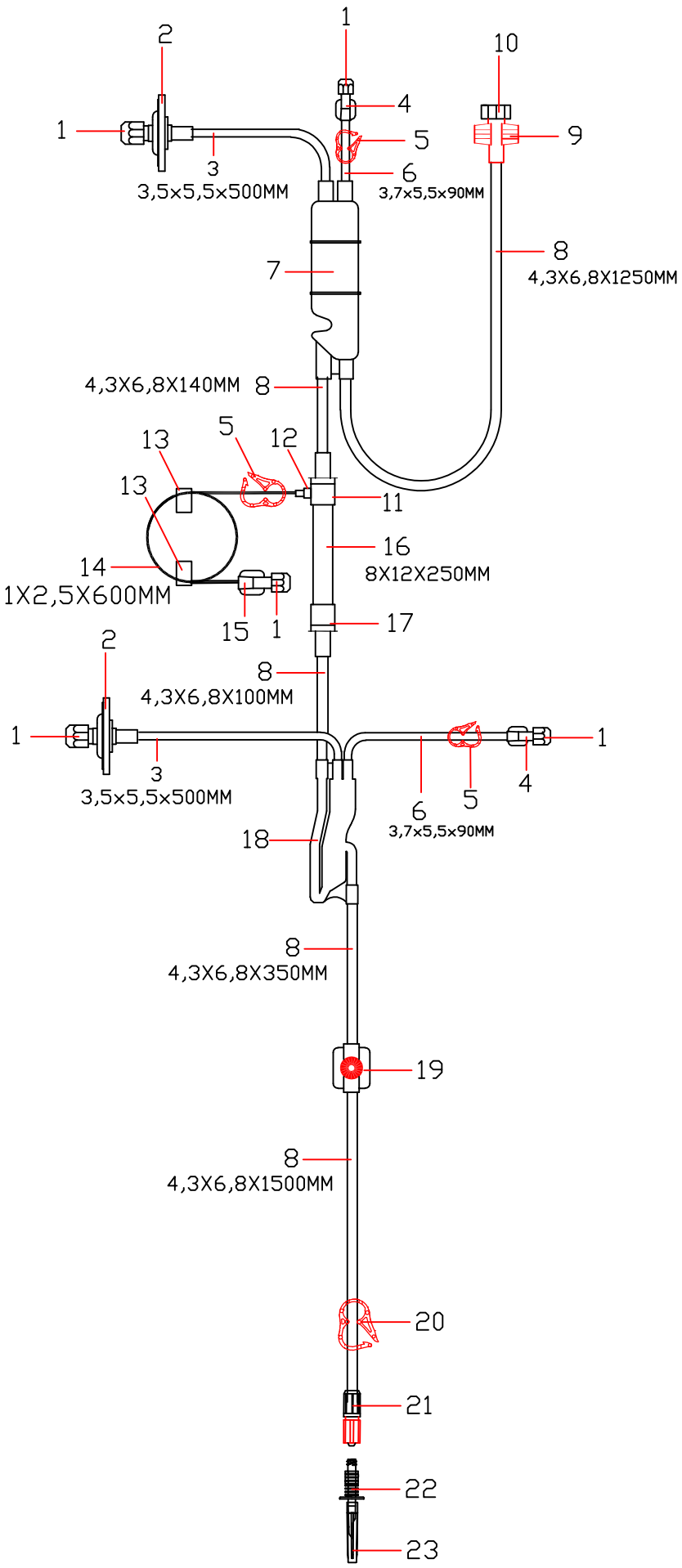
2.1pd



ARTERIAL LINE		
NO.	DESCRIPTION	QTY
1	CAP FOR FLL	5
2	TP	2
3	Ø 3.5 X 5.5 MM TUBE	2*
4	FLL	2
5	RED PINCH CLAMP	3
6	Ø 3.7 X 5.5 MM TUBE	2*
7	CHAMBER (OD:27mm, L:153mm)	1
8	Ø 4.3 X 6.8 MM TUBE	5*
9	RED DIALYSER CONNECTOR	1
10	VENTED CAP FOR DIALYSER CONNECTOR	1
11	T PUMP CONNECTOR	1
12	REDUCER	1
13	COHESIVE PAPER	2
14	Ø 1 X 2.5 MM TUBE	1
15	FLL	1
16	Ø 8 X 12 MM PUMP TUBE	1
17	PUMP CONNECTOR	1
18	CHAMBER (OD:29mm, L:104mm)	1
19	BLOOD INJECTION SITE	1
20	RED PINCH CLAMP	1
21	MLL	1
22	SPIKE	1
23	CAP FOR SPIKE	1

* MORE PIECES, LENGTHS MARKED ON THE DRAWING

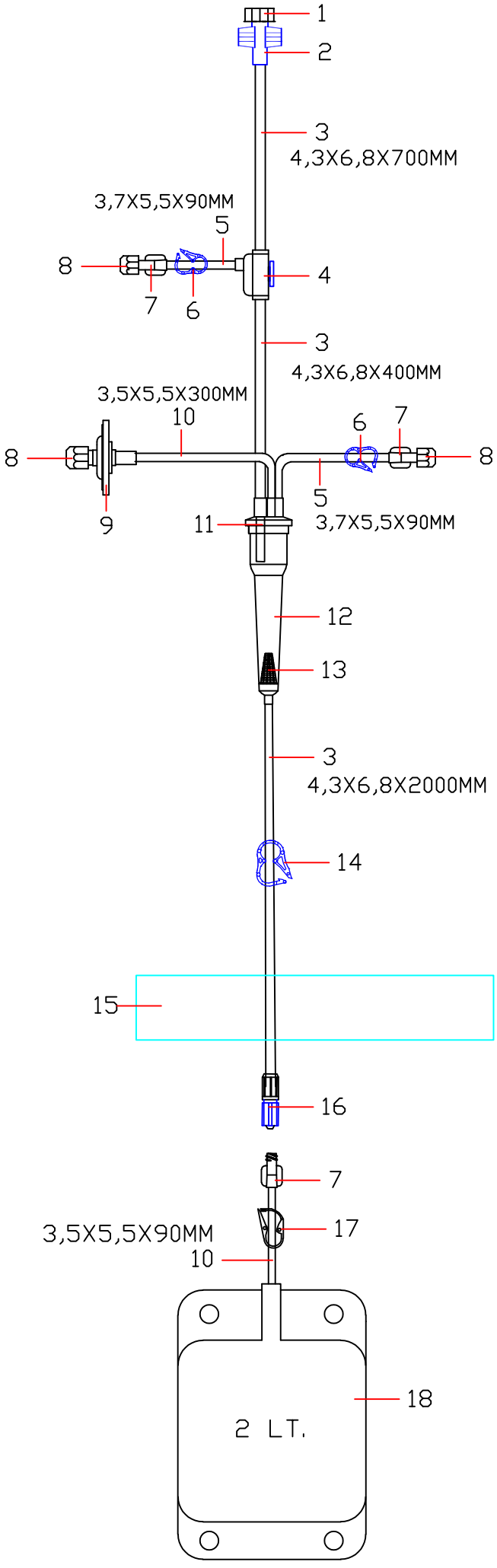
DESCRIZIONE/ DESCRIPTION

LINEA A/V PER NIKKISO DBB03/05/06/07 CON PERFORATORE-ETO

CODICE/ CODE

M90250EP

MEDICA



VENOUS LINE		
NO.	**DESCRIPTION**	**QTY**
1	VENTED CAP FOR DIALYSER CONNECTOR	1
2	BLUE DIALYSER CONNECTOR	1
3	Ø 4.3 X 6.8 MM TUBE	3*
4	BLOOD INJECTION SITE	1
5	Ø 3.7 X 5.5 MM TUBE	2*
6	BLUE PINCH CLAMP	2
7	FLL	3
8	CAP FOR FLL	3
9	TP	1
10	Ø 3.5 X 5.5 MM TUBE	2*
11	COVER FOR CHAMBER	1
12	CHAMBER (OD:22/30mm, L:129mm)	1
13	FILTER	1
14	BLUE PINCH CLAMP	1
15	PE-HD SHEATH	1
16	MLL	1
17	WHITE PINCH CLAMP	1
18	BAG	1

* MORE PIECES, LENGTHS MARKED ON THE DRAWING

DESCRIZIONE/ DESCRIPTION

LINEA A/V PER NIKKISO DBB03/05/06/07 CON PERFORATORE-ETO

CODICE/ CODE

M90250EP

MEDICA

2.1 pd

Reg. Numero / *Reg. Number*	MDR 00048-A	Revisione / *Revision*	0
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CERTIFICATE

Certificato UE del Sistema di Gestione della Qualità
EU Quality Management System Certificate

Kiwa Cermet Italia certifica che, sulla base dei risultati delle valutazioni effettuate, il Sistema di Gestione della Qualità dell'Organizzazione:
Kiwa Cermet Italia certifies that, on the basis of the assessment carried out, the Quality Management System of the Organization:

MEDICA S.p.A.

Operatore economico / *Economic operator:* Fabbricante

SRN: IT-MF-000025691

Sede Legale e Operativa / Legal and Operational Headquarters
Via degli Artigiani, 7 - 41036 Medolla (MO) - Italia

Unità Operativa / Operational Site
Via Degli Artigiani, 5 - 41036 Medolla (MO) - Italia

Unità Operativa / Operational Site
Via Degli Artigiani, 13 - 41036 Medolla (MO) - Italia

Unità Operativa / Operational Site
Via Posta Vecchia, 38 - 41037 Mirandola (MO) - Italia

Unità Operativa / Operational Site
Via della Beverara, 46/D - 40131 Bologna (BO) - Italia

E' conforme ai requisiti applicabili del Regolamento (UE) 2017/745, Allegato IX capo I e III per le seguenti tipologie di dispositivi:
Is in compliance with the applicable requirements of Regulation (EU) 2017/745, Annex IX Chapter I and III, for the following devices types:

U050101 - Sonde per cistomanometria senza palloncino */ Cystomanometry catheters, without balloon*

U050201 - Sonde per studio pressione-flusso urinario per riempimento */ Filling catheters for urinary*

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Organismo Notificato n. 0476
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Giampiero Belcredi

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pressure-flow study

U050301 - Sonde per profilo pressorio uretrale senza palloncino */ Urethral pressure profile catheters without balloon*

U050402 - Sonde per il rilevamento della pressione addominale con palloncino */ Intra-abdominal pressure measurement catheters, with balloon*

U0505 - Sonde per cavernosometria e cavernosografia */ Cavernosometry and cavernosography probes*

U0580 - Dispositivi per urodinamica - Accessori */ Urodynamics devices - Accessories*

U070301 - Dispositivi monouso per riabilitazione biofeedback del pavimento pelvico */ Pelvic floor rehabilitation devices, Biofeedback, single-use*

B030201 - Dispositivi per plasmaferesi e kit */ Plasmapheresis devices and kits,*

B030203 - Dispositivi per rimozione di singoli componenti plasmatici e kit */ Single plasma components removal devices and kits*

C03010101 - CIRCUITI PER CEC */ EXTRACORPOREAL CIRCULATION CIRCUITS*

C03010104 - FILTRI PER CEC */ EXTRACORPOREAL CIRCULATION FILTERS*

F01080201 - FILTRI PER ASSORBIMENTO DI ENDOTOSSINE */ ENDOTOXIN REMOVAL FILTERS*

C0399 - Dispositivi per cardiochirurgia e trapianto di organo - altri */ Cardiosurgery and organ transplantation devices - other*

F010601 - Filtri con coefficiente di ultrafiltrazione < 18 ml/h/mmhg */ Dialysers - ufc < 18 ml/h/mmhg*

F010602 - Filtri con coefficiente di ultrafiltrazione di 18 - 35 ml/h/mmhg */ Dialysers - ufc = 18 - 35 ml/h/mmhg*

F010603 - Filtri con coefficiente di ultrafiltrazione > 35 ml/h/mmhg */ Dialysers - ufc > 35 ml/h/mmhg*

F010604 - Filtri per emodiafiltrazione particolare e altri trattamenti particolari */ Dialysers for special haemodiafiltration and other therapies*

F020199 - Linee arterovenose per emodialisi-emofiltrazione-emodiafiltrazione - altre */ Arteriovenous dialysis lines for haemodialysis - haemofiltration -haemodiafiltration - other*

F0303 - Kit per emodialisi */ Haemodialysis kits*

G010302 - Cateteri per manometria esofagea */ Oesophageal manometry, catheters*

G020603 - Dispositivi per diagnostica colo-rettale */ Devices for colorectal diagnostic proceduresZ12090301* - Apparecchiature per emofiltrazione */ Haemofiltration equipment*

A030499 - Kit per somministrazione - altri */ Administration kits - other*

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Identificazione dei Dispositivi / *Devices identification:*

Tipologia / *Type:*

U050101 - Sonde per cistomanometria senza palloncino / *Cystomanometry catheters, without balloon*

Nome / *Name:*

Cateteri per cisto e uretrometria senza palloncino / *Catheters for cyst- and urethronometry without balloon*

Classe di rischio / *Risk class:*

II a

Tipologia / *Type:*

U050201 - Sonde per studio pressione-flusso urinario per riempimento / *Filling catheters for urinary pressure-flow study*

Nome / *Name:*

Cateteri per lo studio del flusso della pressione urinaria / *Catheters for pressure-flow urinary study*

Classe di rischio / *Risk class:*

II a

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Tipologia / *Type:*

U050301 - Sonde per profilo pressorio uretrale senza palloncino / *Urethral pressure profile catheters without balloon*

Nome / *Name:*

Cateteri per pressione uretrale senza palloncino / *Catheters for urethral pressor without balloon*

Classe di rischio / *Risk class:*

II a

Tipologia / *Type:*

U050402 - Sonde per il rilevamento della pressione addominale con palloncino / *Intra-abdominal pressure measurement catheters, with balloon*

Nome / *Name:*

Cateteri per la misurazione della pressione addominale / *Catheters for measuring abdominal pressure*

Classe di rischio / *Risk class:*

II a

Tipologia / *Type:*

U0505 - Sonde per cavernosometria e cavernosografia / *Cavernosometry and cavernosography probes*

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Identificazione dei Dispositivi / *Devices identification:*

Nome / *Name:*
Cateteri per cavernosometria / *Catheters for cavernosometry devices*

Classe di rischio / *Risk class:*
II a

Tipologia / *Type:*
U0580 - Dispositivi per urodinamica - Accessori / *Urodynamics devices - Accessories*

Nome / *Name:*
Dispositivi per urodinamica / *Urodynamic devices*

Classe di rischio / *Risk class:*
II a

Tipologia / *Type:*
U070301 - Dispositivi monouso per riabilitazione biofeedback del pavimento pelvico / *Pelvic floor rehabilitation devices, Biofeedback, single-use*

Nome / *Name:*
Catheters for pelvic floor biofeedback exercise / *Cateteri per la riabilitazione del pavimento pelvico*

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Classe di rischio / *Risk class:*
II a

Tipologia / *Type:*
B030201 - Dispositivi per plasmaferesi e kit / *Plasmapheresis devices and kits,*

Nome / *Name:*
Plasmafiltri / *Plasmafilters*

Nome commerciale / Brandname:
Plasmart

Classe di rischio / *Risk class:*
II b

Destinazione d'uso / Intended purpose:
Destinato alla separazione della parte liquida e corpuscolata del sangue e alla rimozione di molecole ad alto peso molecolare / *Intended for allowing the separation of the liquid part of the blood from the corpuscular part and the removal of high molecular weight elements.*

