K042938
Page 1 of 2

JAN - 6 2005

510(K) SUMMARY

SUBMITTER:	Gambro Renal Products 10810 West Collins Avenue Lakewood, CO 80215 USA
CONTACT:	Thomas B. Dowell, Manager Regulatory Affairs Phone: (303) 231-4094 Fax: (303) 542-5138
DATE PREPARED:	October 21, 2004
DEVICE NAME:	Prismaflex HF 1000 Set Prismaflex HF 1400 Set
COMMON/UNUSUAL NAME:	Hemofilter and Blood Tubing Set High Permeability Hemodialyzer
CLASSIFICATION NAMES:	High Permeability Hemodialysis System Accessory
CLASSIFICATION PANEL:	KDI Gastroenterology - Urology
CLASSIFICATION:	Class II per 21 CFR 876.5860

PREDICATE DEVICES:		
	Gambro Prisma HF1000 Set	K011221
	Gambro Prismaflex M60/M100 Set	K041005

SUBSTANTIAL EQUIVALENCE:

The proposed Prismaflex HF 1000 and HF 1400 sets are substantially equivalent to the Prisma HF 1000 sets and Prismaflex M60/M100 sets currently on the market. The modifications in the proposed devices are substantially equivalent in design, function, composition, and operation, to the predicate devices that have FDA clearance under 510(k)'s K011221 and K041005.

DEVICE DESCRIPTION:

The Prismaflex disposable sets are sterile disposable extracorporeal circuits containing a PAES hemofilter/dialyzer and fluid circuit for use with the Prismaflex control Unit. These Prismaflex disposable sets allow the following fluid management and renal replacement therapies to be performed:

- SCUF : Slow Continuous Ultrafiltration
- CVVH : Continous Veno-Venous Hemofiltartion
- CVVHD : Continous Veno-Venous Hemodialysis
- CVVHDF : Continuous Veno-Venous Hemodiafiltartion

K042938
Page 2 of 2

INDICATIONS FOR USE:

The Prismaflex Set is indicated for use only with the Prismaflex Control Unit in providing continuous fluid management and renal replacement therapies. The system is intended for patients who have acute renal failure, fluid overload, or both.

TECHNOLOGICAL CHARACTERISTICS:

The proposed device configurations have the same technological characteristics and are similar in design, function, and operation, to the currently marketed configurations.

SUMMARY OF NON-CLINICAL TESTS and CONCLUSION:

In vitro testing was conducted to compare the performance of the proposed device configurations to the predicate configurations. The results of the in vitro testing demonstrate that the proposed configurations are substantially equivalent to the predicate configurations and are suitable for the intended use.

SUMMARY OF CLINICAL TESTS and CONCLUSION:

Not applicable

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 6 2005

Mr. Thomas B. Dowell
Manager Regulatory Affairs
Gambro® Renal Products
10810 W. Collins Avenue
LAKEWOOD CO 80215

Re: K042938
Trade/Device Name: Prismaflex™ HF 1000 Set and Prismaflex™ HF 1400 Set
Regulation Number: 21 CFR §876.5860
Regulation Name: High permeability hemodialysis system
Regulatory Class: II
Product Code: 78 KDI
Dated: December 16, 2004
Received: December 17, 2004

Dear Mr. Dowell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K042938

Device Name:

Prismaflex™ HF 1000 Set
Prismaflex™ HF 1400 Set

Indications For Use:

The Prismaflex Set is indicated for use only with the Prismaflex Control Unit in providing continuous fluid management and renal replacement therapies. The system is intended for patients who have acute renal failure, fluid overload, or both.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) ~~AND~~/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David G. Seymour

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K042938

K042938/A1

GAMBRO Renal Products

December 21, 2004

10810 W. Collins Avenue
Lakewood, Colorado 80215 USA
Tel 303-232-6800

Joshua Nipper, (Biomedical Engineer) Gastroenterology and Renal Devices Branch
Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd
Rockville, Maryland 20850

Subject: K042938
Prismaflex™ HF 1000 and HF 1400 Sets

Dear Mr. Nipper,

Please find the revised page of the draft IFU for the Prismaflex HF 1000 and HF 1400 Sets attached to this memo. As you requested, I have included the information regarding creatinine clearance, which will be added to the table in the released IFU. The values are also shown in the response letter dated December 16, 2004 in question 1(d).

If you have any additional questions please call me at 303-231-4094.

Attachment:

Revised Draft Instructions for Use, page 47

Sincerely,

Thomas B. Dowell
Manager Regulatory Affairs
Gambro Renal Products

Sk 2

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CARACTERISTICAS DEL FILTRO	CARATTERISTICHE DEL FILTRO	FILTERDATA	PRISMAFLEX HF1000 SET	PRISMAFLEX HF1400 SET
CARACTERISTICAS FISICAS	**CARATTERISTICHE FISICHE**	**NOMINELLA FYSISKA KARAKTÄRISTIKA**		
Superficie efectiva	Superficie effettiva	Effektiv yta	1.1 m^2	1.4 m^2
Ø interna de la fibra (humeda)	Ø interno della fibra (bagnata)	Inre kapillärdiameter (våt)	215 µm	
Espesor de la pared de la fibra	Spessore parete della fibra	Tjocklek av kapillärvägg	50 µm	
RENDIMIENTOS IN VITRO ≠	**PRESTAZIONI IN VITRO ≠**	**IN VITRO PRESTANDA ≠**		
Volumen de cebado sanguíneo	**Volume di priming ematico**	**Blodvolym**	81 ml ± 10 %	102 ml ± 10 %
Caídas de presión sangre (post-dilución)	**Perdita di carico ematico (postdiluizione)**	**Blod tryckfall (postdilution)**		
(sangre bovina, Htc****32%, Cp***** 60 g/l, 37°C)	(sangue bovino, Hct****32%, Cp***** 60 g/l, 37°C)	(bovint blod, Htc****32%, Cp*****60 g/l, 37°C)	± 20 %	± 20 %
QB** = 100 ml/min, QUF*** = 2 L/h	QS** = 100 ml/min, QUF*** = 2 L/h	QB** = 100 ml/min, QUF*** = 2 L/h	37 mmHg	29 mmHg
QB** = 200 ml/min, QUF*** = 2 L/h	QS** = 200 ml/min, QUF*** = 2 L/h	QB** = 200 ml/min, QUF*** = 2 L/h	51 mmHg	41 mmHg
QB** = 300 ml/min, QUF*** = 2 L/h	QS** = 300 ml/min, QUF*** = 2 L/h	QB** = 300 ml/min, QUF*** = 2 L/h	66 mmHg	53 mmHg
QB** = 400 ml/min, QUF*** = 2 L/h	QS** = 400 ml/min, QUF*** = 2 L/h	QB** = 400 ml/min, QUF*** = 2 L/h	81 mmHg	64 mmHg
QB** = 450 ml/min, QUF*** = 2 L/h	QS** = 450 ml/min, QUF*** = 2 L/h	QB** = 450 ml/min, QUF*** = 2 L/h	-	69 mmHg
Transmitancia	**Coefficiente di sieving**	**Sievingkoefficient**		
(plasma bovino, Cp 60 g/l, 37° C)	(plasma bovino, Cp 60 g/l, 37° C)	(bovin plasma, Cp 60 g/l, 37 °C)		
QB** = 100 ml/min, QUF*** = 20 ml/min	QS** = 100 ml/min, QUF*** = 20 ml/min	QB** = 100 ml/min, QUF*** = 20 ml/min		
- Urea	- Urea	- Urea	1	
- Creatinina	- Creatinina	- Kreatinin	1	
- Vitamina B12	- Vitamina B12	- Vitamin B12	1	
- Inulina	- Inulina	- Inulin	1	
- Albúmina	- Albumina	- Albumin	< 0.01	

≠ Valores medios caracteristicos medidos en laboratorio sobre un muestro de lotes esterilizados. Los valores pueden variar en función del paciente, asi como de su estado clínico. / Tipici valori medi ottenuti da test di laboratorio su campioni di lotti sterili. I risultati possono variare a seconda del paziente e delle diverse condizioni cliniche. / Vanliga medelvärden erhållna vid laboratorietest av post-steriliserade prov-partier. Resultaten kan variera beroende på patient och kliniska förutsättningar.

CVVHD CLEARANCES (Continuous veno-venous hemodialysis) Clearances versus inlet dialysate flow rate (37°C)
CLAIRANCES EN CVVHD (Hémodialyse veino-veineuse continue) Clairances au bain de dialyse, à débit entrée dialysat (37°C)
CVVHD CLEARANCES (Kontinuierliche veno-venöse Hämodialyse) Clearancewerte abhängig von der Dialysierflüssigkeit-Einlaßrate (37°C)
ACLARAMIENTOS EN CVVHD (Hemodiálisis veno-venosa contínua) Aclaramientos con baño de diálisis a 37°C
CVVHD CLEARANCE (Emodialisi veno-venosa continua) Clearance con dialisato a 37°C
CVVHD CLEARANCE (Kontinuerlig veno-venös hemodialys) Clearance mot dialysatflöde (37°C)
KLARINGEN IN CVVHD (Continue veno-veneuze hemodialyse) Klaringen, snelheid van de dialysaataanvoer (37°C)
ACLARAMENTO EM CVVHD (Hemodiálise veno-venosa contínua) Aclaramento numa solução diálise a 37°C
CVVHD-CLEARANCE (Continuous veno-venous hemodialysis) Clearanceverdi versus inngangsdialyseflow-rate (37°C)
CVVHD CLEARANCE (Kontinuerlig vene-vene hæmodialyse) Clearance kontra flowhastighed for indløbsdialysat (37°C)
CVVHD (Continuous veno-venous hemodialysis) Clearance-arvot sisään tulevaan dialysaatin virtaukseen verrattuina (37°C)

DRAFT

		PRISMAFLEX HF1000 SET				PRISMAFLEX HF1400 SET			
		QB/QS** = 100 ml/min QUF*** = 0 ml/min				QB/QS** = 200 ml/min QUF*** = 0 ml/min			
QD******	(l/h)	1	2.5	4	8	1	2.5	4	8
Urea / Urée / Harnstoff / Urea / Ureum / Karbamid / Ureia / Karbamid / Virtsahappo	(± 10%)	16.5	41	62	88	16.6	41	65	119
Vit B12	(± 20%)	16.2	36	48	63	16.5	38	55	84
Inulin / Inuline / Inulina / Inuliini	(± 20%)	16.0	32	42	52	16.4	35	46	69
Creatinine		16.5	41	61	84	16.6	41	65	114

*** Ultrafiltration flow rate (on PRISMAFLEX system, the ultrafiltration flow rate = fluid removal flow rate + replacement flow rate + pre blood pump flow rate) /
Débit d'ultrafiltration (sur le système PRISMAFLEX, le débit d'ultrafiltration correspond au débit de prélèvement de liquide + débit de solution de réinjection + le débit de la pompe pré-pompe sang (PBP)) /
Ultrafiltrationsflußrate (beim PRISMAFLEX-System ist die Ultrafiltrationsflußrates die Flussigkeitsentfernungsflußrate + Substitutionsflußrate + Prä-Blutpumpen Flußrate) /
Flujo de ultrafiltratión (en el sistema PRISMAFLEX el flujo de ultrafiltración corresponde al flujo de extracción de liquido mas el flujo de solución de reinyección + mas el flujo de infusione pre-bomba de sangre (PBP)) /
Flusso di ultrafiltrazione (il sistema PRISMAFLEX calcola il flusso di ultrafiltrazione nel seguente modo : flusso di rimozione del fluido + flusso di reinfusione + flusso dell'infusione pre-pompa sangue (PBP)) /
Ultrafiltrationshastighet (på PRISMAFLEX, ultrafiltrationshastighet = hastighet på vätskeborttag från patient + hastghet på ersättningslösning + preblodpumps flödeshastighet) /
Ultrafiltratie-snelheid (op PRISMAFLEX -systeem : de ultrafiltratie-snelheid = vochtverwijderings-snelheid + substitutie-snelheid + pre bloedpomp snelheid) /
Fluxo de ultrafiltração (no sistema PRISMAFLEX, o fluxo de ultrafiltração corresponde ao débito de recolha de líquido + débito de solução de reposição + taxa de fluxo pré bomba de sangue) /
Flow-rate for ultrafiltrasjon (på PRISMAFLEX-systemet: flow-rate for ultrafiltrasjon tilsvarer flow-rate for vækefjerning + flow-rate for reinjeksjonsvæske) /
Flowhastighed for ultrafiltration (på PRISMAFLEX-systemet er flowhastigheden for ultrafiltration lig med flowhastigheden for væskeudløb + flowhastigheden for erstatningsvæske + pre-blodpumpe flowhastighed) /
Ultrafiltrausnopeus (tämä nopeus PRISMAFLEX-järjestelmässä = nesteen ulostulovirtaus + korvausnesteen virtausnopeus + esi-veri-pumppu (PBP) virtausnopeus)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 6 2005

Mr. Thomas B. Dowell
Manager Regulatory Affairs
Gambro® Renal Products
10810 W. Collins Avenue
LAKEWOOD CO 80215

Re: K042938
Trade/Device Name: Prismaflex™ HF 1000 Set and Prismaflex™ HF 1400 Set
Regulation Number: 21 CFR §876.5860
Regulation Name: High permeability hemodialysis system
Regulatory Class: II
Product Code: 78 KDI
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Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K042938

Device Name:

Prismaflex™ HF 1000 Set
Prismaflex™ HF 1400 Set

Indications For Use:

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Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lagman

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K042938

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Thomas B. Dowell
Manager Regulatory Affairs
Gambro Renal Products
10810 West Collins Avenue
LAKEWOOD CO 80215

NOV 16 2004

Re: K042938
Trade Name: Gambro Prismaflex™ HF1000 and HF1400 Sets
Dated: October 21, 2004
Received: October 25, 2004

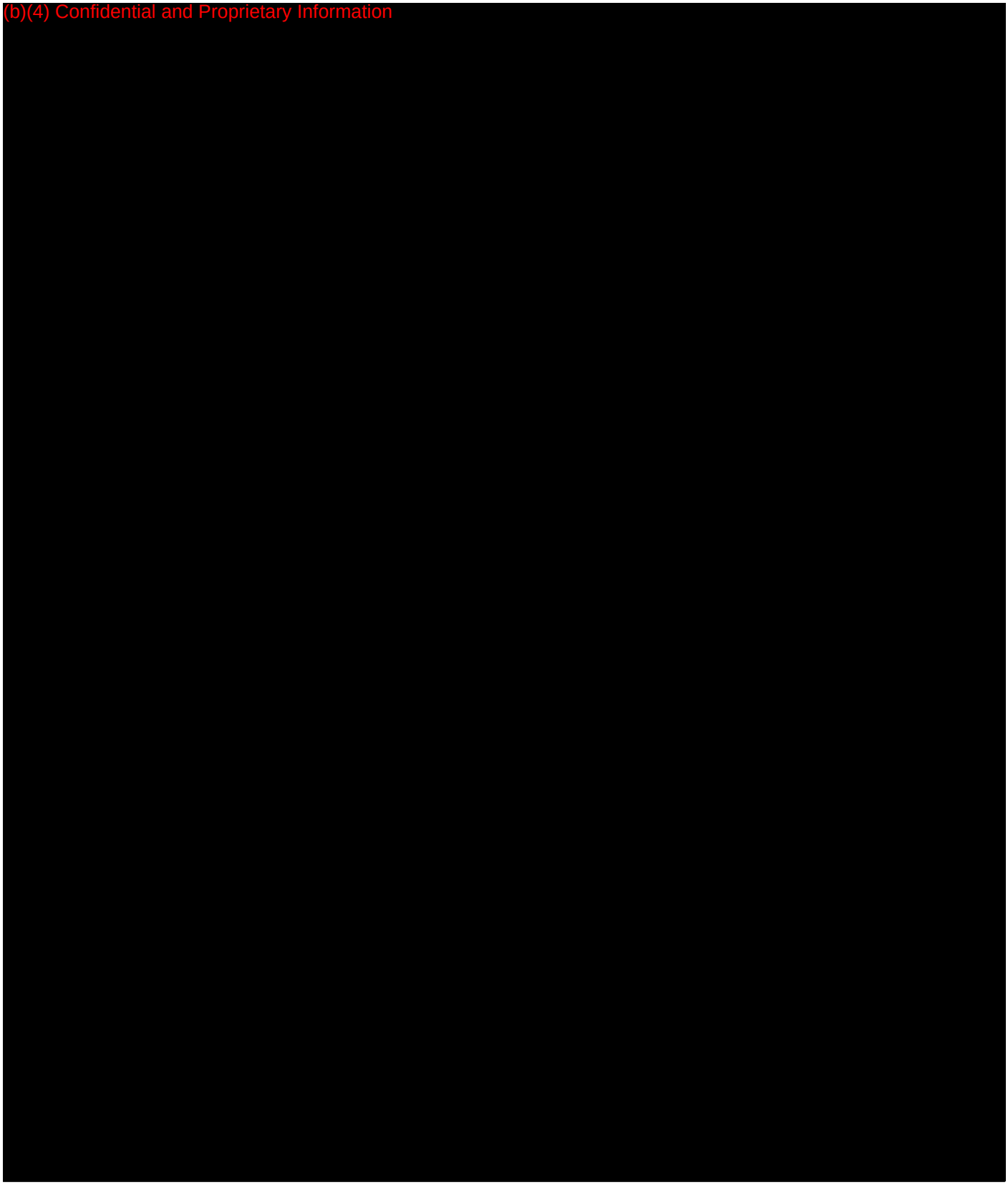
Dear Mr. Dowell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a legally marketed predicate device based solely on the information you provided. To complete the review of your submission, we require the following additional information:

(b)(4) Confidential and Proprietary Information

[redacted]

(b)(4) Confidential and Proprietary Information



(b)(4) Confidential and Proprietary Information

[redacted]

The deficiencies identified above represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device.

We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: http://www.fda.gov/cdrh/modact/leastburdensome.html

You may not market this device until you have provided adequate information described above and required by 21 CFR 807.87(l), and you have received a letter from FDA allowing you to do so. If you market the device without conforming to these requirements, you will be in violation of the Federal Food, Drug, and Cosmetic Act (Act). You may, however, distribute this device for investigational purposes to obtain clinical data if needed to establish substantial equivalence. Clinical investigations of this device must be conducted in accordance with the investigational device exemption (IDE) regulations.

If the information, or a request for an extension of time, is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system. If you submit the requested information after 30 days it will be considered and processed as a new 510(k); therefore, all information previously submitted must be resubmitted so that your new 510(k) is complete. Please note our guidance document entitled, "Guidance for Industry and FDA Staff FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may review this document at http://www.fda.gov/cdrh/mdufma/guidance/1219.html.

The requested information, or a request for an extension of time, should reference your above 510(k) number and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and
Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

If you have any questions concerning the contents of the letter, please contact Mr. Joshua Nipper at (301) 594-1220. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Carolyn Y Neuland

Carolyn Y. Neuland, Ph.D.
Chief, Gastroenterology and Renal
Devices Branch
Division of Reproductive, Abdominal,
and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Thomas B. Dowell
Manager Regulatory Affairs
Gambro Renal Products
10810 West Collins Avenue
LAKEWOOD CO 80215

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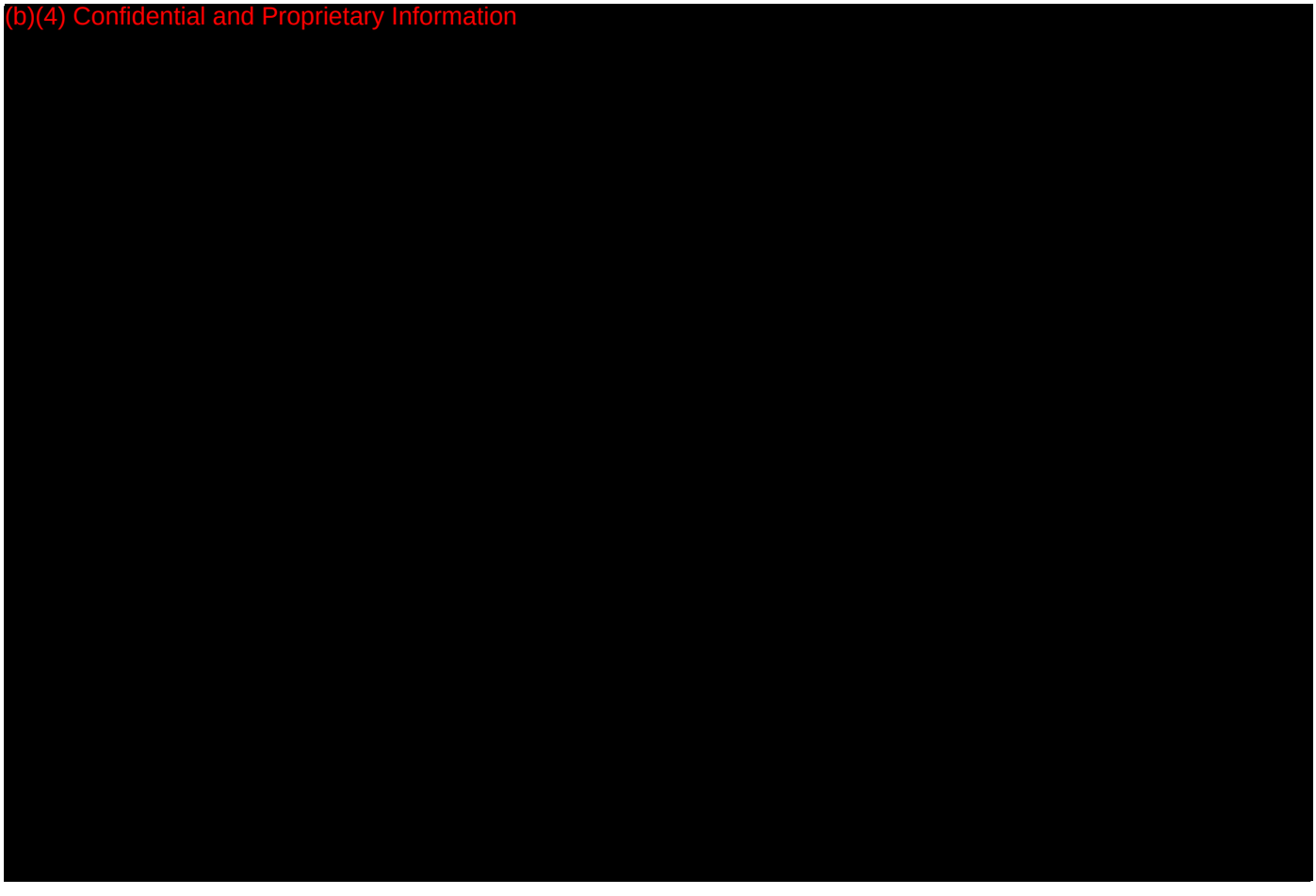
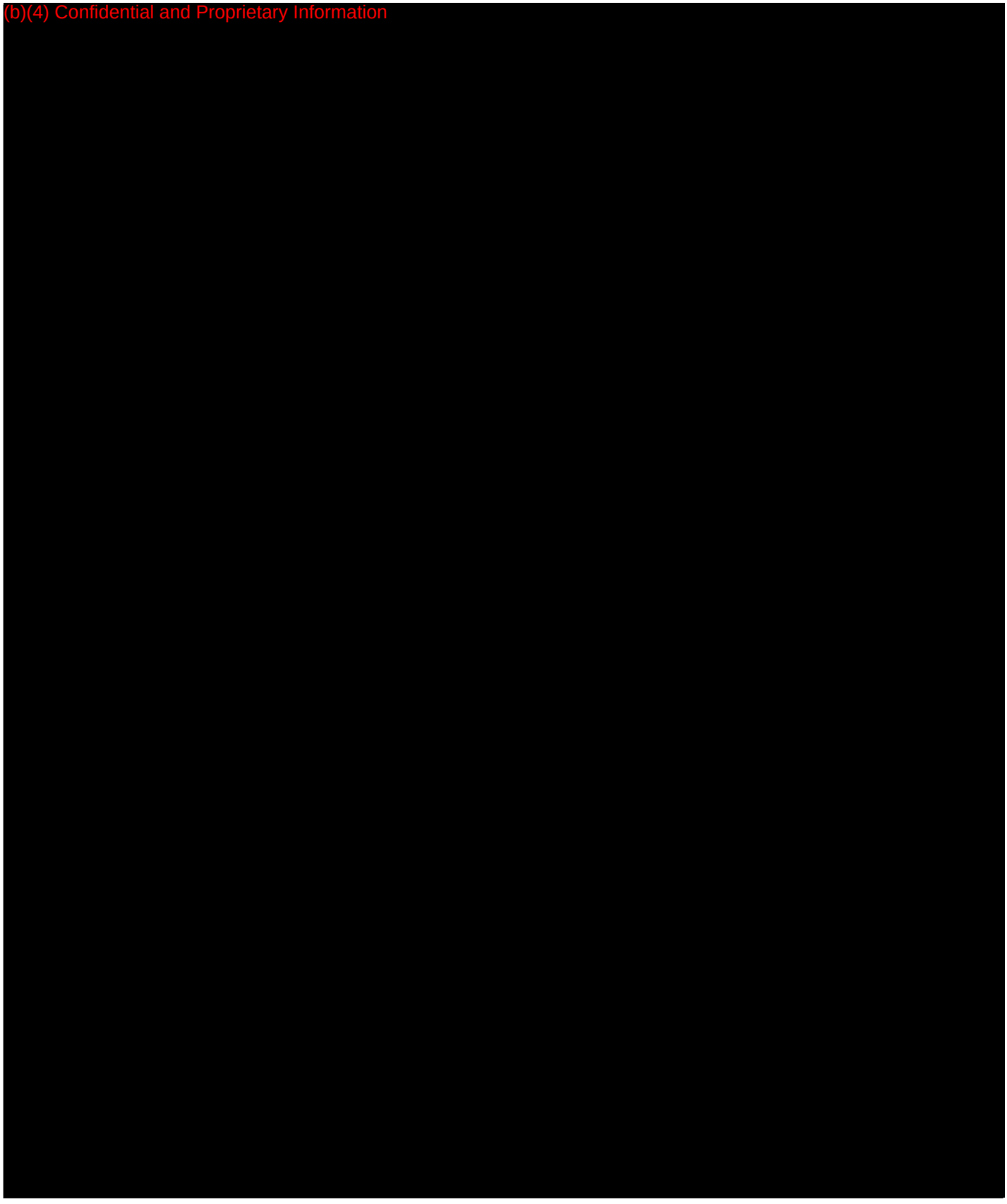


(b)(4) Confidential and Proprietary Information



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Sincerely yours,

/s/

Carolyn Y. Neuland, Ph.D.
Chief, Gastroenterology and Renal
Devices Branch
Division of Reproductive, Abdominal,
and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

cc: HFZ-401 DMC
HFZ-404 510(k) Staff
HFZ-470 DRARD
D.O.

