

1.6 Technical data

1.6.1 Dimensions and weight

• Dimensions

Height:	161 cm
Width:	43 cm
Depth:	46 cm
Base:	51 cm (W) x74 cm (D)

• Weight

System with all options: Approximately 90 kg

1.6.2 Electric safety (Classified according to IEC60601-1)

• Type of protection against electric shock

Class I equipment

• Degree of protection against electric shock (Hydraulic circuit)

Type B Applied part

Symbol:



• Degree of protection against electric shock (Nurse call)

Type B Applied part

Symbol:



• Degree of protection against electric shock (Blood pressure cuff)

Defibrillation-proof Type BF Applied part

Symbol:



• Degree of protection against ingress of water

Protection against dripping water

Symbol: IPX1

• Degree of safety of application in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide



To reduce the risk of serious or fatal injury from fires, never use the DBB-EXA in the presence of flammable anesthetic or gases, such as high pressure oxygen room or oxygen tent.

This equipment is not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.

- **Mode of operation**

Continuous operation

- **Rating label (see "1.2.3 Symbols")**



1.6.3 Electrical power supply

⚠ WARNING The leakage current may exceed the allowable limits, if the DBB-EXA is not connected to the appropriate receptacle, which can result in the risk of electric shock.

⚠ WARNING To reduce risk of serious or fatal patient or operator injury from electric shock, never use any adapter that does not connect properly to the grounding cable.

⚠ WARNING To reduce the risk of serious or fatal patient injury from electric shock, always connect potential equalization terminal to the potential equalization when a patient with central venous catheter is being treated.

- **Voltage**

220-240 V AC $\pm 10\%$, 50 - 60 Hz ± 1 Hz

- **Current**

10 A (220-240 V AC)

• Operating current

Dialysis:	Max. 5A(220 V AC) (at water temperature: 5 °C (41 °F), dialysis fluid temperature: 37 °C (98.6 °F) and dialysis fluid flow: 500 mL/min)
Citric heat/Heat cleaning:	Max. 9A(220 V AC) (at hot water circulation temperature: 90 °C (194 °F) (heater outlet) and hot water circulation flow rate: 800 mL/min)

• Battery

Type:	Nickel-metal hydride battery (Ni-MH battery)
Capacity:	24 V/3200 mAh

NOTICE

Battery is to be disposed of according to the applicable federal, state and local laws and regulations. Failure to follow these instructions may result in groundwater contamination and/or a fine from governing authorities. Consult NIKKISO CO., LTD. or its local representative for disposal.

1.6.4 Operating conditions (Delivery system)

CAUTION

To reduce the risk of minor or moderate patient injury/illness from infection, the following measures must be taken:

- *an air gap must be provided between the DBB-EXA drain line and the main drain port to help prevent back siphoning and possible contamination,*
 - *one way valve must be provided between the DBB-EXA and water supply system to prevent back flow into the water supply system,*
- in accordance with the applicable federal, state and local laws and regulations (e.g. IEC80601-2-30).*

• Water supply

Pressure range of water supply:	1 to 7 bar
Temperature range of water supply:	5 °C to 30 °C
Minimum flow rate of water supply:	800 mL/min average
Maximum flow rate of water supply:	3000mL/min

• Drain

Minimum drain capacity:	800 mL/min average
Drain height:	Maximum 50 cm
Drain temperature:	Maximum 90 °C (disinfection with hot citric acid)

NOTE *The main drain line should have a gradient, and the height of the drain port should be lower than the dialyser and not exceed a maximum height of 50 cm.*

• Concentrate supply

Inlet pressure:	0 to 0.5 bar
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NOTE Do not exceed maximum pressure of 0.5 bar to help avoid conductivity fluctuations, especially with a central concentrate supply.

• Electromagnetic emission and immunity

⚠ CAUTION To reduce the risk of minor or moderate patient injury from DBB-EXA malfunction, never operate devices that cause electromagnetic interference, such as mobile phones or CB wireless transmitters in the vicinity of the DBB-EXA during operation. The use of any devices that emit electromagnetic waves in the vicinity of the DBB-EXA may cause a DBB-EXA malfunction.