Nome / *Name:*
Set per plasmafiltrazione (Sterilizzato ad ossido di etilene) / *Plasmafiltration sets (Sterilized by ethylene oxide)*

Classe di rischio / *Risk class:*
II b

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Destinazione d'uso / Intended purpose:
Destinato alla separazione della parte liquida e corpuscolata del sangue e alla rimozione di molecole ad alto peso molecolare / *Intended for allowing the separation of the liquid part of the blood from the corpuscular part and the removal of high molecular weight elements,*

Nome / *Name:*
Set per plasmafiltrazione (Sterilizzato per irraggiamento) / *Plasmafiltration sets (Sterilized by radiation)*

Classe di rischio / *Risk class:*
II b

Destinazione d'uso / Intended purpose:
Destinato alla separazione della parte liquida e corpuscolata del sangue e alla rimozione di molecole ad alto peso molecolare / *Intended for allowing the separation of the liquid part of the blood from the corpuscular part and the removal of high molecular weight elements,*

Tipologia / *Type:*
B030203 - Dispositivi per rimozione di singoli componenti plasmatici e kit / *Single plasma components removal devices and kits*

Nome / *Name:*
Plasma frazionatori / *Plasma fractionators*

Nome commerciale / Brandname:
FRACTIOsmart™; TheraSorb®-LipoFil; FractioPlas®; SELECTISmart™

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Classe di rischio / *Risk class:*
II b

Destinazione d'uso / Intended purpose:
Destinato alla rimozione di molecole ad alto peso molecolare (virus, auto anticorpi, immuno complessi, LDL) dal plasma / *Intended for removing molecules with heavy molecular weight (viruses, autoantibodies, immune complex, LDL, etcetera) from plasma*

Tipologia / *Type:*
C03010101 - CIRCUITI PER CEC / *EXTRACORPOREAL CIRCULATION CIRCUITS*

Nome / *Name:*
Set e accessori per la gestione extracorporea del sangue e di sue parti / *Sets and accessories for extracorporeal blood and blood parts management*

Classe di rischio / *Risk class:*
II a

Nome / *Name:*
Set e accessori per la perfusione isolata degli arti / *Sets and accessories for isolated perfusion of a limb*

Classe di rischio / *Risk class:*
II a

Nome / *Name:*
Set e accessori per la rimozione della CO2 in eccesso nel sangue / *Sets and accessories for removal of CO2 excess in the blood*

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Identificazione dei Dispositivi / *Devices identification:*

Classe di rischio / *Risk class:*
II a

Nome / *Name:*
Set per emoconcentrazione / *Set for hemoconcentration*

Classe di rischio / *Risk class:*
II b

Destinazione d'uso / Intended purpose:
Destinato alla rimozione di acqua e soluti in stati patologici di uremia, squilibri elettrolitici associato patologie renali acute, edema cerebrale/polmonare, scompenso cardiaco, sepsi e ustioni / *Intended for removing water and various solutes in situations of uremia, electrolyte disturbances associated with acute kidney diseases, cerebral and / or pulmonary edema, heart disease, septic shock, burns.*

Tipologia / *Type:*
C03010104 - FILTRI PER CEC / *EXTRACORPOREAL CIRCULATION FILTERS*

Nome / *Name:*
Emoconcentratori / *Hemoconcentrators*

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Classe di rischio / *Risk class:*
II b

Destinazione d'uso / Intended purpose:
Destinato alla rimozione di acqua e soluti in stati patologici di uremia, squilibri elettrolitici associato patologie renali acute, edema cerebrale/polmonare, scompenso cardiaco, sepsi e ustioni / *Intended for removing water and various solutes in situations of uremia, electrolyte disturbances associated with acute kidney diseases, cerebral and / or pulmonary edema, heart disease, septic shock, burns.*

Tipologia / *Type:*
F01080201 - FILTRI PER ASSORBIMENTO DI ENDOTOSSINE / *ENDOTOXIN REMOVAL FILTERS*

Nome / *Name:*
Dispositivi per la purificazione del dialisato / *Ultrafiltration devices for purification of dialysis fluid*

Nome commerciale / Brandname:
DiaPure®

Classe di rischio / *Risk class:*
II a

Nome / *Name:*
Set di ultrafiltrazione per la purificazione del dialisato / *Set of ultrafiltration for purification of dialysis fluid*

Classe di rischio / *Risk class:*
II a

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Identificazione dei Dispositivi / *Devices identification:*

Tipologia / *Type:*

C0399 - Dispositivi per cardiochirurgia e trapianto di organo - altri / *Cardiosurgery and organ transplantation devices - other*

Nome / *Name:*

Dispositivi di ossigenazione per la perfusione dell'arteria epatica e della vena porta / *Oxygenation devices for liver artery and portal vein perfusion*

Classe di rischio / *Risk class:*

II a

Nome / *Name:*

Dispositivi di ossigenazione per perfusione dell'arteria renale / *Oxygenation devices for kidney artery perfusion*

Classe di rischio / *Risk class:*

II a

Tipologia / *Type:*

F010601 - Filtri con coefficiente di ultrafiltrazione < 18 ml/h/mmhg / *Dialysers - ufc < 18 ml/h/mmhg*

Nome / *Name:*

Dializzatori / *Dialyzers*

Nome commerciale / Brandname:

Smartflux, Spinflux™

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Identificazione dei Dispositivi / *Devices identification:*

Classe di rischio / *Risk class:*
II b

Destinazione d'uso / Intended purpose:
Dispositivo medico per l'emodialisi extracorporea e altri usi associati all'insufficienza renale cronica, destinato a rimuovere sostanze tossiche dal sangue del paziente / *Medical device for extracorporeal hemodialysis and other uses associated with chronic kidney failure, intended to remove toxic substances from blood patient*

Tipologia / *Type:*
F010602 - Filtri con coefficiente di ultrafiltrazione di 18 - 35 ml/h/mmhg / *Dialysers - ufc = 18 - 35 ml/h/mmhg*

Nome / *Name:*
Dializzatori / *Dialyzers*

Nome commerciale / Brandname:
Smartflux, Spinflux™

Classe di rischio / *Risk class:*
II b

Destinazione d'uso / Intended purpose:
Dispositivo medico per l'emodialisi extracorporea e altri usi associati all'insufficienza renale cronica, destinato a rimuovere sostanze tossiche dal sangue del paziente / *Medical device for extracorporeal hemodialysis and other uses associated with chronic kidney failure, intended to remove toxic substances from blood patient*

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Identificazione dei Dispositivi / *Devices identification:*

Tipologia / *Type:*

F010603 - Filtri con coefficiente di ultrafiltrazione > 35 ml/h/mmhg / *Dialysers - ufc > 35 ml/h/mmhg*

Nome / *Name:*

Dializzatori / *Dialyzers*

Nome commerciale / Brandname:

Smartflux, Spinflux™

Classe di rischio / *Risk class:*

II b

Destinazione d'uso / Intended purpose:

Dispositivo medico per l'emodialisi extracorporea e altri usi associati all'insufficienza renale cronica, destinato a rimuovere sostanze tossiche dal sangue del paziente / *Medical device for extracorporeal hemodialysis and other uses associated with chronic kidney failure, intended to remove toxic substances from blood patient*

Tipologia / *Type:*

F010604 - Filtri per emodiafiltrazione particolare e altri trattamenti particolari / *Dialysers for special haemodiafiltration and other therapies*

Nome / *Name:*

Emofiltri / *Hemofilters*

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Organismo Notificato n. 0476
Notified Body nr. 0476

Presidente / President
Giampiero Belcredi

CERTIFICATE

Allegato tecnico al Certificato
Technical sheet enclosed to the Certificate

Identificazione dei Dispositivi / *Devices identification:*

Classe di rischio / *Risk class:*
II b

Destinazione d'uso / Intended purpose:
Filtri destinati alla rimozione di fluidi in eccesso e molecole tossiche dal sangue dei pazienti / *Filters intended for removing excess fluids and toxic substances from patients blood*

Nome / *Name:*
Set per emofiltrazione / *Set for hemofiltration*

Classe di rischio / *Risk class:*
II b

Destinazione d'uso / Intended purpose:
Set destinati alla rimozione di fluidi in eccesso e molecole tossiche dal sangue dei pazienti / *Sets intended for removing excess fluids and toxic substances from patients blood*

Tipologia / *Type:*
F020199 - Linee arterovenose per emodialisi-emofiltrazione-emodiafiltrazione - altre / *Arteriovenous dialysis lines for haemodialysis - haemofiltration -haemodiafiltration - other*

Nome / *Name:*
Set e accessori per emodialisi (Sterilizzato ad ossido di etilene) / *Sets and accessories for hemodialysis (Sterilized by ethylene oxide)*

Classe di rischio / *Risk class:*
II a

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Identificazione dei Dispositivi / *Devices identification:*

Nome / *Name:*
Set e accessori per emodialisi (Sterilizzato per irraggiamento) / *Sets and accessories for hemodialysis (Sterilized by radiation)*

Classe di rischio / *Risk class:*
II a

Tipologia / *Type:*
F0303 - Kit per emodialisi / *Haemodialysis kits*

Nome / *Name:*
Set per trattamenti di emodialisi / *Sets for the hemodialysis treatment*

Classe di rischio / *Risk class:*
II a

Tipologia / *Type:*
G010302 - Cateteri per manometria esofagea / *Oesophageal manometry, catheters*

Nome / *Name:*
Cateteri per la manometria oro-esofagea / *Catheters for oro-esophageal manometry*

Classe di rischio / *Risk class:*
II a

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Identificazione dei Dispositivi / *Devices identification:*

Tipologia / *Type:*
G020603 - Dispositivi per diagnostica colo-rettale / *Devices for colorectal diagnostic procedures*

Nome / *Name:*
Cateteri per manometria anorettale / *Catheters for anorectal manometry*

Classe di rischio / *Risk class:*
II a

Tipologia / *Type:*
Z12090301 - Apparecchiature per emofiltrazione / *Haemofiltration equipment*

Nome / *Name:*
Sistema per emoperfusione e rimozione di endotossine dal sangue / *System for hemoperfusion and endotoxins removal from blood*

Nome commerciale / Brandname:
ESTORFLOW

Classe di rischio / *Risk class:*
II b

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Identificazione dei Dispositivi / *Devices identification:*

Destinazione d'uso / Intended purpose:
ESTORflow è un sistema per la circolazione extracorporea attraverso circuiti dedicati per il trattamento del sangue e la rimozione di endotossine. / *ESTORflow is a medical device intended to use for extracorporeal circulation through circuits equipped with devices for the treatment of blood and endotoxins removal*

Nome / *Name:*
Sistema per reoferesi / *Systems for rheopheresis*

Nome commerciale / Brandname:
AFERsmart MS

Classe di rischio / *Risk class:*
II b

Destinazione d'uso / Intended purpose:
AFERSMART MS è destinato a pazienti che necessitano dei seguenti trattamenti terapeutici:• REOFERESI A DOPPIA FILTRAZIONE / *AFERSMART MS is intended for carrying out the following treatments:• DOUBLE FILTRATION RHEOPHERESIS*

Nome / *Name:*
Sistemi per emoperfusione / *Systems for hemoperfusion*

Nome commerciale / Brandname:
LIPIDsmart

Classe di rischio / *Risk class:*
II b

Destinazione d'uso / Intended purpose:
LIPIDSMART è destinato a pazienti che necessitano dei seguenti trattamenti terapeutici:• EMOPERFUSIONE / *LIPIDsmart is intended for patients that need the following therapeutic treatment:• HEMOPERFUSION*

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Nome / *Name:*
Sistemi per emoperfusione e reoferesi / *Systems for hemoperfusion and rheopheresis*

Nome commerciale / Brandname:
APRED

Classe di rischio / *Risk class:*
II b

Destinazione d'uso / Intended purpose:
APRED è destinato a pazienti che necessitano dei seguenti trattamenti terapeutici:• EMOPERFUSIONE • REOFERESI A DOPPIA FILTRAZIONE • AFERESI / *APRED is intended for carrying out the following treatments:• HEMOPERFUSION• DOUBLE FILTRATION RHEOPHERESIS• APHERESIS*

Nome / *Name:*
Sistemi per emoperfusione, scambio di plasma terapeutico, reoferesi e reoferesi adsorbimento / *Systems for hemoperfusion, therapeutic plasma exchange, rheopheresis and rheopheresis adsoption*

Nome commerciale / Brandname:
AFERsmart Plus

Classe di rischio / *Risk class:*
II b

Destinazione d'uso / Intended purpose:
AFERsmart Plus è destinato a pazienti che necessitano dei seguenti trattamenti terapeutici:• EMOPERFUSIONE• SCAMBIO DI PLASMA TERAPEUTICO • REOFERESI A DOPPIA FILTRAZIONE• REOFERESI AFERESI SELETTIVA• REOFERESI A DOPPIA FILTRAZIONE ADSORBIMENTO / *AFERSMART PLUS is intended for carrying out the following treatments:• HEMOPERFUSION• THERAPEUTIC PLASMA EXCHANGE • DOUBLE FILTRATION RHEOPHERESIS• RHEOPHERESIS SELECTIVE APHERESIS• DOUBLE FILTRATION RHEOPHERESIS ADSORPTION*

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Identificazione dei Dispositivi / *Devices identification:*

Nome / *Name:*
Sistemi per emoperfusione, scambio di plasma terapeutico, reoferesi e reoferesi con adsorbimento / *Systems for hemoperfusion, therapeutic plasma exchange, rheopheresis and rheopheresis adsorbtion*

Nome commerciale / Brandname:
AFERsmart

Classe di rischio / *Risk class:*
II b

Destinazione d'uso / Intended purpose:
AFERsmart è destinato a pazienti che necessitano dei seguenti trattamenti terapeutici:• EMOPERFUSIONE• SCAMBIO DI PLASMA TERAPEUTICO• REOFERESIS A DOPPIA FILTRAZIONE• REOFERESI AFERESI SELETTIVA• REOFERESI A DOPPIA FILTRAZIONE ADSORBIMENTO / *AFERsmart is intended for patients that need the following therapeutic treatments:• HEMOPERFUSION• THERAPEUTIC PLASMA EXCHANGE• DOUBLE FILTRATION RHEOPHERESIS• RHEOPHERESIS SELECTIVE APHERESIS• DOUBLE FILTRATION RHEOPHERESIS ADSORPTION*

Nome / *Name:*
Sistemi per emoperfusione, scambio di plasma terapeutico, reoferesi, reoferesi con adsorbimento e perfusione d'organo / *Systems for haemoperfusion, therapeutic plasma exchange, rheopheresis, rheopheresis adsorption and organ perfusion*

Nome commerciale / Brandname:
PLASMAPHER

Classe di rischio / *Risk class:*
II b

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Reg. Numero / *Reg. Number*	MDR 00048-A	Revisione / *Revision*	0
Primo rilascio / *First issue date*	2023-06-01	Valido da / *Valid from*	2023-06-01
Scadenza / *Valid until*	2028-05-31	Ultima modifica / *Last change date*	2023-06-01
Data Scadenza Precedente / *Previous Expiry*			

CERTIFICATE

Allegato tecnico al Certificato
Technical sheet enclosed to the Certificate

Identificazione dei Dispositivi / *Devices identification:*

Destinazione d'uso / Intended purpose:
PLASMAPHER è destinato a pazienti che necessitano dei seguenti trattamenti terapeutici:• EMOPERFUSIONE• SCAMBIO DI PLASMA TERAPEUTICO • REOFERESI A DOPPIA FILTRAZIONE• REOFERESI AFERESI SELETTIVA• REOFERESI A DOPPIA FILTRAZIONE ADSORBIMENTO• EVLP / *PLASMAPHER is intended for patients that need the following therapeutic treatments: • HEMOPERFUSION • THERAPEUTIC PLASMA EXCHANGE • DOUBLE FILTRATION RHEOPHERESIS • RHEOPHERESIS SELECTIVE APHERESYS • DOUBLE FILTRATION RHEOPHERESIS ADSORPTION• EVLP*

Tipologia / *Type:*
A030499 - Kit per somministrazione - altri / *Administration kits - other*

Nome / *Name:*
Set per il trattamento di perfusione ipotermica di organi / *Sets for the treatment of hypothermic oxygenated organ perfusion*

Classe di rischio / *Risk class:*
II a

Nome / *Name:*
Set per trattamenti di chemio ipertermia locoregionali oncologici / *Sets for the chemohyperthermic locoregional oncological treatments*

Classe di rischio / *Risk class:*
II a

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Reg. Numero / *Reg. Number*	MDR 00048-A	Revisione / *Revision*	0
Primo rilascio / *First issue date*	2023-06-01	Valido da / *Valid from*	2023-06-01
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Data Scadenza Precedente / *Previous Expiry*			

La lista completa dei codici, relativi ai modelli certificati, è disponibile presso Kiwa Cermet Italia.
The complete list of the codes related to the certificated models is available at Kiwa Cermet Italia.
Il presente Certificato è soggetto al rispetto dei requisiti contrattuali di Kiwa Cermet Italia ed è valido solo per le tipologie di dispositivi sopra identificate soggette a sorveglianza periodica.
This Certificate is subject to Kiwa Cermet Italia regulations and it is valid only for the aforementioned types of devices that are subject to periodic survey.
L'allegato tecnico è parte integrante del presente Certificato
The technical sheet is an integrating part of this Certificate.