HFZ470:JoshuaNipper:jcn:11.16.2004

FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HFZ470	Nipper	11/16/04						
HFZ420	Neuland	11/16/04						

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

October 25, 2004

GAMBRO RENAL PRODUCTS
10810 WEST COLLINS AVE.
LAKEWOOD, CO 80215
ATTN: THOMAS B. DOWELL

510(k) Number: K042938
Received: 25-OCT-2004
Product: GAMBRO PRISMAFLEX HF1000 AND HF1400 SETS

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), has received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act(Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in any future correspondence that relates to this submission. We will notify you when the processing of your premarket notification has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

On May 21, 2004, FDA issued a Guidance for Industry and FDA Staff entitled, "FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. Please review this document at http://www.fda.gov/cdrh/mdufma/guidance/1219.html.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC)(HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review". Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html.

You should be familiar with the regulatory requirements for medical device available at Device Advice http://www.fda.gov/cdrh/devadvice/". If you have other procedural or policy questions, or want information on how to check on the status of your submission, please contact DSMICA at (301) 443-6597 or its toll-free number (800) 638-2041, or at their Internet address http://www.fda.gov/cdrh/dsmamain.html or me at (301)594-1190.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Office of Device Evaluation
Center for Devices and Radiological Health

C3

K042938

Special 510(k) Notification

Gambro Prismaflex™ HF 1000 Set / HF 1400 Set

GK

TABLE OF CONTENTS

SECTION I

Letter to the FDA
(including copy of the User Fee Coversheet)

GG

GAMBRO Renal Products

October 21, 2004

10810 W. Collins Avenue
Lakewood, Colorado 80215 USA

Tel 303-232-6800

Food & Drug Administration
Center for Devices & Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, MD
20850

RE: Special 510(k) Notification
Gambro Prismaflex™ HF 1000/HF 1400 Sets

Dear Sir/Madame:

This Premarket Notification (Section 510(k)) is to request FDA authorization to commercially distribute the Prismaflex™ HF 1000 Sets and HF 1400 Sets, which are (b)(4) Confidential and (b)(4) Confidential and Proprietary Information

In accordance with Section 510(k) of the Federal Food, Drug and Cosmetic Act, and in conformance with 21 CFR 807, this Premarket Notification is being submitted prior to the date when Gambro Renal Products proposes to introduce these devices into interstate commerce for commercial distribution.

The medical devices are being submitted in this 510(k) Notification by virtue of the fact that they are substantially equivalent in design, function, composition, and operation, to other acute renal care devices, which were or are currently in commercial distribution in the United States. We consider the information in this notification to be confidential

Please feel free to contact me at (303) 231-4094 (telephone) or (303) 542-5138 (fax) if you have any questions or require additional information regarding this Premarket Notification.

Sincerely yours,

Thomas B. Dowell
Manager Regulatory Affairs
Gambro Renal Products

cc: Emmanuelle Moulin
Francesco Bardelli

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Form Approved:OMB No. 0910-0511 Expiration Date: August 31, 2006. See instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
MEDICAL DEVICE USER FEE COVER SHEET

PAYMENT IDENTIFICATION NUMBER: (b)(4) Confidential and Proprietary Information
Write the Payment Identification Number on your check.

A completed Cover Sheet must accompany each original application or supplement subject to fees. The following actions must be taken to properly submit your application and fee payment:

1. Electronically submit the completed Cover Sheet to the Food and Drug Administration (FDA) before payment is sent.
2. Include a printed copy of this completed Cover Sheet with a check made payable to the Food and Drug Administration. Remember that the Payment Identification Number must be written on the check.
3. Mail Check and Cover Sheet to the US Bank Lock Box, FDA Account, P.O. Box 956733, St. Louis, MO 63195-6733. (*Note: In no case should payment be submitted with the application.*)
4. If you prefer to send a check by a courier, the courier may deliver the check and Cover Sheet to: US Bank, Attn: Government Lockbox 956733, 1005 Convention Plaza, St. Louis, MO 63101. (Note: This address is for courier delivery only. Contact the US Bank at 314-418-4821 if you have any questions concerning courier delivery.)
5. For Wire Transfer Payment Procedures, please refer to the MDUFMA Fee Payment Instructions at the following URL: http://www.fda.gov/cdrh/mdufma/faqs.html#3a. You are responsible for paying all fees associated with wire transfers.
6. Include a copy of the completed Cover Sheet in volume one of the application when submitting to the FDA at either the CBER or CDRH Document Mail Center.

1. COMPANY NAME AND ADDRESS (Include name, street address, city, state, country, and post office code)

GAMBRO RENAL PRODUCTS
10810 WEST COLLINS AVENUE
LAKEWOOD, CO 80215

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)
841155786

2. CONTACT NAME
THOMAS DOWELL

2.1 E-MAIL ADDRESS
tom.dowell@us.gambro.com

2.2 TELEPHONE NUMBER (Include Area Code)
303-231-4094

2.3 FACSIMILE (FAX) NUMBER (Include Area Code)
303-542-5138

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/oc/mdufma

Select an application type:

- ☑ Premarket notification (510(k)); except for third party reviews
- ☐ Biologics License Application (BLA)
- ☐ Premarket Approval Application (PMA)
- ☐ Modular PMA
- ☐ Product Development Protocol (PDP)
- ☐ Premarket Report (PMR)

3.1 Select one of the types below:

- ☑ Original Application

Supplement Types:

- ☐ Efficacy (BLA)
- ☐ Panel Track (PMA, PMR, PDP)
- ☐ Real-Time (PMA, PMR, PDP)
- ☐ 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status.)

- ☐ YES, I meet the small business criteria and have submitted the required qualifying documents to FDA
- ☑ NO, I am not a small business

4.1 If Yes, please enter your Small Business Decision Number:

5. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE **EXCEPTIONS**? IF SO, CHECK THE APPLICABLE EXCEPTION.

- ☐ This application is the first PMA submitted by a qualified small business, including any affiliates, parents, and partner firms
- ☐ This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only
- ☐ The sole purpose of the application is to support conditions of use for a pediatric population
- ☐ The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

6. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).)

☐ YES ☑ NO

7. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION (FOR FISCAL YEAR 2005)

(b)(4) Confidential and Proprietary

Form FDA 3601 (08/2003)

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SECTION II

Pre-Market Submission Coversheet

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH
Pre-market Submission Cover Sheet

Date of Submission: October 21, 2004

FDA DOCUMENT NUMBER: NOT YET ASSIGNED

Section A **Type of Submission**

- ☒ 510(k)
- ☐ 510(k) Add'l information
- ☐ IDE
- ☐ IDE Amendment
- ☐ IDE Supplement
- ☐ IDE Report
- ☐ PMA
- ☐ PMA Amendment
- ☐ PMA Report
- ☐ PMA Supplement - Regular
- ☐ PMA Supplement - Special
- ☐ PMA Supplement - 30 day
- ☐ PMA Supplement - Panel Track

Section B1 **Reason for Submission — 510(k)s Only**

- ☐ New device
- ☐ Additional or expanded indications
- ☒ Change in technology, design, materials, or manufacturing process
- ☐ Other reason (specify):

Section B2 **Reason for Submission — PMAs Only**

- ☐ New device
- ☐ Withdrawal
- ☐ Additional or expanded indications
- ☐ Licensing agreement
- ☐ Change in design, component, or specification:
  - ☐ Software
  - ☐ Color Additive
  - ☐ Other (specify below)
- ☐ Location change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager
  - ☐ Distributor
- ☐ Labeling change:
  - ☐ Indications
  - ☐ Instructions
  - ☐ Performance Characteristics
  - ☐ Shelf life
  - ☐ Trade name
  - ☐ Other (specify below)
- ☐ Process change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager
- ☐ Report submission:
  - ☐ Annual or periodic
  - ☐ Post-approval study
  - ☐ Adverse reaction
  - ☐ Device defect
  - ☐ Amendment
- ☐ Response to FDA correspondence (specify below)
- ☐ Request for applicant hold
- ☐ Request for removal of applicant hold
- ☐ Request for extension
- ☐ Request to remove or add manufacturing site
- ☐ Change in ownership
- ☐ Change in correspondent
- ☐ Other reason (specify):

Section B3 **Reason for Submission — IDEs Only**

- ☐ New device
- ☐ Addition of institution
- ☐ Expansion / extension of study
- ☐ IRB certification
- ☐ Request hearing
- ☐ Request waiver
- ☐ Termination of study
- ☐ Withdrawal of application
- ☐ Unanticipated adverse effect
- ☐ Change in:
  - ☐ Correspondent
  - ☐ Design
  - ☐ Informed consent
  - ☐ Manufacturer
  - ☐ Manufacturing
  - ☐ Protocol – feasibility
  - ☐ Protocol– other
  - ☐ Sponsor
- ☐ Response to FDA letter concerning:
  - ☐ Conditional approval
  - ☐ Deemed approved
  - ☐ Deficient final report
  - ☐ Deficient progress report
  - ☐ Deficient investigator report
  - ☐ Disapproval
  - ☐ Request extension of time to respond to FDA
  - ☐ Request meeting
- ☐ Emergency use:
  - ☐ Notification of emergency use
  - ☐ Additional information
- ☐ Report submission:
  - ☐ Current investigator
  - ☐ Annual progress
  - ☐ Site waiver limit reached
  - ☐ Final
- ☐ IOL submissions only:
  - ☐ Change in IOL style
  - ☐ Request for protocol waiver
- ☐ Other reason (specify):

FDA Document Number: Not Yet Assigned

Section C **Product Classification**

Product code: KDI	C.F.R. Section: 21 CFR 876.5860	Device class: ☐ Class I ☒ Class II ☐ Class III ☐ Unclassified
Classification panel: Gastroenterology - Urology		

Section D **Information on 510(k) Submissions**

Product codes of devices to which substantial equivalence is claimed:

Summary of, or statement concerning, safety and effectiveness data:
☒ 510(k) summary attached
☐ 510(k) statement

1 KDI	2 KDI	3	4	
5	6	7	8	

Information on devices to which substantial equivalence is claimed:

510(k) Number	Trade or proprietary or model name	Manufacturer
1 K011221	1 Prisma HF1000	1 Hospal Industrie
2 K041005	2 Prismaflex M60/M100 Sets	2 Hospal industrie
3	3	3
4	4	4

Section E **Product Information — Applicable to All Applications**

Common or usual name or classification name:

Trade or proprietary or model name	Model number
1 Gambro Prismaflex™ HF1000 Set	1 HF 1000
2 Gambro Prismaflex™ HF1400 Set	2 HF 1400

FDA document numbers of all prior related submissions (regardless of outcome):

1	2	3	4	5	6
7	8	9	10	11	12

Data included in submission: ☒ Laboratory testing ☐ Animal trials ☐ Human trials

Indications (From labeling):

The Prismaflex Set is indicated for use only with the Prismaflex Control Unit in providing continuous fluid management and renal replacement therapies. The system is intended for patients who have acute renal failure, fluid overload, or both.

FDA Document Number: Not Yet Assigned

(b)(4) Confidential and Proprietary Information

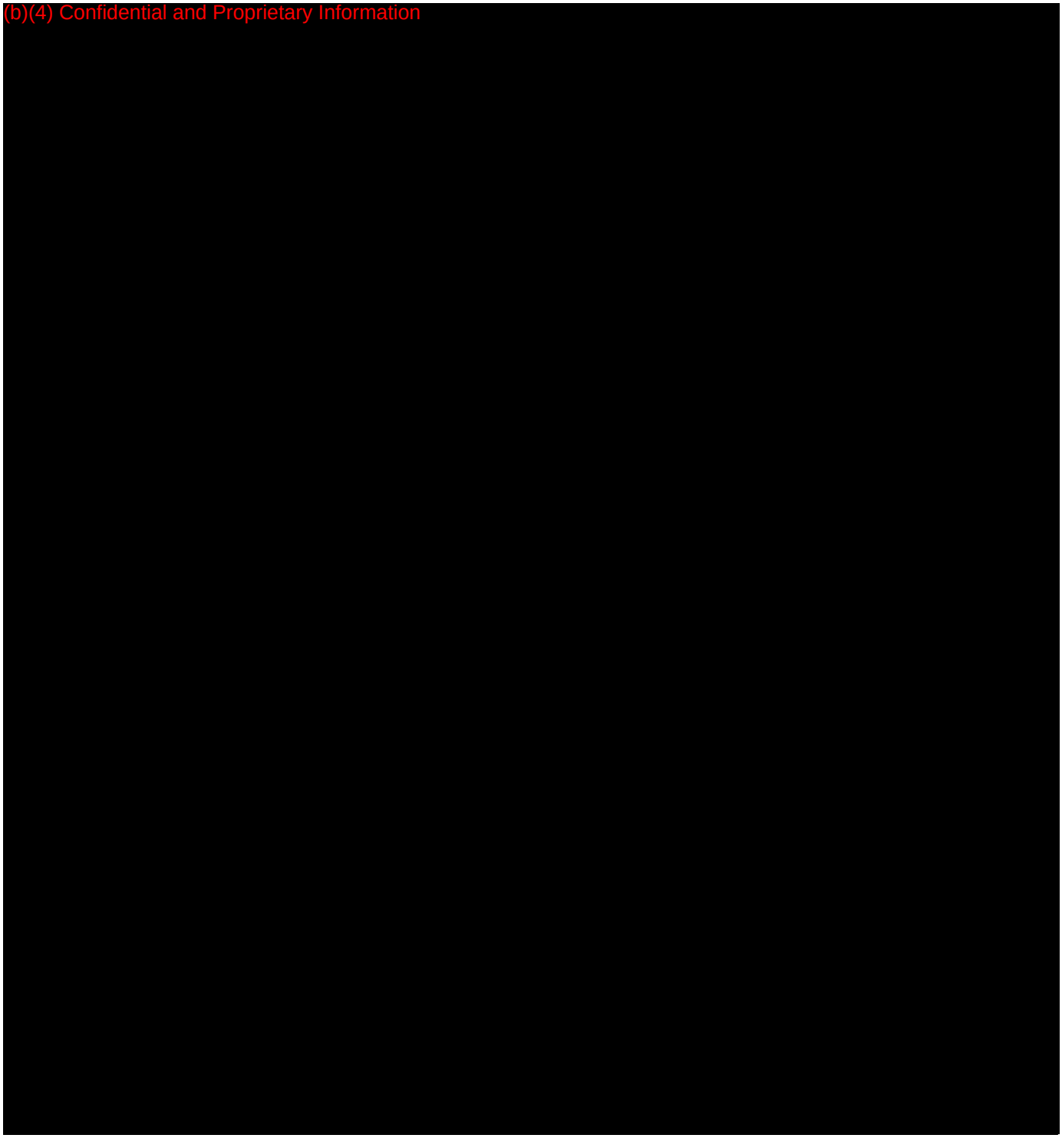
[redacted]

SECTION III

Description of Devices

PRODUCT DESCRIPTION AND SPECIFICATIONS

(b)(4) Confidential and Proprietary Information



(b)(4) Confidential and Proprietary Information

The proposed design modifications are as follows :

[redacted]

75

(continued)

[redacted]

76

(b)(4) Confidential and Proprietary Information

[redacted]

B. TECHNICAL DRAWINGS

(b)(4) Confidential and Proprietary Information

[redacted]

(b)(4) Confidential and Proprietary Information

[redacted]

(b)(4) Confidential and Proprietary Information

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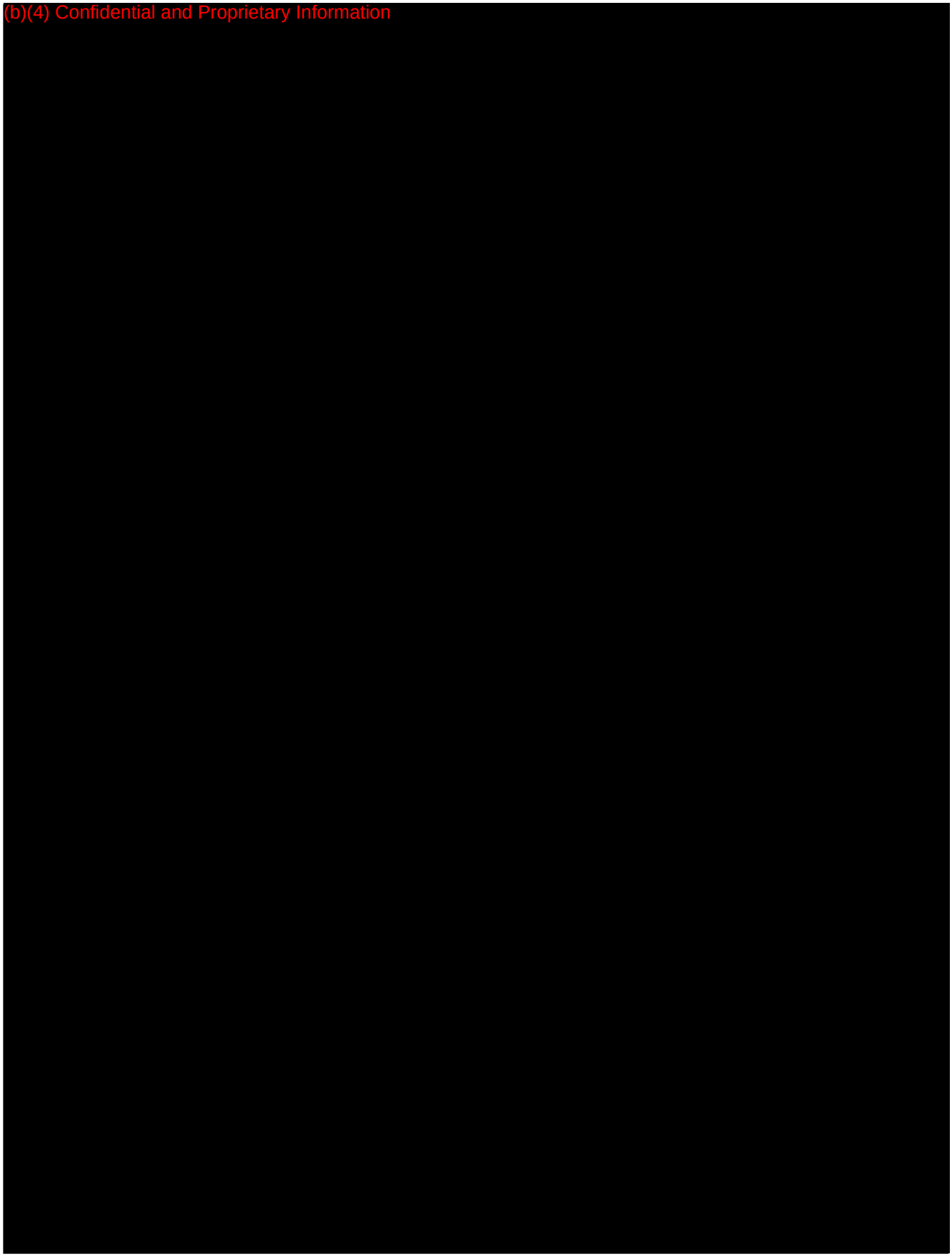
(b)(4) Confidential and Proprietary Information



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C. COMPONENTS PART AND MATERIALS

(b)(4) Confidential and Proprietary Information

[redacted]

2 Tubing

(b)(4) Confidential and Proprietary Information

[redacted]

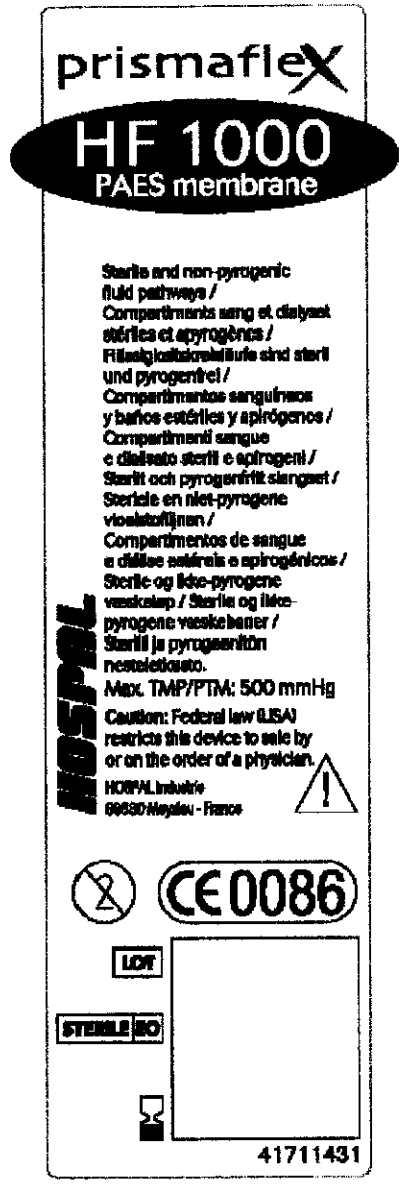
(b)(4) Confidential and Proprietary Information

[redacted]

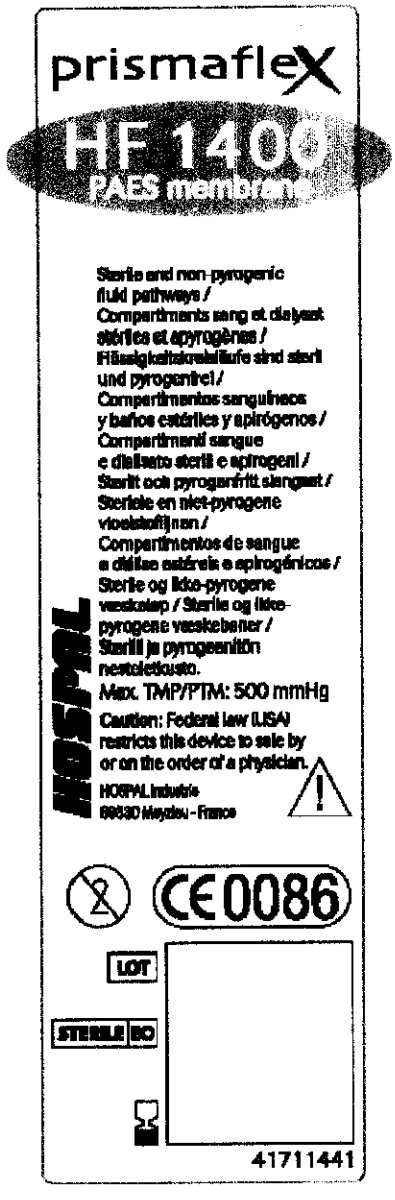
SECTION IV

Labeling

A. PRODUCT LABEL FOR HF 1000 SET



B. PRODUCT LABEL FOR HF 1400 SET



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C. PACKAGE INSERT

The Instructions for Use is attached as appendix A.