⚠ CAUTION To reduce the risk of minor or moderate patient injury from other device malfunctions, the users must try to correct the interference by using the following measures if the DBB-EXA causes harmful interference with any other devices, which can be determined by turning off and on the DBB-EXA:

- Reorient or relocate the device receiving interference.
- Increase the distance between the devices.
- Connect the DBB-EXA to an outlet on a different circuit from that of the other devices.
- Consult the NIKKISO CO., LTD. or its local representative.

The DBB-EXA has been tested and found to comply with the limit for medical devices according to the IEC 60601-1-2:2007.

These limits are designed to provide a reasonable protection against harmful interference in a typical medical facility. The DBB-EXA generates, uses, and radiates radio frequency energy, which may cause harmful interference with other devices in the vicinity if not installed and used in accordance with the instructions. However, there is no guarantee that interference will not occur in any particular installation.

⚠ CAUTION To reduce the risk of minor or moderate patient injury from a DBB-EXA malfunction due to Electrostatic Discharge (ESD), the DBB-EXA must be installed in a room with wood, concrete, or ceramic tiled floors. If the floors are covered with synthetic material, the relative humidity should be at least 30%.

The electric power supply necessary for the operation of the DBB-EXA must conform to the respective laws and regulations in the customer's region.

Never operate devices that cause electromagnetic interference, such as mobile phones or CB wireless transmitters in the vicinity of the DBB-EXA while the DBB-EXA is in operation.


The use of any device that emits electromagnetic waves in the vicinity of the DBB-EXA may cause it to malfunction.

Please follow the information in the technical manual for installation and use.

Emissions test	Compliance level	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The DBB-EXA uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.

Emissions test	Compliance level	Electromagnetic environment - guidance
RF emissions CISPR 11	Class B	The DBB-EXA is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies the electric power to the buildings for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Main power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV Line - Line ±2 kV Line - Ground	±1 kV Line - Line ±2 kV Line - Ground	Main power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% Ut (>95% dip in Ut) for 0.5 cycle 40% Ut (60% dip in Ut) for 5 cycles 70% Ut (30% dip in Ut) for 25 cycles <5% Ut (>95% dip in Ut) for 5 sec	<5% Ut (>95% dip in Ut) for 0.5 cycle 40% Ut (60% dip in Ut) for 5 cycles 70% Ut (30% dip in Ut) for 25 cycles <5% Ut (>95% dip in Ut) for 5 sec	Main power quality should be that of a typical commercial or hospital environment. If the user of the DBB-EXA requires continued operation during main power interruptions, it is recommended that the DBB-EXA be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE "Ut" is the a.c. main voltage prior to application of the test level.			

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms (150 kHz to 80 MHz) 3 V/m (80 MHz to 2.5 GHz)	3 Vrms 3 V/m	<p>Portable and mobile RF communications equipment should be used no closer to any part of the DBB-EXA, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ (80 MHz to 800 MHz) $d = 2.3\sqrt{P}$ (800 MHz to 2.5 GHz)</p> <p>Where "P" is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and "d" is the recommended separation distance in meters (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey "a", should be less than the compliance level in each frequency range "b".</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
<p>NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.</p> <p>NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p> <p>"a" For example, field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the DBB-EXA is used exceeds the applicable RF compliance level above, the DBB-EXA should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the DBB-EXA.</p> <p>"b" Over the frequency range 150kHz to 80MHz, it is preferable that the field strengths be less than 3 V/m.</p>			

Recommended separation distances between portable and mobile RF communications equipment and the DBB-EXA

The DBB-EXA is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the DBB-EXA can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the DBB-EXA as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150kHz to 80MHz $d=1.2\sqrt{P}$	80MHz to 800MHz $d=1.2\sqrt{P}$	800MHz to 2.5GHz $d=2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance "d" in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where "P" is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1
At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2
These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

1.6.5 Water and dialysis fluid used

⚠ WARNING *The dialysis facility is responsible for the hygienic quality of the fluid delivery system.*