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CERTIFICATE

Storia del Certificato
Certificate History

Rev. *Rev.*	**Data** *Date*	**Descrizione modifica** *Description of Change*	**Rapporto di valutazione[1] del** *Certificate History*
0	01/06/2023	Certificazione iniziale *Initial certification*	Rapporto di audit del / *Audit report dated:* 01/03/2023; 02/03/2023; 03/03/2023 Analisi documentazione tecnica del / *Technical documentation analysis dated:* 11/01/2023; 25/01/2023; 01/03/2023; 02/03/2023 Valutazione dati clinici del / *Clinical data assessment dated:* 05/01/2023; 07/01/2023; 11/01/2023

[1] I rapporti di valutazione sono disponibili su richiesta / Assessment reports are available upon request

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MEDICA CE 0476
SEAMLESS INNOVATION FOR LIFE QUALITY
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Tel. +39 0535 51159 – Fax +39 0535 52605

SRN: IT-MF-000025691

TECHNICAL DATASHEET
CODE: M90250EP
Tubing sets, bags and accessories used for the following machine: NIKKISO

2.1 pd

CLASSIFICATION

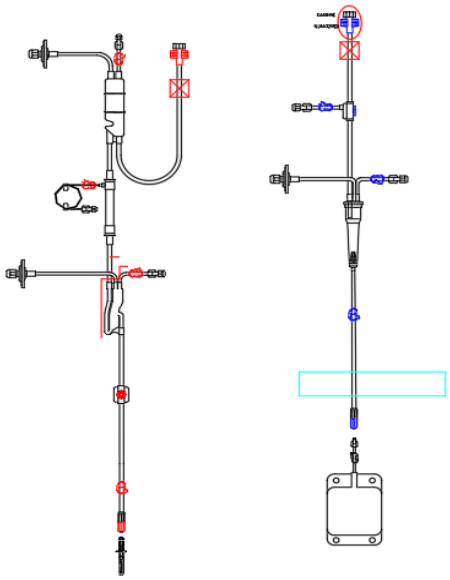
TECHNICAL FILE	BLD - SETS AND ACCESSORIES FOR EXTRACORPOREAL BLOOD MANAGEMENT
DECLARATION OF CONFORMITY	EU-DoC-BLD
CLASS RISK	IIa - Rule 2
EMDN CLASSIFICATION	F020199
GMDN CLASSIFICATION	34999
BASIC UDI-DI (MDR - Annex VI, Part C)	803377232BLD-HML8E
UDI-DI	8033772329293

TECHNICAL CHARACTERISTICS

Arterial line
- Filter connection via Female Twist-Lock connector
- Pump segment [mm] 8x12
- Drip chamber with particle filter
- Arterial drip chamber (pre-pump segment)
- Arterial drip chamber (post-pump segment)
- Sampling port
- Heparin line
- Arterial trasducer protector
- Trasducer protector (pre-filter)
- Arterial spike

Venous line
- Filter connection via Female Twist-Lock connector
- Drip chamber with particle filter
- Venous trasducer protector
- Waste collection bag 2 liters

CONFIGURATION



PACKAGING TECHNICAL CHARACTERISTICS

Pouch material	Shipping box material	Box pieces	Sterilization Method	Validity
Medical paper/Film	CARDBOARD	30	Ethylene oxide	THREE years

INTENDED USE

HEMODIALYSIS LINE: lines used in hemodialysis treatment.

PRINCIPLES OF OPERATION

The blood is extracted from an artery of the patient by needles, cannulas or catheters, and conveyed into the arterial line. The BLD devices are equipped with a pump section, which is inserted in a special seat of the peristaltic pump of the active medical device that manages the treatment, whose rotation cyclically occludes the tube lumen ensuring the necessary flow to the blood to be able to carry out the treatments required. The arterial line is normally connected to a filter (hemodialyser, plasma filter, hemoconcentrator, heat exchanger, oxygenator or other similar devices), which allows the desired blood treatment to be carried out. The venous line is connected to the outlet of the filter, which conveys the blood thus treated to another vascular access of the patient (needles, cannulas or catheters), causing it to be returned to the bloodstream.

INSPECTIONS

The production of SETS AND ACCESSORIES FOR EXTRACORPOREAL BLOOD MANAGEMENT is managed under the Medica Group Quality System certificate UNI EN ISO 9001:2015 ed UNI CEI EN ISO 13485:2021, according to the applicable SOPs (PG, Procedure Gestionali). All the devices undergo leakage tests.

PRODUCTION ENVIRONMENT

All manufacturing activities carried out for BLD devices, including:

- Plastic tubing extrusion and plastic parts moulding;
- Tubing sets assembling and inspection;
- BLD devices final assembling, inspection and single packaging are carried out in controlled contamination areas (clean room) ISO 8 classified, according to ISO 14644, managed in compliance with PG6401 (Management of work environment).

LABELING

Each package and every single shipping box is provided with a label, including data for the identification of the device (code, batch number, manufacturing date, expiry date, number of items and dimensions) and symbols complying with ISO 15223-1 standard.
Each multiple package is provided with a IFU (Instructions for Use) sheet with symbols complying with ISO 15223-1 standard.

PACKAGING

The packaging is compliant with Standard ISO 11607-1, ISO 11607-2 and ISTA 2A.

BIOCOMPATIBILITY

SETS AND ACCESSORIES FOR EXTRACORPOREAL BLOOD MANAGEMENT underwent biocompatibility tests according to their intended are complaint to UNI EN ISO 10993.

STORAGE AND HANDLING

The device must be kept away from heating sources, light and humidity. Handle with care, avoid shocks and falls.

DISPOSAL CONDITIONS

Disposal must take place in accordance with Italian Presidential Decree 254/2003 (implementation of Art. 24 L 179/2002) or according to the legislation in force in the country of use. The used devices must however be considered as hospital waste containing potentially infectious material.

NIKKISO

2.2pd ir 2.5pd

AV18 & C18 Series

Blood tubing lines for hemodialysis (steam sterilized)

Dedicated bloodlines for your **DBB-EXA** dialysis system.

Highlights

- DEHP free
- Sustainable
- Low extracorporeal blood volume
- Reduced blood/air contact
- Easy to setup and prime
- No drain bag required
- Automatic prime, connect and wash back utilizing DBB-EXA D-FAS function

AV18 - AUTOMATIC ONLINE PRIMING - SUSTAINABLE - EFFICIENT -

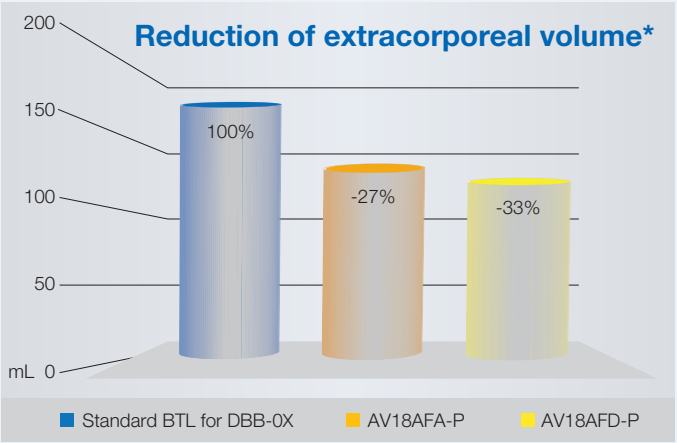
DBB-EXA

CE 0123

AV18 & C18 Series

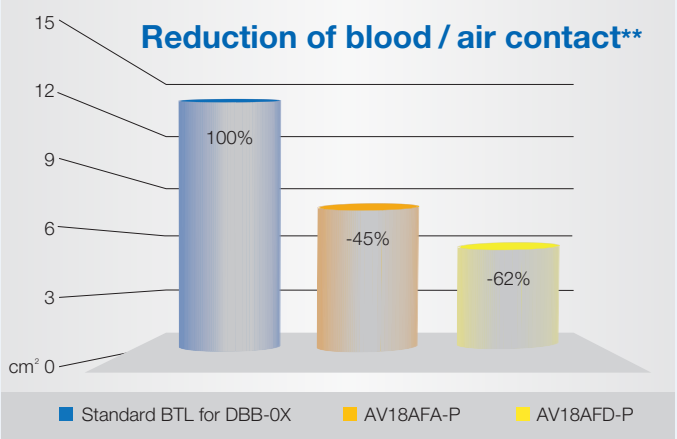
The AV18 & C18 series is tailored for use with DBB-EXA enabling the full utilization of the **D**ialysis **F**ull **A**ssist **S**ystem (D-FAS).
The original NIKKISO tubing specifications guarantee the highest resolution and accuracy while using Haemo-Master or vascular access recirculation rate measurement.

The combination of **DEHP free PVC material** and **high temperature steam sterilization** in accordance with EN ISO 17665-1:2006, is the best choice for biocompatibility and pyrogen-free safety.



*based on manufacturers' data

The AV18 series reduced extracorporeal volume minimizes the blood / air contact.



**based on arithmetic calculations

NIKKISO is offering a wide range of blood tubing lines taking into account the specific requirements of dialysis facilities (e. g. AV18AFA-PL with longer patient lines) as well as the various needs of the nursing staff.

As an example, the AV18AFA-P, with HDF post- and pre-dilution ports, can be used with C18FB-P (with Luer-Lock) or with C18RFC-P (with Luer-Lock and Spike) for **saline** priming.

Online HDF Set

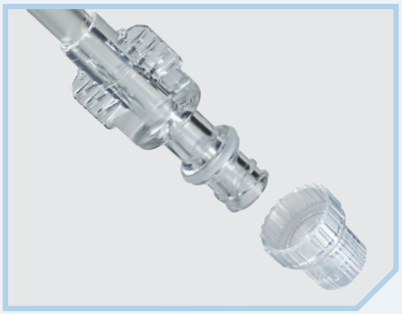
The AV18AFA-HFP conveniently combines a double needle blood tubing line and a substitution line C18AFA-P for Online HDF mode.

HD Set

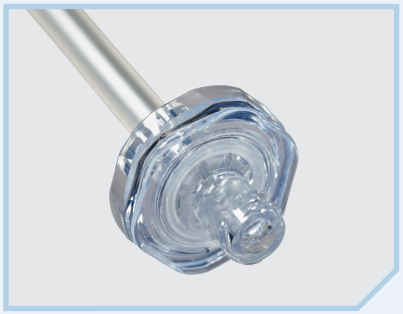
The AV18AFD-P (without dialyzer inlet pressure chamber) is specially designed for HD treatments with a further reduction in blood / air contact.

Steam sterilized blood tubing lines

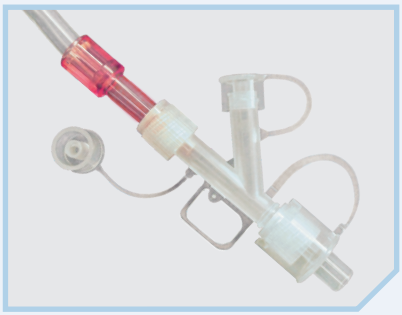
The original NIKKISO blood tubing line components



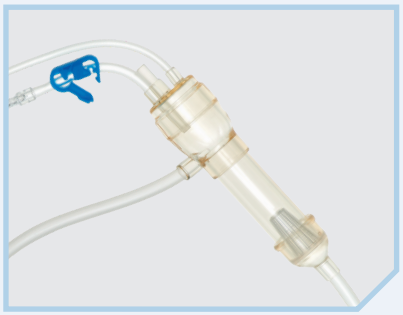
Online port connector, designed for a hygienically secure connection.



Transducer protector filter, designed for a secure and easy connection.



Y-adaptor for D-FAS priming, designed for easy and hygienic usability.



Venous drip chamber, designed for enhanced blood flow and air separation, reducing activation of clotting.

Sterilization

Steam sterilization EN ISO 17665-1:2006

Shelf life

36 months

Therapies

HD, HF, HDF (Post-/Pre-dilution), Double needle, Single needle

Blood tubing lines			
Model	Volume (mL)	Description	Units
Online-Priming (D-FAS)			
2.2pd AV18AFA-P	143	for HD, OHDF, OHF, Bolus	28
AV18AFA-SNP	202	for Single needle HD, Bolus	22
AV18AFA-PL	159	with 50 cm longer patient lines for HD, OHDF, OHF, Bolus	26
AV18AFD-P	132	for HD, Bolus	28
Substitution line			
2.5pd C18AFA-P		for Online HDF, OHF	60
Online HDF Set			
AV18AFA-HFP	143	combines AV-double needle blood tubing line set with substitution line C18AFA-P	24
Infusion lines for saline priming			
C18RFB-P		Infusion line with 2 Luer-Lock fittings	60
C18RFC-P		Infusion line with 1 Luer-Lock and 1 spike	60
Ancillaries			
C18BDD-P***		Sample line	60

*** contains phthalates

For special requirements, please contact your local distributor.

Inherited reliability

Contact

Telephone +49 40 414629 - 0
info@nikkiso-europe.eu

Manufacturer

NIKKISO CO., LTD.