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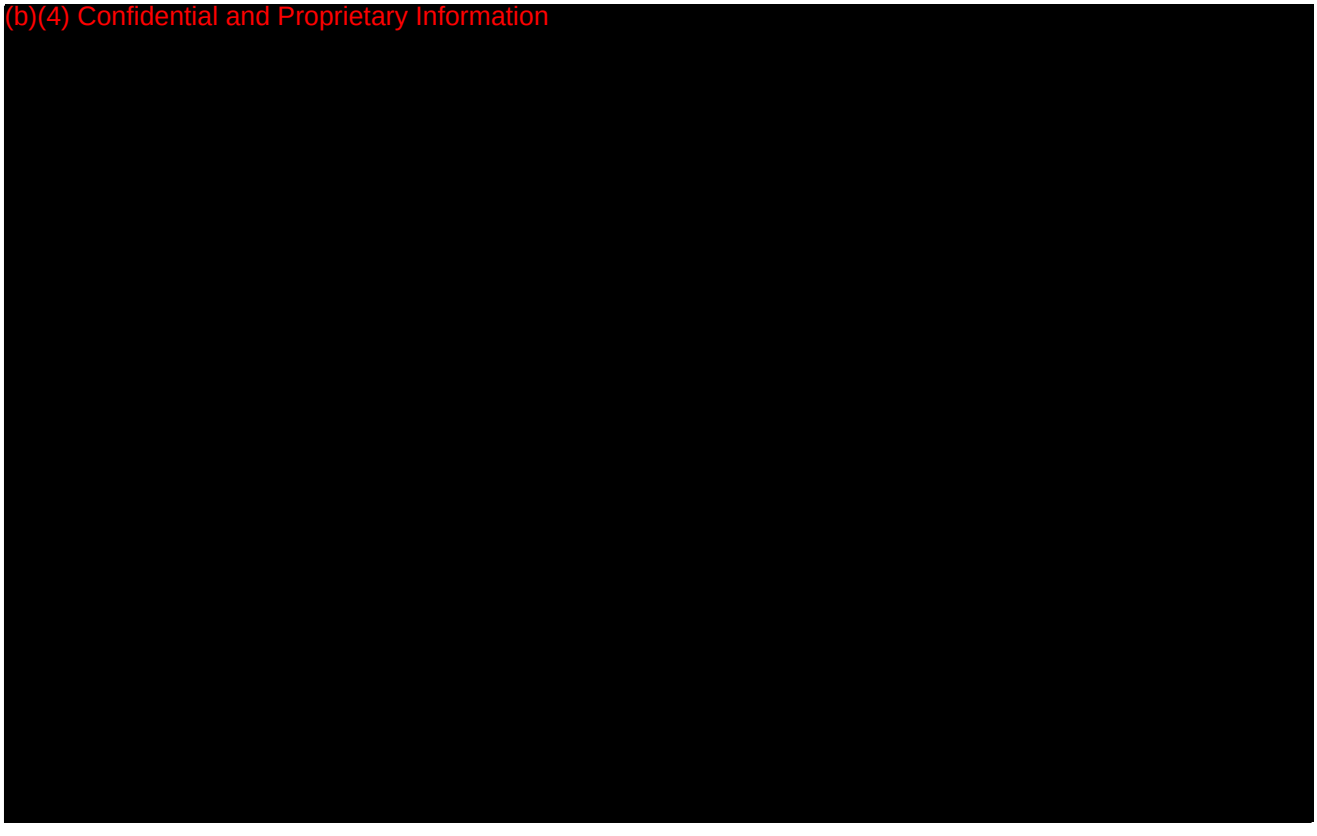
D. PROPOSED MARKETING LITERATURE

The proposed marketing literature is attached as appendix B

SECTION V

Device Performance

(b)(4) Confidential and Proprietary Information



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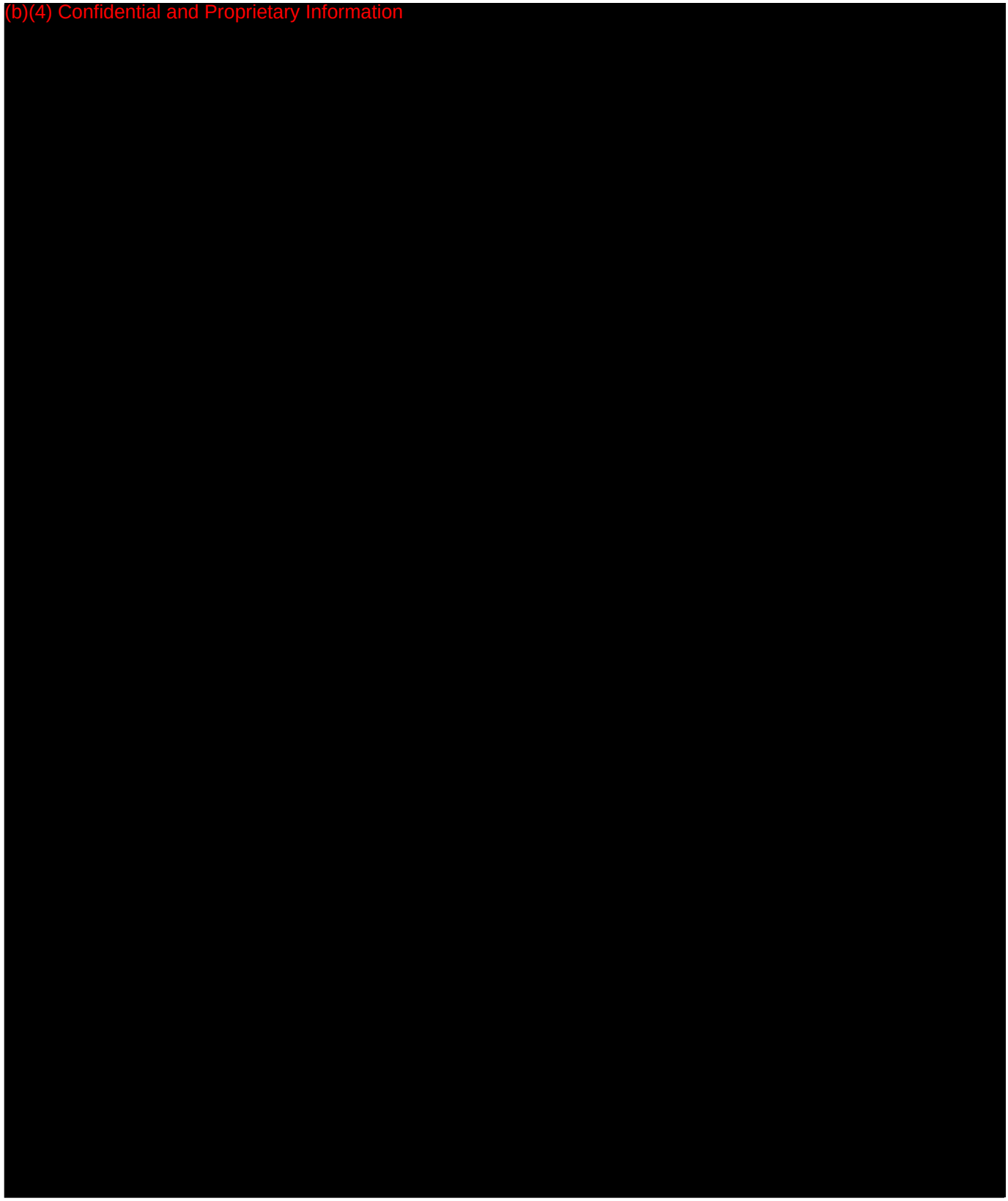

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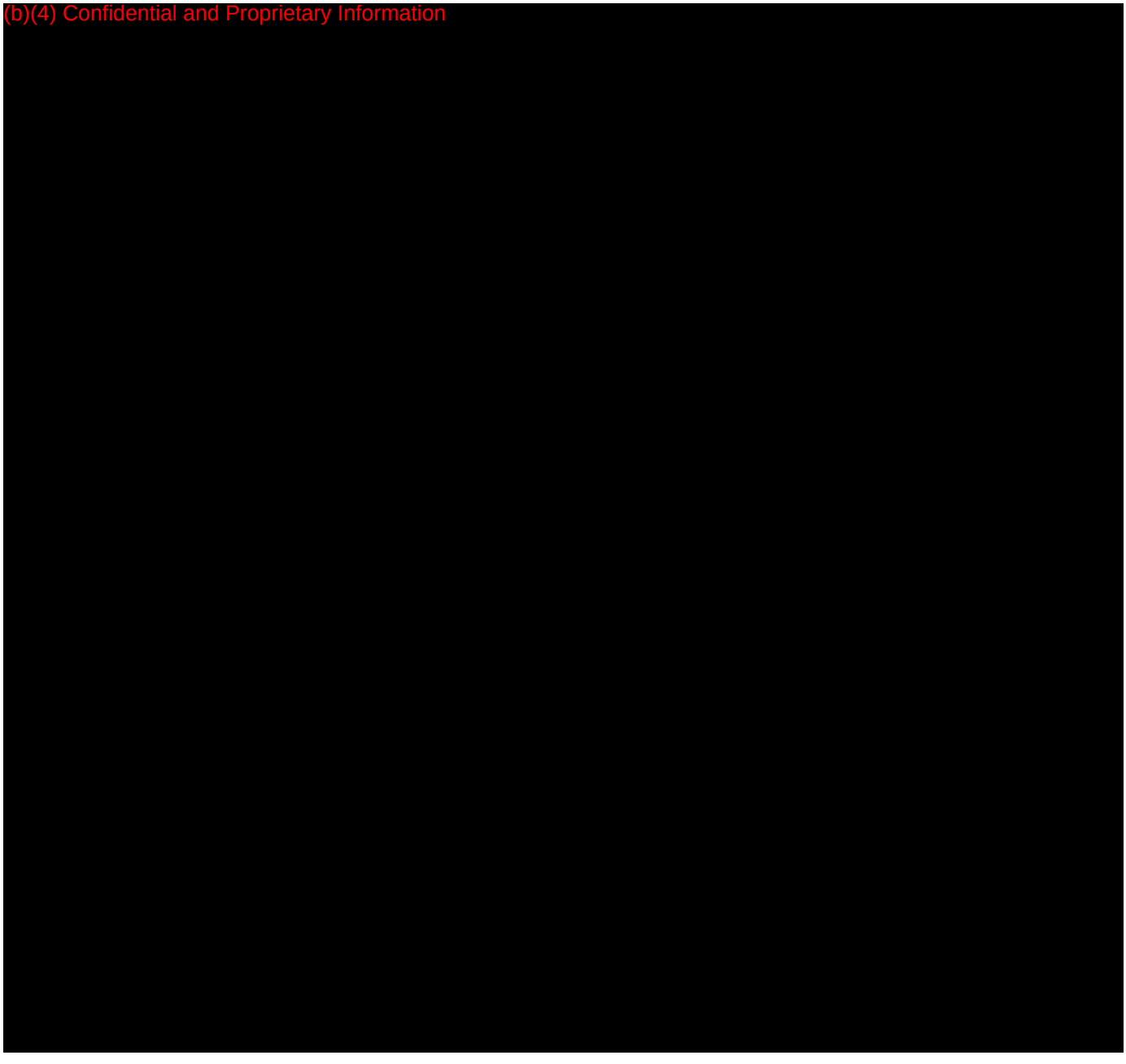

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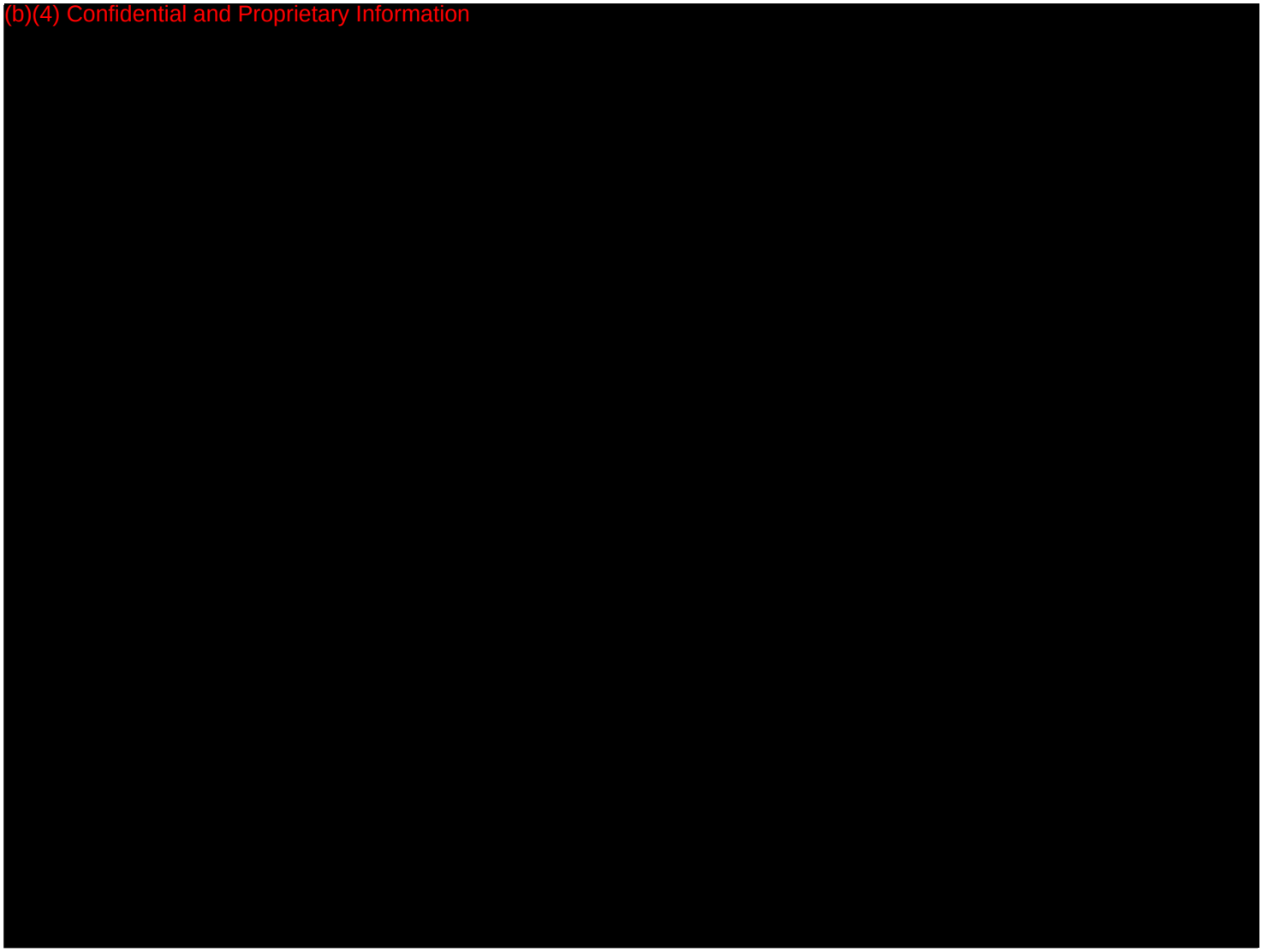

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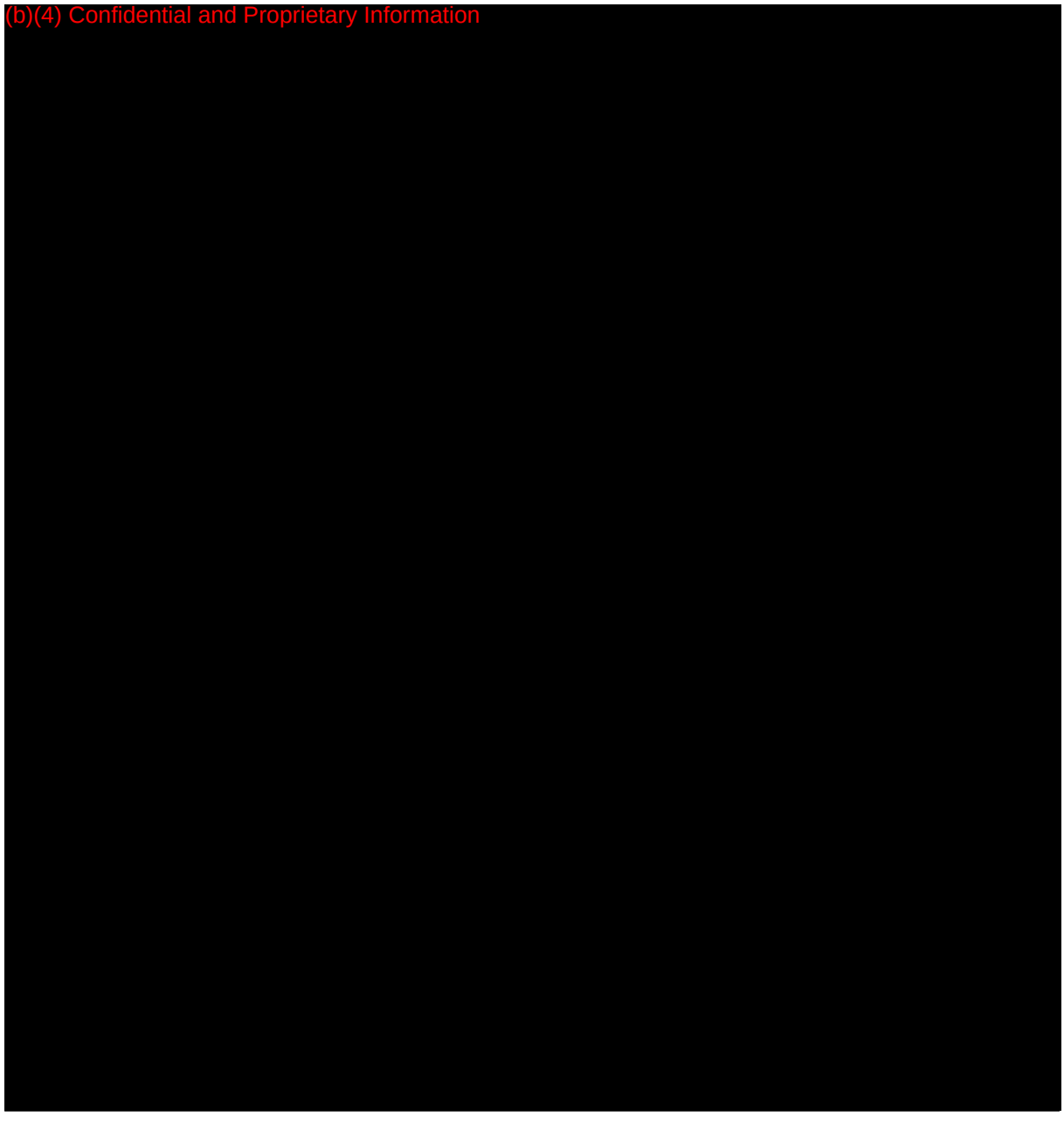


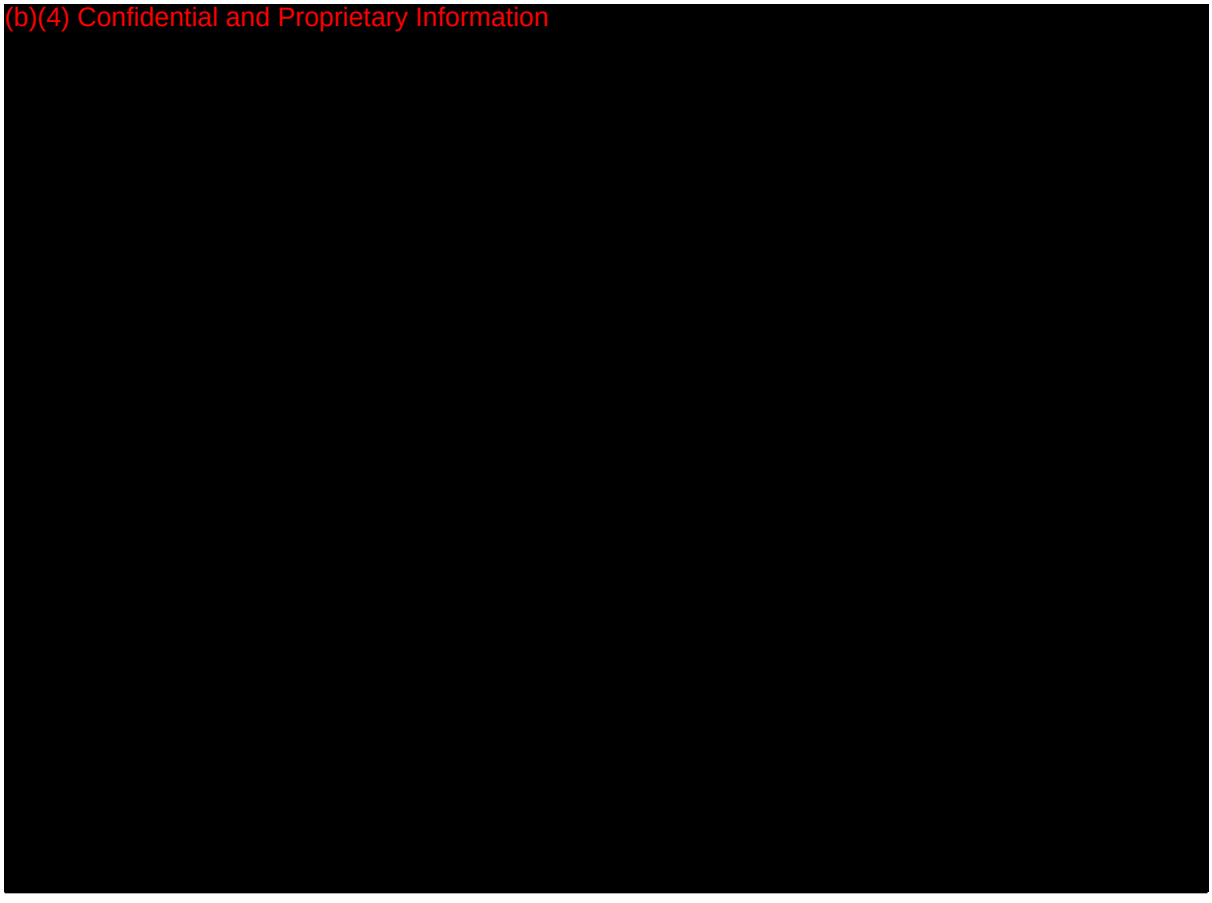
SECTION VI

Sterilization Information

STERILIZATION INFORMATION

A. STERILIZATION PROCESS

(b)(4) Confidential and Proprietary Information



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B. VALIDATION METHOD (b)(4)

(b)(4) Confidential and Proprietary Information

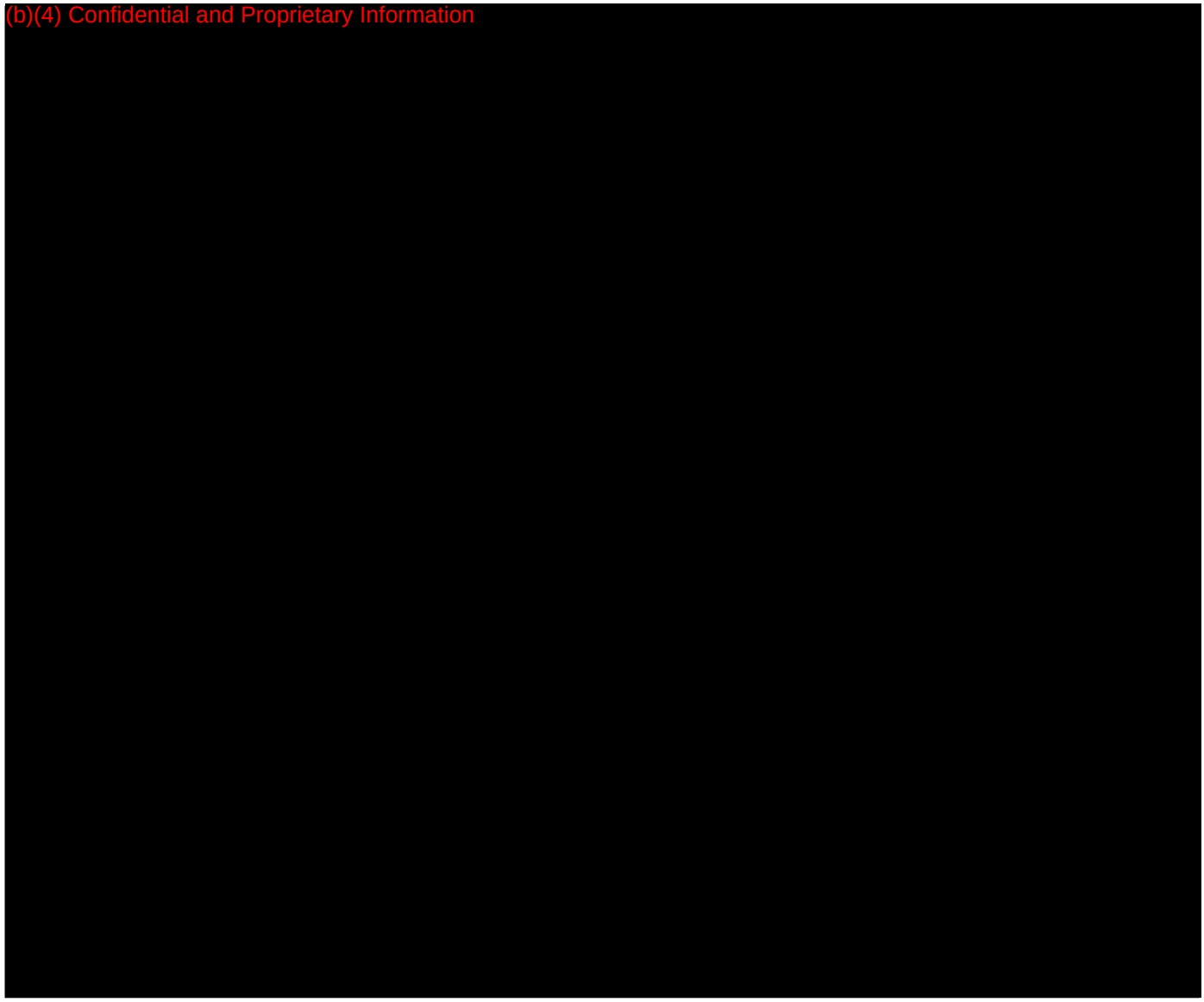
[redacted]

99

(b)(4) Confidential and Proprietary Information

100

(b)(4) Confidential and Proprietary Information



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E. PACKAGING INFORMATION

(b)(4) Confidential and Proprietary Information

SECTION VII

Summary of Design Control Activities

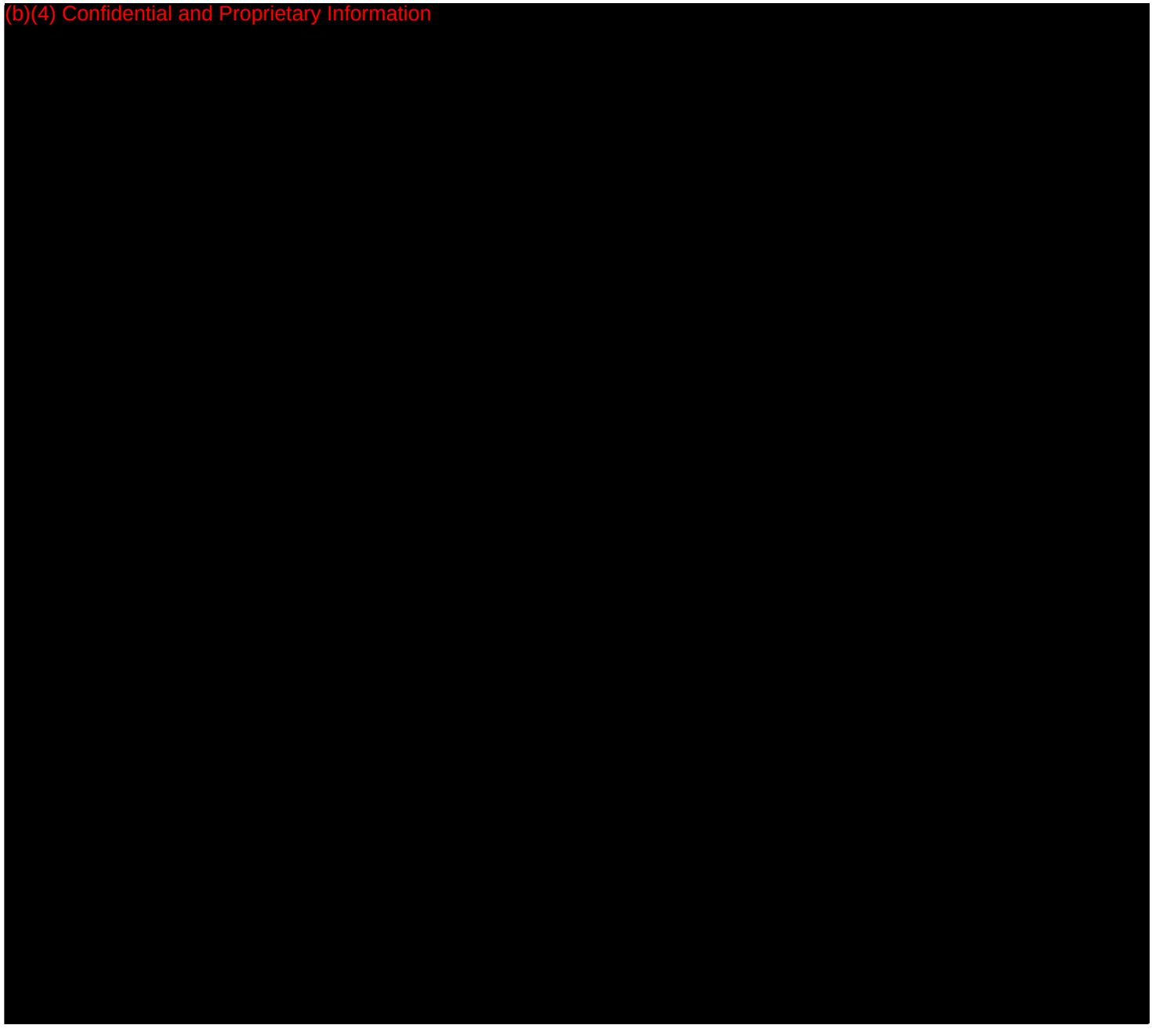
SUMMARY OF DESIGN CONTROL ACTIVITIES

(b)(4) Confidential and Proprietary Information

[redacted]

104

(b)(4) Confidential and Proprietary Information



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B. DECLARATION OF CONFORMITY WITH DESIGN CONTROLS

GAMBRO Renal Products

7, avenue Lionel Terray
BP 126
69653 MEYZIEU CEDEX
FRANCE

Tel + 33 (0)4 72 45 25 25
Fax + 33 (0)4 72 45 24 24

SECTION VII

D. DECLARATION OF CONFORMITY WITH DESIGN CONTROLS

I, Jean-Philippe Bret, in my capacity as Quality Assurance Manager, certify that, as required by the risk analysis, all verification and validation activities were performed by appropriate designated individuals and the results demonstrated that the predetermined acceptance criteria were met.

