



All India Institute of Medical Sciences, Bhubaneswar
At - Sijua (Patrapada), Post - Dumuduma, Bhubaneswar (Odisha) - 751 019

To be uploaded in Website: www.aiimsbhubaneswar.edu.in (Tender)

Reference No: J-11075(016)/2019/S&P

Dated: 04/01/2020

Sub: Procurement Blood Tubing Set (AV set online plus), Citric acid (Citrosteril) & Diasafe Plus (Endotoxin Filter) for the Dialysis of Department of Nephrology at AIIMS, BBSR on Proprietary basis - **Inviting Comments thereon.**

1. The Department of AIIMS, Bhubaneswar has proposed to procure Blood Tubing Set (AV set online plus), Citric acid (Citrosteril) & Diasafe Plus (Endotoxin Filter) for (Make:Fresenius) from **M/s Fresenius Medical Care (OEM** for Fresenius range of products) has authorised **M/s Vikas Medical Devices** as authorised partner for distribution to AIIMS Bhubaneswar.
2. The Notice is being uploaded for general information of prospective manufacturer/Authorized Distributor/Dealers to submit their objection/proposal/comments, if any, on proprietorship of the item.
3. In case the product of any manufacturer/Authorized distributor/Dealer conforms to the enclosed specifications, they may submit their proposal for the supply of the same along with the brochures, point by point compliance of the enclosed specifications along with all documentary evidence. One quotation of the product may also be submitted.
4. The objections/comments/proposal should be sent in sealed cover to the Office of Sr. Procurement Cum Stores Officer, AIIMS, Bhubaneswar (Odisha) – 751019 or through E-mail to spo@aiimsbhubaneswar.edu.in, stokee_tapan@aiimsbhubaneswar.edu.in so as to reach on or before **date: 20-04-2019** failing which it will be presumed that no other firm is interested to offer comments/protest/object and case will be decided on its merits.
5. The ref. no. – **J-11075(016)/2019/S&P** dt: **04-01-2020**, due on dated: **20-04-2020** should be superscripted on sealed envelope.
6. Price reasonability that firm has not supplied in a lower price to any Govt. Dept/PSU/reputed private organisation.

Enclosure:

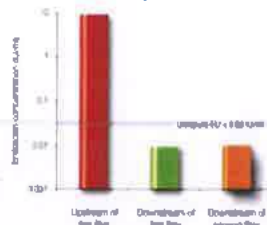
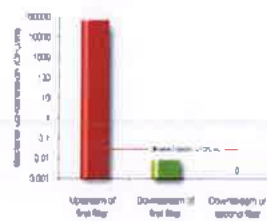
- (a) Proprietary Article Certificate from HOD Nephrology, AIIMS Bhubaneswar. - **Annexure-I**
- (b) PAC of M/s. Fresenius Medical Care - **Annexure-II**
- (c) Price Quote and Certificate of Authorization - **Annexure-III**
- (d) Brochures - **Annexure-IV**

-----s/d-----

Sr. Procurement-cum-Stores Officer
AIIMS Bhubaneswar
Sijua, Patrapada
Bhubaneswar
Odisha-751019

Ensure delivery of ultrapure dialysate

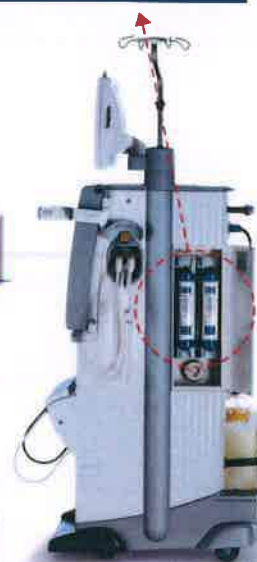
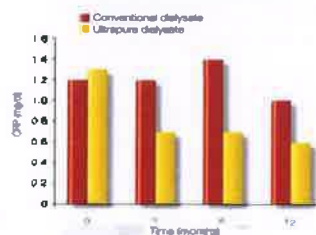
- **ONLINE HDF uses two DIASAFE®plus filters in series to provide extremely high microbiological safety for your patients**



¹ Adapted from: Taylor, D. et al., *Journal of Finance*, 2000, 55, 215-238.

- A Fresenius Polysulfone® filter for ultrapure dialysate fluid preparation, two DIASAFE® plus filters for ONLINE therapy

Recommended Microbiological Quality Standards	Microbial contamination (CFU/ml)	Bacterial endotoxins (IU/ml)
US standard (AAMI)	< 200	< 2
European standard (ERA-EDTA)	< 100	< 0.25
ULTRAPURE	< 0.1	< 0.03



USE

Bloodlines, Tubing Systems, Accessories

Product Range

Ensuring safety with the authentic
Fresenius Medical Care Original Bloodlines...