20-3, Ebisu 4-Chome, Shibuya-ku
Tokyo 150-6022, Japan
Telephone: +81-3-3443-3727
Fax: +81-3-3440-0681
Website: www.nikkiso.com

European Authorized Representative

NIKKISO Europe GmbH

Desbrocksriede 1
D-30855 Langenhagen
Telephone: +49 511 679999 - 0
Fax: +49 511 679999 - 11
E-Mail: info@nikkiso-europe.eu

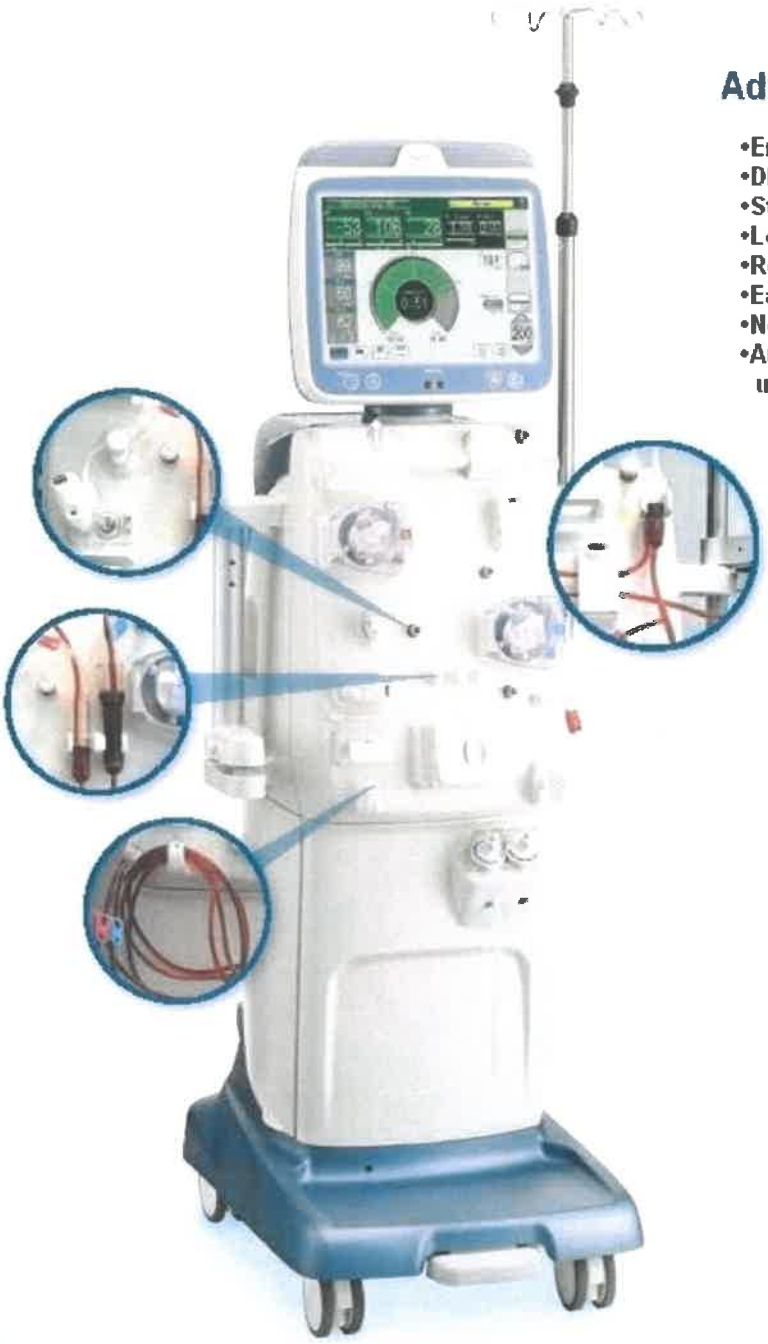
Local partner

C18 SFD-P	Circulation adaptor	50 / 650	24	58,5x37,5x30,0	2,78

2.2pd ir 2.5pd

NIKKISO

Steam sterilized blood lines
NIKKISO AV 18 series for DBB-EXA



Advantages of AV 18 series

- Environmentally friendly
- DEHP free
- Steam Sterilized
- Low extracorporeal blood volume
- Reduced blood/air contact
- Easy to setup and prime
- No drain bag required
- Automatic prime, connect and washback utilizing DBB-EXA D-FAS function

CE 0123

Innovations for Human Care.

NIKKISO AV 18 Serie

Low force closing clamps
with save guard

Open pressure transducer
protectors
with ergonomic housing

Save On Line port connection
with O - ring sealing

Venous drip chamber
with high in flow and
air deposition

Dialyser inlet chamber
with reduced volume

The environmentally friendly steam sterilized AV 18 NIKKISO blood lines with reduced blood/air contact provides an efficient treatment by reducing costs and effort.

The optimised design of the AV-18 series integrated with the DBB-EXA Dialysis Fully Automated System reduces workload for the operator.

2.2 pirkimo dalis

2.5 pirkimo dalis

Blood lines			
Modell	Volume (ml)	Therapie	Units
Online -Priming			
AV18 AFA-P	143	HD,OHDF,OHF, Bolus	28
AV18 AFA-SNP	198	Single Needle HD, Bolus	22
AV18 AFA-HFP	143	Online HDF	24
Substitution line			
C18 AFA-P	N.A.	Online HDF, OHF	60
Infusion line			
C18 RFB-P	N.A.	Infusion line 2 x Luer Lock	60
C18 RFC-P	N.A.	Infusion line 1x Luer Lock, 1 x spike	60

Therapies
HD, HF, HDF (Post / Predilution) Double needle, Single needle
Sterilisation
Steam sterilisation, EN ISO 17665-1:2006
Shelf life
36 month

www.nikkiso-europe.eu

Manufacturer
NIKKISO CO.;LTD
20-3,Ebisu
4-chrome,Shibuya-ku
Tokyo 150-6022, Japan

Phone: + 81-3-3443-3727
Fax: + 81-3-3440-0681

Internet: ww.nikkiso.com

EC-Representive
NIKKISO Europe GmbH
Desbrocksriede 1
D-30855 Langenhagen

Phone: + 49511-679999-0
Fax: + 49-51169999-11

E-Mail: info@nikkiso-europe.eu
Internet: ww.nikkiso-europe.eu

Exclusive distribution by:
NIKKISO Europe GmbH
Kapstadtring 7
D-22397 Hamburg

Phone: + 4940414629-0
Fax: + 4940414629-49

E-Mail: info@nikkiso-europe.eu
Internet: ww.nikkiso-europe.eu

DO-F470-00
Realease 07/2017
Version 1.0
CE 0123

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

2.2-2.6pd

Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 023235 0138 Rev. 02

Manufacturer: **NIKKISO CO., LTD.**
20-3, Ebisu 4-Chome, Shibuya-ku
Tokyo
150-6022 JAPAN

Product Category(ies): **Hemodialysis Equipment, Apheresis Equipment, and Closed-loop Blood Glucose Controller, Blood Tubing Lines, Tubing for Blood Glucose Monitoring, Infusion Administration, Hemodialyzer, Cytapheresis Adsorber, Hemofilter and Filters for Dialysate Purification**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: **JA1442576**

Valid from: **2020-04-22**
Valid until: **2024-05-26**

Date, 2020-04-22

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

2.2-2.6pd

NIKKISO CO.,LTD.
20-3, Ebisu 4-Chome, Shibuya-ku, Tokyo 150-6022, Japan
TEL : +81-3-3443-3711 FAX : +81-3-3473-4963
URL https://www.nikkiso.com

May 9, 2024

Declaration letter - Change of EC representative
Medical Device Regulation (MDR) (EU) 2017/745 Article 12: Change of authorised representative

Dear Sir or Madam,

we would like to announce that we;

NIKKISO CO., LTD.
20-3 Ebisu 4-Chome, Shibuya-ku, Tokyo,
150-6022 Japan

as the manufacturer of in the "G1 023235 0138 Rev.02_MDD-Ann.II_EC Certificate" listed product categories will be change the EC representative according to Medical Device Regulation (MDR) (EU) 2017/745 Article 12: Change of authorised representative, from;

Nikkiso Europe GmbH,
Desbrooksriede 1,
D-30855 Langenhagen
Phone: +49-511-679999-0, Fax: +49-511-679999-11

to;

NIKKISO Medical Europe GmbH
Kapstadtring 7
D-22297 Hamburg
Phone: +49-40-414629-0, Fax: +49-40-414629-49

Both companies are subsidiaries of the NIKKISO CO., LTD.

The change of the EC representative is a label change and has no influence on the Safety and Performance of the following product categories.

- Hemodialysis Equipment,
- Apheresis Equipment,
- Blood Tubing Lines,
- Hemodialyzer,
- Cytapheresis Adsorber,
- Filters for Dialysate Purification

Therefore, labeling of products which has been distributed with the name of "Nikkiso Europe GmbH" as EC representative will be shifted to "NIKKISO Medical Europe GmbH". It is planned to implement the change of EC REP in 2024.

Yours sincerely,

Satoko Hina
General Manager, Regulatory Affairs Department, Medical Division
(Person responsible for regulatory compliance)
NIKKISO CO., LTD.

2.2-2.6pd

NIKKISO CO.,LTD.
20-3, Ebisu 4-Chome, Shibuya-ku, Tokyo 150-6022, Japan
TEL +81-3-3443-3711 FAX +81-3-3473-4963
URL:http://www.nikkiso.com

May 9, 2024

To whom it may concern:

Statement on transition for MDR

We would like to confirm that our MDD EC certification for the products described below, which expire on 2024-05-26 continue to be valid according to the MDR transitional provisions outlined in amended Art. 120 of EU-MDR. This means that new MDD EC certificate will not be issued since below described products are already covered by the formal application in the framework of MDR (Regulation EU 2023/607 amending Regulations (EU) 2017/745). The attached letter from notified body (TÜV SÜD) confirms this formal application..

Product which conformity is declared under No. G1 023235 0138 Rev. 02:

- Device 1 Hemodiaysis Equipment DBB-EXA, DBB-EXA ES
- Device 2 Hemodialyzer for Hemodialysis FD series (excluding FDX-80GW)
- Device 3 Filter for Dialysate purification EF-02D series
- Device 4 Blood Tubing Lines for Hemodialysis AV18 series, C18 series, AV06 series, C07J-P, AL series, ES series
- Device 5 Blood Tubing Lines for Apheresis ABT series

Product which conformity is not declared under certificate above and not related to you:

- Device 6 Tubing system for plasmaphresis LT series

Satoko Hina
General Manager, Regulatory Affairs Department
Medical Division
NIKKISO CO., LTD.

Manufacturer's Declaration

in relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices, in particular with respect to

- the validity of certificates issued under Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) or Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and/or*[1]
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	NIKKISO CO., LTD.
Manufacturer address and contact details	20-3, Ebisu 4-Chome, Shibuya-ku, Tokyo, 150-6022, Japan Email: medicalra@nikkiso.co.jp
Single Registration Number (SRN) (if available)	JP-MF-000019276

Authorised Representative name (if applicable)	NIKKISO Medical Europe GmbH
Authorised Representative address and contact details	Kapstadtring 7, Hamburg, 22297, Germany Email: regulatory@nikkiso-europe.eu
Single Registration Number (SRN) (if available)	Not available

Notified body name (if applicable)	TÜV SÜD Product Service GmbH ☒ See attached schedule
Notified body number (if applicable)	0123 ☒ See attached schedule
Directive Certificate number(s) to which this confirmation is made (if applicable)	G1 023235 0138 ☒ See attached schedule
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	May 26, 2024 ☒ See attached schedule
End date of extended validity/transition period	December 28, 2028 ☒ See attached schedule

[1] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body.

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** (or see attached schedule, if multiple certificates) the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and/or*[2]
- the listed **device(s)** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

➢ **Directive Certificate(s)** as listed above or in the attached schedule

- Directive Certificate(s) covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 26 May 2021 and have not been withdrawn afterwards.

  Choose applicable statements:

  ☐ Expired *before* 20 March 2023:

  ☐ Before the original date of expiry as indicated on the Directive Certificate(s), we and the notified body have signed written agreement(s) in accordance with Section 4.3, second subparagraph of Annex VII to this Regulation for the conformity assessment(s) in respect of the device(s) covered by the expired certificate(s) or in respect of a device(s) intended to substitute that/those device(s), or

  ☐ A Competent Authority has granted a derogation from the applicable conformity assessment procedure in accordance with Article 59(1) MDR (may be provided upon request), or

  ☐ A Competent Authority has required the manufacturer, in accordance with Article 97(1) MDR, to carry out the applicable conformity assessment procedure (may be provided upon request)

  Choose one of the following statements only if a derogation per Article 59(1) or a requirement per Article 97(1) has been granted by a Competent Authority:

  ☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

  ☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

[2] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body

☒ Expired/expires *after* 20 March 2023:

Choose one applicable statement:

☒ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➢ **Upclassified devices**

In case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body:

Choose one applicable statement:

☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitutes and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➢ **Quality Management System (QMS)**

Choose one applicable statement:

☐ A QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024.

☒ A QMS in accordance with Article 10(9) MDR is in place.

☐ A notified body has issued the attached certificate for the MDR-compliant QMS.

➢ **Device(s) as listed in the attached schedule**

- The device(s) continue to comply with the AIMDD or MDD.
- There are no significant changes in the design and intended purpose.
- The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Signed for and on behalf of the manufacturer:

Full Company Name	NIKKISO CO., LTD.
Location & Date	Location: Tokyo, Japan, Date: April 30, 2024
Signature, Print Name, Title	 Satoko Hina, Person responsible for regulatory compliance, Medical Division
Contact Details (at least email)	Email: medicalra@nikkiso.co.jp

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

Identification of the device(s)[3] (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
Hemodialysis Equipment	**G1 023235 0138**	**May 26, 2024**	**TÜV SÜD Product Service GmbH, 0123**	**TÜV SÜD Product Service GmbH, 0123**	**December 28, 2028**	**N/A**
Hemodialyzer for Hemodialysis	**G1 023235 0138**	**May 26, 2024**	**TÜV SÜD Product Service GmbH, 0123**	**TÜV SÜD Product Service GmbH, 0123**	**December 28, 2028**	**N/A**
Filters for Dialysate Purification	**G1 023235 0138**	**May 26, 2024**	**TÜV SÜD Product Service GmbH, 0123**	**TÜV SÜD Product Service GmbH, 0123**	**December 28, 2028**	**N/A**
Blood Tubing Lines for Hemodialysis	**G1 023235 0138**	**May 26, 2024**	**TÜV SÜD Product Service GmbH, 0123**	**TÜV SÜD Product Service GmbH, 0123**	**December 28, 2028**	**N/A**
Blood Tubing Lines for Apheresis	**G1 023235 0138**	**May 26, 2024**	**TÜV SÜD Product Service GmbH, 0123**	**TÜV SÜD Product Service GmbH, 0123**	**December 28, 2028**	**N/A**

[3] for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 023235 0138 Rev. 02

Manufacturer: **NIKKISO CO., LTD.**
20-3, Ebisu 4-Chome, Shibuya-ku
Tokyo
150-6022 JAPAN

Product Category(ies): **Hemodialysis Equipment, Apheresis Equipment, and Closed-loop Blood Glucose Controller, Blood Tubing Lines, Tubing for Blood Glucose Monitoring, Infusion Administration, Hemodialyzer, Cytapheresis Adsorber, Hemofilter and Filters for Dialysate Purification**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: **JA1442576**

Valid from: **2020-04-22**
Valid until: **2024-05-26**

Date, 2020-04-22

Christoph Dicks
Head of Certification/Notified Body

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

A4 / 07.17

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

Template – INTERNAL

Confirmation Letter Template Regarding Amending Regulation (EU) 2023/607

Your reference/letter of	Our reference/name	Tel. extension/Email	Fax extension	Date
CBW 23235	Yuya Kawakami	Yuya.Kawakami@tuvsud.com		2024-04-30

TÜV SÜD Product Service GmbH
Receipt of formal application

Reference: Report #JA2023226

To whom it may concern,

Confirmation of the status of a formal application in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 (in the following referenced as MDR) as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

With this letter TÜV SÜD Product Service GmbH, designated under MDR and identified by the number 0123 on NANDO, confirms that we have received **a formal application** in accordance with Section 4.3, first subparagraph of Annex VII of MDR with the above stated manufacturer with the following SRN Number:

SRN Number: JP-MF-000019276

The devices covered by the formal application mentioned above are identified in the Table below.