Meyzieu, July 5, 2004

Jean Philippe BRET
Quality Assurance Manager
GAMBRO Hospal Industrie

I, Jean-Philippe Bret, in my capacity as Quality Assurance Manager, certify that the Gambro Hospal Industrie manufacturing facility is in conformance with the design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review.

Meyzieu, July 5, 2004

Jean Philippe BRET
Quality Assurance Manager
GAMBRO Hospal Industrie

HOSPAL INDUSTRIE

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SECTION VIII

Statement of Equivalence And Comparative Date

STATEMENT OF EQUIVALENCE & COMPARATIVE DATA

A. STATEMENT OF EQUIVALENCE

Gambro believes the proposed Prismaflex HF 1000/HF 1400 sets are substantially equivalent to the current Prisma HF 1000 sets and Prismaflex M60/M100 sets.
The current Prisma HF 1000 sets and Prismaflex M60/M100 sets have been cleared for marketing/sale in the United States under respective 510(k) notifications K011221 and K041005.

The modifications in the proposed Prismaflex HF 1000/HF 1400 sets are substantially equivalent in design, function, composition and operation to the current Prisma HF 1000 sets and Prismaflex M60/M100 sets.

These modifications detailed in this submission do not affect the intended use or alter fundamental scientific technology of the device.

(b)(4) Confidential and Proprietary Information

[redacted]

B. COMPARISON TABLE

(b)(4) Confidential and Proprietary Information

[redacted]

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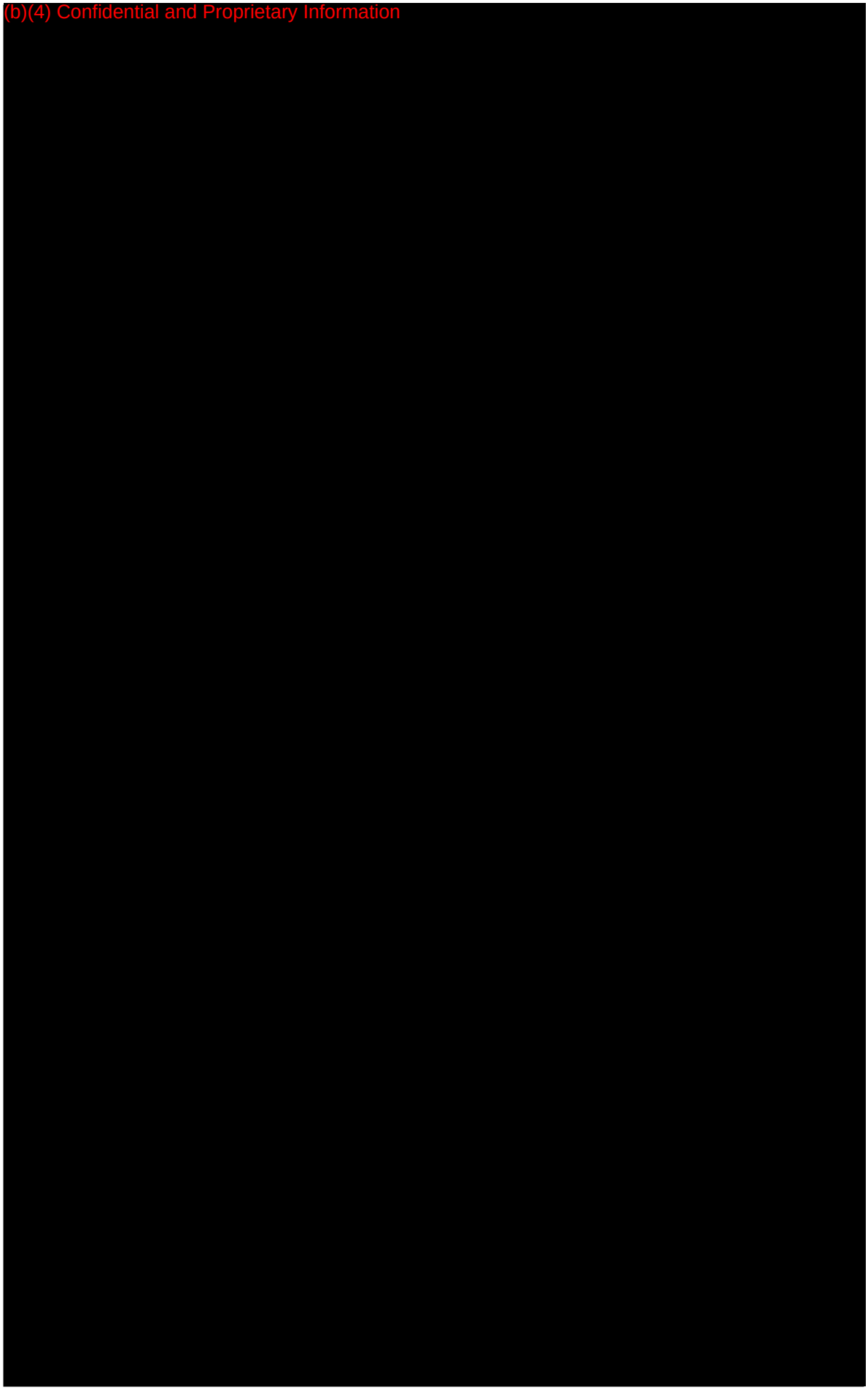
(b)(4) Confidential and Proprietary Information

[redacted]

(b)(4) Confidential and Proprietary Information



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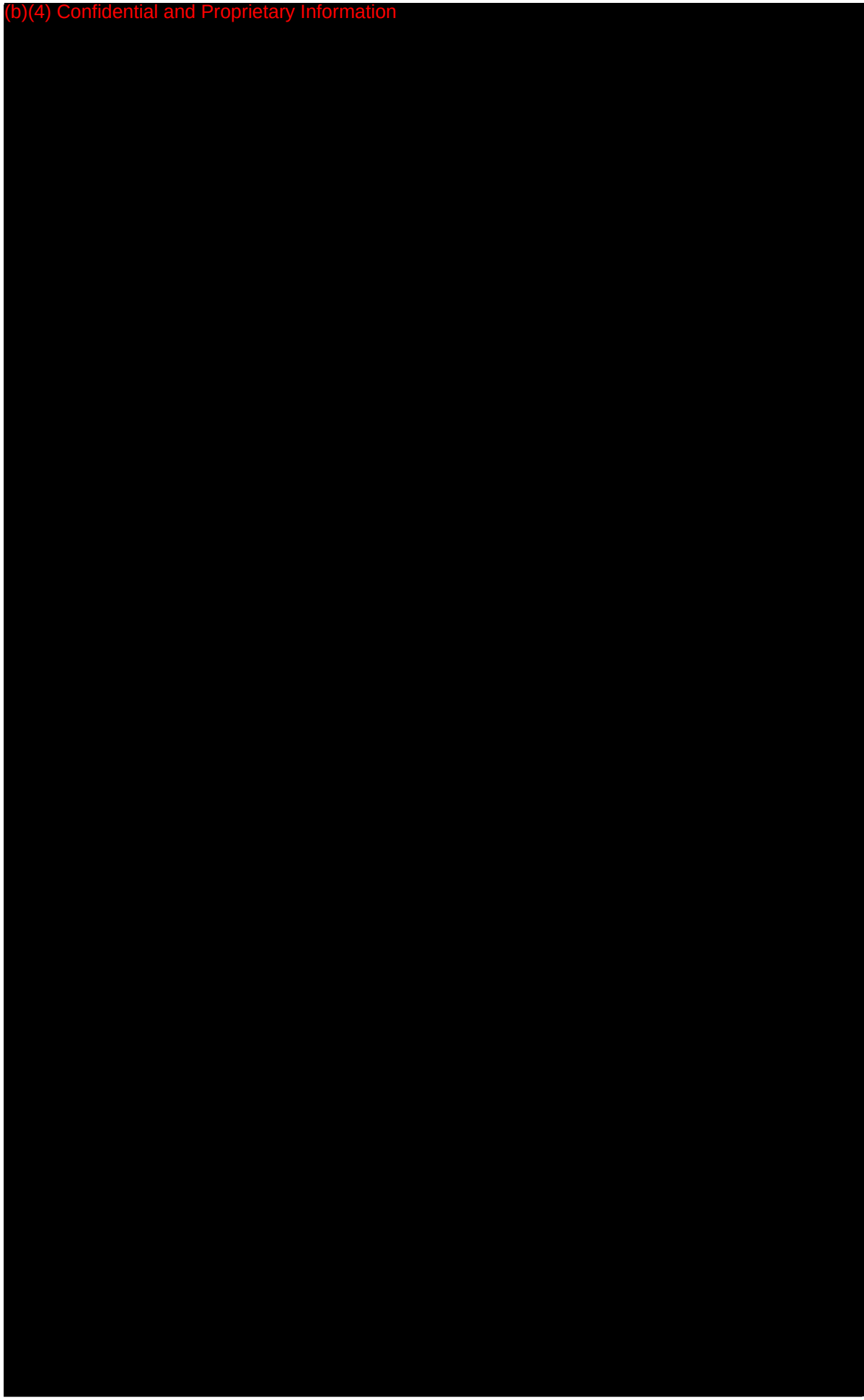
(b)(4) Confidential and Proprietary Information



(b)(4) Confidential and Proprietary Information

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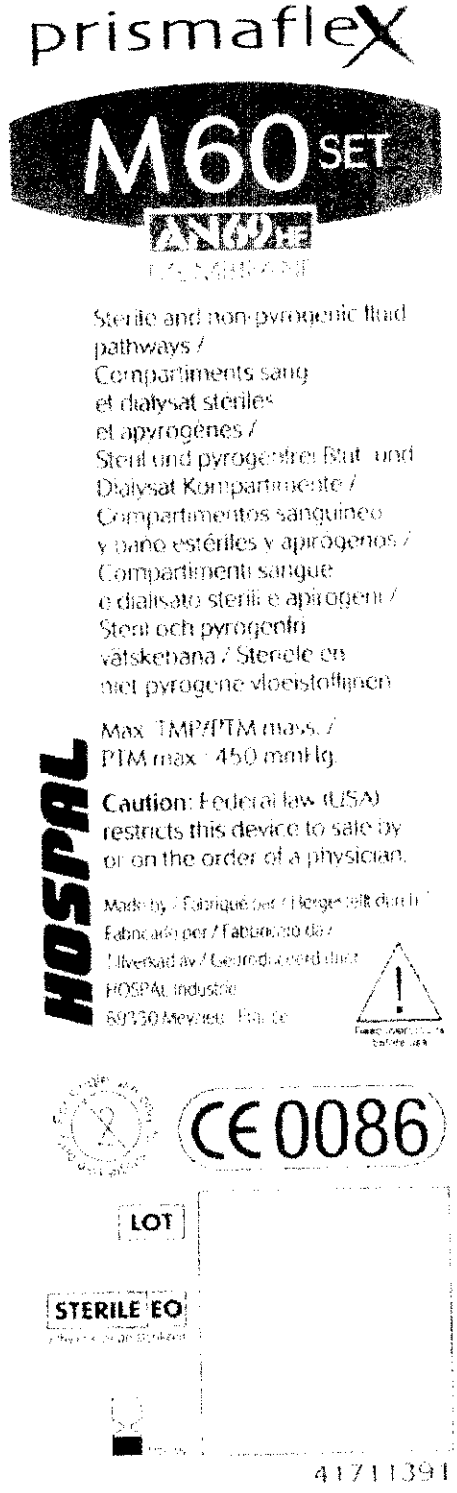
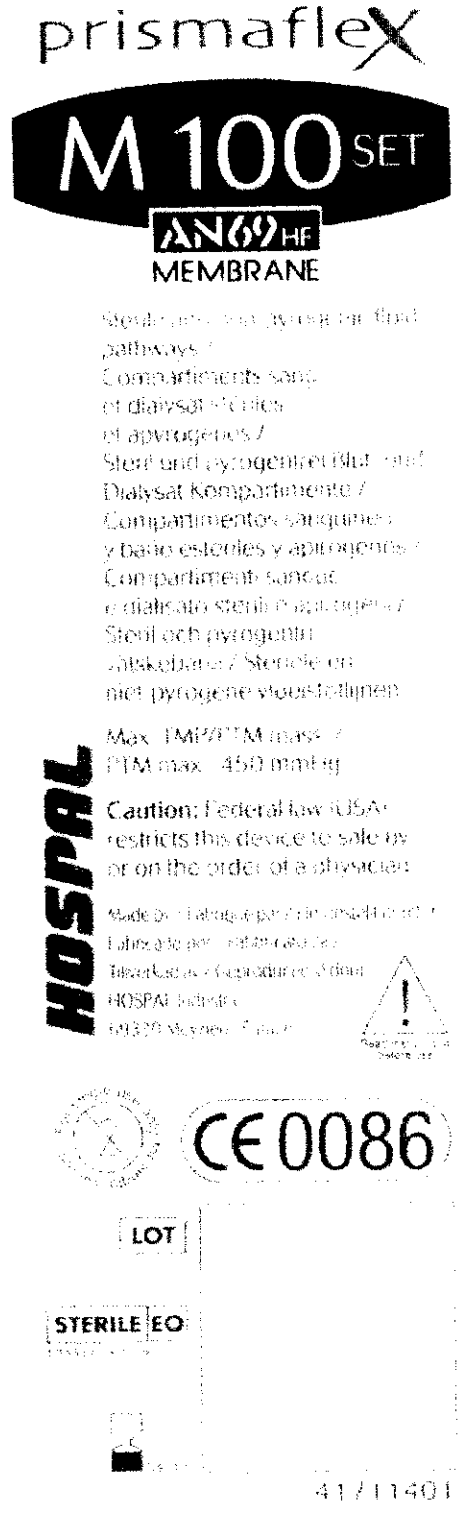
C. PREDICATE DEVICES LABELING AND PACKAGE INSERTS

PRISMAFLEX M60 SET / PRISMAFLEX M100 SET





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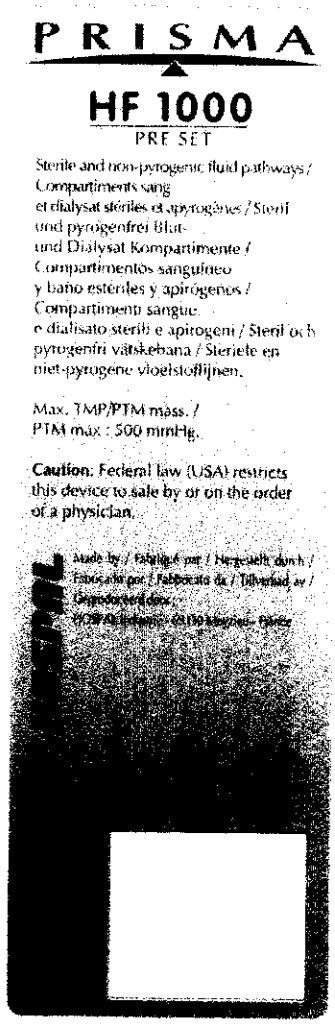
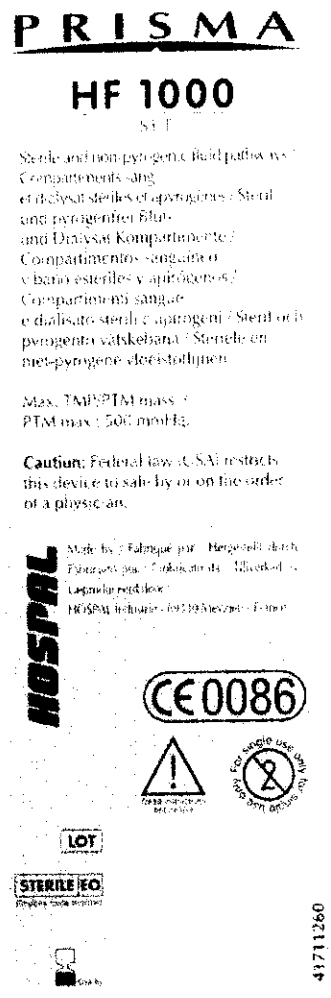
PRISMA HF 1000 Pre Set



PRISMA HF 1000 Set



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PACKAGE INSERTS

PREDICATE PRISMAFLEX M60/M100 Sets

The Instructions for Use for the M60/M100 predicate devices are attached as appendix C.

PREDICATE PRISMA HF 1000 Set

The Instructions for Use for the HF1000 predicate devices are attached as appendix D.

D. FDA 510(k) CLEARANCE LETTERS FOR PREDICATE DEVICES

The 510(k) clearance letters for the predicate devices are attached as appendix E.

SECTION IX

510(k) Summary

510(K) SUMMARY

SUBMITTER:

Gambro Renal Products
10810 West Collins Avenue
Lakewood, CO 80215
USA

CONTACT:

Thomas B. Dowell, Manager Regulatory Affairs
Phone: (303) 231-4094
Fax: (303) 542-5138

DATE PREPARED: October 21, 2004

DEVICE NAME:
Prismaflex HF 1000 Set
Prismaflex HF 1400 Set

COMMON/UNUSUAL NAME:
Hemofilter and Blood Tubing Set
High Permeability Hemodialyzer

CLASSIFICATION NAMES: High Permeability Hemodialysis System Accessory

CLASSIFICATION PANEL: KDI Gastroenterology - Urology

CLASSIFICATION: Class II per 21 CFR 876.5860

PREDICATE DEVICES:

Gambro Prisma HF1000 Set	K011221
Gambro Prismaflex M60/M100 Set	K041005

SUBSTANTIAL EQUIVALENCE:

The proposed Prismaflex HF 1000 and HF 1400 sets are substantially equivalent to the Prisma HF 1000 sets and Prismaflex M60/M100 sets currently on the market. The modifications in the proposed devices are substantially equivalent in design, function, composition, and operation, to the predicate devices that have FDA clearance under 510(k)'s K011221 and K041005.

DEVICE DESCRIPTION:

The Prismaflex disposable sets are sterile disposable extracorporeal circuits containing a PAES hemofilter/dialyzer and fluid circuit for use with the Prismaflex control Unit. These Prismaflex disposable sets allow the following fluid management and renal replacement therapies to be performed:

- SCUF : Slow Continuous Ultrafiltration
- CVVH : Continous Veno-Venous Hemofiltartion
- CVVHD : Continous Veno-Venous Hemodialysis
- CVVHDF : Continuous Veno-Venous Hemodiafiltartion

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INDICATIONS FOR USE:

The Prismaflex Set is indicated for use only with the Prismaflex Control Unit in providing continuous fluid management and renal replacement therapies. The system is intended for patients who have acute renal failure, fluid overload, or both.

TECHNOLOGICAL CHARACTERISTICS:

The proposed device configurations have the same technological characteristics and are similar in design, function, and operation, to the currently marketed configurations.

SUMMARY OF NON-CLINICAL TESTS and CONCLUSION:

In vitro testing was conducted to compare the performance of the proposed device configurations to the predicate configurations. The results of the in vitro testing demonstrate that the proposed configurations are substantially equivalent to the predicate configurations and are suitable for the intended use.

SUMMARY OF CLINICAL TESTS and CONCLUSION:

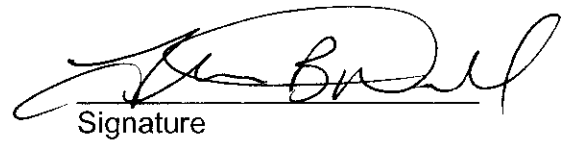
Not applicable

SECTION X

Truthful & Accurate Statement

PREMARKET NOTIFICATION
TRUTHFUL AND ACCURATE STATEMENT*
(As required by 21CFR 807.87 (k))

I certify that, in my capacity as Manager Regulatory Affairs, Gambro Renal Products, I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.



Signature

Thomas B. Dowell
Typed Name

10/21/04
Dated

Number not yet assigned
Premarket Notification (510(k)) Number

SECTION XI

Indications For Use Statement

INDICATIONS FOR USE STATEMENT

510(k) Number (if known):

Device Name:

Prismaflex™ HF 1000 Set
Prismaflex™ HF 1400 Set

Indications For Use:

The Prismaflex Set is indicated for use only with the Prismaflex Control Unit in providing continuous fluid management and renal replacement therapies. The system is intended for patients who have acute renal failure, fluid overload, or both.

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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prismaflex

HF 1000 SET
HF 1400 SET

Instructions for use
Notice d'utilisation
Gebrauchsanweisung
Folleto de utilización
Istruzioni per l'uso
Handhavandeinstruktioner
Gebruiksaanwijzing
Instruções de uso
Bruksanvisning
Brugsanvisning
Käyttäjän opas

CE 0086

HOSPAL
Renal Intensive Care

Ref.4071802

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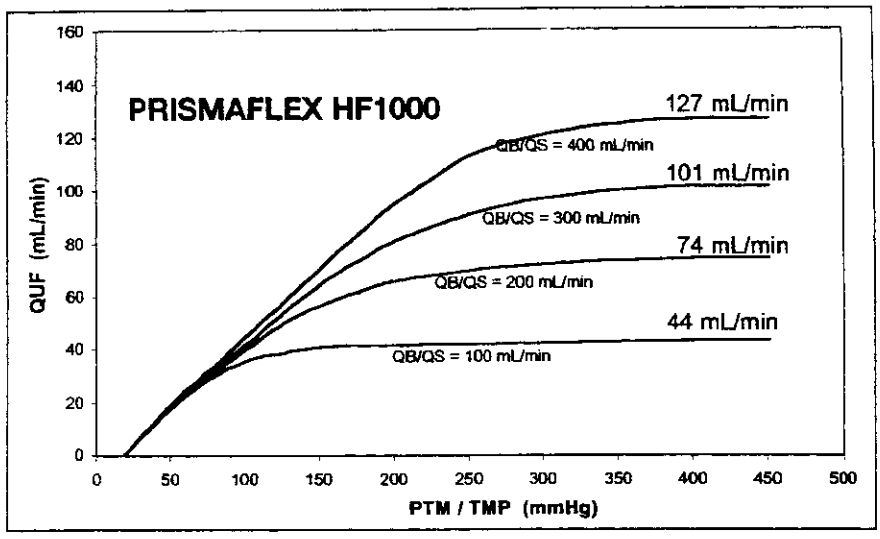

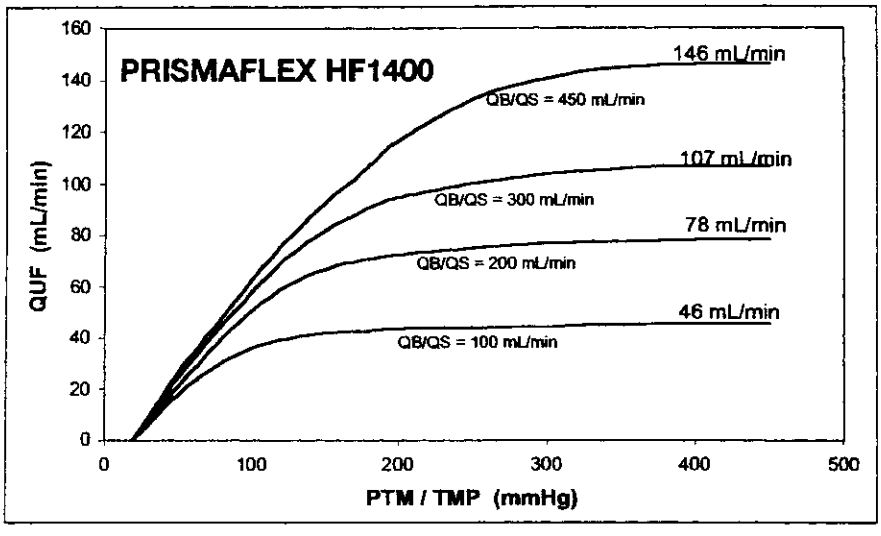

"In vitro" ultrafiltration with blood (values ± 15 %)
(Bovine blood at 37°C, Hct 32 %, Protein concentration 60 g/l)
Ultrafiltration is controlled by the PRISMAFLEX System and is independent of the ultrafiltration coefficicent (KUF)

Ultrafiltration au sang "in vitro" (valeurs à ± 15 %)
(Sang de boeuf à 37°C, Hématocrite = 32 %, Concentration protéique = 60 g/l)
L'ultrafiltration est maîtrisée par le système PRISMAFLEX et est indépendante du coefficient d'ultrafiltration (KUF)

Ultrafiltration mit Blut "in vitro" (Werte bei ± 15 %)
(Rinderblut bei 37°C, Hkt 32 %, Protein-Konzentration 60 g/l)
Die Ultrafiltration wird von der PRISMAFLEX Maschine auf dem richtingen Wert gehalten und hängt nicht vom Ultrafiltrationskoeffizienten (KUF) ab.

Ultrafiltracion con sangre "in vitro" (valores a ± 15 %)
(Sangre bovina a 37°C, Hematocrito = 32 %, Concentración protéica = 60 g/l)
La ultrafiltración controlada por el sistema PRISMAFLEX, es independiente del coeficiente de ultrafiltración (KUF)

Ultrafiltrazione con sangue "in vitro" (valori a ± 15 %)
(Sangue bovino a 37°C, ematocrito = 32 %, Concentrazione proteica = 60 g/l)
L'ultrafiltrazione è controllata dal Sistema PRISMAFLEX ed è indipendente dal coefficiente di ultrafiltrazione (KUF)

"In vitro" ultrafiltration med blod (värden ± 15 %)
(Bovint blod vid 37°C, Hct 32 %, Proteinkoncentration 60 g/l)
Ultrafiltrationen kontrolleras av PRISMAFLEX systemet och är obeorende av koefficienten för ultrafiltration (KUF)

-Ultrafiltratie met "In vitro"-bloed (waarden op ± 15 %)
(Runderbloed 37°C, Hematocrietwaarde = 32 %, Eiwitgehalte = 60 g/l)
Ultrafiltratie wordt gecontroleerd door het PRISMAFLEX Systeem en is onafhankelijk van de ultrafiltratie coefficiënt.