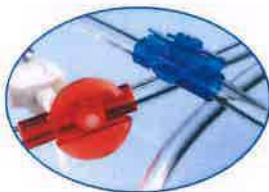
Quality

- Certified quality systems for development, production and sales
- Perfect compatibility to machine interfaces



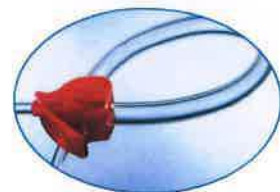
Biocompatibility

- Use of plasticisers with high haemocompatibility and low cytotoxic reaction
- Free of DEHP



Safety

- Assurance of highest safety and performance with all dialysis machines
- Transducer protector with integrated inspection windows
- Injection port with enlarged finger-protection shield



Handling

- Clearly colour-coded components
- Ergonomic components and layout



**Paediatric
Bloodlines are
also available**

Product Model Type	Category	To be used with	Filling Volume	Article No.
AV-Set-E	Adult Bloodlines	4008	145 ml	AP16842
AV-Set-E	Adult Bloodlines	4008	151 ml	AP16845
AV-Set ONLINEplus 5008-R	Adult Bloodlines	5008/5008 S	132 ml	F0000394
AV-Set-FMC Paed R	Paediatric Bloodlines	2008/4008	117 ml	F00001064
AV-Set-FMC Paed R	Paediatric Bloodlines	2008/4008	56 ml	F00001063

Puristeril® 340

Disinfecting Agent for Haemodialysis
Machines Based on Peracetic Acid

Superior efficacy

- Shows the superior efficacy of a peracetic acid –based disinfectant
- Exceptionally broad spectrum of microbicidal activity at low concentration and short exposure times
- Decomposes in a non-toxic way
- Easily removable after use, by rinsing with water
- Low pH helps in easy decalcification of haemodialysis machines

Designed for cold disinfection

- Haemodialysis Machines
- Water Treatment Systems

Spectrum Disinfection

- Bactericidal activity
- Fungicidal activity
- Sporicidal activity
- Virucidal activity (HBV/HCV/HIV)



Available as:

Article	Quantity	Art. No.
Puristeril® 340	1 x 5 kg	508 562 1

Citrosteril

For Heat Disinfection of Hemodialysis Machines with Recirculation

- Thermochemical disinfection
- pH value 1.7 to 2.0
- Excellent removal of CaCO_3
- Disinfection and decalcification in one process
- Active ingredients composed of natural substances
- Biodegradable
- Odourless
- Free from colouring additives
- Decalcification of reverse osmosis units

The synergistic effect of its components makes Citrosteril a potent disinfection solution

Citrosteril at 84°C has broad spectrum of

- Microbicidal activity
- Bactericidal activity
- Virus inactivating (HBV, HCV, HIV)
- Fungicidal activity



Specifications :

100 g Citrosteril contains :	
21 g citric acid 1-hydrate; lactic acid, malic acid	
Unit	Art No.
1 x 5 L	506 S33 1

Hygiene

Citrosteril

Heat Disinfectant for Haemodialysis Machines
with Recirculation



**FRESENIUS
MEDICAL CARE**

Citrosteril

Heat Disinfectant for Haemodialysis Machines with Recirculation

Disinfectant for chemo-thermal disinfection of haemodialysis machines¹.

- pH value 1.7 to 2.0
- excellent removal of limescale
- disinfection and decalcification in one process
- active ingredients composed of natural substances
- biodegradable
- odourless
- free from colouring additives

Action

The synergistic effect of its components makes Citrosteril a potent disinfectant solution.

Citrosteril at 84°C has a broad spectrum of micro-biocidal activity and works bactericidal and virucidal² including HBV/HCV/HIV.