Please note that this letter only confirms the status of the formal application.

To benefit from the additional transitional provisions in the framework of Regulation EU 2023/607, TÜV SÜD Product Service GmbH and the manufacturer need to sign a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR latest until 26 September 2024.

In case of inquiries please contact medical_devices@tuvsud.com.

On behalf of the Notified Body TÜV SÜD Product Service GmbH,
<Date> 2024-04-30

TÜV SÜD Product Service GmbH
Medical and Health Services

<Yuya Kawakami>
Conformity Assessment Responsible (CARE)

Confirmation Letter Template Regarding Amending Regulation (EU) 2023/607

Devices covered by the formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR

Device name or Basic UDI-DI (under MDR application)
Device 1 Hemodialysis Equipment Basic UDI-DI：4987671HD-EqA2P
Device 2 Hemodialyzer for Hemodialysis Basic UDI-DI：4987671HemodialyzerAHS
Device 3 Filters for Dialysate Purification Basic UDI-DI：4987671Filter-ReAUE
Device 4 Blood Tubing Lines for Hemodialysis Basic UDI-DI：4987671BTLACC
Device 5 Blood Tubing Lines for Apheresis Basic UDI-DI：4987671Aphe-BTLAT5
Device 6 Tubing system for plasmapheresis Basic UDI-DI：4987671Aphe-BTLAT5

NIKKISO

2.3 pirkimo dalis

Bloodlines & substitution fluid systems

For the complete treatment range

Innovations for Human Care.

NIKKISO bloodlines convenient & safe

For NIKKISO machines

NIKKISO bloodlines

The AV-06 bloodline series has been specially designed for the use on NIKKISO hemodialysis systems DBB-05, DBB-06 and DBB-07.

Thanks to the universal connection options (post- and pre-dilution), only one bloodline system is required for hemodialysis, hemo-filtration and hemodiafiltration. Thus, storage requirements are minimized considerably.

2.3 pirkimo dalis

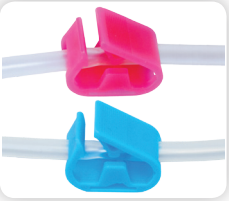
Bloodlines AV-06 series				
Model	Priming volume blood (ml)	Treatment options	Sterilization method	Available for
AV-06JA-P with pre-art. drip chamber	176	HD, HF, HDF (pre / post) Double-needle dialysis	Steam sterilization (autoclave)	DBB-05 DBB-06 DBB-07
AV-06JC-P without pre-art. drip chamber	165			DBB-05* DBB-06 DBB-07
AV-06JH-P** with pre-art. drip chamber, saline line and spike	174			DBB-05 DBB-06 DBB-07
AV-06JA-SN-P	230	Single-needle dialysis		DBB-05 DBB-07
Substitution fluid systems				
EFL-015	Online HDF set		ETO	DBB-05 DBB-07
C07J-P	Online HDF line		Steam sterilization (autoclave)	DBB-07

* *from serial number 68140-01 or 69013-N1*
** *available on request*

Innovations for Human Care.

Ergonomic grooved patient luer lock connectors with lock-ring ejection mechanism

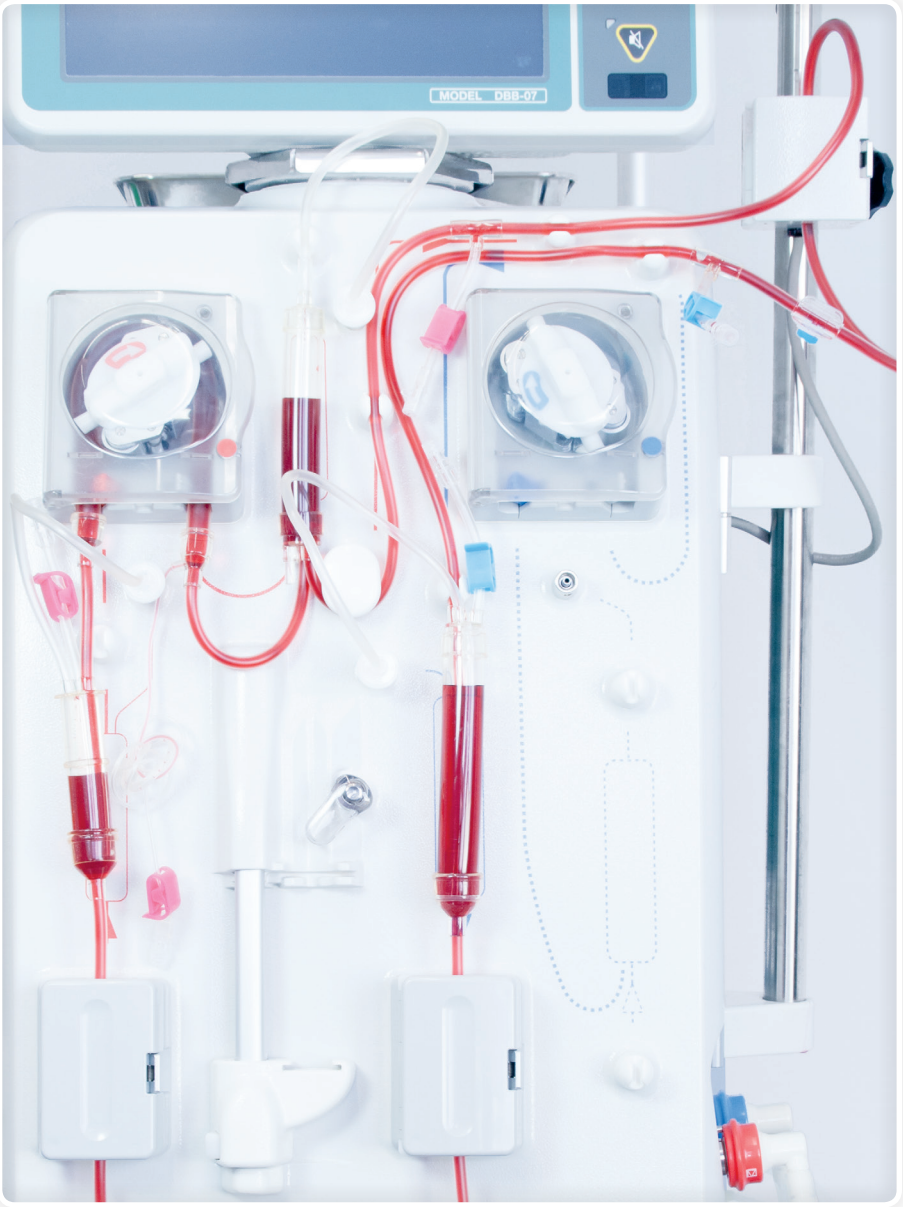
Easy to use dialyzer connectors



Easy to handle color-coded clamps for arterial and venous line

Large open pressure transducer protector filters with inspection window

Heparin line with smart ergonomic clamp and secured protection cap



DBB-07 with Haemo-Master and bloodline AV-06JA-P

AV-06 series

The highly efficient steam sterilization method (autoclave) used for the AV-06 series is particularly eco-friendly. The components and drip chambers are designed for a low priming volume and reduced air contact. The recirculation connector (for A/V line) is included as standard. The capless transducer protectors and the perfectly fitting line lengths facilitate the set-up on the machine.

The double-needle bloodline **AV-06JA-P** includes an arterial drip chamber before the blood pump. Furthermore, it has capless transducer protectors and two discharge hooks.

The double-needle bloodline **AV-06JC-P** does not include an arterial drip chamber before the blood pump.

The double-needle bloodline **AV-06JH-P** has an integrated saline infusion line with spike connector.

The single-needle bloodline **AV-06JA-SN-P** is designed for high stroke volumes to meet the best effectiveness of unipuncture treatments.

Treatments

HD, HF, HDF (pre/post), Double-needle dialysis, single-needle dialysis

Sterilization method

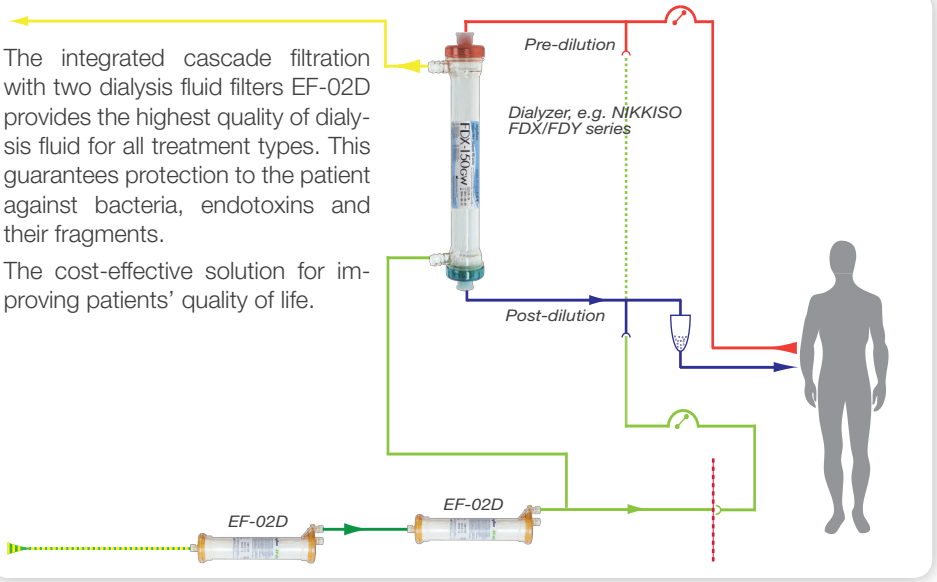
Steam sterilization (EN ISO 17665-1:2006)

Shelf life	36	months
Packaging units	24	pieces / box
	528	pieces / pallet
AV-06JA-SN-P	18	pieces / box
	396	pieces / pallet

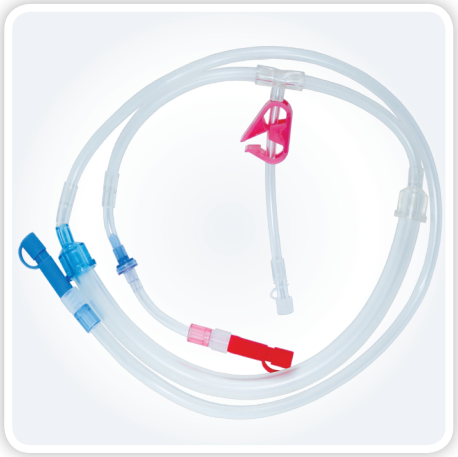
Substitution fluid system C07J-P for DBB-07

The integrated cascade filtration with two dialysis fluid filters EF-02D provides the highest quality of dialysis fluid for all treatment types. This guarantees protection to the patient against bacteria, endotoxins and their fragments.

The cost-effective solution for improving patients' quality of life.



Economic reusable cascade filtration

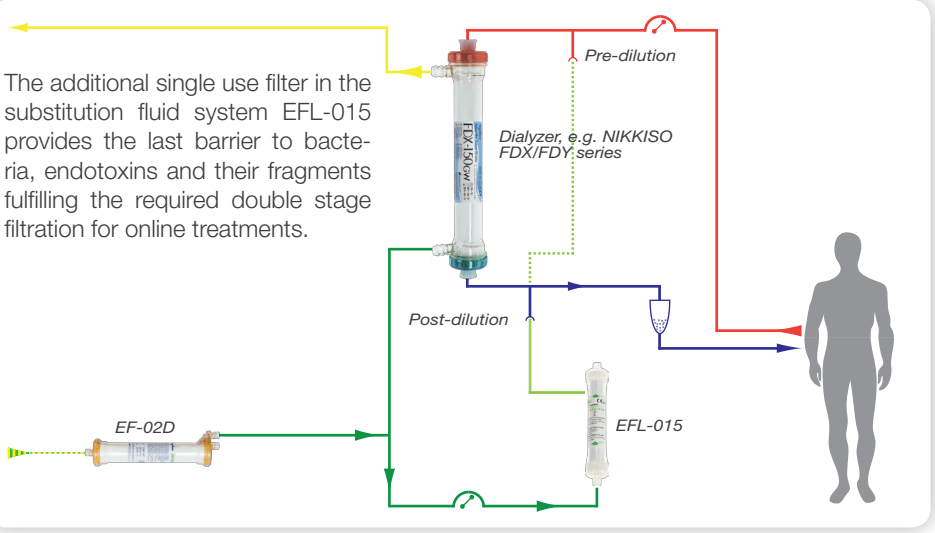


Cost-effective steam sterilized substitution line C07J-P

2.3 pirkimo dalis

Substitution fluid system EFL-015 for DBB-05

The additional single use filter in the substitution fluid system EFL-015 provides the last barrier to bacteria, endotoxins and their fragments fulfilling the required double stage filtration for online treatments.



DBB-05 protection system for patients in Online HDF mode

Substitution fluid system EFL-015 including a single use filter

www.nikkiso-europe.eu

Manufacturer
NIKKISO CO., LTD.
20-3, Ebisu 4-Chome, Shibuya-ku
Tokyo 150-6022, Japan
Telephone: +81-3-3443-3727
Fax: +81-3-3440-0681
Website: www.nikkiso.com

European representative
NIKKISO Europe GmbH
Desbrocksriede 1
D-30855 Langenhagen
Telephone: +49 511 679999 - 0
Fax: +49 511 679999 - 11
E-Mail: info@nikkiso-europe.eu
Website: www.nikkiso-europe.eu

Sales office
NIKKISO Europe GmbH
Kapstadtring 7
D-22297 Hamburg
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NIKKISO

2.4 pirkimo dalis

Dialysis Fluid Filters EF-01D & EF-02D

Improving patients' quality of life

Innovations for Human Care.

CE
0123

Data Sheet

	Dialysis Fluid Filter EF-01D	Dialysis Fluid- & Online* Filter EF-02 D
NIKKISO	Dialysis fluid filter for preparation of ultraclean dialysis fluid and in combination with single use substitution system EFL-015 for preparation of substitution fluid for Online HF/HDF therapy.	Dialysis fluid filter for preparation of ultraclean dialysis fluid and in combination with single use substitution system EFL-015 or with two* EF-02 D for preparation of substitution fluid for Online HF/HDF therapy.
		

Specifications

	EF-01D (wet)	EF-02 D (dry)
Effective surface area (m^2)	1,2	1,0
Membrane thickness (µm)	30	50
Inner diameter hollow fiber (µm)	210	210
Membrane material	PEPA® (Polyester-Polymer Alloy)	PEPA® (Polyester-Polymer Alloy)
Housing material	Polycarbonate	Polysulfone
Potting compound material	Polyurethane	Polyurethane
Gasket material	Silicon rubber	Silicon rubber
Cap material	Polysulfone	Polysulfone
Sterilization	Gamma ray	Gamma ray
For dialysis equipment model	DBB-03, DBB-05 *(until SN 603132-04)*	DBB-05 *(from SN 603133-01)*, DBB-06, DBB-07

Performance data

	EF-01D (wet)	EF-02 D (dry)
Logarithm reduction value for bacteria (LRV)	≥ 8	≥ 8
Logarithm reduction value for endotoxins (LRV)	≥ 3	≥ 3
Filtration factor (mL/h x mmHg)	580	480
Life time (hours)	750	750

Disinfection

	EF-01D (wet)	EF-02 D (dry)
Recommended disinfectants	Citric acid, Peracetic acid, Sodium hypochlorite For details on the chemicals to be used for cleaning and disinfection, please refer to the dialysis equipment´s instruction manual.	