A ultrafiltração com sangue "in vitro" (valores a ± 15 %)
(Sangue bovino à temperatura de 37°C, Hematócrito = 32 %, Concentração protéica = 60 g/l)
A ultrafiltração controlada pelo sistema PRISMAFLEX e é independente do coeficiente de ultrafiltração (KUF)

"In vitro"-ultrafiltrasjon med blod (verdier ± 15 %)
(Bovint blod ved 37°C, Hct 32 %, proteinkonsentrasjon 60 g/l)
Ultrafiltrasjon kontrolleres av PRISMAFLEX-systemet, og er uavhengig av ultrafiltrasjonskoeffisienten (KUF)

"In vitro"-ultrafiltrering med blod (værdier ± 15 %)
(Bovint blod ved 37°C, Hct 32 %, proteinkoncentration 60 g/l)
Ultrafiltreringen styres af PRISMAFLEX-systemet og er uafhængigt af koefficienten for ultrafiltrering (KUF)

Veren ultrafiltraatio "In vitro" (arvot ± 15 %)
(Raavaan 37°C verta, Hct 32 %, proteiinipitoisuus 60 g/l)
Ultrafiltraatio tapahtuu PRISMAFLEX-ohjausyksikön alaisena ja se on riippumaton ultrafiltraation kertoimesta (KUF)

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DEFINITION OF SYMBOLS USED ON LABELING OF PRODUCT

LOT	manufacturing batch number
STERILE EO	sterilized by ethylene oxide (EtO); followed by the sterilization date
	expiration date of the product
	product for single use only
	Read instructions before using the product.

⚠ **Caution :** Federal law (USA) restricts this device to sale by or on the order of a physician.

DEFINITION OF EXPRESSIONS USED IN THIS MANUAL

In this document :

⚠ **"Warning"** is used to alert the user/operator **not to take** a certain action which, if taken, can cause a potential hazard and result in a serious adverse reaction, injury or death.

⚠ **"Caution"** is used to alert the user/operator **to take** a certain action to protect against a potential hazard, which, if ignored, could have an adverse effect on the patient or on the device.

"Note" is used as a reminder to the user/operator on normal treatment activity and on what is a suitable action in a particular situation.

SCUF : Slow Continuous UltraFiltration
CVVH : Continuous Veno-Venous Hemofiltration
CVVHD : Continuous Veno-Venous HemoDialysis
CVVHDF : Continuous Veno-Venous HemoDiaFiltration
Predilution : addition of replacement fluid to the blood stream upstream to the filter
Postdilution : addition of replacement fluid to the blood stream downstream to the filter

PRODUCT DESCRIPTION

- The PRISMAFLEX HF1000/HF1400 Set is a disposable, extracorporeal circuit for use with the PRISMAFLEX System.
- The PRISMAFLEX HF1000/HF1400 Set consists of a PAES hollow fiber hemofilter/dialyzer* and tubing lines.
- This filter is permanently connected to a blood access line (red-striped), a blood return line (blue-striped), a dialysate inlet line (green-striped) and an effluent outlet line (yellow-striped).
- The other lines of the set include :
  - a replacement solution line (purple-striped)
  - a pre blood pump line (white striped)
  - an anticoagulant line (syringe)
- The configuration of the PRISMAFLEX set allows the following uses depending on the configuration of the automated clamps on the machine :
  - purple circuit : replacement in pre or post dilution (CVVH and CVVHDF),
  - green circuit :
    - * dialysate in CVVHD and CVVHDF,
    - * replacement in post dilution in CVVH.
- The pre blood pump line allows the addition of infusion solution close to the end of the patient access line and before the blood pump. This can be used as an additional pre-dilution infusion to the replacement circuit.
- The PRISMAFLEX Set provides for a specific small volume deaeration chamber in which blood sedimentation will take place in most of the cases ; this matches with the normal operation of the device.
- A 5-liter bag is provided to be connected to the end of the blood return line to initially collect priming solution, during priming. Then, during treatment, this bag is used to collect ultrafiltrate and/or used dialysate (connection at effluent line). Other sterile 5 and 10 liter bags and sterile, non pyrogenic spikes can be ordered separately.
- All line connectors are compatible with the ISO 594/1 & 2 international standards concerning conical fittings.
- The fluid pathways of the PRISMAFLEX Set are guaranteed sterile and non pyrogenic.
- The PRISMAFLEX HF1000/HF1400 Set is sterilized by ethylene oxide (EtO). Deaeration is such that EtO residuals comply with the ones described in ISO 10993-7.
- Expiration date : Please refer to product label.
- The PRISMAFLEX Set is manufactured by HOSPAL Industrie, Meyzieu, France.

* In this document the hemofilter/dialyzer will be referred to as "filter".

INDICATIONS

The PRISMAFLEX Set is indicated for use only with the PRISMAFLEX Control Unit in providing continuous fluid management and renal replacement therapies. The system is intended for patients who have acute renal failure, fluid overload, or both.

This set is intended for use in the following veno-venous therapies: SCUF ; CVVH ; CVVHD ; CVVHDF.

All treatments administered via the PRISMAFLEX Set must be prescribed by a physician. The size, weight, state of uremia, cardiac status, and general physical condition of the patient must be carefully evaluated by the prescribing physician before each treatment.

The PRISMAFLEX HF1000/HF1400 sets should be restricted to patients with a body weight greater than 30kg (66lb).

CONTRAINDICATIONS

There are no known contraindications to continuous renal replacement therapies.

CAUTIONS AND WARNINGS

Note : *Additional warnings and cautions pertaining to the PRISMAFLEX system are included in the PRISMAFLEX Control Unit Operator's Manual.*

⚠ Cautions

1. Carefully read these Instructions for Use and the PRISMAFLEX Control Unit Operator's Manual before using this product.
2. Store the PRISMAFLEX Set in a dry place, between 0° C (32° F) and 30° C (86° F).
3. Some solvents and other chemicals, if used in contact with the filter, could damage the set. No chemical of this type should be used without permission of the manufacturer. The following are especially forbidden :
   a) halogenated aromatic and aliphatic solvents;
   b) ketonic solvents.
4. To prevent contamination, this PRISMAFLEX Set must be used as soon as its packaging and sterilization caps are removed.
5. Do not use this set if the packaging is damaged, if the sterilization caps are missing or loose, or if any of the lines in the set are kinked.
6. Do not try to remove the filter from the cartridge plate.
7. Destroy this set after single use, using aseptic technique for potentially contaminated equipment. Do not resterilize.
8. Use aseptic techniques when handling all blood and fluid lines in the set.

9a. Use only prescribed dialysate and replacement solutions with the PRISMAFLEX System. These solutions must have a density similar to that of saline solutions (close to 1) in order to avoid errors in the volumes used for fluid exchange.

9b. In CVVHD and CVVHDF modes, the use of non sterile dialysate could induce risks of bacterial and pyrogenic contamination for the patient. In the United States, dialysate should conform to AAMI standard RD5.

9c. In CVVH modes and CVVHDF, if a commercially available replacement solution is used, it must be labeled as intended for intravenous injection.

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10. Connect the PRISMAFLEX Set to a patient via venous blood access and return devices. A double-lumen venous catheter is the recommended blood access device; however, two single-lumen venous catheters can also be used. There are 3 possible accesses for PRISMAFLEX System therapies: subclavian, jugular or femoral vein.
11. During priming and operation, observe closely for leakage at joints and connections within the set, notably the bags. Leakage can cause blood loss or air embolism. If leakage cannot be stopped by tightening the connections, replace the set.
12. Before connecting the blood return line to the patient, check for absence of air between the segment of line inserted in the air detector and the patient-end of the return line.

    If air is present in this part of the return line, connect the access line to the patient and start the blood pump while leaving the return line connected to the collection bag. Purge the air present in the end-part of the return line, then stop the blood pump. Disconnect the return line from the collection bag, and connect it to the patient.

    If the amount of air in the blood circuit is too large, reprime the circuit completely before patient connection.
13. After priming is complete, do not remove the pressure pods from the pressure sensor housings. If pods are removed, the set must be changed or the Diaphragm Reposition procedure performed (refer to PRISMAFLEX Control Unit Operator's Manual).
14. If the patient is not immediately connected to the PRISMAFLEX Set after priming is complete, flush the set with at least 1 000 ml priming solution (saline or alkaline solution (pH ≥ 7.3) with heparin added) prior to connecting the patient. This requires use of a new bag of priming solution.

15a. Use a 21-gauge or smaller needle to obtain blood/fluid samples or remove trapped air from the PRISMAFLEX Set. Use of larger needles can cause holes in the sample sites, resulting in blood loss or air embolism.

15b. The following plastic needle is compatible with the PRISMAFLEX access sites: MEDIC M8 - 5005 (MediSystem).

16. The PRISMAFLEX Control Unit may not be able to detect disconnections of the set from the patient's catheter. Carefully observe the set and all operations while using the PRISMAFLEX System for a patient treatment.
17. Due to the nature of use of the PRISMAFLEX Set (low blood flow rates, extended treatment time, and other special factors), the possibility for coagulation within the blood flowpath is substantially enhanced. Give careful attention to the possible medical hazards associated with coagulation of the blood flowpath and comply with the minimum blood flow rates specifications of each filter (see the "Filter Operating Specifications" section).
18. Filter performance specifications require a minimum blood flow rate, specific to each filter, to avoid risk of hemoconcentration. (See "Filter Operating Specifications" section.)
19. During use, closely monitor the patient's clotting parameters, especially when increasing the amount of anticoagulant delivered or after changing the anticoagulant syringe.
20. To assure proper anticoagulant flow control, only the following syringes are permitted: Terumo (30 ml), 3 S (Bertoni) (30 ml), BD 30 Plastipack (30 ml), RR Prontosiringa (30 ml), Ico Gamma Plus (30 ml), Dispomed (30 ml), Ico Gamma Plus (20 ml), Ico Steril (20 ml), BD 20 Plastipack (20 ml), Terumo 20 (20 ml), RR 20 (20 ml), Monoject 20 (20 ml), BD 10 (10 ml), Terumo 10 (10 ml), Fresenius Luer lock (30, 20 and 10 cc). The use of other syringes can be a hazard for the patient. Particularly if there is no Luer-lock on the syringe, the seal between the syringe and the heparin line can no longer be guaranteed.
21. When not using the pre blood pump infusion circuit, it is recommended to clamp this circuit close to its connection to the access line; this will prevent the sedimentation of blood into the pre blood infusion line.
22. Always inspect the blood flowpath for signs of clotting before returning the blood in the set to the patient. If clotting is suspected, do not return the blood to the patient.
23. In case of re-circulation mode, the set must be replaced **whenever patient reconnection is not possible within at most a few minutes.**

    In case of poor blood return, the set must be replaced.

    In all cases, it is essential to reprime the set with fresh saline immediately before patient connection.
24. The PRISMAFLEX set offers a specific design of the deaeration chamber which aims to trap air before blood is returned to the patient.
25. The PRISMAFLEX Set is not designed for a heater to be connected to the replacement solution line. A heater generates air bubbles which collect in the return deaeration chamber. Therefore, it is recommended not to use a heater on the replacement solution line.
26. The PRISMAFLEX set is not designed for a heater to be connected to the dialysate solution line. A heater generates air bubbles which collect in the filtrate/dialysate compartment of the filter and decrease diffusive performance of the device. Therefore it is recommended not to use a heater on the dialysate solution line.

In general terms, introduction of air in the dialysate circuit should be minimised throughout the course of the treatment, especially when replacing dialysate solution bags.

27. Hypothermia must be monitored in all CRRT treatments, and special attention should be paid when increasing exchange volumes above 2 L/h; it may be necessary to warm the patient because of hypothermia.
28. The blood return line (blue-striped) is equipped with a Luer-lock connection near the blue sample site.
    This connector is intended to join the extension line of a blood warmer. Refer to the specific Instructions for Use and strictly follow detailed instructions for set up of this line. Do not use this connection for any other purpose.
29. Do not attach/connect the extension line of a blood heater to the return line downstream of the air detector. The PRISMAFLEX System cannot detect air introduced in the line downstream of the air detector.

⚠ Warnings

1. The use of operating procedures other than those published by the manufacturer or the use of accessory devices not recommended by the manufacturer can result in patient injury or death.
2. Use only PRISMAFLEX Sets with the PRISMAFLEX Control Unit. The use of non-PRISMAFLEX Sets can result in patient injury or death.
3. Should acute allergic reactions (first-use syndrome) occur in patients receiving treatment via the PRISMAFLEX HF1000/HF1400 Set, **immediately stop the treatment** and administer appropriate intervention.
4. Do not allow air to enter the blood compartment of the filter after priming is started. If a large amount of air enters, the set must be replaced.
5. Since drugs can pass through the membrane of the filter, the dosage of associated drug treatments must be adjusted for patients on continuous renal replacement therapy.
6. To assure adequate filter performance, it is recommended that the set be changed every 24 hours of use. However, the set must be changed after 3 days (72 hours) and/or the maximum process volume of blood (780L) whichever occurs first. Continued use beyond these limits (either 72 hours or 780L) could result in rupture of the pump segments, with risk of patient injury or death.

SPECIFICATIONS

See Tables at end of document.

SET MATERIALS

PAES hollow fiber	: PolyarylEtherSulfone
Housing and headers	: Polycarbonate
Potting compound	: Polyurethane
Tubing material	: Plasticized polyvinyl chloride (PVC)
Cartridge	: PETG

***Note :** The following information is available from the manufacturer upon request :*

- *information about test methods used to obtain performance characteristics*
- *the number and range of particles in the effluent from the dialyzer prepared as recommended for clinical use*
- *the types and amounts of residue from the sterilization process*

INSTRUCTIONS FOR USE

***Note :** Use the set by following the detailed on-line instructions provided by the PRISMAFLEX Control Unit. Additional information is available in the PRISMAFLEX Control Unit Operator's Manual.*

***Note :** a TMP > 40 kPa (300 mmHg) does not allow a higher ultrafiltration.*

Perform the following procedures when the appropriate instructions appear on the display of the PRISMAFLEX Control Unit.

Load Set

1. Remove the set from the packaging support. Holding the filter vertically (so that the label is the right way up), carefully snap the set cartridge into the cartridge carrier (center of front panel).
2. Attach the 3 pressure pods to their proper pressure housings. Press effluent line into blood leak detector; snap discharger ring into its guide.
3. Temporarily hang access/effluent Y line on priming hook.
4. Place deaeration chamber in its holder; attach chamber monitor line to return pressure port.
5. Insert return line into air detector and return line clamp.

6. Connect return line to effluent bag.
7. Open effluent scale; hang collection/effluent bag. Close scale.

Prepare and Connect Solutions

1. Hang bag of priming solution (saline or alkaline solution (pH ≥ 7.3) with added 5000IU heparin/liter) on priming hook (left corner hook top of front panel). Connect access (red)/effluent (yellow) Y-line to priming solution bag.
2. If required, connect pre blood pump (PBP) line (white) to pre blood pump (PBP) bag; hang bag on its scale.
3. Hang replacement solution (CVVH, CVVHDF) on purple scale hook. Connect replacement solution line (purple) to replacement solution bag.
4. In CVVHD/CVVHDF hang dialysate on green scale hook. Connect dialysate line (green). In CVVH hang replacement solution on green scale hook (postdilution replacement). Connect green striped line to bag.

   Note : *See Caution no. 9 a, b, c.*
5. Connect anticoagulant line to filled anticoagulant syringe. Install syringe in pump. (see Help)
6. Unclamp any clamped lines. **Verify all connections are secure.** Press PRIME to start automatic priming.

Prime Set

Note: *See Cautions no. 11 through 14, cautions no. 25, 26 and 29, and Warning no. 4.*

Priming includes multiple self-tests and takes approximately 10 minutes. After the cycle is complete :

1. Examine set carefully to be certain all connections are secure, all lines are unobstructed, and there are no leaks in the tubing.
2. Leave priming solution and prime collection bags attached until ready to connect patient.
3. Continue chosen treatment by following the instructions on the display of the PRISMAFLEX Control Unit.

The PRISMAFLEX Set must be carefully deaerated.

Anticoagulation Considerations

Note: *See Cautions no. 17 through 20 and Warning no. 6.*

Initiate anticoagulation of the blood flowpath, as prescribed by the physician. During use, monitor the patient's clotting parameters; adjust the anticoagulation settings on the PRISMAFLEX Control Unit, according to the physician's prescription. If prescribed, do not forget to infuse a loading dose of anticoagulant immediately after patient connection.

Anticoagulation plays an important part in extending filter life by retarding plugging and clotting.

Change Set Procedure

To remove this set, load a new set and continue with present treatment :

Press "STOP" from the Status screen, then press "CHANGE SET" and follow the on-line instructions.

Note: *Operator can return blood to the patient prior to disconnecting, if desired (see Caution no. 22.)*

Temporary Disconnection Procedure

To temporarily disconnect the patient from the set :

Press "STOP" from the Status screen, then press "TEMP DISCON" and follow the on-line instructions.

Note: *Operator must return blood in the set to the patient and immediately reprime the set via on-line instructions. (see Cautions no. 22 and 23.)*

End Treatment Procedure

To end the present treatment and remove this set :

Press "STOP" from the Status screen, then press "END TREATMENT" and follow the on-line instructions.

Note: *Operator can return blood to the patient prior to disconnecting, if desired. (See Caution no. 22.)*

MANUAL TERMINATION

Manual termination may be necessary due to power loss or an alarm of the PRISMAFLEX Control Unit. The alarm screen tells the operator if a manual termination is required.

Note: *The following instructions are also found in "Troubleshooting" in the PRISMAFLEX Control Unit Operator's Manual.*

A. With Blood Return

Note : *See Caution no. 22.*

Note : *A sterile spike connector may be required.*

1. Turn off the power. Clamp the access line (red-striped) and disconnect from the patient. Attach the access line to a 1-liter bag of sterile saline. (Use spike connector if needed.) Unclamp the access line.
2. Press the return clamp button (left side of the return line clamp assembly) and hold in the "in" position. With the other hand, remove the return line (blue-striped) from the return line clamp.
3. Visually check the the fluid level in the dearation chamber. If the level is below the horizontal line remove the excess air through the sample site on the chamber monitor line (chamber monitor line connects the deaeration chamber with the return pressure port on the control unit) as follows:
   a. Insert a sterile, 20 gauge needle attached to a <5-cc syringe into the sample site on the chamber monitor line.
   b. Aspirate air/blood until fluid level is at the horizontal line on the dearation chamber.
4. Remove the pump crank from its holder on the rear panel. Insert crank into the rotor of the blood pump and turn clockwise until sufficient blood is returned to the patient.

⚠ **Warning:** *The alarm system is disabled. Visually check for air in the blood return line until the patient is disconnected.*

5. Clamp the return line (blue-striped) and disconnect from the patient. Clamp lines to all bags.
6. Press the two clips of the cartridge carrier to release the cartridge. Starting with the peristaltic pump, insert the pump crank into the rotor and turn each pump counterclockwise.
7. When the pump segments are free, grasp the cartridge and pull out to disengage the lines from the pinch valves. Take the set off the control unit and discard as usual.

Note : *Remaining solutions may be used with a new set, if desired.*

⚠ **Warning:** *Ensure patient is disconnected from set before removing set from control unit.*

B. Without Blood Return

Note: *The patient will lose the blood contained in the blood flowpath during a manual termination without blood return.*

1. Turn off the power. Clamp the access line (red-striped) and return line (blue-striped) and disconnect from the patient.
2. Clamp lines to all bags.
3. Press the two clips of the cartridge carrier to release the cartridge. Starting with the blood pump, insert the pump crank into the rotor and turn each pump counterclockwise.
4. When the pump segments are free, grasp the cartridge and pull out to disengage the lines from the pinch valves. Take the set off the control unit and discard as usual.

SPECIAL PROCEDURES IN CASE OF COMPLICATION

Filter Membrane Blood Leaks

Blood leaks through the filter membrane are automatically detected by the PRISMAFLEX Control Unit alarm system. A warning alarm is generated and blood loss is limited by immediate stoppage of all pumps.

To return blood to the patient, press STOP from the alarm screen, then press CHANGE SET from the Stop screen and follow the on-line instructions.

External Blood Leaks

Note : *See Cautions no. 15, 16 and 20.*

External blood leakage may not be immediately identified by monitoring equipment and could result in significant blood loss. Check the filter and all connections of the disposable tubings during treatment to minimize the risk of leakage. If an external blood leakage is observed, immediately stop the blood pump. Initiate corrective action by securing connections or replacing the PRISMAFLEX Set.

If necessary, administer adequate replacement solution to the patient to compensate for blood loss.

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Hypersensitivity Reactions

Note : *See Warning no. 3.*

Should acute allergic reactions (first use syndrome) occur within the first few minutes of the treatment, it is important to react immediately by discontinuing the session and administering appropriate treatment.

Adverse reactions may occur due to the complex interaction between blood and the artificial surfaces of the entire extracorporeal circuit. These reactions may also be precipitated and/or exacerbated by other external factors involved with the individual patient's specific disease process and the treatment of renal insufficiency. Certain types of adverse reaction may occur due to operational factors associated with the treatment. Therefore, proper management of the fluid removal, electrolyte balance, anticoagulation and blood flow rate as well as monitoring of the overall treatment parameters are essential to avoid side-effects which may be associated with hemodialysis / hemofiltration therapies.

Hypersensitivity reactions have been observed during dialysis. Symptoms of a hypersensitivity reaction may be gastrointestinal, mucocutaneous, respiratory, cardiovascular or systemic in nature and range from very mild to severe. Such symptoms have been described as anaphylactic-like reactions within the first few minutes. Manifestations include nausea, malaise, weakness, a sensation of burning or heat throughout the body, profuse perspiration, respiratory distress and in some instances hypotension and cardiopulmonary arrest. Should a combination of such symptoms appear, particularly at the start of the treatment session, it is important to react immediately by discontinuing the session and administering appropriate treatment. Blood in the extracorporeal circuit must not be returned to the patient.

Extra care must be taken when treating patients who have exhibited possible hypersensitivity symptoms during previous treatments, or patients who have a history of being highly sensitive and allergic to a variety of substances. A physician must be consulted to evaluate the risk and prescribe the appropriate precautions if a possible sensitivity is suspected.

The following factors are considered essential to minimize the risk of a hypersensitivity reaction and other side-effects.

1. Strict adherence to the set-up, priming and rinsing procedures detailed in the manufacturer's Instructions for Use.
2. Setting and monitoring the treatment operating parameters according to the manufacturer's recommendations specified for each type of PRISMA Set and to the patient's needs and tolerance.
3. Strict adherence to all WARNINGS and CAUTIONS given by the manufacturer in the "Instructions for Use".

WARRANTY AND LIMITATION OF LIABILITY

a) The manufacturer warrants that the PRISMAFLEX Set has been manufactured in accordance with its specifications and in compliance with good manufacturing practices, other applicable industry standards and regulatory requirements.

If provided with the lot/serial number of the defective product, the manufacturer will, by replacement or credit, remedy manufacturing defects in the PRISMAFLEX Set becoming apparent before the expiration date.

b) The warranty under paragraph a) above is in lieu of, and to the exclusion of, any other warranty, whether written or oral, express or implied, statutory or otherwise, and there are no warranties of merchantability or other warranties, which extend beyond those described in paragraph a) above. The remedy set out above for manufacturing defects is the sole remedy available to any person due to defects in the PRISMAFLEX Set and the manufacturer shall not be liable for any consequential or incidental loss, damage, injury or expense arising directly or indirectly from the use of the PRISMAFLEX Set, whether as a result of any defect therein or otherwise.

c) The manufacturer shall not be liable for any misuse, improper handling, non-compliance with warnings and instructions, damage arising from events after the manufacturer's release of the PRISMAFLEX Set, failure or omission to inspect the PRISMAFLEX Set before use in order to ensure that the PRISMAFLEX Set is in proper condition, or any warranty given by independent distributors or dealers.

d) The manufacturer is HOSPAL Industrie, Meyzieu, France.

FILTER DATA	CARACTERISTIQUES DU FILTRE	FILTER-DATEN	PRISMAFLEX HF1000 SET	PRISMAFLEX HF1400 SET
NOMINAL PHYSICAL CHARACTERISTICS	**CARACTERISTIQUES PHYSIQUES**	**PHYSIKALISCHE EIGENSCHAFTEN**		
Effective surface area	Surface efficace	Effektive Oberfläche	1.1 m²	1.4 m²
Fiber internal diameter (wet)	Ø interne de la fibre (humide)	Innendurchmesser (feucht)	215 µm	
Fiber wall thickness	Epaisseur de paroi de la fibre	Wandstärke	50 µm	
IN VITRO PERFORMANCES *	**PERFORMANCES IN VITRO ***	**IN VITRO LEISTUNGEN ***		
Blood priming volume	**Volume de remplissage sang**	**Blutfüllvolumen**	81 ml ± 10 %	102 ml ± 10 %
Blood pressure drop (post dilution)	**Perte de charge sang (post dilution)**	**Blut druckabfall (Postdilution)**		
(bovine blood, Htc****32%, Cp***** 60 g/l, 37°C)	(sang de bœuf, Htc****32%, Cp***** 60 g/l, 37°C)	(Rinderblut, Hkt****32%, Pt***** 60 g/l, 37°C)		
QB** = 100 ml/min, QUF*** = 2 L/h	QS** = 100 ml/min, QUF*** = 2 L/h	QB** = 100 ml/min, QUF*** = 2 L/h	37 mmHg	29 mmHg
QB** = 200 ml/min, QUF*** = 2 L/h	QS** = 200 ml/min, QUF*** = 2 L/h	QB** = 200 ml/min, QUF*** = 2 L/h	51 mmHg	41 mmHg
QB** = 400 ml/min, QUF*** = 2 L/h	QS** = 400 ml/min, QUF*** = 2 L/h	QB** = 400 ml/min, QUF*** = 2 L/h	81 mmHg	64 mmHg
Sieving coefficient	**Transmittance**	**Siebkoeffizient**		
(bovine plasma, Cp 60 g/l, 37° C)	(plasma de bœuf, Cp 60 g/l, 37° C)	(Rinderplasma, Pt 60 g/l, 37° C)		
QB** = 100 ml/min, QUF*** = 20 ml/min	QS** = 100 ml/min, QUF*** = 20 ml/min	QB** = 100 ml/min, QUF*** = 20 ml/min		
- Urea	- Urée	- Harnstoff	1	
- Creatinine	- Créatinine	- Kreatinin	1	
- Vitamin B12	- Vitamine B12	- Vitamin B12	1	
- Inulin	- Inuline	- Inulin	1	
- Albumin	- Albumine	- Albumin	< 0.01	

* Typical mean values obtained from laboratory testing of post-sterilization sample lots. Results may vary depending on patient and clinical conditions. / Valeurs moyennes caractéristiques mesurées au laboratoire sur un échantillonnage de lots stérilisés. Les résultats sont susceptibles de varier en fonction du patient et de son état clinique. / Typische Mittelwerte, die an strilen Produkten im Labor ermittelt wurden. Die angegebenen Werte können abhängig vom Patienten und den klinischen Bedingungen schwanken.