⚠ CAUTION *The water used in the DBB-EXA must be treated using a reverse osmosis system and/or other water treatment methods and must conform to the applicable standards (see below). Failure to follow this water standard can result in minor or moderate patient injury/illness, including hemolysis and inflammation.*

• Standards for water, concentrate and dialysate quality

- *1 ISO 13958:2009 Concentrates for haemodialysis and related therapies
- *2 ISO 13959:2009 Water for haemodialysis and related therapies
- *3 ISO 11663:2009 Quality of dialysis fluid for haemodialysis and related therapies

• Water, concentrate and dialysate quality

	Water	Concentrate	Dialysate (standard)	Dialysate (ultrapure)	Online prepared substitution fluid
Microbial counts (CFU/mL)	<100	<100	<100	<0.1	<10 ⁻⁶
Endotoxin concentration (EU/mL)	<0.25	<0.25	<0.5	<0.03	<0.03
CFU:colony-forming unit EU:endotoxin units					

• Inspection results

Ensure that a high level of sterility is maintained when sampling. The sampling port must be disinfected in accordance with specifications before each sampling and the sterile syringe must be sealed airtight immediately after taking the sample. It is absolutely mandatory to maintain the specified storage conditions during transport as well as the maximum storage period of the sample.

1.6.6 Environmental conditions

• Operating conditions

Ambient temperature: 10 to 35 °C (50 to 95 °F)
 Relative humidity: 30 to 85% (No condensation allowed)
 Barometric pressure: 70 to 106 kPa (11 to 15 PSI)

• Storage and transportation (dry machine)

Ambient temperature: -20 to +60 °C (-4 to 140 °F)
 Relative humidity: 10 to 95% (Non-condensation).



CAUTION *Strictly adhere to these environmental requirements when storing the DBB-EXA for more than 15 weeks to help prevent minor or moderate patient injury from malfunctions.*

1.6.7 External connection options

Status display For connecting an external status monitor display.
 Alarm output (Staff call) For connection to an external personnel-paging device.
 Contact output (DC 24V/120mA max.)



WARNING *If the alarm output conversion box is connected to hospital or facility equipment, double insulation (see "1.2.2 Glossary") must be used to help protect the patient and operator from serious or fatal injury from electric shock.*

CAUTION

Do not use the alarm output instead of audible and/or visible alarm from the DBB-EXA. The alarm output is not intended to replace the audible and/or visible alarm. Audible and visible alarms must be used correctly to help prevent minor or moderate patient injury. The operator must directly check the patient's condition and status of the DBB-EXA during treatment.

External input 1	This input can be used to stop the machine.
External input 2	This input can be used to stop the machine.
Nurse call	For connection to a switch.
Output for external equipment1	This output signal is not used.
BPM switch	For connection to an BPM switch.
RS232	This outlet is not used.
LAN	For connection to a LAN.
CF card reader	For inserting CF card.
USB	For connection to an USB.

WARNING

Data on the network should be used for treatment information reference only, and the operator should not make any decisions of medical relevance without additional verification of the accuracy of this data.

The accuracy of the data must be verified by the operator before starting further treatment.

The operator should routinely provide direct care to the patient at the bedside even if the network system is used. Failure to properly monitor the patient can result in serious patient injury or death.

WARNING

To reduce the risk of serious or fatal injury, accessory equipment connected to the analog and digital interfaces must be certified according to the respective IEC standards (i.e. IEC 60950 for data processing equipment and IEC 60601-1 for medical equipment). Furthermore, all configurations shall comply with the IEC 60601-1 system standard. Anyone who connects additional equipment to the signal input or signal output is configuring a medical system and is, therefore, responsible to ensure that the system complies with the IEC 60601-1 requirements. If in doubt, consult your local representative.

CAUTION

To reduce the risk of minor or moderate patient injury from a DBB-EXA malfunction due to ESD, always discharge any static electricity to the metallic ground before touching the connector with the ESD warning symbol.

The connector with the ESD warning symbol tends to be affected by static electricity.

NOTICE

Attach a ferrite-core fitting to the network cable to help prevent ESD damage to the DBB-EXA.