** Preparation of substitution fluid for Online HF/HDF therapy with two EF-02 D as double filtration (cascade) only in combination with dialysis system DBB-07.*

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Manufacturer

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Local partner

DBB-05

options	BPM
	AFBF (normal HDF)
	Blood volume monitoring / measurement (BVM)
	Communication unit for Network (TCP/IP)
	Nurse call switch

2.6.1.1-2 pirkimo dalis

type / options DBB-05

No.	Item	Type C	Type D	Type E	Note
1	HD	Installed	Installed	Installed	
2	Single pump single needle	Installed	Installed	Installed	Click-Clack
3	Communication unit for Maintenance	Installed	Installed	Installed	RS-232C
4	External indicator	Installed	Installed	Installed	
5	Level adjuster pump	Installed	Installed	Installed	
6	Signal out put (alarm etc.,)	Installed	Installed	Installed	For hospital facility
8	Concentrate pipe rinsing	Installed	Installed	Installed	For A and B concentrate piping
9	Dialysate filter	Installed	Installed	Installed	
10	Bicarbonate cartridge holder	Installed	Installed	Installed	
7	Double pump single needle		Installed	Installed	
11	Central concentrate supply			Installed	2 ways for A concentrate
12	On-line HDF, HF		Option	Option	
13	Normal HDF		Option	Option	With AFBF
14	Blood pressure monitoring (BPM)	Option	Option	Option	
15	Blood volume monitoring / measurement	Option	Option	Option	
16	Communication unit for Network	Option	Option	Option	TCP/IP
17	Nurse call switch	Option	Option	Option	Connected to machine
18	AFBF(normal HDF)	Option	Option	Option	Connected to machine

NIKKISO

2.6.1.1-3 pd

Hemodialysis Equipment

DBB-EXA

D-FAS

NEW
available from SW 1.7
features

CE 0123

Innovations for Human Care.

Concept

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

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

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

Ecological

Environment awareness is a part of NIKKISO's corporate philosophy. New products and technology developments aim to reduce the environmental impact and **to preserve resources**.

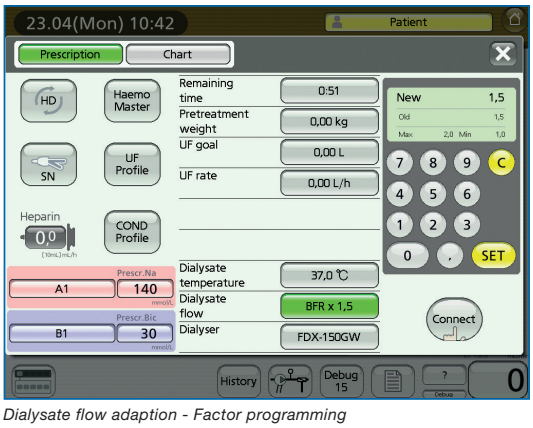
Resource-saving appliance management

NEW feature

- **Drain of bloodline sets:** The reduced weight of the contaminated waste that needs to be disposed of has a **positive impact** on logistics and environment.
- Optimized energy use via **integrated heat exchanger** between in- and outflow.
- 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 may help to optimize **dialysis fluid consumption and costs in terms of energy, water etc.** without compromising Kt/V.



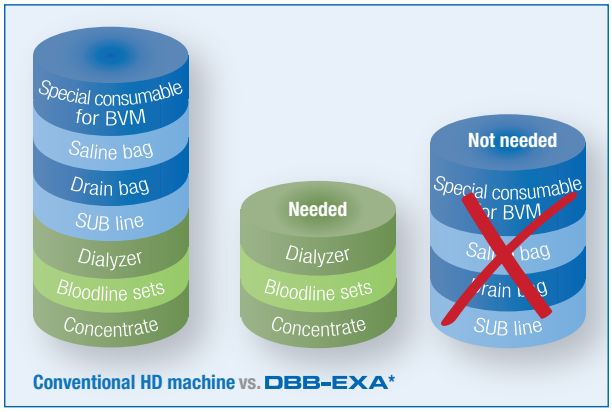
Dialysate flow adaption - Factor programming

Reducing costs

Reduced consumables, waste weight reduction and minimized maintenance costs lower the treatment costs with DBB-EXA.

Reduced consumables

- 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**, therefore eliminating extra costs.
- Online priming solution and substitution fluid is purified using the integrated **reusable** double filtration (cascade) with two EF-02 D endotoxin retentive filters (ETRF).
- 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 utilized in priming for both dialysis fluid and saline.
- BVM can be measured with NIKKISO standard bloodline set. **No need for special consumables for BVM.**



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

Less waste

Drain of bloodline sets: This newly implemented feature can lead to significant cost-savings by reducing the weight of the contaminated waste.

Minimized maintenance costs

With **inherited reliability** and time-proven mechanical components of the DBB series, DBB-EXA can minimize maintenance costs with simple preventive maintenance and **long MTBF** (Mean Time Between Failure).

Smart design for patients & users

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 sleek and compact design.
The operator will appreciate well-thought-out features facilitating handling and daily routine.

Integrated document holder keeping patients area neat and tidy.

Grip handle with integrated cable hook for ease of maneuverability.

Blood pressure monitor cuff holder with **detachable flap** for ease of cleaning.

- The slim dimensions and the **ergonomic design** soften the mechanical aspect and make it easy to integrate DBB-EXA into a modern dialysis facility.
- The screen motion sensor enabling **automatic switch-off / on** of screen provides a more **comfortable** treatment environment for the patients.
- Integrated BVM, online port and drain port give the machine a **neat appearance**.
- The **contactless** patient card keeps the card reader surface clean ensuring **smooth data transfer**.

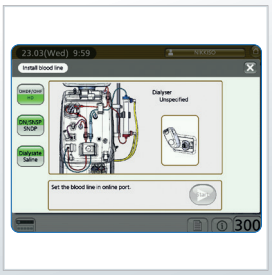
Connectivity for external alarming device

DBB-EXA is the first dialysis system complying with IEC PAS 63023 (Publicly Available Specification).
According to the signal from **an external alarming device** (e. g. a Venous Needle Dislodgement System) DBB-EXA triggers an alarm and **immediately switches** into a safe mode **to minimize risk to the patient**.

User-friendly interface

The user-friendly interface has **operational guidance** with intuitive graphical instructions. Using D-FAS and patient card, the number of screens and data entry is minimized to simplify the operation and reduce set-up time.
Displayed information can be **customized individually** to fulfill all the dialysis facilities requirements.

Basic screen during a treatment
Monitors and keys are customizable.



Preparation screen
Intuitive guidance to set up bloodline set.

The **drain port** negates the need for a waste bag during priming.

15 inch flat touch screen with wide viewing angle.
4 colored status display on top of the screen **with 360° visibility**.

Smooth curved surfaces allowing for **easy cleaning**.

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

* for details, see p. 14

Automation

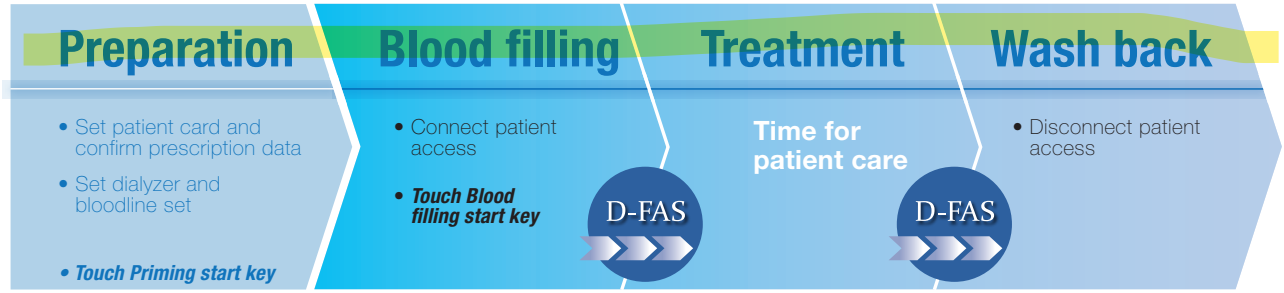
Dialysis Full Assist System

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 Full Assist 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.



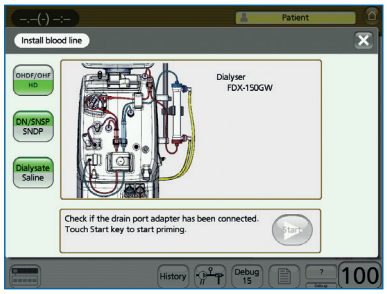
Bringing nursing staff back to patient care.

Advantages

- **Reducing** standard operational tasks between treatments such as preparation, connecting and disconnecting patients.
- **Minimizing** 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 utilizing **dialysis fluid or saline** (based on the facilities policy).
- Automatic wash back solution **can be switched** from dialysis fluid to saline. So the operator can keep the automatic wash back procedure even if the power supply is interrupted.
- D-FAS blood filling is **selectable** with or without UF.

D-FAS priming

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



Guidance screen for set-up

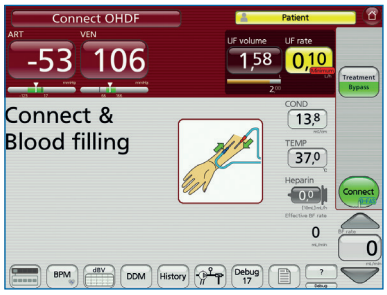
D-FAS blood filling

With DBB-EXA, the venous and arterial patient access are connected **at the same time**.

The operator simply connects the arterial and venous patient access and starts **D-FAS blood filling**.

Depending on the **patient's condition**, it can be defined via the settings whether the patient should be connected **with or without UF**.

By selecting **D-FAS blood filling with UF**, the priming solution can automatically be removed through the dialyzer, therefore the **patients UF removal can be minimized.**



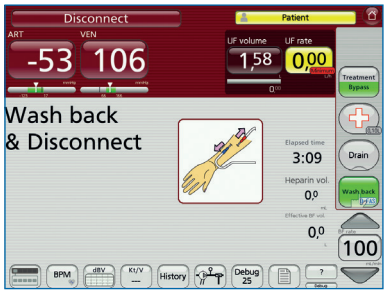
D-FAS Connect & Blood filling screen

D-FAS wash back

The wash back process starts once the pre-set condition is fulfilled (time complete, UF complete or time & UF complete).

After 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.**

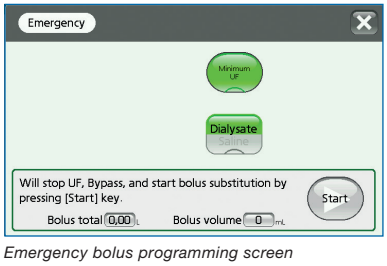
All the operator needs to do is simply disconnect the patient.



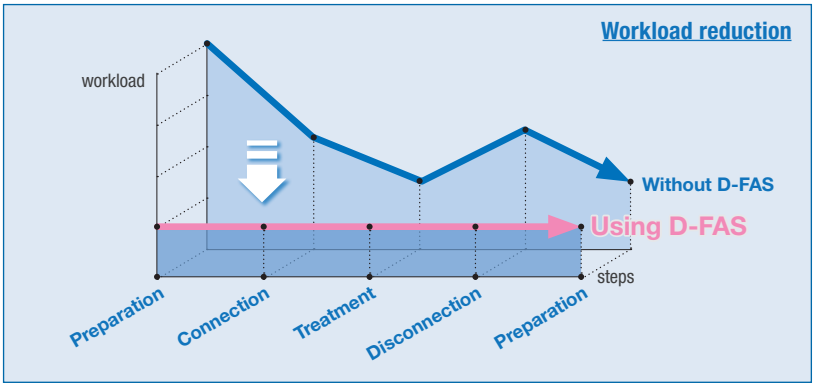
D-FAS Wash back & Disconnect screen

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.



Emergency bolus programming screen



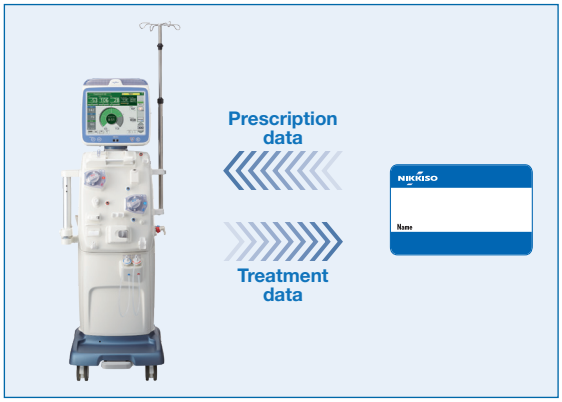
*Graphical representation of the workload **with** and **without** D-FAS (example)*

Automation

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

EASY - FAST - FLEXIBLE (without network system)

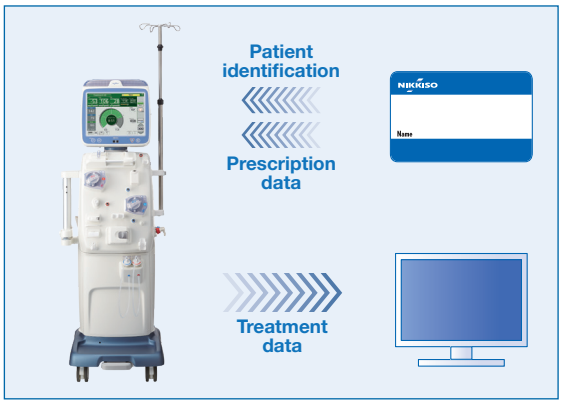
The **prescription data** can be imported to the DBB-EXA via the personal patient card, easily and fast, and without any cable connection. The last 3 treatments are available on the **contactless** (RFID technology) patient card as a data package for export to the data management system.
Not requiring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



Data transfer with patient card

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 via patient card, 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.



Data transfer with patient card and network system

Contactless patient card reader

Advantages of the Dialysis Dose Monitor

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

Dialysis Dose Monitor

Positive long-term prognosis & higher quality of life

Several studies have proven that a positive long-term prognosis and improved quality of life (QOL) of patients **depend on the actual delivery of dialysis dose**. Adequate dialysis dose may improve QOL[1-3].

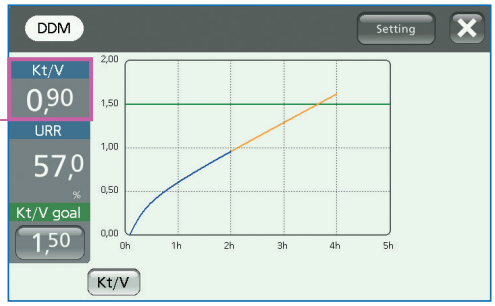
Insufficient clearance performance can have various reasons:

- No counter flow of blood and dialysis fluid due to incorrect connection
- Vascular access recirculation*
- Secondary membrane formation and/or dialyzer clotting
- Frequent alarms of dialysis machine which shorten effective treatment time
- Reduced effective blood flow etc.