Specification

100 g Citrosteril contains:

21 g citric acid 1-hydrate; lactic acid, malic acid

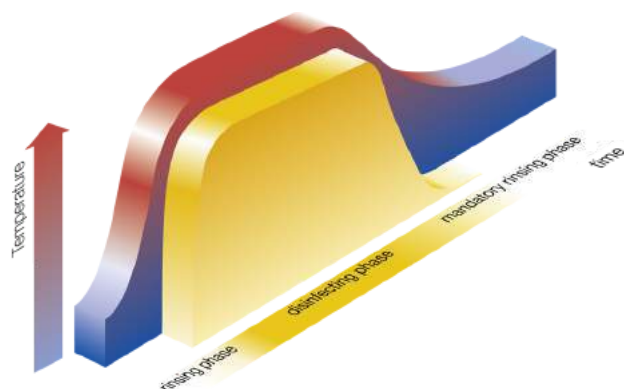
Ordering information

Unit	Language combination	Art. No.
1 × 5 L (single canister)	multilingual	F00005157
2 × 5 L (carton)	multilingual	F00005158
6 × 2 L (carton)	multilingual	508 536 1

Literature:

1. Solbach W, Universität zu Lübeck: Verification of the sporicidal efficacy of the product Citrosteril at 85°C in the Fresenius 5008 dialysis machine, 20.12.2002
2. Labor Dr. Merk & Kollegen, Ochsenhausen: Antiviral efficacy of Citrosteril against bovine Parvovirus, 9.9.2005

Further information is available on request.



**FRESENIUS
MEDICAL CARE**



DIASAFE[®] *plus*

Fresenius Polysulfone[®] Dialysis Fluid Filter



**FRESENIUS
MEDICAL CARE**

THE RENAL COMPANY

A LIFELONG COMMITMENT

Cardioprotective Haemodialysis



Despite significant improvements in the quality and efficacy of haemodialysis therapy in recent years, cardiovascular disease (CVD) remains the leading cause of death for dialysis patients. Today, almost every other dialysis patient dies from cardiovascular complications.

Fresenius Medical Care is supporting nephrologists worldwide in reducing their patients' risks for cardiovascular morbidity and mortality.

Innovative membranes like Fresenius Polysulfone® and Helixone®, modern monitoring devices like the Blood Volume Monitor, the Blood Temperature Monitor and Online Clearance Monitoring (OCM®), ultrapure dialysis fluid prepared with DIASAFE®*plus* and modern ONLINE haemodiafiltration systems support the reduction of CVD risk factors.

Moreover, one of our major goals in coming years is the development and implementation of innovative new therapies and products that further improve the cardiovascular prognosis of dialysis patients.

The Dialysis Fluid Filter DIASAFE[®]plus

The quality and purity of the dialysis fluid are of major concern in modern-day renal replacement therapies, as large volumes of dialysis fluid come into contact with the patient's bloodstream during each treatment.

Bacterial endotoxins present in contaminated dialysis fluid may elicit undesirable acute reactions and influence the long-term outcome of patients on chronic haemodialysis.

Although water used for the production of dialysis fluid is treated by a series of purification steps, it still may not meet the stringent requirements on bacterial contamination levels laid down by various regulatory bodies.

By the application of special filters that are highly efficient in retaining bacterial contaminations, the re-quired purity grades of dialysis fluid can be achieved easily.

The DIASAFE[®]plus filter, located at the end of the water treatment chain, ensures the safe production of ultrapure dialysis fluid. This is attributed to the excellent endotoxin-retention capabilities of its Fresenius Polysulfone[®] fibres.

Fresenius
Fresenius
Polysulfone[®]

DIASAFE[®]plus is an integral part of contemporary dialysis machines. Only three handling steps are necessary to install or exchange DIASAFE[®]plus (Fig. 1):

- Open the locks of the filter holder
- Slide DIASAFE[®]plus filter into the guide grooves
- Close the locks - DIASAFE[®]plus is ready to use

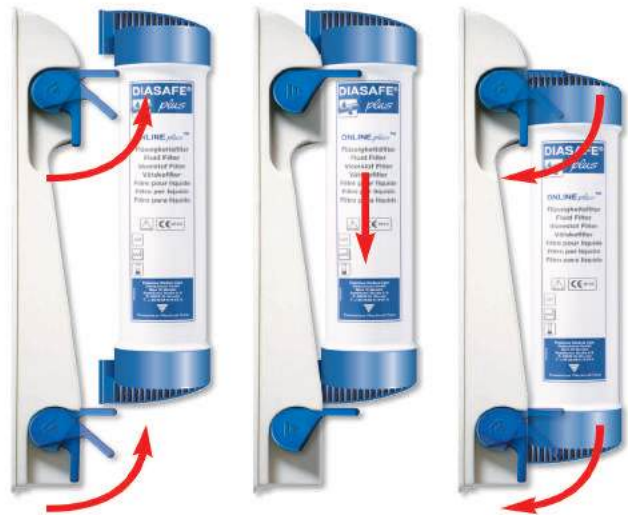


Fig.: DIASAFE[®]plus can be connected with 3 rapid handling steps only. The DIAFIX[™] lock system ensures a safe and hygienic connection.