1.6.8 Hydraulic circuit

NOTE *Alarm settings marked with an asterisk (*) in this section can be changed. see "6 Setting" for information regarding setting the limits.*

• Blood leak detector

Protective system (Blood leak)

Method:	Optical
Sensitivity:	0.3 mL* Blood/1L dialysis fluid (Blood: Hematocrit $32 \pm 2\%$, dialysis fluid temperature: 37°C [98.6°F])
Alarm response:	The response from the blood leak detector is delayed to rule out turbulence. The delayed response may depend on the volume between the dialyser and the blood leak detector as well as on the UF rate in isolated ultrafiltration (ISO-UF).

• TMP

Protective system (Ultrafiltration)

Method:	Monitoring of TMP	
Measurement range:	-100 to +500 mmHg	
Measurement accuracy:	± 10 mmHg	
Auto alarm limit:	Upper limit:	+70 mmHg*
	Lower limit:	-70 mmHg*
Auto forecast alarm limit:	Upper limit:	+20 mmHg*
		+50 mmHg*(SN)
	Lower limit:	-20 mmHg*
		-50 mmHg*(SN)
Fixed alarm limits:	Upper limit:	+500 mmHg*
	Lower limit:	-30 mmHg*

- Definitions

$$TMP = \left(\frac{PB_i + PBo}{2} \right) - \left(\frac{PD_i + PDo}{2} \right) - Offset$$

PD _i	=	dialysis fluid pressure on the inlet side of the dialyser
PD _o	=	dialysis fluid pressure on the outlet side of the dialyser
PB _i	=	blood pressure on the inlet side of the dialyser
PB _o	=	blood pressure on the outlet side of the dialyser
Offset	=	flow-dependent pressure variations, head pressure, etc.

• Dialysis fluid pressure

Protective system (Ultrafiltration)

Method:	Monitoring of Dialysis fluid pressure	
Measurement range:	-600 to +600 mmHg	
Measurement accuracy:	± 10 mmHg	
Auto alarm limit:	Upper limit:	+70 mmHg*
	Lower limit:	-70 mmHg*
Fixed alarm limits:	Upper limit:	+300 mmHg*
	Lower limit:	-300 mmHg*

• Water pressure

Measurement range:	0.00 to 1.00 bar
Measurement accuracy:	±0.02 bar
Alarm limit:	Upper limit 0.55 bar
	Lower limit 0.15 bar

• UF (see "1.2.2 Glossary")

UF rate:	0.00; 0.10 to 4.00* L/h
UF accuracy:	±30 mL/h (At dialysis fluid 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)
UF profile:	UF profile with step change Continuous UF profile without step change
Protective system (Ultrafiltration)	
Method:	Monitoring of UF pump rate with cell
Alarm limit:	Upper limit: +5%* +0.05L/h Lower limit: -5%* -0.05L/h
Protective system (Ultrafiltration)	
Method:	Monitoring of UF pump valve leak with cell
Alarm limit:	0.7V*
Protective system (Ultrafiltration)	
Method:	Monitoring of SV leak with cell
Alarm limit:	Small: 0.4V* Quantity: 2.5V*

• UFK

Measurement range:	0 to +300 mL/h/mmHg
Measurement accuracy:	±10%

• Acetate dialysis

- Total conductivity

Setting range:	12.7 to 15.2 mS/cm
Dilution rate	Acetate concentrate: Treated water = 1:16 to 1: 46
Total conductivity profile:	Conductivity profile with step change (see Operating instructions sec. 9.3.1). Continuous conductivity profile without step change (see Operating instructions sec. 9.3.1).
Protective system (Dialysis fluid composition)	
Method:	Monitoring of Total conductivity
Measurement range:	10.0 to 20.0 mS/cm (100 to 200 mmol/L)
Measurement accuracy:	±0.2 mS/cm (±2 mmol/L)
Alarm limit:	Upper limit: Set value +5% Lower limit: Set value -5%