* more informations for monitoring recirculation see page 13

Reaching treatment goals

Reaching the individual treatment goals **can only be achieved by continuously monitoring the current status.** At the same time, necessary adaption of treatment parameters must be considered. By using the Dialysis Dose Monitor (DDM), measured Kt/V is displayed in graphic form with a projection line. **Deviations from the treatment goal may be timely recognized and treatment parameters may be adjusted.**

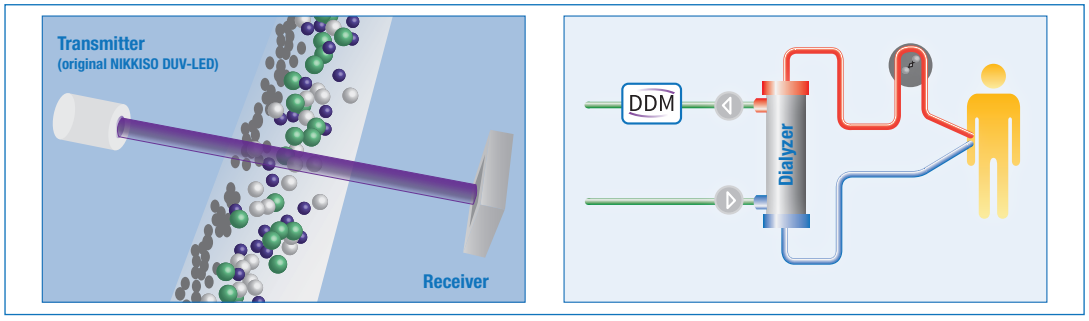


K, Kt, Kt/V and eKt/V are **numerically** displayed by pressing this **key**

Treatment-specific projection line

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.[4] The continuously measured values are inserted in the formulas for single pool Kt/V (spKt/V) (based on Daugirdas) and for urea reduction ratio (URR). The results are **immediately** displayed.



Measurement principle with DUV-LED

Location of the module directly in the drain system of the DBB-EXA

REFERENCES

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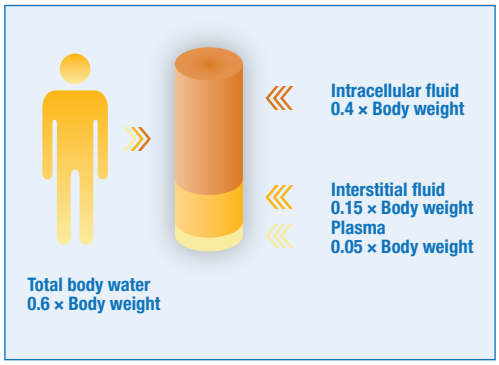
4. Uhlin, F; Fridolin, I; Magnusson, M. et al. Dialysis dose (Kt/V) and clearance variation sensitivity using measurement of ultraviolet-absorbance (on-line), blood urea, dialysate urea and ionic dialysance. NDT 2006, 21, 2225-2231.

Useful features

Monitoring patient blood pressure and blood volume

Common complications during hemodialysis 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 hypotension[5]. **Fluid management becomes a key clinical objective.**



Distribution of fluids in human body

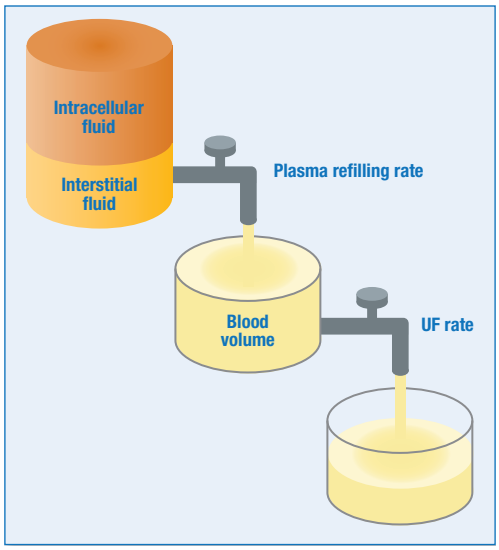
Body water distribution in the human body

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)[6].

UF rate and Plasma refilling rate

Ultrafiltration 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 to or less than PRR, blood volume is kept the same or recovered. If UF rate is greater than PRR, blood volume is reduced.

Inappropriate reduction in blood volume not fitting patient condition can result in a blood pressure drop[7].



Fluid balance between different compartments

REFERENCES

5. Daugirdas JT, Ing TS. Handbook of Dialysis Second Edition. Little, Brown and Company, Boston, MA: 1994; 149-157
6. Koeppen BM, Stanton BA. Renal Physiology Fifth Edition. Mosby, Maryland Heights, MO: 2012; 1-14
7. 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

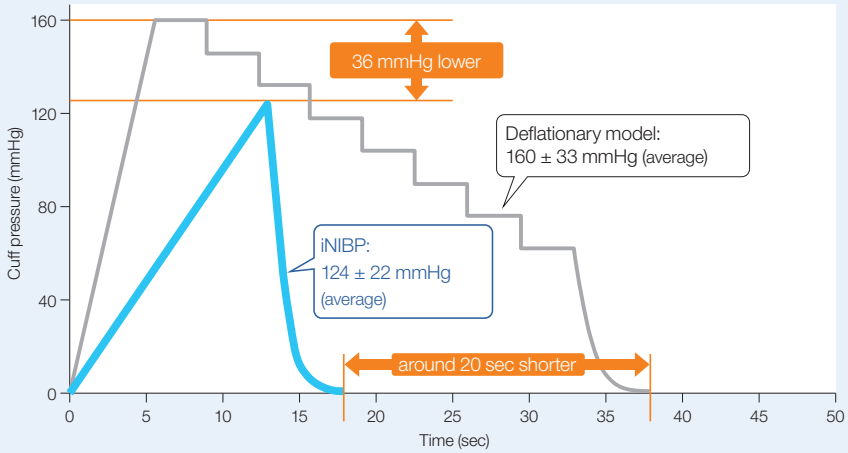
Blood pressure monitors

DBB-EXA can measure the blood pressure with the integrated BPM. Measurement timing can be selected between manual, auto measurement or continuous.

Blood Pressure Monitor with linear inflation technology

iNIBP gradually increases cuff pressure whilst simultaneously measuring pulse oscillations during inflation. The cuff pressure is immediately released after systolic pressure is detected. Therefore, when compared to conventional deflationary method, **the iNIBP measurement time is shorter and target inflation pressure is lower, maximizing patient comfort.**[8]

Maximum cuff pressure and time reduction



It is reported that the maximum inflation pressure is reduced by 36 mmHg and the measurement time is shortened by about 20 seconds from deflationary model[8].

Comparison between Blood Pressure Monitor with linear inflation technology versus conventional deflationary (step-down) method

Blood Pressure Monitor with conventional depressurization method

The conventional blood pressure monitor quickly increases cuff pressure until the target pressure is reached and then gradually releases the pressure (deflationary/step-down method) until pulse waves are detected to measure the blood pressure.

Both Blood Pressure Monitors enable the results to be displayed in **graphical form.**
The blood pump speed and UF rate can be automatically reduced to customizable values if the SYS blood pressure alarm setting is reached.

REFERENCES

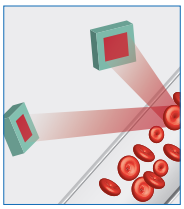
8. Onodera, J; Kotake, Y; Fukuda, M et al. Validation of inflationary non-invasive blood pressure monitoring in adult surgical patients. J Anesth. 2011, 25(1), 127–130.

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.

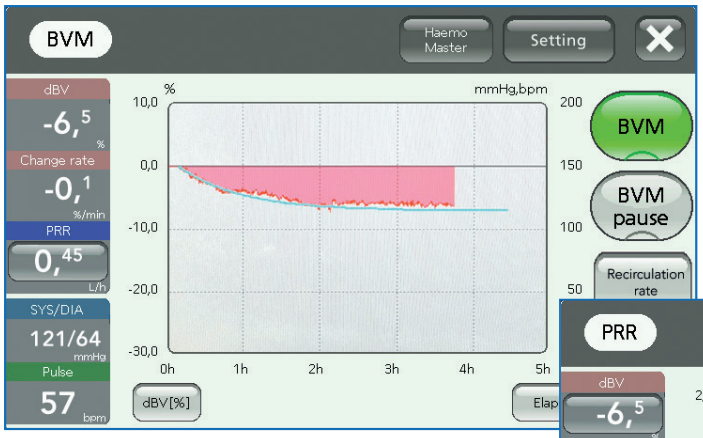
BVM sensors



Measurement principle

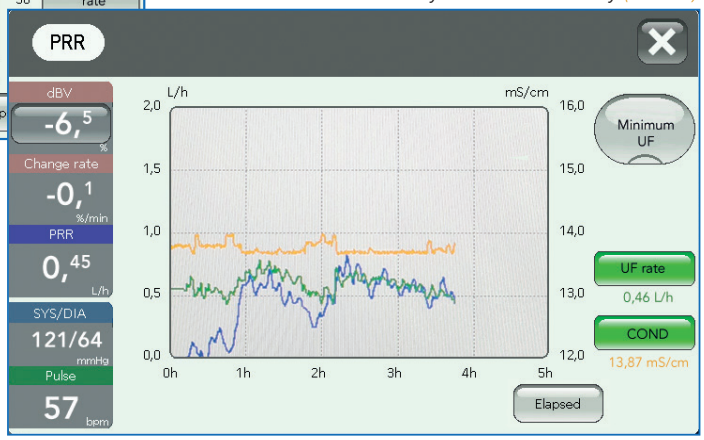
Blood volume measurement is considered as a useful tool to help improve tolerance and the hemodynamic response[11].

Estimated patient Plasma Refilling Rate **(PRR)** is calculated from UF rate and dBV trend. Nephrologists can refer to the PRR to help estimate adequate UF rate to stabilize the dBV. The monitored dBV and PRR are displayed in graphical form and clinicians can observe the patient fluid status visually.



Patient-specific progression curves showing relative blood volume change (dBV)

Plasma Refilling Rate (PRR)
UF rate (BV-UFC)
Dialysis fluid conductivity (BV-COC)



Patient-specific progression curves showing Plasma Refilling Rate (PRR), UF rate (BV-UFC) and dialysis fluid conductivity (BV-COC)

BV-UFC and BV-COC

A patient-specific ideal blood volume curve can be 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[9-11].

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9. Carlo Basile, Rosa Giordano, Luigi Vernaglione, et al. Efficacy and safety of haemodialysis treatment with the Hemocontrol biofeedback system: a prospective medium-term study. Nephrol Dial Transplant 2001; 16: 328-334
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11. Santoro A, Mancini E, Basile C, et al. Blood volume controlled hemodialysis in hypotension-prone patients: A randomized, multicenter controlled trial, Kidney Int 2002; 62: 1034-1045

Vascular access recirculation rate measurement*

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.

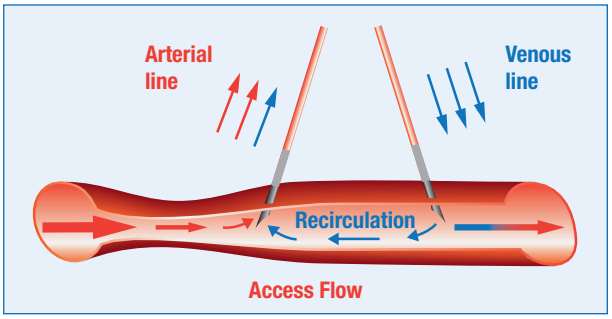
Recirculation

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.**

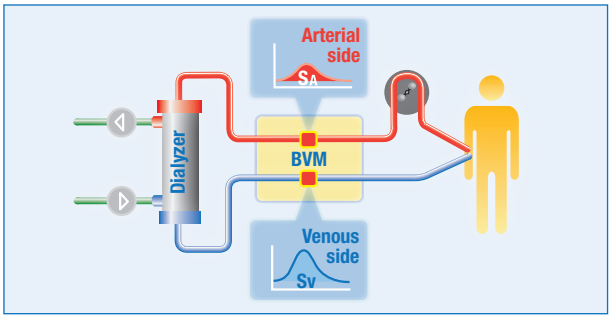
Many factors (invisible for the operator) can influence recirculation in the vascular access. Abnormalities, such as reduced arterial blood flow or obstruction in venous side can result in extracorporeal blood flow being higher than the real vascular access blood flow.

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

The *vascular access recirculation rate measurement* feature for detection and monitoring of recirculation is an outstanding tool to ensure a long-term assessment of vascular access.



Example of recirculation caused by vascular access stenosis

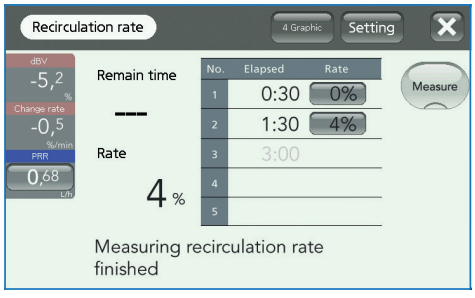


Recirculation rate – Measurement principle

Protecting vascular access

The newly developed **recirculation rate measurement system** is based on the Blood Volume Measurement (BVM) hardware that is used in the DBB-EXA. It is a double measuring system in the arterial and venous bloodline. If access recirculation exists, a blood marker produced by rapid ultrafiltration as a mass of concentrated blood in the extracorporeal venous line occurs in the arterial line. 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:

$$\text{Vascular access recirculation rate (\%)} = S_A / S_v \times 100$$



Recirculation rate – Schedule and results

Up to five automated measurements per treatment can be scheduled. Manual initiation of the measurement is also possible. The special measurement method allows recirculation measurement in the treatment modalities HD, HDF, HF and ISO-UF **without any blood dilution or infusion**. This also applies when using double-lumen catheters.

The original NIKKISO AV18 series blood tubing lines are specially designed for BVM and the recirculation rate measurement.

*hereafter referred to as "recirculation rate"

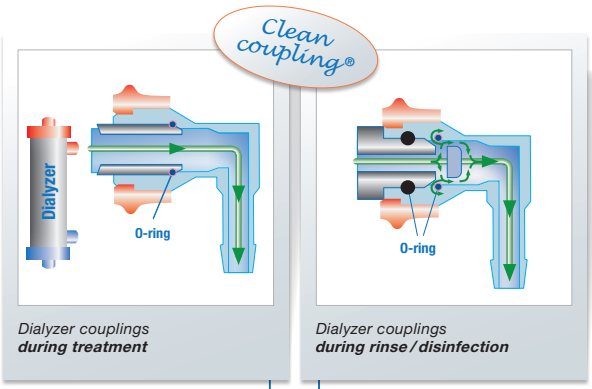
Hygiene & Treatment optimization

Hygiene

Dialysis fluid and substitution fluid are both purified using the integrated reusable double filtration (cascade) with two EF-02 D endotoxin retentive filters (ETRF). Consequently, **the dialysis fluid is as purified as the substitution fluid**.

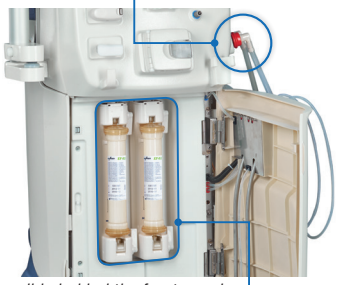
Dialyzer couplings and online port are designed and manufactured in such a way that during disinfection **all dialysis fluid contact areas are disinfected** to help avoid contamination.

By reducing the number of connections required for priming, recirculation, connection, bolus and wash back, DBB-EXA helps prevent the contamination of the patient access connection **and reduce the risk of vascular access infection.**



Dialyzer couplings ***during treatment***

Dialyzer couplings ***during rinse / disinfection***



EF-02D easily accessible behind the front panel for a user-friendly replacement

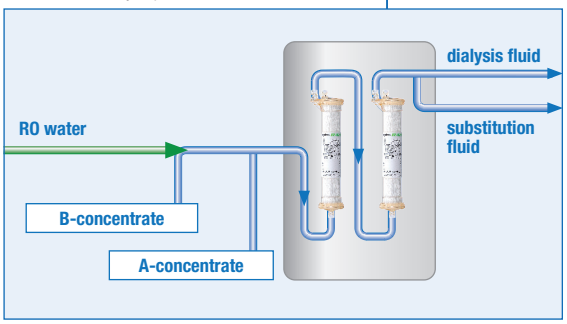
Online HDF

Hemodiafiltration (HDF) has an **improved clearance of low molecular weight protein** compared with hemodialysis (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[12-15]. The ESHOL study reported that post-dilution Online HDF with high convection volume **reduces all-cause mortality**[16].