The use of DIASAFE[®]plus is a key step towards Good Dialysis Practice.

Dialysis Fluid Purity

Dialysis fluids may contain microbial impurities such as endotoxins derived from bacterial fragments. Endotoxins are known to cause acute adverse reactions and promote long-term complications in haemodialysis patients ^(1, 2).

The toxic properties of endotoxins can be ascribed mainly to their lipid A component, which is not exposed by intact bacteria, but released only during growth or lysis of gram-negative bacteria ^(3, 4).

Endotoxin fragments may have molecular weights well below 2000 Da. These fragments are small enough to pass across both, low- and high-flux haemodialysis membranes into the patient's bloodstream (Fig. 2).

With respect to endotoxin permeability, significant differences exist between the various types of dialysis membranes, thereby offering variable degrees of safety during haemodialysis ⁽³⁾.

In order to avoid endotoxin-related complications during routine haemodialysis, the European Best Practice Guidelines for Haemodialysis (EBPG) ⁽⁵⁾ advise the usage of water having a purity level in compliance with the recommendations of the European Pharmacopoeia. However, the usage of ultrapure water for conventional high-flux dialysis is strongly recommended by the EBPG (Table 1).

Ultrapure water or dialysis fluid can easily be achieved through the application of special dialysis fluid filters – such as DIASAFE[®]plus.

	Pure water	Ultrapure water
Microbial contaminations (CFU/mL)	≤ 100	< 0.1
Bacterial endotoxins (IU/mL)	< 0.25	< 0.03

Table : The different purity levels of pure and ultrapure water according to the EBPG.