GENERAL DATA / CARACTERISTIQUES GENERALES / ALLGEMEINE DATEN / CARACTERISTICAS GENERALES / CARATTERISTICHE GENERALI / ALLMÄN DATA / ALGEMENE TECHNISCHE GEGEVENS / CARACTERÍSTICAS GERAIS / GENERELLE DATA / GENERELLE SPECIFIKATIONER / YLEISET MITTAUSARVOT

	PRISMAFLEX HF1000 SET	PRISMAFLEX HF1400 SET
Weight / Poids / Gewicht / Peso / Peso / Vikt / Gewicht / Vekt / Peso / Vægt / Paino	780 g	820 g
Overall dimensions / Dimensions totales / Außenmaße / Dimensiones totales / Dimensioni / Storlek / Totale afmetingen / Dimensões totais / Mål / Ydermål / Ulkomitat		
length / longueur / Länge / Largo / lunghezza / Längd / lengte / comprimento / længde / Længde / pituus	27 cm	27 cm
width / largeur / Breite / Ancho / larghezza / Bredd / breedte / largura / bredde / Bredde / leveys	22 cm	22 cm
height / hauteur / Höhe / Altura / altezza / Höjd / hoogte / altura / høyde / Højde / korkeus	9 cm	9 cm
Blood volume in set / Volume sang dans le set / Blutvolumen im Set / Volumen de sangre en el set / Volume ematico nel set / Blodvolym i setet / Hoeveelheid bloed in set / Volume de sangue no set / Blodvolum i sett / Blodvolumen i sættet / Veren tilavuus setissä (± 10%)	165 ml	186 ml

FILTER OPERATING SPECIFICATIONS / CARACTERISTIQUES DE FONCTIONNEMENT DU FILTRE / BETRIEBSPEZIFIKATIONEN FÜR DEN FILTER / CARACTERISTICAS DE FUNCIONAMIENTO DEL FILTRO / CARATTERISTICHE DI FUNZIONAMENTO DEL FILTRO / ANVÄNDNINGSSPECIFIKATIONER FÖR FILTER / FILTERPRESTATIES / CARACTERÍSTICAS DE FUNCIONAMENTO DO FILTRO / SPESIFIKASJONER FOR BRUK AV FILTER / SPECIFIKATIONER FOR BRUG AF FILTER / FILTTRIN TOIMINTAOMINAISUUDET

	PRISMAFLEX HF1000 SET	PRISMAFLEX HF1400 SET
Maximum TMP* / PTM* Maximum / Maximum TMP* / PTM* máxima / PTM* massima / Maximalt TMP* / Maximum TMP* / PTM* Máximao / Maksimal TMP* / Maks. TMP* / Maksimi TMP*	500 mmHg 66.6 kPa	
Maximum blood pressure / Pression sang maximum / Maximum Filter-Blutdruck / Presión sanguinea máxima / Pressione ematica massima / Maximalt blodtryck / Maximum bloeddruk / Pressão sanguínea máxima / Maksimalt blodtrykk / Maks. blodtryk / Maksimi verenpaine	500 mmHg 66.6 kPa	
Minimum blood flow rate / Débit sang minimum / Mindest-Blutflußrate / Flujo sanguíneo mínimo / Flusso ematico minimo / Minimalt Blodflöde / Minimum Bloedsnelheid / Fluxo sanguíneo mínimo / Minimum blodflow-rate / Min. blodflowhastighed / Minimi verenpaine	75 ml/min	100 ml/min

* Transmembrane pressure / Pression transmembranaire / Transmembrandruck / Presión transmembránica / Pressione transmembrana / Transmembrantryck / Transmembraandruk / Pressão transmembranária / Transmembrantrykk / Transmembrantryk / Kalvoon vaikuttava paine

** Arterial blood flow rate / Débit sang / Arterieller Blutfluß / Flujo sanguíneo arterial / Flusso ematico arterioso / Arteriellt blodflöde / Arteriële bloedsnelheid / Fluxo de sangue arterial / Arterielt blodflow-rate / Arteriel blodflowhastighed / Valtimoveren virtausmäärä

CARACTERISTICAS DEL FILTRO	CARATTERISTICHE DEL FILTRO	FILTERDATA	PRISMAFLEX HF1000 SET	PRISMAFLEX HF1400 SET
CARACTERISTICAS FISICAS	**CARATTERISTICHE FISICHE**	**NOMINELLA FYSISKA KARAKTÄRISTIKA**		
Superficie efectiva	Superficie effettiva	Effektiv yta	1.1 m²	1.4 m²
Ø interna de la fibra (húmeda)	Ø interno della fibra (bagnata)	Inre kapillärdiameter (våt)	215 µm	
Espesor de la pared de la fibra	Spessore parete della fibra	Tjocklek av kapillärvägg	50 µm	
RENDIMIENTOS IN VITRO *	**PRESTAZIONI IN VITRO ***	**IN VITRO PRESTANDA ***		
Volumen de cebado sanguíneo	**Volume di priming ematico**	**Blodvolym**	81 ml ± 10 %	102 ml ± 10 %
Caídas de presión sangre (post-dilución)	**Perdita di carico ematica (postdiluizione)**	**Blod trycktall (postdilution)**		
(sangre bovina, Htc****32%, Cp***** 60 g/l, 37°C)	(sangue bovino, Hct****32%, Cp***** 60 g/l, 37°C)	(bovint blod, Htc****32%, Cp*****60 g/l, 37°C)		
QB** = 100 ml/min, QUF*** = 2 L/h	QS** = 100 ml/min, QUF*** = 2 L/h	QB** = 100 ml/min, QUF*** = 2 L/h	37 mmHg	29 mmHg
QB** = 200 ml/min, QUF*** = 2 L/h	QS** = 200 ml/min, QUF*** = 2 L/h	QB** = 200 ml/min, QUF*** = 2 L/h	51 mmHg	41 mmHg
QB** = 400 ml/min, QUF*** = 2 L/h	QS** = 400 ml/min, QUF*** = 2 L/h	QB** = 400 ml/min, QUF*** = 2 L/h	81 mmHg	64 mmHg
Transmitancia	**Coefficiente di sieving**	**Sieviagkoefficient**		
(plasma bovino, Cp 60 g/l, 37° C)	(plasma bovino, Cp 60 g/l, 37° C)	(bovin plasma, Cp 60 g/l, 37 °C)		
QB** = 100 ml/min, QUF*** = 20 ml/min	QS** = 100 ml/min, QUF*** = 20 ml/min	QB** = 100 ml/min, QUF*** = 20 ml/min		
- Urea	- Urea	- Urea	1	
- Creatinina	- Creatinina	- Kreatinin	1	
- Vitamina B12	- Vitamina B12	- Vitamin B12	1	
- Inulina	- Inulina	- Inulin	1	
- Albúmina	- Albumina	- Albumin	< 0.01	

* Valores medios característicos medidos en laboratorio sobre un muestro de lotes esterilizados. Los valores pueden variar en función del paciente, así como de su estado clínico. / Tipici valori medi ottenuti da test di laboratorio su campioni di lotti sterili. I risultati possono variare a seconda del paziente e delle diverse condizioni cliniche. / Vanliga medelvärden erhållna vid laboratorietest av post-steriliserade prov-partier. Resultaten kan variera beroende på patient och kliniska förutsättningar.

CVVHD CLEARANCES (Continuous veno-venous hemodialysis) Clearances versus inlet dialysate flow rate (37°C)
CLAIRANCES EN CVVHD (Hémodialyse veino-veineuse continue) Clairances au bain de dialyse, à débit entrée dialysat (37°C)
CVVHD CLEARANCES (Kontinuierliche veno-venöse Hämodialyse) Clearancewerte abhängig von der Dialysierflüssigkeit-Einlaßrate (37°C)
ACLARAMIENTOS EN CVVHD (Hemodiálisis veno-venosa continua) Aclaramientos con baño de diálisis a 37°C
CVVHD CLEARANCE (Emodialisi veno-venosa continua) Clearance con dialisato a 37°C
CVVHD CLEARANCE (Kontinuerlig veno-venös hemodialys) Clearance mot dialysatflöde (37°C)
KLARINGEN IN CVVHD (Continue veno-veneuze hemodialyse) Klaringen, snelheid van de dialysaataanvoer (37°C)
ACLARAMENTO EM CVVHD (Hemodiálise veno-venosa contínua) Aclaramento numa solução diálise a 37°C
CVVHD-CLEARANCE (Continuous veno-venous hemodialysis) Clearanceverdi versus inngangsdialyseflow-rate (37°C)
CVVHD CLEARANCE (Kontinuerlig vene-vene hæmodialyse) Clearance kontra flowhastighed for indløbsdialysat (37°C)
CVVHD (Continuous veno-venous hemodialysis) Clearance-arvot sisään tulevaan dialysaatin virtaukseen verrattuina (37°C)

		PRISMAFLEX HF1000 SET				PRISMAFLEX HF1400 SET			
		QB/QS** = 100 ml/min QUF*** = 0 ml/min				QB/QS** = 200 ml/min QUF*** = 0 ml/min			
QD******	(l/h)	1	2.5	4	8	1	2.5	4	8
Urea / Urée / Harnstoff / Urea / Ureum / Karbamid / Ureia / Karbamid / Virtsahappo	(± 10%)	16.5	41	62	88	16.6	41	65	119
Vit B12	(± 20%)	16.2	36	48	63	16.5	38	55	84
Inulin / Inuline / Inulina / Inuliini	(± 20%)	16.0	32	42	52	16.4	35	46	69

*** Ultrafiltration flow rate (on PRISMAFLEX system, the ultrafiltration flow rate = fluid removal flow rate + replacement flow rate + pre blood pump flow rate) /
Débit d'ultrafiltration (sur le système PRISMAFLEX, le débit d'ultrafiltration correspond au débit de prélèvement de liquide + débit de solution de réinjection + le débit de la pompe pré-pompe sang (PBP)) /
Ultrafiltrationsflußrate (beim PRISMAFLEX-System ist die Ultrafiltrationsflußrates die Flussigkeitsentfernungsflußrate + Substitutionsflußrate + Prä-Blutpumpen Flußrate) /
Flujo de ultrafiltración (en el sistema PRISMA el flujo de ultrafiltración corresponde al flujo de extracción de liquido mas el flujo de solución de reinyección + mas el flujo de infusione pre-bomba de sangre (PBP)) /
Flusso di ultrafiltrazione (il sistema PRISMAFLEX calcola il flusso di ultrafiltrazione nel seguente modo : flusso di rimozione del fluido + flusso di reinfusione + flusso dell'infusione pre-pompa sangue (PBP)) /
Ultrafiltrationshastighet (på PRISMA, ultrafiltrationshastighet = hastighet på vätskeborttag från patient + hastghet på ersättningslösning + preblodpumps flödeshastighet) /
Ultrafiltratie-snelheid (op PRISMAFLEX -systeem : de ultrafiltratie-snelheid = vochtverwijderings-snelheid + substitutie-snelheid + pre bloedpomp snelheid) /
Fluxo de ultrafiltração (no sistema PRISMAFLEX, o fluxo de ultrafiltração corresponde ao débito de recolha de líquido + débito de solução de reposição + taxa de fluxo pré bomba de sangue) /
Flow-rate for ultrafiltrasjon (på PRISMAFLEX-systemet: flow-rate for ultrafiltrasjon tilsvarer flow-rate for vækefjerning + flow-rate for reinjeksjonsvæske) /
Flowhastighed for ultrafiltration (på PRISMAFLEX-systemet er flowhastigheden for ultrafiltration lig med flowhastigheden for væskeudløb + flowhastigheden for erstatningsvæske + pre-blodpumpe flowhastighed) /
Ultrafiltrausnopeus (tämä nopeus PRISMAFLEX-järjestelmässä = nesteen ulostuiovirtaus + korvausnesteen virtausnopeus + esi-veri-pumppu (PBP) virtausnopeus)

FILTER DATA	CARACTERÍSTICAS DO FILTRO	FILTERDATA	PRISMAFLEX HF1000 SET	PRISMAFLEX HF1400 SET
NOMINALE FYSIEKE EIGENSCHAPPEN	**CARACTERÍSTICAS FÍSICAS**	**NOMINELLE FYSISKE EGENSKABER**		
Effectief oppervlak	Superficie eficaz	Effektivt overfladeareal	1.1 m²	1.4 m²
Inw. vezeldiam. (nat)	Diâmetro interno da fibra (húmida)	Intern diameter, fiber (våt)	215 µm	
Wanddikte vezel	Espessura da parede da fibra	Fiberveggtykkelse	50 µm	
IN VITRO PRESTATIES *	**RESULTADOS IN VITRO ***	**IN VITRO-YTELSE ***		
Bloed prining volume	**Volume de sangue injectado**	**Blodprimingvolum**	81 ml ± 10 %	102 ml ± 10 %
Bloed drukdaling (Post-dilutie)	**Descida da pressão sanguínea (pós diluição)**	**Blod trykkfall (post dilution)**		
(bovine blood, Htc****32%, Cp*****60 g/l, 37°C)	(sangue bovino, Htc****32%, Cp***** 60 g/l, 37°C)	(bovine blod, Htc****32%, Cp***** 60 g/l, 37°C)		
QB** = 100 ml/min, QUF*** = 2 L/h	QB** = 100 ml/min, QUF*** = 2 L/h	QB** = 100 ml/min, QUF*** = 2 L/t	37 mmHg	29 mmHg
QB** = 200 ml/min, QUF*** = 2 L/h	QB** = 200 ml/min, QUF*** = 2 L/h	QB** = 200 ml/min, QUF*** = 2 L/t	51 mmHg	41 mmHg
QB** = 400 ml/min, QUF*** = 2 L/h	QB** = 400 ml/min, QUF*** = 2 L/h	QB** = 400 ml/min, QUF*** = 2 L/t	81 mmHg	64 mmHg
Sieving coëfficient	**Coeficiente de Sieving**	**Sievingkoeffisient**		
(bovine plasma, Cp 60 g/l, 37 °C)	(plasma bovino, Cp 60 g/l, 37° C)	(bovin plasma, Cp 60 g/l, 37° C)		
QB** = 100 ml/min, QUF*** = 20 ml/min	QB** = 100 ml/min, QUF*** = 20 ml/min	QB** = 100 ml/min, QUF*** = 20 ml/min		
- Ureum	- Ureia	- Urea	1	
- Creatinine	- Creatinina	- Kreatinin	1	
- Vitamine B12	- Vitamina B12	- Vitamin B12	1	
- Inuline	- Inulina	- Inulin	1	
- Albumine	- Albumina	- Albumin	< 0.01	

* Typisch gemiddelde waarden verkregen na het testen van stalen na sterilisatie. Resultaten kunnen verschillen afhankelijk van de patiënt en de klinische situatie. / Valores médios típicos medidos em laboratório sobre uma amostragem de lotes esterilizados. Os resultados podem variar consoante o paciente e o seu estado clínico. / Typiske gjennomsnittsverdier oppnådd ved laboratorietesting av stikkprøver av steriliserte lot. Resultatene kan variere i henhold til pasient og kliniske forhold.

FILTERDATA	FILTTERIN TEKNISET TIEDOT		PRISMAFLEX HF1000 SET	PRISMAFLEX HF1400 SET
NOMINELLE FYSISKE SPECIFIKATIONER	**FYSIKAALISET NIMELLISARVOT**			
Effektivt overfladeareal	Tehollisen pinnan laajuus		1.1 m²	1.4 m²
Fibrenes indvendige diameter (våde)	Kuidun sisähalkaisija (kosteana)		215 µm	
Fibrenes vægtykkelse	Kuidun seinämän paksuus		50 µm	
IN VITRO-YDEEVNE *	**IN VITRO OMINAISUUDET ***			
Blodprimingvolumen	**Veren valmistelutilavuus**		81 ml ± 10 %	102 ml ± 10 %
Blood pressure drop (post dilution)	**Veren paineen pudotus (laimennuksen jälkeen)**			
(bovine blood, Htc****32%, Cp***** 60 g/l, 37°C)	(naudan veri, Htc****32%, Cp***** 60 g/l, 37°C)			
QB** = 100 ml/min, QUF*** = 2 L/h	QB** = 100 ml/min, QUF*** = 2 L/h		37 mmHg	29 mmHg
QB** = 200 ml/min, QUF*** = 2 L/h	QB** = 200 ml/min, QUF*** = 2 L/h		51 mmHg	41 mmHg
QB** = 400 ml/min, QUF*** = 2 L/h	QB** = 400 ml/min, QUF*** = 2 L/h		81 mmHg	64 mmHg
Sievingskoefficient	**Suodatuskerroin**			
(bovint plasma, Cp 60 g/l, 37° C)	(naudan plasma, Cp 60 g/l, 37° C)			
QB** = 100 ml/min, QUF*** = 20 ml/min	QB** = 100 ml/min, QUF*** = 20 ml/min			
- Karbamid	- Virtsahappo		1	
- Kreatinin	- Kreatiini		1	
- Vitamin B12	- Vitamiini B12		1	
- Inulin	- Inuliini		1	
- Albumin	- Albumiini		< 0.01	

* Typiske gennemsnitsværdier, der er opnået ved laboratorietest af eftersteriliserede prøveemner. Resultaterne kan variere afhængigt af patienten og de kliniske forhold. / Jälkisteriloiduista laboratoriokokeiden näyte-eristä saadut keskiarvot. Tulokset voivat vaihdella potilaasta ja kliinisistä olosuhteista riippuen.

**** Hematocrit / Hématocrite / Hämatokrit / Hematocrito / Ematocrito / Hematokrit / Hematocriet / Hematócrito / Hematokritt / Hæmatokrit / Hematokritti

***** Protein concentration / Concentration protéique / Protein-Konzentration / Concentración proteica / Concentrazione proteica / Proteinkoncentration / Proteïne concentratie / Concentração proteica / Proteinkonsentrasjon / Proteinkoncentration / Proteiinipitoisuus

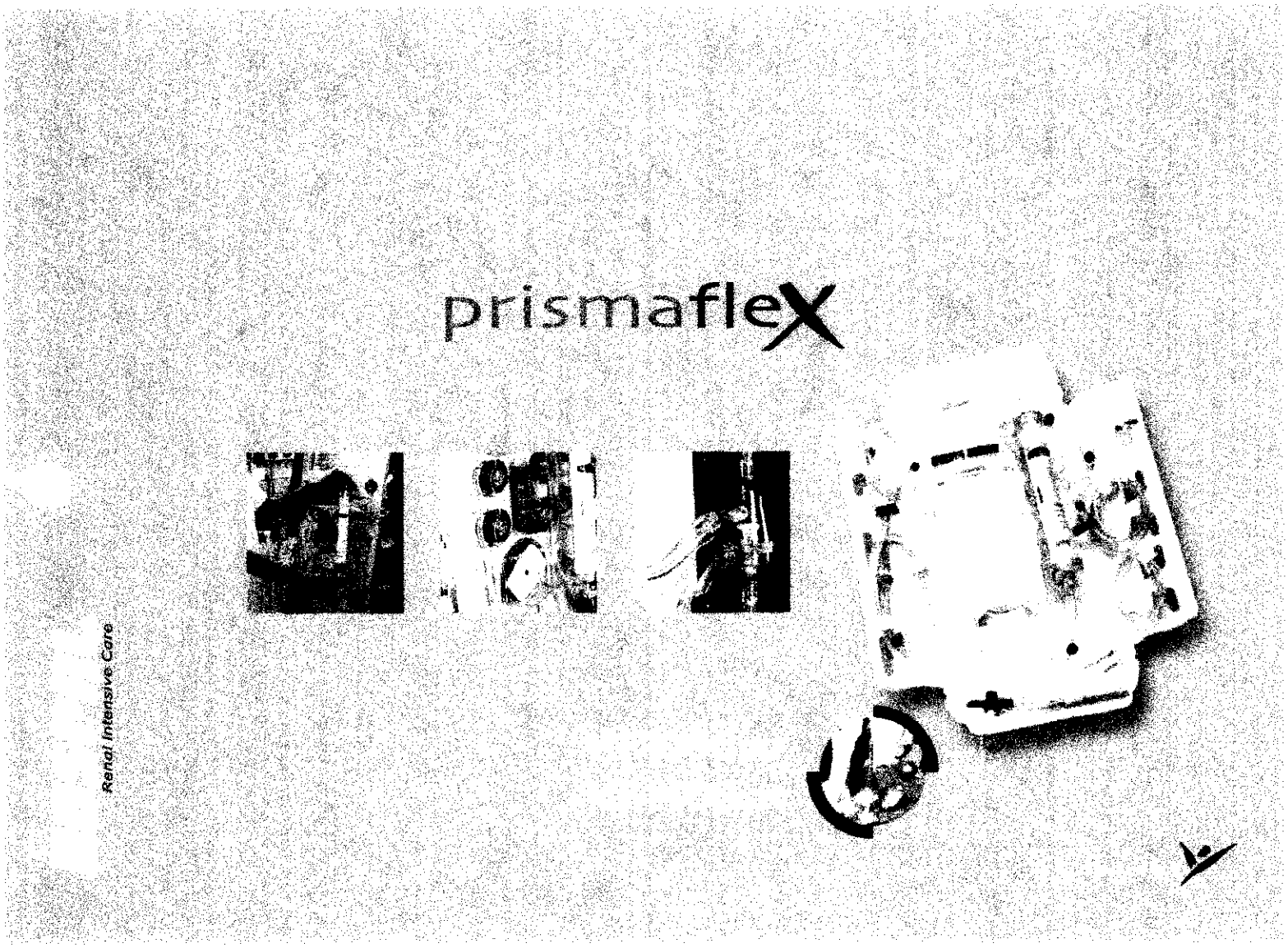
****** Dialysate flow rate / Débit dialysat / Dialysatflußrate / Flujo de líquido de diálisis / Flusso dialisato / Dialysatflöde / Dialysaatsnelheid / Fluxo da solução de diálise / Flow-rate for dialysevæske / Flowhastighed for dialysa / Dialysaatin virtausmäärä

The PRISMAFLEX HF1000/HF1400 are protected by one or more of the following patents/patent applications:

- US4861242, US4749619, US5139669, US5182868, US5259903, US5449430, US5441636, US5644402, US5722399, US5679245, US5776345, US5910252, US5762805, US5578223, US5725775, US5698090, US5211849;
- EP0441721, EP0466620, EP0490749, EP0611227, EP0611228, EP0678301, EP0701830, EP0829265, EP0706044, EP0607301;
- GB2208897;
- CA1284598, CA2035138, CA2115414, CA2115415, CA2158245, CA2444794, CA2303714, CA2119375;
- JP1772297, JP3254222, JP3273623, JP117332/96, JP3469287, JP315530/94, JP3413412, JP3140781;
- DE P-3828123.6;
- FR8811046;
- IT-MI2002A001390, IT-MI2002A001389, IT-MI2003A000214, IT-MI2003A000212, IT-MI2003A000213, IT-MI2003A000216, IT-MO2003A000165, IT-MI2003A000211, IT-MO2003A000259, IT-MO2003A000293, IT1223781;
- PCT/IB03/02281, PCT/IB2004/000055, PCT/IB2004/000062, PCT/IB2004/000105, PCT/IB2004/000061, PCT/IB2004/000104.

HOSPAL
Renal Intensive Care

CE 0086



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HF1000 SET / HF1400 SET

prismaflex

General data

	Prismaflex HF1000 Set	Prismaflex HF1400 Set
Weight	790 g	1000 g
Overall dimensions	27 x 22 x 9 cm	27 x 22 x 9 cm
Blood volume in set	165 ml	165 ml

Materials

- PAES hollow fiber: Polyarylethersulfone
- Filter housing and headers: Polycarbonate
- Filter potting compound: Polyurethane
- Tubing material: plasticized polyvinyl chloride (PVC)
- Cartridge: PETG
- Sterilization mode: EtO (ethylene oxide)

Filter operating specifications

- Maximum TMP* (mmHg/kPa): 500/66.6
- Maximum blood pressure (mmHg/kPa): 500/66.6
- Minimum blood flow rate:
  Prismaflex HF1000 Set: 75 ml/min
  Prismaflex HF1400 Set: 100 ml/min

Filter data

- Nominal physical characteristics
  - Effective surface area:
    Prismaflex HF1000 Set: 1.15 m²
    Prismaflex HF1400 Set: 1.40 m²
  - Fiber internal diameter (wet): 215 µm
  - Fiber wall thickness: 50 µm

In vitro performances

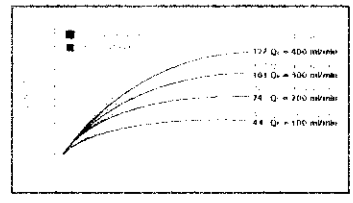
- **Blood pressure drop (in post dilution mode)**
  (bovine blood, Hematocrit 32% Pc* = 60 g/l, T = 37°C)**

	Prismaflex HF1000 Set	Prismaflex HF1400 Set
Qb** = 100 ml/min Qd** = 2l/h	12 mmHg	7 mmHg
Qb** = 200 ml/min Qd** = 2l/h	43 mmHg	25 mmHg
Qb** = 400 ml/min Qd** = 2l/h	171 mmHg	93 mmHg

- Sieving coefficient
  (bovine plasma, Pc 60 g/l, T = 37°C)
  Q_b = 100 ml/min, Q_{ult} = 20 ml/min (HF1000);
  Q_b = 300 ml/min, Q_{ult} = 60 ml/min (HF1400);
  Urea = 1, Creatinine = 1, Vitamin B12 = 1,
  Inulin = 0.99, Albumin <0.01

CVVH Performances

- "In vitro" ultrafiltration with blood (in post-dilution) values ±(5%) (Continuous venovenous hemofiltration) (Bovine blood at 37°C, Hematocrit 32%, Pc*** 60 g/l).