• Bicarbonate dialysis

- Bicarbonate conductivity

Setting range:	2.3 to 7.0 mS/cm
Dilution rate	Bicarbonate concentrate: Treated water = 1:16 to 1: 46
Bicarbonate	Conductivity profile with step change (see Operating instructions sec. 9.3.1).
Conductivity profile:	Continuous conductivity profile without step change (see Operating instructions sec. 9.3.1).
Protective system (Dialysis fluid composition)	
Method:	Monitoring of Bicarbonate conductivity
Measurement range:	2.00 to 8.00 mS/cm
Measurement accuracy:	±0.1 mS/cm
Alarm limit:	Upper limit: Set value+5%
	Lower limit: Set value-5%
Alarm delay time:	Max. 10 minutes

- Total conductivity

Setting range:	12.7 to 15.2 mS/cm
Dilution rate	Acid concentrate: Bicarbonate solution = 1:16 to 1: 46
Total conductivity profile:	Conductivity profile with step change (see Operating instructions sec. 9.3.1). Continuous conductivity profile without step change (see Operating instructions sec. 9.3.1).
Protective system (Dialysis fluid composition)	
Method	Monitoring of Total conductivity
Measurement range:	10.0 to 20.0 mS/cm (100 to 200 mmol/L)
Measurement accuracy:	±0.2 mS/cm (±2 mmol/L)
Alarm limit:	Upper limit: Set value+5%
	Lower limit: Set value-5%

• Dialysis fluid temperature

Setting range:	34.0* to 40.0*°C (93.2 to 104 °F)
Protective system (Dialysis fluid temperature)	
Method:	Monitoring of Dialysis fluid temperature
Measurement range:	10.0 to 45.0 °C (50 to 113 °F)
Measurement accuracy:	Measurement value ±0.8°C (±1.4 °F)
	Flow rate of dialysis fluid: 500 mL/min at a constant ambient temperature
Fixed alarm limit:	Upper limit: 41 °C
Auto alarm limit:	Upper limit: Set value +1 °C* (+1.8 °F)
	Lower limit: Set value -1 °C* (-1.8 °F)

• Dialysis fluid flow rate

Setting range:	Single ETRF 300 to 800 mL/min Double ETRF 300 to 700 mL/min
Flow rate accuracy:	Set value $\pm 10\%$
Protective system (Ultrafiltration)	
Method:	Monitoring of Duplex pump rate with cell
Alarm limit:	Upper limit: $+10\%^*$ Lower limit: $-10\%^*$
Protective system (Ultrafiltration)	
Method:	Monitoring of Duplex pump valve leak with cell
Alarm limit:	$0.7V^*$

NOTE Approximately 120 to 150 liters of dialysis fluid is consumed during normal dialysis.

1.6.9 Extracorporeal blood circuit and alarm

WARNING Although the protective systems help reduce the risk of extracorporeal blood loss, some risk may still remain.

NOTE Alarm settings marked with an asterisk (*) in this section can be changed. see "6 Setting" for information regarding setting the limits.

• Arterial pressure

Protective system (Arterial pressure)

Method:	Monitoring of Arterial pressure
Measurement range:	-300 to +500 mmHg
Measurement accuracy:	± 10 mmHg
Auto alarm limit:	Upper limit: $+70$ mmHg* Lower limit: -70 mmHg*
Fixed alarm limit:	Upper limit: $+100$ mmHg* Lower limit: -250 mmHg*
Alarm delay time:	Max. 2 seconds

• Venous pressure

Protective system (Extracorporeal blood loss to the environment)

Method:	Monitoring of Venous pressure
Measurement range:	-300 to +500 mmHg
Measurement accuracy:	± 10 mmHg
Auto alarm limit:	Upper limit: $+60$ mmHg* Lower limit: -40 mmHg*
Fixed alarm limit:	Upper limit: $+300$ mmHg* $+400$ mmHg*(SN) Lower limit: -10 mmHg* $+10$ mmHg*(SN)
Alarm delay time:	Max. 2 seconds

• Dialyser inlet pressure (optional)

Measurement range:	-300 to +735 mmHg
Measurement accuracy:	±10 mmHg
Auto alarm limit:	Upper limit: +70 mmHg* Lower limit: -70 mmHg*
Fixed alarm limits:	Upper limit: +500 mmHg* Lower limit: -50 mmHg*
Alarm delay time:	Max. 2 seconds