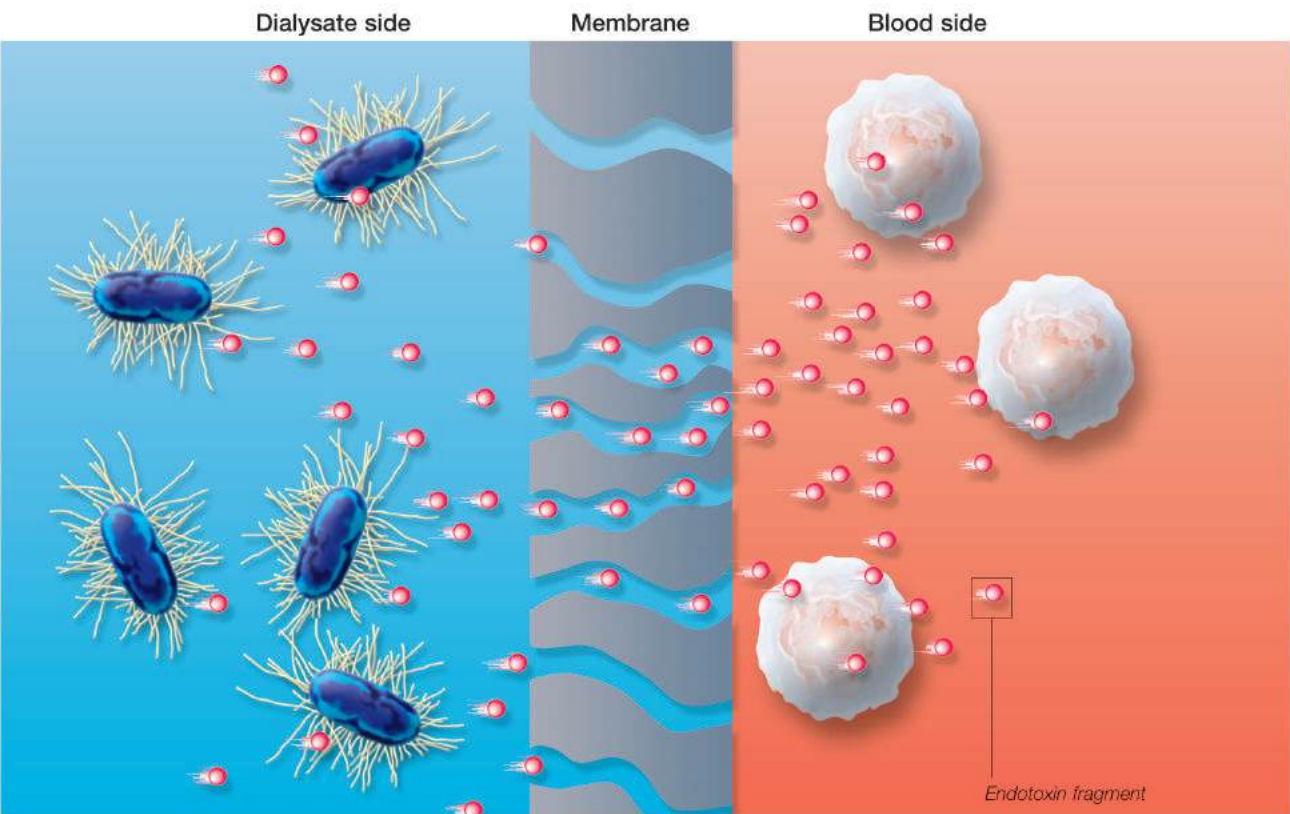


Fig.: Fragments of bacterial endotoxins enter the patient's blood-stream and activate leucocytes, thereby leading to acute and chronic complications in haemodialysis patients.

Clinical Advantages of Using Ultrapure Dialysis Fluid

Endotoxins can activate immune-competent cells in a number of ways, thereby contributing to chronic inflammation that is present in all haemodialysis patients ⁽⁶⁾ (Fig. 3). Recent evidence demonstrates that chronic inflammation is a major risk factor for progressive atherosclerotic cardiovascular disease (CVD) ⁽⁷⁾.

Besides the application of haemodialysis membranes with a high biocompatibility, the usage of ultrapure dialysis fluid, in particular, has been shown to reduce markers of chronic inflammation in haemodialysis patients ⁽⁸⁾. Therefore, it is suggestive that ultrapure dialysis fluid has a beneficial effect on inflammatory diseases such as atherosclerotic CVD ⁽⁹⁾.

Moreover, oxidative stress – a situation, in which the normal balance between production of reactive oxygen species (ROS) and antioxidant activity is tilted in favour of ROS – is increased by several treatment-related stimuli, including bacterial endotoxins derived from the dialysis fluid ^(10, 11).

As oxidative stress is associated with the progression of malnutrition, anaemia and inflammatory diseases such as atherosclerosis, it appears desirable to reduce dialysis-induced oxidative mechanisms, e. g. through the usage of biocompatible membranes and ultrapure dialysis fluid ^(10, 11).

The importance of ultrapure dialysis fluid in routine haemodialysis treatments is emphasized by the finding that endotoxins act in synergy with advanced glycation end-products (AGE), which enhance inflammation and oxidative stress ⁽¹²⁾. Furthermore, the use of ultrapure dialysis fluid has been shown to reduce the plasma levels of the AGE compound pentosidine ⁽¹³⁾.

Finally, ultrapure dialysis fluid has also been shown to improve iron utilization and the response to erythropoietin; thus, ultrapure dialysis fluid could be beneficial for anaemia treatment allowing for a reduction in erythropoietin dosage, while maintaining optimal haemoglobin levels ^(14, 15).

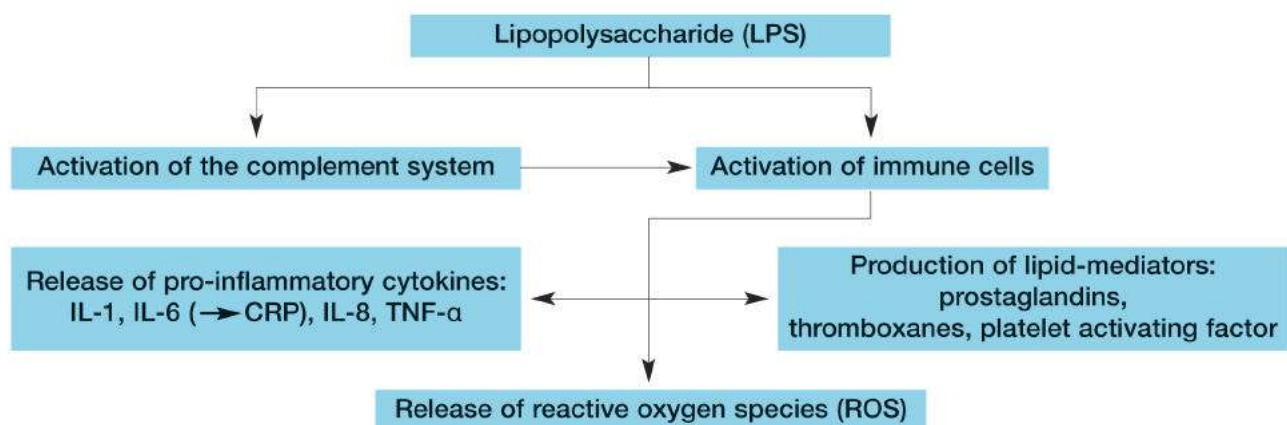


Fig. : Endotoxins (LPS) stimulate the release of pro-inflammatory cytokines, reactive oxygen species and lipid-mediators from immune-competent cells.