CVVHD Clearances

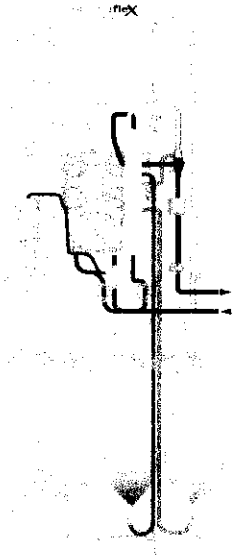
- Clearances values inlet dialysate flow rate (Continuous venovenous hemodiafysis) (Saline, T = 37°C).

		Prismaflex HF1000 Set Qb*** = 100 ml/min Qd*** = 0 ml/min		Prismaflex HF1400 Set Qb*** = 100 ml/min Qd*** = 0 ml/min		Qb*** = 200 ml/min Qd*** = 2000 ml/h
Q	100 ml/min	1	0.5	1	0.5	1
Urea	60 l/min	1.0	0.5	1.0	0.5	1.0
Vitamin B12	1.2 l/h	0.5	0.1	0.5	0.1	0.5
Inulin	0.2 l/h	0.5	0.1	0.5	0.1	0.5

*Transmembrane pressure **Access blood flow rate
***Patient concentration ****Ultrafiltration flow rate (Qf)
(1) Effective dialysate flow rate = the Prescribed fluid removal flow rate + any Concurrent flow rate + post blood pump flow rate

Ordering information

	Catalog N°	N° units/box
PRISMAFLEX HF1000 Set	8120030	4
PRISMAFLEX HF1400 Set	8120040	4
SP4M 5 liter bag	GH2295J	50



MOSPAL Renal Intensive Care

9733107 06.04

prismaflex

M 60 SET
M 100 SET

AN69 HF
MEMBRANE

Instructions for use
Notice d'utilisation
Gebrauchsanweisung
Istruzioni per l'uso
Gebruiksaanwijzing

CE 0086

HOSPAL

ENGLISH

DEFINITION OF SYMBOLS USED ON LABELING OF PRODUCT

LOT	manufacturing batch number
STERILE EO	sterilized by ethylene oxide (EtO); followed by the sterilization date
	expiration date of the product
	product for single use only
	Read instructions before using the product.

⚠ **Caution :** Federal law (USA) restricts this device to sale by or on the order of a physician.

DEFINITION OF EXPRESSIONS USED IN THIS MANUAL

In this document :

⚠ **"Warning"** is used to alert the user/operator **not to take** a certain action which, if taken, can cause a potential hazard and result in a serious adverse reaction, injury or death.

⚠ **"Caution"** is used to alert the user/operator **to take** a certain action to protect against a potential hazard, which, if ignored, could have an adverse effect on the patient or on the device.

"Note" is used as a reminder to the user/operator on normal treatment activity and on what is a suitable action in a particular situation.

SCUF : Slow Continuous UltraFiltration
CVVH : Continuous Veno-Venous Hemofiltration
CVVHD : Continuous Veno-Venous HemoDialysis
CVVHDF : Continuous Veno-Venous HemoDiaFiltration
Predilution : addition of replacement fluid to the blood stream upstream to the filter
Postdilution : addition of replacement fluid to the blood stream downstream to the filter

PRODUCT DESCRIPTION

- The PRISMAFLEX M60/M100 Set is a disposable, extracorporeal circuit for use with the PRISMAFLEX System.
- The PRISMAFLEX M60/M100 Set consists of a AN69 HF hollow fiber hemofilter/dialyzer* and tubing lines.
- This filter is permanently connected to a blood access line (red-striped), a blood return line (blue-striped), a dialysate inlet line (green-striped) and an effluent outlet line (yellow-striped).
- The other lines of the set include :
  - a replacement solution line (purple-striped)
  - a pre blood pump line (white striped)
  - an anticoagulant line (syringe)
- The configuration of the PRISMAFLEX set allows the following uses depending on the configuration of the automated clamps on the machine :
  - purple circuit : replacement in pre or post dilution (CVVH and CVVHDF)
  - green circuit :
    - * dialysate in CVVHD and CVVHDF
    - * replacement in post dilution in CVVH
- The pre blood pump line allows the addition of infusion solution close to the end of the patient access line and before the blood pump. This can be used as an additional pre-dilution infusion to the replacement circuit.
- The PRISMAFLEX Set provides for a specific small volume deaeration chamber in which blood sedimentation will take place in most of the cases ; this matches with the normal operation of the device.
- A 5-liter bag is provided to be connected to the end of the blood return line to initially collect priming solution, during priming. Then, during treatment, this bag is used to collect ultrafiltrate and/or used dialysate (connection at effluent line). Other sterile 5 and 10 liter bags and sterile, non pyrogenic spikes can be ordered separately.
- All line connectors are compatible with the ISO 594/1 & 2 international standards concerning conical fittings.
- The fluid pathways of the PRISMAFLEX Set are guaranteed sterile and non pyrogenic.
- The PRISMAFLEX M60/M100 Set is sterilized by ethylene oxide (EtO). Deaeration is such that EtO residuals comply with the ones described in ISO 10993-7.
- Expiration date : Please refer to product label.
- The PRISMAFLEX Set is manufactured by HOSPAL Industrie, Meyzieu, France.

* In this document the hemofilter/dialyzer will be referred to as "filter".

INDICATIONS

The PRISMAFLEX Set is indicated for use only with the PRISMAFLEX Control Unit in providing continuous fluid management and renal replacement therapies. The system is intended for patients who have acute renal failure, fluid overload, or both.

This set is intended for use in the following veno-venous therapies: SCUF ; CVVH ; CVVHD ; CVVHDF.

All treatments administered via the PRISMAFLEX Set must be prescribed by a physician. The size, weight, state of uremia, cardiac status, and general physical condition of the patient must be carefully evaluated by the prescribing physician before each treatment.

The pediatric use of the PRISMAFLEX M60 Set should be restricted to children with a body weight greater than 10kg (22lb).

The PRISMAFLEX M100 Set should be restricted to patients with a body weight greater than 30kg (66lb).

CONTRAINDICATIONS

There are no known contraindications to continuous renal replacement therapies.

CAUTIONS AND WARNINGS

Note : *Additional warnings and cautions pertaining to the PRISMAFLEX system are included in the PRISMAFLEX Control Unit Operator's Manual.*

⚠ Cautions

1. Carefully read these instructions for Use and the PRISMAFLEX Control Unit Operator's Manual before using this product.
2. Store the PRISMAFLEX Set in a dry place, between 0° C (32° F) and 30° C (86° F).
3. Some solvents and other chemicals, if used in contact with the filter, could damage the set. No chemical of this type should be used without permission of the manufacturer. The following are especially forbidden :
   a) halogenated aromatic and aliphatic solvents;
   b) ketonic solvents
4. To prevent contamination, this PRISMAFLEX Set must be used as soon as its packaging and sterilization caps are removed.
5. Do not use this set if the packaging is damaged, if the sterilization caps are missing or loose, or if any of the lines in the set are kinked.
6. Do not try to remove the filter from the cartridge plate.
7. Destroy this set after single use, using aseptic technique for potentially contaminated equipment. Do not resterilize.
8. Use aseptic techniques when handling all blood and fluid lines in the set.
9a. Use only prescribed dialysate and replacement solutions with the PRISMAFLEX System. These solutions must have a density similar to that of saline solutions (close to 1) in order to avoid errors in the volumes used for fluid exchange.
9b. In CVVHD and CVVHDF modes, the use of non sterile dialysate could induce risks of bacterial and pyrogenic contamination for the patient. In the United States dialysate should conform to AAMI standard RD5.
9c. In CVVH modes and CVVHDF, if a commercially available replacement solution is used, it must be labeled as intended for intravenous infusion.

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10. Connect the PRISMAFLEX Set to a patient via venous blood access and return devices. A double-lumen venous catheter is the recommended blood access device; however, two single-lumen venous catheters can also be used. There are 3 possible accesses for PRISMAFLEX System therapies: subclavian, jugular or femoral vein.
11. During priming and operation, observe closely for leakage at joints and connections within the set, notably the bags. Leakage can cause blood loss or air embolism. If leakage cannot be stopped by tightening the connections, replace the set.
12. Before connecting the blood return line to the patient, check for absence of air between the segment of line inserted in the air detector and the patient-end of the return line.

    If air is present in this part of the return line, connect the access line to the patient and start the blood pump while leaving the return line connected to the collection bag. Purge the air present in the end-part of the return line, then stop the blood pump. Disconnect the return line from the collection bag, and connect it to the patient.

    If the amount of air in the blood circuit is too large, reprime the circuit completely before patient connection.
13. After priming is complete, do not remove the pressure pods from the pressure sensor housings. If pods are removed, the set must be changed or the Diaphragm Reposition procedure performed (refer to PRISMAFLEX Control Unit Operator's Manual).
14. If the patient is not immediately connected to the PRISMAFLEX Set after priming is complete, flush the set with at least 1000 ml priming solution (saline or alkaline solution (pH ≥ 7.3) with heparin added) prior to connecting the patient. This requires use of a new bag of priming solution.

15a. Use a 21-gauge or smaller needle to obtain blood/fluid samples or remove trapped air from the PRISMAFLEX Set. Use of larger needles can cause holes in the sample sites, resulting in blood loss or air embolism.

15b. The following plastic needle is compatible with the PRISMAFLEX access sites: MEDIC M8 - 5005 (MediSystem).

16. The PRISMAFLEX Control Unit may not be able to detect disconnections of the set from the patient's catheter. Carefully observe the set and all operations while using the PRISMAFLEX System for a patient treatment.
17. Due to the nature of use of the PRISMAFLEX Set (low blood flow rates, extended treatment time, and other special factors), the possibility for coagulation within the blood flowpath is substantially enhanced. Give careful attention to the possible medical hazards associated with coagulation of the blood flowpath and comply with the minimum blood flow rates specifications of each filter (see the "Filter Operating Specifications" section).
18. Filter performance specifications require a minimum blood flow rate, specific to each filter, to avoid risk of hemoconcentration. (See "Filter Operating Specifications" section.)
19. During use, closely monitor the patient's clotting parameters, especially when increasing the amount of anticoagulant delivered or after changing the anticoagulant syringe.
20. To assure proper anticoagulant flow control, only the following syringes are permitted: Terumo (30 ml), 3 S (Bertoni) (30 ml), BD 30 Plastipack (30 ml), RR Prontosiringa (30 ml), Ico Gamma Plus (30 ml), Dispomed (30 ml), Ico Gamma Plus (20 ml), Ico Steril (20 ml), BD 20 Plastipack (20 ml), Terumo 20 (20 ml), RR 20 (20 ml), Monoject 20 (20 ml), BD 10 (10 ml), Terumo 10 (10 ml), Fresenius Luer lock (30, 20 and 10 cc). The use of other syringes can be a hazard for the patient. Particularly if there is no Luer-lock on the syringe, the seal between the syringe and the heparin line can no longer be guaranteed.
21. When not using the pre blood pump infusion circuit, it is recommended to clamp this circuit close to its connection to the access line; this will prevent the sedimentation of blood into the pre blood infusion line.
22. Always inspect the blood flowpath for signs of clotting before returning the blood in the set to the patient. If clotting is suspected, do not return the blood to the patient.
23. In case of re-circulation mode, the set must be replaced **whenever patient reconnection is not possible within at most a few minutes**.

    In case of poor blood return, the set must be replaced.

    In all cases, it is essential to reprime the set with fresh saline immediately before patient connection.
24. The PRISMAFLEX set offers a specific design of the deaeration chamber which aims to trap air before blood is returned to the patient.
25. The PRISMAFLEX Set is not designed for a heater to be connected to the replacement solution line. A heater generates air bubbles which collect in the return deaeration chamber. Therefore, it is recommended not to use a heater on the replacement solution line.
26. The PRISMAFLEX set is not designed for a heater to be connected to the dialysate solution line. A heater generates air bubbles which collect in the filtrate/dialysate compartment of the filter and decrease diffusive performance of the device. Therefore it is recommended not to use a heater on the dialysate solution line.

In general terms, introduction of air in the dialysate circuit should be minimised throughout the course of the treatment, especially when replacing dialysate solution bags.

27. Hypothermia must be monitored in all CRRT treatments, and special attention should be paid when increasing exchange volumes above 2 L/h; it may be necessary to warm the patient because of hypothermia.
28. The blood return line (blue-striped) is equipped with a Luer-lock connection near the blue sample site.

    This connector is intended to join the extension line of a blood warmer. Refer to the specific Instructions for Use and strictly follow detailed instructions for set up of this line. Do not use this connection for any other purpose.
29. Do not attach/connect the extension line of a blood heater to the return line downstream of the air detector. The PRISMAFLEX System cannot detect air introduced in the line downstream of the air detector.

⚠ Warnings

1. The use of operating procedures other than those published by the manufacturer or the use of accessory devices not recommended by the manufacturer can result in patient injury or death.
2. Use only PRISMAFLEX Sets with the PRISMAFLEX Control Unit. The use of non-PRISMAFLEX Sets can result in patient injury or death.
3. Should acute allergic reactions (first-use syndrome) occur in patients receiving treatment via the PRISMAFLEX M60/M100 Set, **immediately stop the treatment** and administer appropriate intervention. Pay special attention to patients receiving ACE inhibitors and/or having already shown similar allergic reactions. (See "Hypersensitivity Reactions" section.)
4. Do not allow air to enter the blood compartment of the filter after priming is started. If a large amount of air enters, the set must be replaced.
5. Since drugs can pass through the membrane of the filter, the dosage of associated drug treatments must be adjusted for patients on continuous renal replacement therapy.
6. To assure adequate filter performance, it is recommended that the set be changed every 24 hours of use. However, the set must be changed after 3 days (72 hours) and/or the maximum process volume of blood (780L) whichever occurs first. Continued use beyond these limits (either 72 hours or 780L) could result in rupture of the pump segments, with risk of patient injury or death.

SPECIFICATIONS

See Tables at end of document.

SET MATERIALS

AN69 HF hollow fiber	: Acrylonitrile and sodium methallyl sulfonate copolymer
Housing and headers	: Polycarbonate
Potting compound	: Polyurethane
Tubing material	: Plasticized polyvinyl chloride (PVC)
Cartridge	: PETG

***Note** : The following information is available from the manufacturer upon request :*

- *information about test methods used to obtain performance characteristics*
- *the number and range of particles in the effluent from the dialyzer prepared as recommended for clinical use*
- *the types and amounts of residue from the sterilization process*

INSTRUCTIONS FOR USE

***Note** : Use the set by following the detailed on-line instructions provided by the PRISMAFLEX Control Unit. Additional information is available in the PRISMAFLEX Control Unit Operator's Manual.*

***Note** : a TMP > 40 kPa (300 mmHg) does not allow a higher ultrafiltration.*

Perform the following procedures when the appropriate instructions appear on the display of the PRISMAFLEX Control Unit:

Load Set

1. Remove the set from the packaging support. Holding the filter vertically (so that the label is the right way up), carefully snap the set cartridge into the cartridge carrier (center of front pane
2. Attach the 3 pressure pods to their proper pressure housings. Press effluent line into blood leak detector; snap discharger ring into its guide.
3. Temporarily hang access/effluent Y line on priming hook.

4. Place deaeration chamber in its holder, attach chamber monitor line to return pressure port.
5. Insert return line into air detector and return line clamp.
6. Connect return line to effluent bag.
7. Open effluent scale; hang collection/effluent bag. Close scale.

Prepare and Connect Solutions

1. Hang bag of priming solution (saline or alkaline solution (pH ≥ 7.3) with added 5000IU heparin/liter) on priming hook (left corner hook top of front panel). Connect access (red)/effluent (yellow) Y-line to priming solution bag.
2. If required, connect PBP line (white) to pre blood pump (PBP) bag; hang bag on its scale.
3. Hang replacement solution (CVVH, CVVHDF) on purple scale hook. Connect replacement solution line (purple) to replacement solution bag.
4. In CVVHD/CVVHDF hang dialysate on green scale hook. Connect dialysate line (green). In CVVH hang replacement solution on green scale hook (postdilution replacement). Connect green striped line to bag.
   Note : *See Caution no. 9 a, b, c.*
5. Connect anticoagulant line to filled anticoagulant synnge. Install syringe in pump. (see Help)
6. Unclamp any clamped lines. **Verify all connections are secure.** Press PRIME to start automatic priming.

Prime Set

Note: *See Cautions no. 11 through 14, cautions no. 25, 26 and 29, and Warning no. 4.*

Priming includes multiple self-tests and takes approximately 10 minutes. After the cycle is complete :

1. Examine set carefully to be certain all connections are secure, all lines are unobstructed, and there are no leaks in the tubing.
2. Leave priming solution and prime collection bags attached until ready to connect patient.
3. Continue chosen treatment by following the instructions on the display of the PRISMAFLEX Control Unit.

The PRISMAFLEX Set must be carefully deaerated.

Anticoagulation Considerations

Note: *See Cautions no. 17 through 20 and Warning no. 6.*

Initiate anticoagulation of the blood flowpath, as prescribed by the physician. Dunng use, monitor the patient's clotting parameters; adjust the anticoagulation settings on the PRISMAFLEX Control Unit, according to the physician's prescription. If prescribed, do not forget to infuse a loading dose of anticoagulant immediately after patient connection.

Anticoagulation plays an important part in extending filter life by retarding plugging and clotting.

Change Set Procedure

To remove this set, load a new set and continue with present treatment :

Press "STOP" from the Status screen, then press "CHANGE SET" and follow the on-line instructions.

Note: *Operator can return blood to the patient prior to disconnecting, if desirec (see Caution no. 22.)*

Temporary Disconnection Procedure

To temporarily disconnect the patient from the set :

Press "STOP" from the Status screen, then press "TEMP DISCON" and follow the on-line instructions.

Note: *Operator must return blood in the set to the patient and immediately reprime the set via on-line instructions. (see Cautions no. 22 and 23.)*

End Treatment Procedure

To end the present treatment and remove this set :

Press "STOP" from the Status screen, then press "END TREATMENT" and follow the on-line instructions.

Note: *Operator can return blood to the patient prior to disconnecting, if desirec (See Caution no. 22.)*

MANUAL TERMINATION

Manual termination may be necessary due to power loss or an alarm of the PRISMAFLEX Control Unit. The alarm screen tells the operator if a manual termination is required.

Note: *The following instructions are also found in "Troubleshooting" in the PRISMAFLEX Control Unit Operator's Manual.*

A. With Blood Return

Note : *See Caution no. 22.*

Note : *A sterile spike connector may be required.*

1. Turn off the power. Clamp the access line (red-striped) and disconnect from the patient. Attach the access line to a 1-liter bag of sterile saline. (Use spike connector if needed.) Unclamp the access line.
2. Press the return clamp button (left side of the return line clamp assembly) and hold in the "in" position. With the other hand, remove the return line (blue-striped) from the return line clamp.
3. Visually check the the fluid level in the dearation chamber. If the level is below the horizontal line remove the excess air through the sample site on the chamber monitor line (chamber monitor line connects the deaeration chamber with the return pressure port on the control unit) as follows:
   a. Insert a sterile, 20 gauge needle attached to a <5-cc syringe into the sample site on the chamber monitor line.
   b. Aspirate air/blood until fluid level is at the horizontal line on the dearation chamber.
4. Remove the pump crank from its holder on the rear panel. Insert crank into the rotor of the blood pump and turn clockwise until sufficient blood is returned to the patient.

⚠ **Warning:** *The alarm system is disabled. Visually check for air in the blood return line until the patient is disconnected.*

5. Clamp the return line (blue-striped) and disconnect from the patient. Clamp lines to all bags.
6. Press the two clips of the cartridge carrier to release the cartridge. Starting with the peristaltic pump, insert the pump crank into the rotor and turn each pump counterclockwise.
7. When the pump segments are free, grasp the cartridge and pull out to disengage the lines from the pinch valves. Take the set off the control unit and discard as usual.

Note : *Remaining solutions may be used with a new set, if desirec.*

⚠ **Warning:** *Ensure patient is disconnected from set before removing set from control unit.*

B. Without Blood Return

Note: *The patient will lose the blood contained in the blood flowpath during a manual termination without blood return.*

1. Turn off the power. Clamp the access line (red-striped) and return line (blue-striped) and disconnect from the patient.
2. Clamp lines to all bags.
3. Press the two clips of the cartridge carrier to release the cartridge. Starting with the blood pump, insert the pump crank into the rotor and turn each pump counterclockwise.
4. When the pump segments are free, grasp the cartridge and pull out to disengage the lines from the pinch valves. Take the set off the control unit and discard as usual.

SPECIAL PROCEDURES IN CASE OF COMPLICATION

Filter Membrane Blood Leaks

Blood leaks through the filter membrane are automatically detected by the PRISMAFLEX Control Unit alarm system. A warning alarm is generated and blood loss is limitec by immediate stoppage of all pumps.

To return blood to the patient, press STOP from the alarm screen, then press CHANGE SET from the Stop screen and follow the on-line instructions.

External Blood Leaks

Note : *See Cautions no. 15, 16 and 21.*

External blood leakage may not be immediately identified by monitoring equipment and could result in significant blood loss. Check the filter and all connections of the

disposable tubings during treatment to minimize the risk of leakage. If an external blood leakage is observed, immediately stop the blood pump. Initiate corrective action by securing connections or replacing the PRISMAFLEX Set.

If necessary, administer adequate replacement solution to the patient to compensate for blood loss.

Hypersensitivity Reactions

Note : *See Warning no. 3.*

Should acute allergic reactions (first use syndrome) occur within the first few minutes of the treatment, it is important to react immediately by discontinuing the session and administering appropriate treatment.

Patients receiving angiotensin converting enzyme (ACE) inhibitors as medication can develop, within the first few minutes of a treatment, symptoms similar to acute allergic reactions i.e bronchospasm, edema of airways or larynx, dyspnea, angioedema, urticaria, nausea, vomiting, diarrhea, respiratory arrest, abdominal cramping, hypotension, hypovolemic shock and death.

However, for these patients, administration of antihistamines often does not alleviate the symptoms. In this case, treatment **must** be stopped and a more aggressive first-line therapy for an anaphylactoid reaction should be initiated immediately after the onset of symptoms.

Therefore, special attention ought to be paid to patients receiving ACE inhibitors and/or having already shown similar reactions.

WARRANTY AND LIMITATION OF LIABILITY

a) The manufacturer warrants that the PRISMAFLEX Set has been manufactured in accordance with its specifications and in compliance with good manufacturing practices, other applicable industry standards and regulatory requirements.

If provided with the lot/serial number of the defective product, the manufacturer will, by replacement or credit, remedy manufacturing defects in the PRISMAFLEX Set becoming apparent before the expiration date.

b) The warranty under paragraph a) above is in lieu of, and to the exclusion of, any other warranty, whether written or oral, express or implied, statutory or otherwise, and there are no warranties of merchantability or other warranties, which extend beyond those described in paragraph a) above. The remedy set out above for manufacturing defects is the sole remedy available to any person due to defects in the PRISMAFLEX Set and the manufacturer shall not be liable for any consequential or incidental loss, damage, injury or expense arising directly or indirectly from the use of the PRISMAFLEX Set, whether as a result of any defect therein or otherwise.

c) The manufacturer shall not be liable for any misuse, improper handling, non-compliance with warnings and instructions, damage arising from events after the manufacturer's release of the PRISMAFLEX Set, failure or omission to inspect the PRISMAFLEX Set before use in order to ensure that the PRISMAFLEX Set is in proper condition, or any warranty given by independent distributors or dealers.

d) The manufacturer is HOSPAL Industrie, Meyzieu, France.

FILTER DATA	CARACTERISTIQUES DU FILTRE	FILTER-DATEN
NOMINAL PHYSICAL CHARACTERISTICS	**CARACTERISTIQUES PHYSIQUES**	**PHYSIKALISCHE EIGENSCHAFTEN**
Effective surface area	Surface efficace	Effektive Oberfläche
Fiber internal diameter (wet)	Ø interne de la fibre (humide)	Innendurchmesser (feucht)
Fiber wall thickness	Epaisseur de paroi de la fibre	Wandstärke
IN VITRO PERFORMANCES ≠	**PERFORMANCES IN VITRO ≠**	**IN VITRO LEISTUNGEN ≠**
Blood priming volume	**Volume de remplissage sang**	**Blutfüllvolumen**
Blood pressure drop (post dilution)	**Perte de charge sang (post dilution)**	**Blut druckabfall (Postdilution)**
(bovine blood, Htc****32%, Cp***** 60 g/l, 37°C)	(sang de bœuf, Htc****32%, Cp***** 60 g/l, 37°C)	(Rinderblut, Hkt****32%, Pt***** 60 g/l, 37°C)
QB** = 100 ml/min, QUF*** = 1 L/h	QS** = 100 ml/min, QUF*** = 1 L/h	QB** = 100 ml/min, QUF*** = 1 L/h
QB** = 180 ml/min, QUF*** = 2 L/h	QS** = 180 ml/min, QUF*** = 2 L/h	QB** = 180 ml/min, QUF*** = 2 L/h
QB** = 250 ml/min, QUF*** = 2 L/h	QS** = 250 ml/min, QUF*** = 2 L/h	QB** = 250 ml/min, QUF*** = 2 L/h
QB** = 400 ml/min, QUF*** = 2 L/h	QS** = 400 ml/min, QUF*** = 2 L/h	QB** = 400 ml/min, QUF*** = 2 L/h
Sieving coefficient	**Transmittance**	**Siebkoeffizient**
(bovine plasma, Cp 60 g/l, 37° C)	(plasma de bœuf, Cp 60 g/l, 37° C)	(Rinderplasma, Pt 60 g/l, 37° C)
QB** = 100 ml/min, QUF*** = 20 ml/min	QS** = 100 ml/min, QUF*** = 20 ml/min	QB** = 100 ml/min, QUF*** = 20 ml/min
- Urea	- Urée	- Harnstoff
- Creatinine	- Créatinine	- Kreatinin
- Vitamin B12	- Vitamine B12	- Vitamin B12
- Inulin	- Inuline	- Inulin
- Myoglobin	- Myoglobine	- Myoglobin
- Albumin	- Albumine	- Albumin

≠ Typical mean values obtained from laboratory testing of post-sterilization sample lots. Results may vary depending on patient and clinical conditions. / Valeurs moyennes caractéristiques mesurées au laboratoire sur un échantillonnage de lots stérilisés. Les résultats sont susceptibles de varier en fonction du patient et de son état clinique. / Typische Mittelwerte, die an strilen Produkten im Labor ermittelt wurden. Die angegebenen Werte können abhängig vom Patienten und den klinischen Bedingungen schwanken.