• Pressure loss (Dialyser pressure difference) (optional)

Measurement range:	-300 to +600 mmHg
Measurement accuracy:	±10 mmHg
Fixed alarm limits:	Upper limit: +400 mmHg* Lower limit: -60 mmHg*
Alarm delay time:	Max. 2 seconds

- Definition

$P_d = P_{Bi} - P_{Bo}$

P_d = dialyser pressure difference

P_{Bi} = blood pressure on the inlet side of the dialyser

P_{Bo} = blood pressure on the outlet side of the dialyser

• Air detector

Protection system (Air infusion)

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)

• Blood pump



WARNING An excessively negative pre-pump arterial pressure can cause the actual blood flow to decrease, potentially reducing the efficiency of the treatment.



CAUTION To reduce the risk of minor or moderate patient injury from inadequate treatment, use only bloodline sets approved by NIKKISO CO., LTD. for use with the DBB-EXA (see Operating instructions, sec. 1.9.2).

Setting range:	40 to 600 mL/min
Display method:	Blood flow rate = Rotation of blood pump
Flow rate accuracy:	Set value $\pm 10\%$ (Inflow Pressure $-150\text{mmHg} \leq P \leq +150\text{mmHg}$) Set value -20 to 0% (Inflow Pressure $-200\text{mmHg} \leq P < -150\text{mmHg}$)
Inflow pressure:	-200 mmHg minimum $+150$ mmHg maximum
Outlet pressure:	$+500$ mmHg maximum
Protection system (Extracorporeal blood loss due to coagulation)	
Method:	Monitoring of Blood pump (PUMP) flow rate
Protection system:	Monitoring of stoppage Monitoring of rotation (Reverse rotation)
Display method:	Blood flow rate = Rotation of blood pump
Reminder alarm (BP OFF, BP cover open, blood flow set 0):	20 seconds

• Effective blood flow rate

Measurement range:	0 to 999 mL/min
Measurement accuracy:	$\pm 10\%$

The effective blood flow refers to the blood flow rate compensated by the arterial pressure.

The effective blood flow is obtained using equation below.

$$Q_r = Q_{ba} \times \left(1 - A_p \times \frac{-0.075}{100} \right)$$

Q_r	=	Effective blood flow (mL/min)
Q_{ba}	=	Flow rate of the arterial blood pump (mL/min)
A_p	=	Arterial pressure (mmHg)
Constant: -0.075^*		

• Blood flow volume

Measurement range:	0 to 999.9 L
Measurement accuracy:	$\pm 10\%$

• HP

Setting range:	0.0 to 9.9 mL/h
Output rate accuracy:	Set value $\pm 10\%$
Back pressure:	$+500$ mmHg
Syringe type:	30 mL (Luer Lock) or 20 mL (Luer Lock), 20 mL (Luer Lock) or 10 mL (Luer Lock) (optional)
Bolus process:	0.0 to 9.9 mL
Max. bolus accumulation capacity:	1 x syringe capacity (30 mL, 20 mL, or 10 mL)
Alarm limit:	Upper limit: $+20\%$ Lower limit: -20%

• HP total flow volume

Measurement range: 0 to 99.9 mL

Measurement accuracy: $\pm 10\%$



The HP is used only for infusion of heparin solution.

Do not use this pump for the infusion of any other chemicals or medications under any circumstances. Doing so can cause serious patient injury or death.

• SNSP with Arterial clamp (optional)

Single needle dialysis (SN) pressure (Venous pressure):

Measurement range : -200 to +600 mmHg

Measurement accuracy : ± 10 mmHg

Control

SN control pressure : Upper limit: +200 mmHg*
Lower limit: +50mmHg*

Monitoring

SN pressure alarm limits : Upper limit: +50 mmHg*
Lower limit: -50 mmHg*

SN switching time alarm limits : Arterial phase:18 sec.*
Venous phase:18 sec.*

Average blood flow

Measurement range : 0 to 999 mL/min

Measurement accuracy : $\pm 10\%$

The average blood flow rate refers to the average rate of the blood flowing through the dialyser in a particular period.