DIASAFE[®] *plus* in the ONLINE*plus*[™] System

Ultrapure dialysis fluid prepared with the DIASAFE[®] *plus* dialysis fluid filter, together with haemodialysers containing endotoxin-retaining membranes (Fresenius Polysulfone[®] or Helixone[®]) are the main building blocks for a high-quality haemodialysis treatment.

The ONLINE*plus*[™] system takes the quality standards of convective treatment modalities as haemodiafiltration/haemofiltration (HDF/HF) one step further: using two DIASAFE[®] *plus* dialysis fluid filters in series, an extremely high

microbiological safety is achieved by double filtration of the substitution fluids used in ONLINE HDF/HF therapies ⁽¹⁶⁾. Besides improving hygiene and safety of convective therapy modalities, the ONLINE*plus*[™] option also offers additional treatment features and adds to ease of handling.

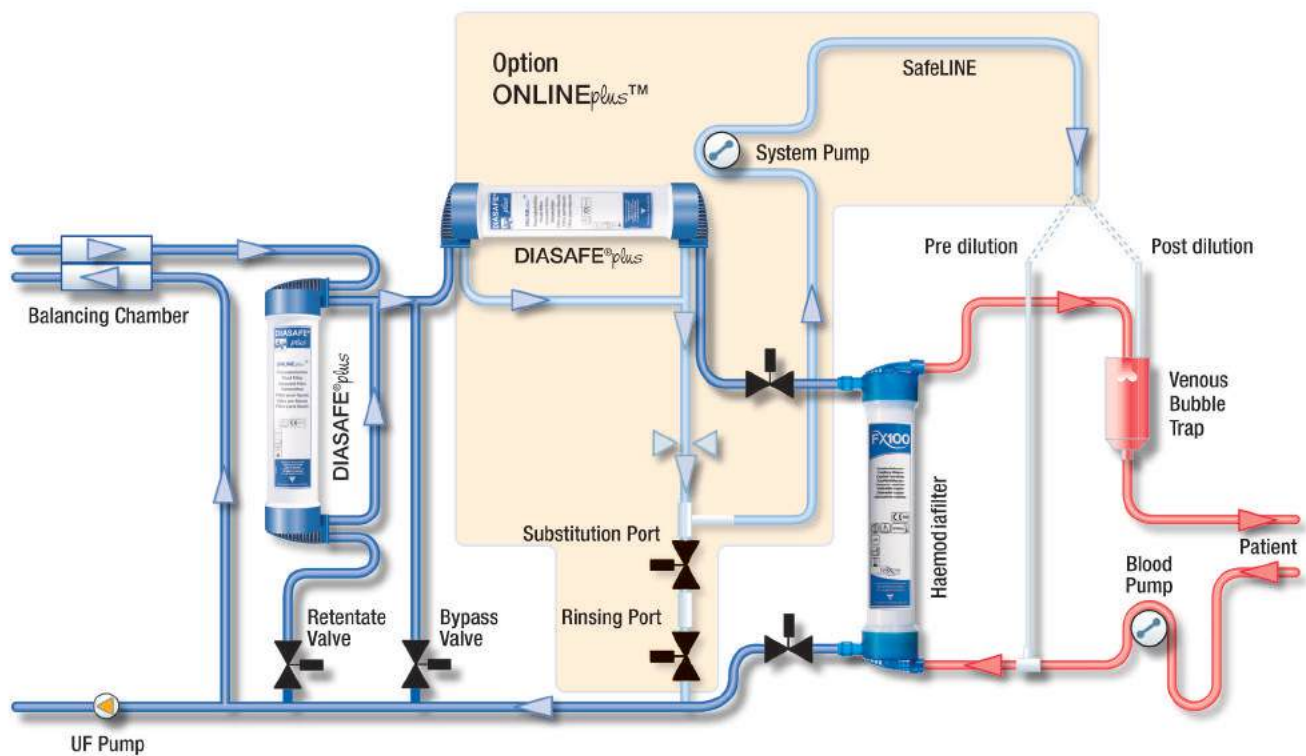


Fig. : Schematic flow chart of ONLINE haemodiafiltration with the ONLINE*plus*[™] system