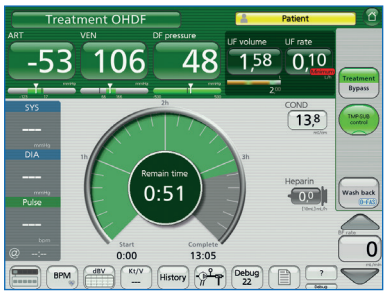
DBB-EXA is a flexible dialysis machine which can perform different treatment methods such as post- or pre-dilution HDF, HF, HD and isolated UF.

DBB-EXA can optimize the substitution rate based on the set ratio with blood flow rate. Also substitution rate can be controlled automatically within set TMP limits. **This helps prevent high blood concentration and TMP alarms**.



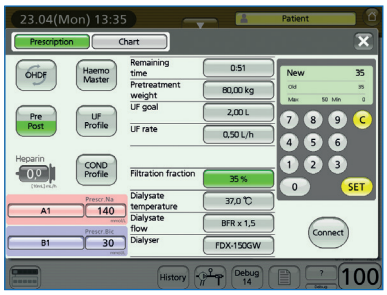
Hydraulic system with two endotoxin retentive filters EF-02D

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 optimize the convective volume **for improved therapy outcome**. The calculation of the optimal substitution volume is based on the patient's individual blood parameters.

Both *TMP-SUB control* and *Filtration Fraction* functions avoid excessive hemoconcentration and TMP alarms whilst optimizing substitution volume.

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14. Penne EL, Blankestijn PJ, Bots ML, et al. Resolving controversies regarding hemodiafiltration versus hemodialysis : the Dutch Convective Transport Study. Semin Dial 2005; 18: 47-51
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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

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 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)
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 (ETRF)	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

* Those specifications are valid for software version 1.6 or above and may differ depending on the DBB-EXA type (type A, B or C).

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 *For iNIBP:* Pressure display range: 0 to 300 mmHg Pressure display accuracy: Less than ±3 mmHg Measurement range: Adult systolic blood pressure (SYS): 40 to 280 mmHg Mean arterial pressure (MAP): 10 to 280 mmHg Diastolic blood pressure (DIA): 10 to 235 mmHg Pulse rate: 30 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)
Vascular access recirculation rate measurement	Usable treatment modes: HD, ISO-UF, OHF, OHDF Measurement range: 0~100 % Measurement accuracy: ±10 (recirculation ratio %) Measurement times: Maximum 5 times Usable blood flow rate range: 100~600 ml/min Usable hematocrit value range: BVM measurement range 15 to 50 % Usable blood tubing lines: NIKKISO AV18-series

Accessories

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

Cleaning program

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

Inherited reliability

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Local partner

2.6.1.1 pd

NIKKISO

For all existing treatment modes

Dialysis System DBB-05

Innovations for Human Care.

CE 0123

NIKKISO

Times are changing
We have the solution

DBB-05 Dialysis system

Your needs are our motivation

Your needs, as well as a sense of responsibility towards our clients are central to our work. With our innovative products, we are committed to providing the best possible treatment and therefore quality of life for people with kidney diseases. We scrutinize all our daily operations for the benefit of our customers, in order to preserve proven techniques and to constantly develop areas where there is scope for improvement.
The general situation in the European health care is subject to constant pressure to reduce expenses and this also affects you as a nephrologist and the dialysis treatments you are performing.
The DBB-05 dialysis machine has the advantages of a maximised operating life and minimum maintenance and repair requirements.
The uniformed designed disposables for the entire DBB-series give you purchasing and logistical advantages.
All those benefits help you to reduce your treatment costs.

Intuitive operating

Efforts to reduce material costs are not the only consideration; time is also a major factor.
With intuitive usage, a touch screen monitor provides a simple and quick interface between the operator and the various functions of the DBB-05.
The user interface, which is identical to the ones of DBB-06 and DBB-07, ensures a quick and easy learning of the system, less need for training, and a seamless integration into an existing NIKKISO machine fleet.
The DBB-05 has been developed by operators, for operators and fits in perfectly with daily dialysis routines.

Comfortable treatment

Dialysis patients spend a considerable amount of time in dialysis. For this reason we have taken patients' needs into consideration in the development of the DBB-05 dialysis system.
Reduced operating noise, avoiding unnecessary alarms, reduced preparation times and an individual patient monitor displaying the most important information are all just some of the reasons why dialysis patients appreciate the DBB-05.

Durability

In the past, operating lifespans for dialysis machines were seven to eight years but demands are much higher today. NIKKISO's decades of experience in developing and manufacturing complex hydraulic systems for a broad range of industry sectors including aeronautics, was all channelled into the hydraulic system in the DBB-05.
We only produce components and functional units that guarantee a maximum operational lifespan, in line with the current standards in technology. So we can achieve a mean time between failures (MTBF) of 12,5 months (evidenced by NIKKISO service reports).
The reliability of our machines is enhanced through our network of selected co-operation partners which guarantee comprehensive service and excellent support. Therefore, your machine fleet works reliably and under your costs controlling.

DBB-05 Series

- Reliable thanks to proven techniques
- Intuitive user interface
- Rotatable touch screen
- Electric level adjustment via touch screen
- Modularly extendable
- Flexible for all treatment modes

from Basic to Premium

DBB-05, Type E

Flexible double pump system with two connections to the central concentrate system

Type E fits perfectly in dialysis centres equipped with central concentrate system and allows an easy and comfortable selection between two different types of concentrates directly via touch screen.

DBB-05, Type D

Flexible double pump system for advanced treatment modes

Type D enables effective single-needle treatments in double pump mode. The options for online HDF/HF treatments, for acetate-free biofiltration (AFBF) and the side monitor are available for type D.

DBB-05, Type C with side monitor

Basic single pump system with movable side monitor

The basic system can be equipped with a movable side monitor. The side monitor considerably facilitates the operation of the system from the bed or the armchair.

DBB-05, Type C

Basic single pump system

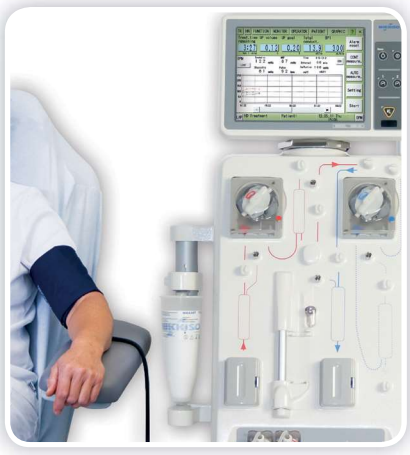
The system for standard low- or high-flux dialysis treatment. Even the basic version offers function modes for optimizing treatments, such as UF-profiling or sequential ultrafiltration. The single pump mode also allows for single-needle dialysis treatments (click-clack).

dialysis system DBB-05

A modern dialysis system
The best treatment

The modules of the DBB-05

Active blood pressure measurement

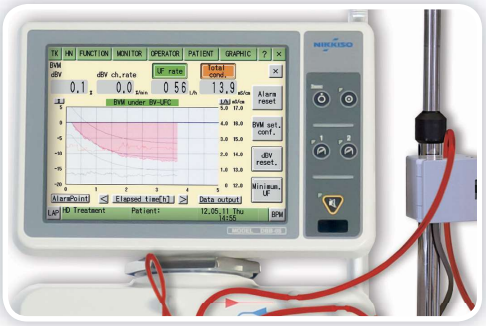


Active blood pressure measurement

Safety ensured by continuous measurement

If desired, continuous blood pressure measurement (BPM) can be carried out during the treatment.
On the screen, you can follow the blood pressure course chronologically. An automatic deactivation of the UF rate also occurs when the selected pressure limits are reached.

Haemo-Master



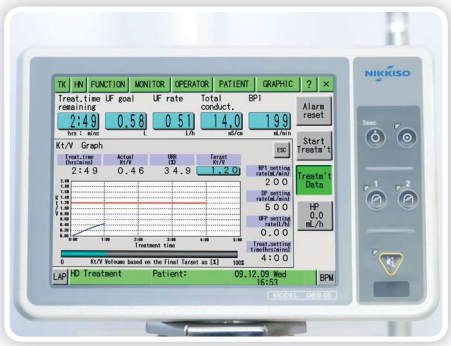
Haemo-Master with download tool

Fewer complications during treatment

Unforeseen complications during the dialysis session occur in up to 30% of all treatments. Roughly half of all episodes are caused by hypotensions.
With Haemo-Master, the advanced blood volume measurement (BVM) option, the relative plasma volume is measured during the treatment and the UF rate and sodium concentration in the dialysis fluid are regulated as a feedback system. Thus, hypotensive episodes are either reduced or prevented altogether.

Innovations for Human Care.

Display of the current Kt/V value



Dialysis Dose Monitor

Reaching treatment goals through Kt/V measurement

Kt/V is seen as a central quality parameter for the quantification of the delivered dialysis dose. In some countries Kt/V is used as a parameter for the evaluation of dialysis quality as well as for the reimbursement.
The main objective is to optimise the delivered dialysis dose and to enable you to create a complete documentation of the dialysis efficiency.
The optional Dialysis Dose Monitor (DDM), with the real continuously measurement of of blood urea nitrogen (BUN) correlated substances, can help achieving your treatment goals.

External scale

External scale for HDF/HF/AFBF with solution bags

Be flexible for the right treatment

The external scale offers at the moment the most flexible system on the market. The DBB-05 with external scale can perform online treatments but also HDF, HF and AFBF treatments with solution bags.
The acetate-free biofiltration (AFBF) is a special kind of treatment without acetate and bicarbonate in the dialysate. The patient blood level of bicarbonate will be exactly controlled by the external scale.
This ensures an optimal correction of the metabolic acidosis. This therapy is accepted to be biocompatible.

Network connection

Be connected

Data and information from the treatment procedure are sent simply and conveniently to your office via the clinic network. Of course the DBB-05 offers various interfaces for the main software solutions on the market. NIKKISO is cooperating with a successful and experienced partner. Please contact your NIKKISO representative.

NIKKISO

As little as possible
As much as necessary

You now have the choice

Resource-saving appliance management

- Automatic flow reduction in standby periods
- Maximum possible reduction of dead spaces in the hydraulics cycle (total volume only 1.4 litres)
- Optimised energy use as standard via integrated heat exchangers between in- and out-flow
- Appropriately sized user display with selectable screensaver and movement notification

Standard features

- Disinfectable concentrate suction nozzles
- Clean coupling® for better hygiene (dialyzer connector)
- Single-needle with double*1 or single pump
- Dialyzer inlet pressure monitoring
- Online Kt/V calculation
- Dialysate filter setting for extra pure dialysis fluid
- Electric level adjustment via touch screen
- Serial data interface / Connection to nurse call
- Holder for standard bicarbonate cartridges
- Integrated service mode for function analysis
- Clearly visible status display
- Rotatable touch screen
- Graphical User Interface (GUI)
- Eco-friendly concentrate-, water- and energy-saving mode
- Battery backup of extracorporeal circuit

Options

- Online HDF –
  Automatic regulation of the substituate rate for the following therapy types: HDF pre- and post dilution and HF pre- and post dilution*1
- External scale –
  HDF/HF/AFBF (Acetate-Free Bio Filtration) with solution bags*1
- Haemo-Master (BV-UFC/COC) with download tool –
  Blood volume measurement with active regulation of the UF rate and conductivity in the dialysis fluid
- Blood pressure monitor (BPM) –
  Continuous measurement with display of the blood pressure course on the monitor, automatic deactivation of the UF rate when the selected limits are reached
- Dialysis Dose Monitor (Kt/V)
- Central concentrate system for two concentrate connections (CCS)*2
- Network – Integration of the dialysis system into the clinic network
- Side monitor*3

Innovations for Human Care.

Technical information

General information

Dimensions	1.460 x 390 x 480 (HxWxD in mm) Base: 490 x 750 (WxD in mm)
Weight	85 kg standard system (approx. 110 kg with options)
Energy supply	230 V AC, ±10 %, 50/60 Hz
Power input	Dialysis: max. 5 A At a water temperature of 5 °C, a dialysis fluid temperature of 37 °C and a dialysate flow rate of 500 mL/min Heat disinfection: max. 9 A Temperature of the circulating hot water: 90 °C at departure from heating element; Flow rate of the circulating hot water: 800 mL/min
Water supply	Pressure : 1 to 7 bars at 0.8L/min Temperature: 5 to 30 °C
Water discharge	max. 0.8L/min Connection height: max. 500 mm
Concentrate	Central concentrate supply Inflow pressure 0 to 0.5 bars
External connections	Status display (External status monitor display) Alarm output (Staff call) Alarm input (for connection to an external device) Nurse call (for external pushbutton switch) Output (for external auxiliary equipment) RS-232C interface 1 (BVM data and service interface) RS-232C interface 2 (treatment data interface)

Treatment modes

Acetate dialysis

Bicarbonate dialysis with powder or fluid bicarbonate concentrate

Single-needle (double pump*1 or single pump)

ISO-UF program (sequential UF)

Online haemo(dia)filtration*1

Haemo(dia)filtration with scale*1

Acetate-free biofiltration*1

UF, sodium and bicarbonate profiles

Blood circuit

Arterial pressure	Measurement range: Measurement accuracy:	-300 to 300 mmHg ±10 mmHg
Venous pressure	Measurement range: Measurement accuracy:	-200 to 500 mmHg ±10 mmHg
Dialyser inlet blood-pressure	Measurement range: Measurement accuracy:	-200 to 735 mmHg ±10 mmHg
Arterial blood pump	Blood flow rate: Flow rate accuracy:	40 to 600 mL/min ±10 %
Heparin pump	Feed rate: Feed rate accuracy: Bolus amount: Injection volume:	0.0 to 9.9 mL/h ±5 % 0.1 to 9.9 mL 30/20/10 mL
Air detector	Method: Sensitivity: 0.02 mL (air bubble) Blood flow rate: 250 mL/min; 0.0003 mL (microfoam: blood/air mixture) Blood flow rate: 250 mL/min	ultrasonic waves

Dialysis fluid monitor

Dialysis fluid	Setting range: Temperature:	300 to 800 mL/min 34.0 to 40.0 °C
Acetate dialysis	Setting range:	12.5 to 15.5 mS/cm
Bicarbonate dialysis	Setting range:	2.3 to 7.0 mS/cm
Ultrafiltration	Setting range: Accuracy:	0.00; 0.10 to 4.00 L/h ±30 mL/h
Blood leak detector	Method: Sensitivity: (blood: haematocrit 20 %; dialysate temperature: 37 °C) 0.40 mL blood/min (max. dialysate flow rate: 800 mL/min)	optical detector 0.5 mL blood/1L dialysis fluid

Cleaning and disinfection

Rinsing

Sodium hypochlorite, acetic acid, peracetic acid

Heat cleaning > 85 °C

Citro-thermal disinfection > 85 °C

**1 only Type D and E*
**2 Standard feature for Type E*
**3 availability on request (depending on software language*

Always close to you

Competent partners

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

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