The average blood flow rate is obtained using equation 1 below.

$$Q_m = Q_{ba} \times \frac{t_a}{C_t} \quad \text{Equation 1}$$

Q_m	=	Average blood flow (mL/min)
Q_{ba}	=	Flow rate of the arterial blood pump (mL/min)
C_t	=	Cycle time (sec.) = $t_a + t_{sn}$
t_a	=	Arterial phase period (sec.)
t_{sn}	=	Venous phase period (sec.)

Stroke volume:

Measurement range: 0 to 99.9 mL

Measurement accuracy: $\pm 10\%$

The stroke volume here refers to the amount of blood sent to the dialyser by the blood pump (PUMP).

The stroke volume is obtained using equation 2 below.

$$Sv = Qm \times \frac{Ct}{60} \quad \text{Equation 2}$$

Qm	=	Average blood flow (mL/min)
Sv	=	Stroke volume (mL)
Ct	=	Cycle time (sec.) = ta + tsn
ta	=	Arterial phase period (sec.)
tsn	=	Venous phase period (sec.)

• Audible alarm

Loudness:	72.4 dB (Factory default)
Silence period	120 seconds (Factory default)

• Alarm over ride

Override time:	10 seconds (Factory default)
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1.6.10 BPM (optional) (see Operating instructions Chapter 10.)

NOTE Alarm settings marked with an asterisk (*) in this section can be changed.
See the Technical Manual Chapter 6 for information regarding setting the limits.

Measurement technology:	Oscillometric								
Measurement method:	Linear deflation method								
Pressure display range:	10 to 300 mmHg								
Pressure display accuracy:	Less than ± 3 mmHg								
Measurement range:									
Adult	<table> <tr> <td>Systolic blood pressure (SYS)</td><td>60 to 250 mmHg</td></tr> <tr> <td>Mean arterial pressure (MAP)</td><td>45 to 235 mmHg</td></tr> <tr> <td>Diastolic blood pressure (DIA)</td><td>40 to 200 mmHg</td></tr> <tr> <td>Pulse rate</td><td>40 to 200 beat per minute</td></tr> </table>	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 beat per minute
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 beat per minute								
Pulse rate accuracy:	$\pm 2\% \pm 2$ beats								
Degree of protection against electrical shock (Blood pressure cuff):	Defibrillation - proof Type BF Applied part								

Alarm limits:

Adult	SYS alarm upper limit	200 mmHg*
	SYS alarm lower limit	80 mmHg*
	MAP alarm upper limit	180 mmHg*
	MAP alarm lower limit	60 mmHg*
	DIA alarm upper limit	160 mmHg*
	DIA alarm lower limit	50 mmHg*
	Pulse rate alarm upper limit	170 beats per minute*
	Pulse rate alarm lower limit	50 beats per minute*

Reference standard: IEC80601-2-30, Ed.1.0 (2009)
EN1060-3: 1997/A2: 2009

1.6.11 Blood volume monitor (BVM) (optional) (see Operating instructions Chapter 11.)

Measurement principle:	Near-infrared reflection method
Applicable blood flow rate range:	40 to 600mL/min
Applicable hematocrit range:	15 to 50%
dBV monitoring accuracy:	±2.3dBV% (Double needle)
Alarms:	dBV drop alarm 1, dBV drop alarm 2, dBV changed rate alarm, dBV deviation alarm (lower, upper).

1.6.12 Online HDF/HF

• Hydraulic unit

NOTE Alarm settings marked with an asterisk (*) can be changed.
see the service manual for further information on setting the limits.

- TMP (The values will change as follows for online HDF/HF treatment.)