References

1. Dasgupta MK: Biofilms and infection in dialysis patients. *Seminars in Dial* 15: 338-346, 2002.
2. Brunet P and Berland Y: Water quality and complications of haemodialysis. *Nephrol Dial Transplant* 15: 578-580, 2000.
3. Lonnemann G: Chronic inflammation in hemodialysis: the role of contaminated dialysate. *Blood Purif* 18: 214-223, 2000.
4. Golenbock DT et al.: Lipid A-like molecules that antagonise the effects of endotoxins on human monocytes. *J Biol Chem* 266: 19490-19498, 1991.
5. European Best Practice Guidelines for Haemodialysis (Part 1), Section IV – Dialysis fluid purity. *Nephrol Dial Transplant* 17 (Suppl. 7): 45-62, 2002.
6. Ward DM: Hemodialysis water: an update on safety issues, monitoring and adverse clinical effects. *ASAIO J* 50 (6): XIII-XIX, 2004.
7. Yao Q et al.: Inflammation as a cause of malnutrition, atherosclerotic cardiovascular disease and poor outcome in hemodialysis patients. *Hemodial Int* 8: 118-129, 2004.
8. Schiff H et al.: Effects of ultrapure dialysis fluid on nutritional status and inflammatory parameters. *Nephrol Dial Transplant* 16: 1863-1869, 2001.
9. Lonnemann G: When good water goes bad: how it happens, clinical consequences and possible solutions. *Blood Purif* 22: 124-129, 2004.
10. Locatelli F et al.: Oxidative stress in end-stage renal disease: an emerging threat to patient outcome (consensus paper). *Nephrol Dial Transplant* 18: 1272-1280, 2003.
11. Ward RA and McLeish KR: Oxidant stress in hemodialysis patients: what are the determining factors? *Artif Organs* 27: 230-236, 2003.
12. Reznikov LL et al.: Effect of advanced glycation end products on endotoxin-induced TNF- α , IL-1 and IL-8 in human peripheral blood mononuclear cells. *Clin Nephrol* 61: 324-336, 2004.
13. Izuwara Y et al.: Ultrapure dialysate decreases plasma pentosidine, a marker of carbonyl stress. *Am J Kidney Dis* 43: 1024-1029, 2004.
14. Sitter T et al.: Dialysate related cytokine induction and response to recombinant human erythropoietin in hemodialysis patients. *Nephrol Dial Transplant* 15: 1207-1211, 2000.
15. Hsu PY et al.: Ultrapure dialysate improves iron utilisation and erythropoietin response in chronic haemodialysis patients – a prospective cross-over study. *J Nephrol* 17: 693-700, 2004.
16. Weber C et al.: Novel online infusate-assisted dialysis system performs microbiologically safely. *Artif Organs* 24: 323-328, 2000.

Technical Data

Membrane material	Fresenius Polysulfone [®]
Effective Surface (m ²)	2.2
Weight (g)	170
Housing material	Polypropylene
Potting material	Polyurethane
Sealings	Silicone
Connection to machine	DIAFIX™ Lock System
Filtration rate	5 mL/min mm HG (3.75 L/min bar; max. 2 bar)
Operating time	Standard HD: max. 12 weeks ONLINE HF/HDF, ONLINE priming / rinsing: max. 12 weeks or 100 treatments
Disinfection	Puristeril [®] 340 or Puristeril [®] <i>plus</i> (peracetic acid) Diasteril [®] (hydroxyacetic acid) or Citrosteril [®] (citric acid) Sporotal [®] 100 (sodium hypochlorite) max. 11 times
Article number	F00005662



**FRESENIUS
MEDICAL CARE**

THE RENAL COMPANY

Fresenius Medical Care Asia-Pacific Ltd · 51/F, Sun Hung Kai Centre, 30 Harbour Road, Wanchai, Hong Kong
Phone: (852) 2583 0888 · Fax: (852) 2583 0200 · www.fmc-ag.com



INDIA

Proprietary Certificate

To
All India Institute Of Medical Sciences
Near Biju Pattnaik Police Academy
Sijua, Bhubaneswar-751019
Odisha

We, **Fresenius Medical Care India Private Limited** hereby certify that below mentioned products are proprietary items of Fresenius Medical Care AG & Co. KGaA.

The below mentioned products are manufactured by and only for Fresenius Medical Care AG & Co. KGaA.

