.0 mS/cm Accuracy: ±0.1 mS/cm Total conductivity setting range: 12.7 to 15.2 mS/cm Accuracy: ±0.2 mS/cm Acetate dialysis Total conductivity setting range: 12.7 to 15.2 mS/cm Accuracy: ±0.2 mS/cm
Transmembrane pressure (TMP)	Measurement range: -100 to +500 mmHg Measurement accuracy: ±10 mmHg
Blood leak detector	Method: Optical Sensitivity: 0.3 mL Blood / 1 L Dialysis fluid (Blood: Hematocrit 32 ± 2 %; Dialysis fluid temperature: 37 °C)
Ultrafiltration	UF rate: 0.00; 0.10 to 4.00 L/h UF accuracy (Balance): ±30 mL/h (At dialysis fulid flow rate 300 to 500 mL/min) ±0.1 % of the dialysis fluid flow rate (At dialysis fluid flow rate 501 to 800 mL/min)
Dialysis Dose Monitor	Measurement principle: Absorptiometry Applicable Treatment mode: HD, On-line HDF Applicable Kt/V range: 0 to 3.0 Kt/V monitoring accuracy: ±0.1 (Kt/V 0 to 1) ±10 % (Kt/V 1 to 3) Applicable URR range: 0 % to 100 % URR monitoring accuracy: ±5 %
Endotoxin retentive filter	EF-02D

Treatment options

Online HDF/HF	Substitution flow setting range: 0.00; 0.10 to 18.00 L/h (Online HDF) 0.00; 0.10 to 30.00 L/h (Online HF) Flow rate accuracy: ±10 % of set value
Single needle treatment	Single needle single pump treatment Single needle double pump treatment SN control pressure: Upper limit: +400 mmHg Lower limit: 0 mmHg
UF profiles	9 programmable profiles available
Conductivity profiles	9 programmable profiles available

Cleaning program

Disinfection and decalcification	50 % Citric acid DIALOX (Peracetic acid)
Disinfection and degreasing	Sodium hypochlorite solution (Maximum 10 %)
Decalcification	30 % Acetic acid

Accessories

Hook for Concentrate bags	Max. load 10 kg
Patient card	MIFARE Classic 4K Capacity: 4096 byte
Nurse call switch	

* Those specifications may differ depending on the DBB-EXA type (type A, B or C).

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Always close to you

Competent partners

For all questions concerning dialysis, please contact us or our local partner:

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