Auto set alarm range	Upper limit:	+100 mmHg*
	Lower limit:	-70 mmHg*
Auto forecast alarm range	Upper limit:	+50 mmHg*
	Lower limit:	-50 mmHg*

• Definition 1 (Online HDF)

$$TMP = \left(\frac{PBi + PBo}{2} \right) - \left(\frac{PDi + PDo}{2} \right) - Offset$$

• Definition 2 (Online HF)

$$TMP = \left(\frac{PBi + PBo}{2} \right) - PDo - Offset$$

PDi	=	dialysis fluid pressure on the inlet side of the dialyser
PDo	=	dialysis fluid pressure on the outlet side of the dialyser
PBi	=	blood pressure on the inlet side of the dialyser
PBo	=	blood pressure on the outlet side of the dialyser
Offset	=	flow-dependent pressure variations

• Pressure monitoring (extracorporeal blood circuit)

- Venous pressure

(The values will change as follows for online HDF/HF treatment.)

Auto set alarm range	Upper limit:	+70 mmHg*
	Lower limit:	-70 mmHg*

- Dialyser inlet pressure

(The values will change as follows for online HDF/HF treatment.)

Auto set alarm range	Upper limit:	+120 mmHg*
	Lower limit:	-70 mmHg*

- Substitution fluid pump (PUMP 2)

When using the online HDF tube set.

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

- NOTE**
- In the online HDF/HF operating mode, the second pump is operated as a substitution fluid pump (PUMP 2); therefore SN blood pump operation is not possible.
 - The substitution fluid pump runs intermittently when the substitution rate is less than 1.2 L/h which is the minimum speed of the substitution pump. The pump runs at 1.2 L/h and stops alternately so as to achieve the desired substitution volume.

- SUB rate

Setting range : Post dilution: 0 to 50%
Pre dilution: 0 to 999%

- Bolus substitution fluid

Setting range : 40 to 500 mL/min
Flow rate accuracy : Set value $\pm 10\%$
Bolus process : 0 to 500 mL
Max. bolus accumulation capacity/time : 1000 mL/per treatment

- Wash back

Setting range : 40 to 500 mL/min
Flow rate accuracy : Set value $\pm 10\%$
Wash back process : 0 to 500 mL
Max. wash back accumulation capacity/time : 1000 mL/per treatment

- Additional wash back volume

Artery additional wash back volume : 0 to 99 mL
Vein additional wash back volume : 0 to 99 mL

1.6.13 Materials utilized for piping

Materials which contact the water, concentrates, and dialysis fluid are listed below.

- Stainless steel
- Fluoro-rubber
- Silicon (SI)
- Ceramic
- Polysulfone (PSU)
- Polyimide (PI)
- Glass
- Polypropylene (PP)
- Polyphenylene ether (PPE)
- Titanium
- Polytetrafluoroethylene (PTFE)
- ethylene-tetrafluoroethylene plastic (ETFE)
- Polyphenylenesulphone (PPSU)

1.6.14 USB memory, CF card

- | | |
|------------|--|
| USB Memory | - Supports USB 2.0 or both USB 3.0 and 2.0
- Device with operation confirmed in "18.6 USB check" |
| CF Card | - Type: TYPE1
- Format: FAT16 or FAT32
- Drive voltage: 3.3 V
- Device with operation confirmed in "18.5 CF card check" |

1.6.15 Patient card

- | | |
|------------------------|---|
| Communication method | NFC (Near Field Communication)
ISO/IEC 14443 TypeA |
| International Standard | EU: R&TTE(1999/5/EC)
USA: FCC ID:AK8RCS632U
CANADA: IC No.:409B-RCS632U |
| Frequency | 13.56MHz |
| Communication speed | ISO/IEC 14443 TypeA:106kbps |
| Communication Field | Maximum 25 mm |
| Using Card | Mifare Classic (Standard) 4K |
| Card capacity | 4096 byte
*However, the usable range is 3440 bytes. |

1.6.16 Dialysis Dose Monitor (optional)

- | | |
|---------------------------|---|
| Measurement principle | : Absorptiometry |
| Applicable Treatment mode | : HD, Online HDF |
| Applicable Kt/V range | : 0 to 3.0 |
| Applicable Kt range | : 0 to 300.0 |
| Applicable K range | : 0 to 999.9 |
| Kt/V monitoring accuracy | : ± 0.1 (Kt/V 0 to 1)
$\pm 10\%$ (Kt/V 1 to 3) |
| Applicable URR range | : 0% to 100% |
| URR monitoring accuracy | : $\pm 5\%$ |