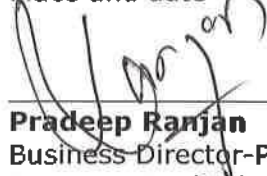
S. No.	Item	Article No.
1	Diasafe Plus	5008201
2	Water Inlet Filter	6438791
3	Citrosteril 2 x 5 L	F00005158
4	AV-Set Online Plus 5008 -R	F00000384

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Only M/s Fresenius Medical Care India Private Limited or any other authorized representative as appointed by M/s Fresenius Medical Care India Pvt. Ltd. is authorized to bid, negotiate, sale, service and conclude the contract in regard to this business in India.

Gurugram, 03.01.2020

Place and date



Pradeep Ranjan
Business Director-Products
Fresenius Medical Care India Pvt. Ltd.
SAS Tower-B, 14th Floor
Sector-38
Gurugram 122001



Fresenius Medical Care India Private Limited

CIN - U24231DL2006FTC147436

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New No. -7, South Boag Road,
T. Nagar, Chennai - 600 017
Tel : 044 - 4396 0900
Fax : 044 - 4396 0915



FMC/E/084/19-20

Date: 3rd January 2019

To
All India Institute Of Medical Sciences
Near Biju Pattnaik Police Academy
Sijua, Bhubaneswar-751019
Odisha
Sub:- Proposal for consumables.

Dear Sir,
Greetings! As desired, Please find our offer for consumables as mentioned below for your
Perusal

SI No:	Product Code	ITEM DESCRIPTION	Qty	MRP	Price per Unit in INR	GST	Pack Size
1	5008201	Diasafe Plus	1	12191.00	4200.00	18%	1
2	F00005158	Citrosteril	1	11493.00	3300.00	18%	2
3	F00000384	AV-set Online Plus 5008S	1	615.00	370.00	12%	20

Terms & Condition:

- Exclusive rate contract, to the valid for one year from the date of contract.
- Payment should be within 45days from the date of submission of invoice.
- Order should be name of our authorized dealer **Vikas Medical Devices, Plot No- 839, Mahaveer Nagar, Jharpada, Bhubaneswar-751006, Odisha.**

Thanking you and assuring you are best services at all the time.

Yours truly,
For Fresenius Medical Care India Private Limited


Tapas Paul
(Zonal Business manager- East)

Fresenius Medical Care India Private Limited

CIN - U24231DL2006FTC147436

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Fax : 022 - 4217 6501

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781, Anandpur,
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Tel. : 033 - 3090 9500
Fax : 033 - 3090 9506

Branch Office Chennai :
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New No. -7, South Boag Road,
T. Nagar, Chennai - 600 017
Tel. : 044 - 4396 0900
Fax : 044 - 4396 0915

AIIMS, BHUBANESWAR

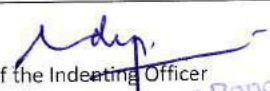
**Proprietary Article Certificate
Valid for the Current Financial Year**

File No. and Date Reference :		
1	Description of article	Endotoxin Filter (Diaseal plus) - compatible with SODS
2	Forecast of quantity /annual requirement	Approximately 80 (Eighty) per year
3	Approximate estimated value for above quantity	4956 x 80 =
4	Maker's name and address	Frederick medical care
5	Name(s) of authorized dealers/ stockists	Vikas medical devices, BBSR
6	I approve the above purchase on PAC basis and certify that : - Note- Tick to retain only one out of (b), C-1) or (c-2) whichever is applicable and cross out others. Please do confirm (a) by ticking it - without which PAC certificate will be invalid.	
6 (a)	This is the only firm who is manufacturing / stocking this item. AND	☒
6 (b)	A Similar article is not manufactured / sold by any other firm, which could be used in lieu OR	☒
6 (c-1)	No other make/brand will be suitable for following tangible reasons (like OEM/ Warranty, spares.) : OR	
6 (c)	No other make/brand will be suitable for following intangible reasons (if PAC was also given in the last procurement cycle, please also bring out efforts made since then to locate more sources) : OR	
7	Reference of concurrence of finance wing to the proposal :	
History of PAC Purchase of this item for past three years may be given below :		
Name of the Supplier		
Order/ Tender Reference & Date	Quantity Ordered	Basic Rate on Order (Rs.)
		Adverse Performance Reported if Any

Signature of the Indicating Officer

Signature of Approving Authority.....

Date..... Designation of Officer.....


Dr. Sandip Kumar Panda
 MD, DM (Nephrology)
 Asst. Professor, Nephrology
 Regd. No.: 10013 (OMC)
 AIIMS, Bhubaneswar-751013