GENERAL DATA / CARACTERISTIQUES GENERALES / ALLGEMEINE DATEN / CARATTERISTICHE GENERALI / ALGEMENE TECHNISCHE GEGEVENS

	PRISMAFLEX M60 SET	PRISMAFLEX M100 SET
Weight / Poids / Gewicht / Peso / Gewicht	750 g	800 g
Overall dimensions / Dimensions totales / Außenmaße / Dimensioni / Totale afmetingen		
length / longueur / Länge / lunghezza / lengte	27 cm	27 cm
width / largeur / Breite / larghezza / breedte	22 cm	22 cm
height / hauteur / Höhe / altezza / hoogte	9 cm	9 cm
Blood volume in set / Volume sang dans le set / Blutvolumen im Set / Volume ematico nel set / Hoeveelheid bloed in set (± 10%)	103 ml	149 ml

FILTER OPERATING SPECIFICATIONS / CARACTERISTIQUES DE FONCTIONNEMENT DU FILTRE / BETRIEBSPEZIFIKATIONEN FÜR DEN FILTER / CARATTERISTICHE DI FUNZIONAMENTO DEL FILTRO / FILTERPRESTATIES

	PRISMAFLEX M60 SET	PRISMAFLEX M100 SET
Maximum TMP* / PTM* Maximum / Maximum TMP* / PTM* massima / Maximum TMP*	450 mmHg 60 kPa	
Maximum blood pressure / Pression sang maximum / Maximum Filter-Blutdruck Pressione ematica massima / Maximum bloeddruk	500 mmHg 66.6 kPa	
Minimum blood flow rate / Débit sang minimum / Mindest-Blutflußrate Flusso ematico minimo / Minimum Bloedsnelheid	50 ml/min	75 ml/min

CARATTERISTICHE DEL FILTRO	FILTER DATA	PRISMAFLEX M60 SET	PRISMAFLEX M100 SET
CARATTERISTICHE FISICHE	**NOMINALE FYSIEKE EIGENSCHAPPEN**		
Superficie effettiva	Effectief oppervlak	0.60 m^2	0.90 m^2
Ø interno della fibra (bagnata)	Inw. vezeldiam. (nat)	240 µm	
Spessore parete della fibra	Wanddikte vezel	50 µm	
PRESTAZIONI IN VITRO ≠	**IN VITRO PRESTATIES ≠**		
Volume di priming ematico	**Bloed priming volume**	42 ml ± 10 %	66 ml ± 10 %
Perdita di carico ematico (postdiluizione)	**Bloed drukdaling (Post-dilutie)**		
(sangue bovino, Hct****32%, Cp***** 60 g/l, 37°C)	(bovine bloed, Htc****32%, Cp*****60 g/l, 37°C)		
QS** = 100 ml/min, QUF*** = 1 L/h	QB** = 100 ml/min, QUF*** = 1 L/h	47 mmHg	31 mmHg
QS** = 180 ml/min, QUF*** = 2 L/h	QB** = 180 ml/min, QUF*** = 2 L/h	91 mmHg	60 mmHg
QS** = 250 ml/min, QUF*** = 2 L/h	QB** = 250 ml/min, QUF*** = 2 L/h		73 mmHg
QS** = 400 ml/min, QUF*** = 2 L/h	QB** = 400 ml/min, QUF*** = 2 L/h		105 mmHg
Coefficiente di sieving	**Sieving coëfficient**		
(plasma bovino, Cp 60 g/l, 37° C)	(bovine plasma, Cp 60 g/l, 37 °C)		
QS** = 100 ml/min, QUF*** = 20 ml/min	QB** = 100 ml/min, QUF*** = 20 ml/min		
- Urea	- Ureum	1	
- Creatinina	- Creatinine	1	
- Vitamina B12	- Vitamine B12	1	
- Inulina	- Inuline	0.95	
- Mioglobina	- Myoglobine	0.55	
- Albumina	- Albumine	< 0.01	

≠ Tipici valori medi ottenuti da test di laboratorio su campioni di lotti sterili. I risultati possono variare a seconda del paziente e delle diverse condizioni cliniche. / Typisch gemiddelde waarden verkregen na het testen van stalen na sterilisatie. Resultaten kunnen verschillen afhankelijk van de patiënt en de klinische situatie.

CVVHD CLEARANCES (Continuous veno-venous hemodialysis) Clearances versus inlet dialysate flow rate (37°C)
CLAIRANCES EN CVVHD (Hémodialyse veino-veineuse continue) Clairances au bain de dialyse, à débit entrée dialysat (37°C)
CVVHD CLEARANCES (Kontinuierliche veno-venöse Hämodialyse) Clearancewerte abhängig von der Dialysierflüssigkeit-Einlaßrate (37°C)
CVVHD CLEARANCE (Emodialisi veno-venosa continua) Clearance con dialisato a 37°C
KLARINGEN IN CVVHD (Continue veno-veneuze hemodialyse) Klaringen, snelheid van de dialysaataanvoer (37°C)

		PRISMAFLEX M60 SET QB/QS** = 100 ml/min QUF*** = 0 ml/min			PRISMAFLEX M100 SET QB/QS** = 150 ml/min QUF*** = 0 ml/min			
QD*****	(l/h)	1	2.5	4	1	2.5	4	8
	(ml/min)	17	42	67	17	42	67	133
Urea / Urée / Harnstoff / Urea / Ureum	(± 10%)	17	39	54	17	41	63	95
Vit B12	(± 20%)	14	23	28	16	30	37	45
Inulin / Inuline / Inulin / Inulina / Inuline	(± 20%)	12	17	19	14	23	26	30

* Transmembrane pressure / Pression transmembranaire / Transmembrandruck / Pressione transmembrana / Transmembraandruk

** Arterial blood flow rate / Débit sang / Arterieller Blutfluß / Flusso ematico arterioso / Arteriele bloedsnelheid

*** Ultrafiltration flow rate (on PRISMAFLEX system, the ultrafiltration flow rate = fluid removal flow rate + replacement flow rate) /
Débit d'ultrafiltration (sur le système PRISMAFLEX, le débit d'ultrafiltration correspond au débit de prélèvement de liquide + débit de solution de réinjection) /
Ultrafiltrationsflußrate (beim PRISMAFLEX -System ist die Ultrafiltrationsflußrates die Flussigkeitsentternungsflußrate + Substitutionsflußrate) /
Flusso di ultrafiltrazione (il sistema PRISMAFLEX calcola il flusso di ultrafiltrazione nel seguente modo : flusso di rimozione del fluido + flusso di reinfusione) /
Ultrafiltratie-snelheid (op PRISMAFLEX -systeem : de ultrafiltratie-snelheid = vochtverwijderings-snelheid + substitutie-snelheid)

**** Hematocrit / Hématocrite / Hämatokrit / Ematocrito / Hematocriet

***** Protein concentration / Concentration protéique / Protein-Konzentration / Concentrazione proteica / Proteine concentratie

***** Dialysate flow rate / Débit dialysat / Dialysatflußrate / Flusso dialisato / Dialysaatsnelheid

This product and devices incorporating this product are covered by one or several of the following patents: / Ce produit et les éléments qui le constituent sont couverts par un ou plusieurs des brevets suivants : / Dieses Produkt sowie seine verschiedenen Elemente sind durch eines oder mehrere der folgenden Patente geschützt: / Il prodotto qui descritto e i sistemi e dispositivi che lo costituiscono sono coperti da uno o più dei seguenti brevetti: / Dit produkt en de systemen en apparaten waarvan dit produkt deeluitmaakt, vallen onder één of verschillende van de volgende patenten:
US 4 749 619; US 5 139 669; US 5 182 868; US 5 259 903; US 5 449 430; US 5 441 636; US 5 679 245; US 5 762 805; US 5 776 345; US 5 910 252; US 4 861 242; EP 0 441 721; EP 0 441 721; EP 0 466 620; EP 0 490 789; EP 0 611 227; EP 0 611 228; JP 9264222; JP 9268400; JP 9273623; JP 016642/94; JP 017588:94; JP 1772297; CA 2 035 138; CA 2 115 415; CA 2 115 414; CA 1 284 598; FR90 15744; GB 2208897

Other patents pending. / D'autres demandes de brevet ont été déposés. / Weitere Patente wurden angemeldet. / Altri brevetti sono attualmente in fase di approvazione. / Andere patentaanvragen lopen.

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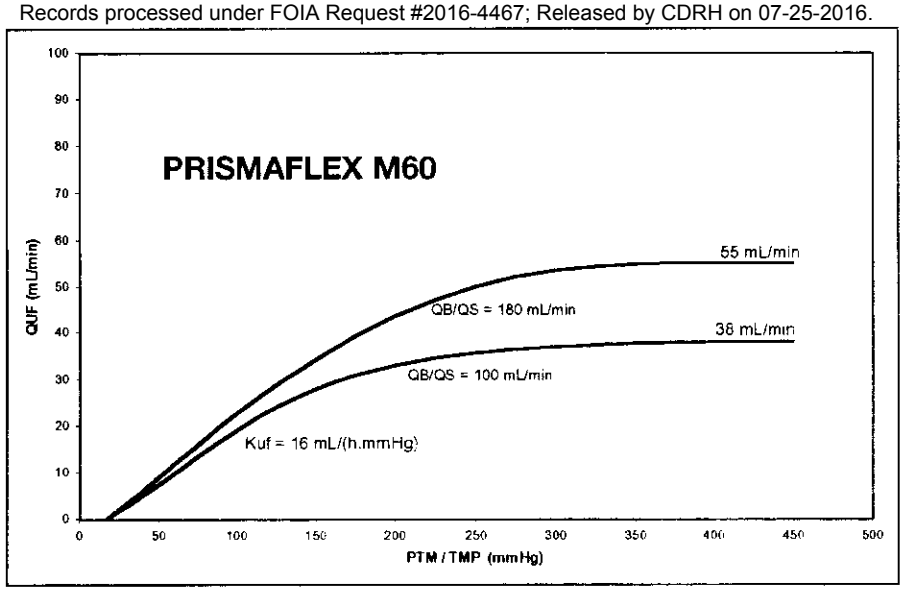

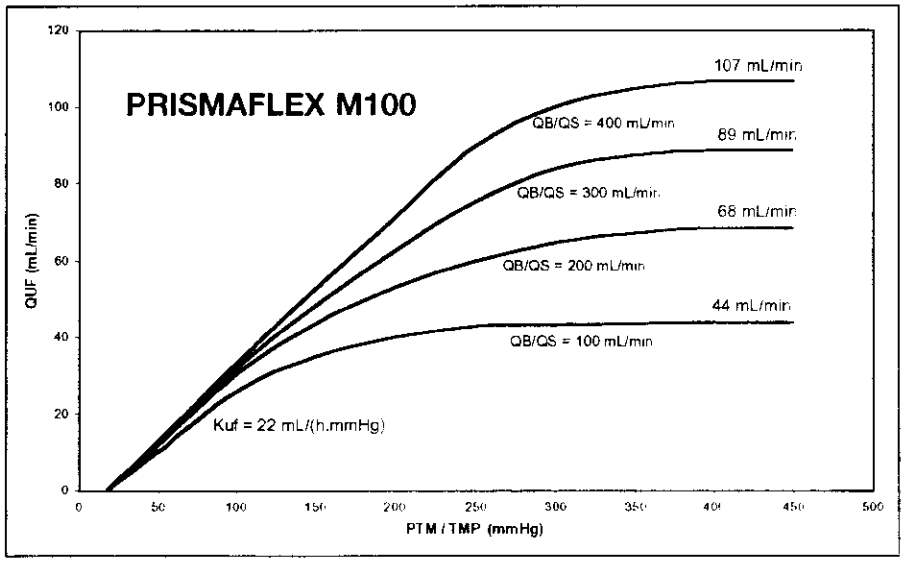

"In vitro" ultrafiltration with blood (values ± 15%)
(Bovine blood at 37°C, Hct 32 %, Protein concentration 60 g/l)
Ultrafiltration is controlled by the PRISMAFLEX System and is independent of the ultrafiltration coefficient (KUF).

Ultrafiltration au sang "in vitro" (valeurs à ± 15%)
(Sang de bœuf à 37°C, Hématocrite = 32 %, Concentration protéique = 60 g/l)
L'ultrafiltration est maîtrisée par le système PRISMAFLEX et est indépendante du coefficient d'ultrafiltration (KUF).

Ultrafiltration mit Blut "in vitro" (Werte bei ± 15 %)
(Rinderblut bei 37°C, Hkt 32 %, Protein-Konzentration 60 g/l)
Die Ultrafiltration wird von der PRISMAFLEX Maschine auf dem richtingen Wert gehalten und hängt nicht vom Ultrafiltrationskoeffizienten (KUF) ab.

Ultrafiltrazione con sangue "in vitro" (valori a ± 15%)
(Sangue bovino a 37°C, ematocrito = 32 %, Concentrazione proteica = 60 g/l)
L'ultrafiltrazione è controllata dal Sistema PRISMAFLEX ed è indipendente dal coefficiente di ultrafiltrazione (KUF).

-Ultrafiltratie met "in vitro"-bloed (waarden op ± 15%)
(Runderbloed 37°C, Hematocrietwaarde = 32 %, Eiwitgehalte = 60 g/l)
Ultrafiltratie wordt gecontroleerd door het PRISMAFLEX Systeem en is onafhankelijk van de ultrafiltratie coefficient.

HOSPAL
Renal Intensive Care

SACIPrint - 04/04 - Tel. 04 72 45 27 27

CE 0086

PRISMA

HF1000 SET
HF1000 PRE SET

Instructions for use
Notice d'utilisation
Gebrauchsanweisung
Folleto de utilización
Istruzioni per l'uso
Gebruiksaanwijzing
Handhavandeinstruktioner

HOSPAL
Renal Intensive Care

DEFINITION OF SYMBOLS USED ON LABELING OF PRODUCT

LOT	manufacturing batch number
STERILE EO	sterilized by ethylene oxide (EtO); followed by the sterilization date
	expiration date of the product
	product for single use only
	Read instructions before using the product.

DEFINITION DES SYMBOLES UTILISES SUR L'ETIQUETAGE DU PRODUIT

LOT	numéro de lot de fabrication
STERILE EO	stérilisé à l'oxyde d'éthylène (EtO); suivi de la date de stérilisation
	date de péremption du produit
	produit à usage unique
	Lire les instructions avant utilisation du produit.

DEFINITION DER AUF DEN PRODUKTETIKETTEN VERWENDETEN SYMBOLE

LOT	Nummer der Fertigungsserie
STERILE EO	Sterilisiert mit Äthylenoxyd (EtO), gefolgt vom Sterilisierungsdatum
	Verfallsdatum des Produktes
	Nur zum einmaligen Gebrauch
	Anweisungen vor Einsatz lesen.

DEFINICION DE LOS SIMBOLOS UTILIZADOS EN LA ETIQUETA DEL PRODUCTO

LOT	número de lote de fabricación
STERILE EO	esterilizado por con óxido de etileno (EtO) seguido del fecha de esterilización
	fecha de caducidad del producto
	un solo uso
	Leer las instrucciones antes de la utilización.

DEFINIZIONE DEI SIMBOLI UTILIZZATI SULLE ETICHETTE DEL PRODOTTO

LOT	numero del lotto di produzione
STERILE EO	sterilizzato con ossido di etilene oxide (EtO) ; segue la data di sterilizzazione
	data di scadenza del prodotto
	monouso
	Leggere le istruzioni prima dell'uso.

FÖRKLARING AV SYMBOLER

LOT	lot nr.
STERILE EO	steriliserats med etylenoxid (EtO): steriliseringsdatum
	sista giltighetsdag
	endast for engångsbruk
	Läs instruktionerna före användning.

BETEKENIS VAN DE SYMBOLEN

LOT	partijnummer van de leverancier
STERILE EO	gesteriliseerd met ethyleenoxide (EtO) : sterilisatiedatum
	geldigheidsdatum
	voor éénmalig gebruik
	Lees de instructies voor het gebruik.

This product and systems and devices incorporating this product are covered by one or several of the following patents : / Ce procuit et les éléments qui le constituent sont couverts par un ou plusieurs des brevets suivants : / Dieses Produkt sowie seine verschiedenen Elemente sind durch eines oder mehrere der folgenden Patente geschützt: / Este producto y los elementos que lo constituyen están cubiertos por una o varias de las siguientes patentes. / Il prodotto qui descritto e i sistemi e dispositivi che lo costituiscono sono coperti da uno o più dei seguenti brevetti: / Denna produkt och system och apparater som ingår i denna produkt innefattas av ett eller flera av följande patent. / Dit produkt en de systemen en apparaten waarvan dit produkt deeluitmaakt, vallen onder één of verschillende van de volgende patenten:
US Re 34 239, US 4 861 242, US 4 935 141, US 5 236 586, US 5 441 656, US 5 679 242 ; CA 1 284 598 ; GE 2206887 ; EP 0 305 787, EP 0 525 317, EP 0 611 227, EP 0 611 228 ; JP 1772297.
Other patents pending. / D'autres demandes de brevet ont été déposés. / Weitere Patente wurden angemeldet. / Otras peticiones de patentes han sido depositadas. / Altri brevetti sono attualmente in fase di approvazione. / Andra sökta patent. / Andere octrooiaanvragen zijn

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ENGLISH

This product is distributed by :

- **AUSTRALIA** : GAMBRO Pty Ltd, 3 Hudson Avenue, Baulkham Hills NSW 2154
- **BELGIUM**: HOSPAL RENAL INTENSIVE CARE, 11 Groenveldstraat, BE-3001 Heverlee
- **CANADA**: HOSPAL-GAMBRO Inc, 9157 Champ d'Eau, CDN St Léonard, Québec H1P 3M3
- **UNITED KINGDOM**: HOSPAL GAMBRO Ltd, Unit 1 Ermine Business Park, GB-Huntingdon, Cambridgeshire PE29 6XX
- **USA** : GAMBRO Renal Care Products, Inc, 10810 West Collins Ave, Lakewood CO 80215-4498

⚠ **Caution :** Federal law (USA) restricts this device to sale by or on the order of a physician.

DEFINITION OF EXPRESSIONS USED IN THIS MANUAL

In this document :

« **Warning** » is used to alert the user/operator **not to take** a certain action which, if taken, can cause a potential hazard and result in a serious adverse reaction, injury or death ;

« **Caution** » is used to alert the user/operator **to take** a certain action to protect against a potential hazard, which, if ignored, could have an adverse effect on the patient or on the device ;

« ***Note*** » is used as a reminder to the user/operator on normal treatment activity and on what is a suitable action in a particular situation.

PRODUCT DESCRIPTION

- The PRISMA Set is a disposable, extracorporeal circuit for use with the PRISMA System.
- The PRISMA HF1000 Set consists of a PAES hollow fiber hemofilter/dialyzer* and tubing lines.
- This filter is permanently connected to a blood access line (red-striped), a blood return line (blue-striped), a dialysate inlet line (green-striped) and an effluent outlet line (yellow-striped).
- Other lines of the set include a replacement solution line (purple-striped) and an anticoagulant line.
- A prime collection bag is connected to the end of the blood access line to collect priming solution ; a 5-liter effluent bag is provided to be connected to the end of the effluent outlet line to collect ultrafiltrate and/or used dialysate. Other sterile 5-liter bags and sterile, non pyrogenic spikes can be ordered separately.
- All line connectors are compatible with the ISO 594/1 & 2 international standards concerning conical fittings.
- Two types of PRISMA HF1000 Sets are available :
  - post dilution : provides for addition of replacement solution *after* blood leaves the filter.
  - pre dilution : provides for addition of replacement solution *before* blood enters the filter.
- The fluid pathways of the PRISMA Set are guaranteed sterile and non pyrogenic.
- The PRISMA HF1000 Set is sterilized by ethylene oxide (EtO). Deaeration is such that EtO residuals comply with the ones described in ISO 10993-7.
- Expiration date : Please refer to product label.
- The PRISMA Set is manufactured by HOSPAL Industrie, Meyzieu, France.

* In this document the hemofilter/dialyzer will be referred to as "filter".

INDICATIONS

The PRISMA Set is indicated for use only with the PRISMA Control Unit in providing continuous fluid management and renal replacement therapies. The system is intended for patients who have acute renal failure, fluid overload, or both.

This set is intended for use in the following veno-venous therapies : Slow Continuous Ultrafiltration (SCUF), Continuous Veno-venous Hemofiltration (CVVH), Continuous Veno-venous Hemodialysis (CVVHD), and Continuous Veno-venous Hemodiafiltration (CVVHDF).

All treatments administered via the PRISMA Set must be prescribed by a physician. The size, weight, state of uremia, cardiac status, and general physical condition of the patient must be carefully evaluated by the prescribing physician before each treatment.
The PRISMA HF1000 and HF1000 PRE sets should be restricted to patients with a body weight greater than 30kg (66lb).

CONTRAINDICATIONS

There are no known contraindications to continuous renal replacement therapies.

CAUTIONS AND WARNINGS

***Note** : Additional warnings and cautions pertaining to the PRISMA system are included in the PRISMA Control Unit Operator's Manual.*

⚠ Cautions

1. Carefully read these instructions for Use and the PRISMA Control Unit Operator's Manual before using this product.
2. Store the PRISMA Set in a dry place, between 0° C (32° F) and 30° C (86° F).
3. Some solvents and other chemicals, if used in contact with the filter, could damage the set. No chemical of this type should be used without permission of the manufacturer. The following are especially forbidden :
   a) halogenated aromatic and aliphatic solvents;
   b) ketonic solvents.
4. To prevent contamination, this PRISMA Set must be used as soon as its package and sterilization caps are removed.
5. Do not use this set if the package is damaged, if the sterilization caps are missing or loose, or if the blood lines are kinked.
6. Destroy this set after single use, using aseptic technique for potentially contaminated equipment. Do not resterilize.
7. Use aseptic techniques when handling all blood and fluid lines in the set.
8. Use only prescribed dialysate and replacement solutions with the PRISMA System. In the United States, dialysate should conform to AAMI Standard RD5. If a commercially available replacement solution is used, it must be labeled as intended for intravenous injection. These solutions must have a density similar to that of saline solutions (close to 1) in order to avoid errors in the volumes used for fluid exchange.
   The use of a nonsterile dialysate could induce risks of bacterial or pyrogenic contamination for the patient.
9. Connect the PRISMA Set to a patient via venous blood access and return devices. A double-lumen venous catheter is the recommended blood access device; however, two single-lumen venous catheters can also be used. There are 3 possible accesses for PRISMA System therapies : subclavian, jugular or femoral vein.
10. During priming and operation, observe closely for leakage at joints and connections within the set, especially for collection bags and dialysate/filtrate ports of the filter. Leakage can cause blood loss or air embolism. If leakage cannot be stopped by tightening the connections, replace the set.
11. Before connecting the blood return line to the patient, check for absence of air between the segment of line inserted in the air detector and the patient-end of the return line.
    If air is present in this part of the return line, connect the access line to the patient and start the blood pump while leaving the return line connected to the priming solution bag. Purge the air present in the end-part of the return line, then stop the blood pump. Disconnect the return line from the priming solution bag, and connect it to the patient.
    If the amount of air in the blood circuit is too large, reprime the circuit completely before patient connection.
12. After priming is complete, do not remove the pressure pods from the pressure sensor housings. If pods are removed, the set must be changed or the Diaphragm Reposition procedure performed (refer to PRISMA Control Unit Operator's Manual).
13. If the patient is not immediately connected to the PRISMA Set after priming is complete, flush the set with at least 500 ml priming solution (saline or alkaline solution (pH ≥ 7.3) with heparin added) prior to connecting the patient. This requires use of a new bag of priming solution.
14. Use a 20-gauge or smaller needle to obtain blood/fluid samples or remove trapped air from the PRISMA Set. Use of larger needles can cause holes in the sample sites, resulting in blood loss or air embolism.
15. The PRISMA Control Unit may not be able to detect disconnections of the set from the patient's catheter. Carefully observe the set and all operations while using the PRISMA System for a patient treatment.
16. Due to the nature of use of the PRISMA Set, (low blood flow rates, extended treatment time, and other special factors), the possibility for coagulation within the blood flowpath is substantially enhanced. Give careful attention to the possible medical hazards associated with coagulation of the blood flowpath and comply with the minimum blood flow rates specifications of each filter (see the "Filter Operating Specifications" section).
17. Filter performance specifications require a minimum blood flow rate, to avoid risk of hemoconcentration. (See "Filter Operating Specifications" section).
18. During use, closely monitor the patient's clotting parameters, especially when increasing the amount of anticoagulant delivered or after changing the anticoagulant syringe.

19. To assure proper anticoagulant flow control, use only 20-cc BD, Braun, Monoject (Sherwood Medical), or Terumo Luer-lock syringes. The use of other syringes can be a hazard for the patient. Particularly if there is no Luer-lock on the syringe, the seal between the syringe and the heparin line can no longer be guaranteed.
20. Always inspect the blood flowpath for signs of clotting before returning the blood in the set to the patient. If clotting is suspected, do not return the blood to the patient.
21. In case of temporary disconnection, the set must be replaced **whenever patient reconnection is not possible within at most a few minutes.**

    In case of poor blood return, the set must be replaced.

    In all cases, it is essential to reprime the set with fresh saline immediately before patient connection.
22. The PRISMA Set is not designed for a heater to be connected to the replacement solution line. A heater generates air bubbles which collect in the return line pressure pod. Therefore, it is recommended **not to use** a heater on the replacement solution line.

    However, in CVVH, it may be necessary to warm the patient because of hypothermia.
23. If a heater has been connected to the dialysate inlet line, the PRISMA Control Unit automatic priming sequence will not extend to the additional segment of line, which will have to be primed before connection to the PRISMA Set (see operating instructions supplied with this accessory).
24. Do not connect a blood heater to the return line downstream of the air bubble detector. The PRISMA System cannot detect air introduced in the line downstream of the air detector.
25. The blood return line (blue-striped) is equipped with a Luer-lock connection near the blue sample site.

    This connection joins the Prismatherm II Extension Line to the PRISMA Set when the Prismatherm II Blood Warmer is used. Refer to the Prismatherm II Extension Line Instructions For Use and strictly follow detailed instructions for set up of this line. Do not use this connection for any other purpose.

⚠ Warnings

1. The use of operating procedures other than those published by the manufacturer or the use of accessory devices not recommended by the manufacturer can result in patient injury or death.
2. Use only PRISMA Sets with the PRISMA Control Unit. The use of non-PRISMA Sets can result in patient injury or death.
3. Should acute allergic reactions (first-use syndrome) occur in patients receiving treatment via the PRISMA Set, **immediately stop the treatment** and administer appropriate intervention. (See "Adverse reactions" section.)
4. Do not allow air to enter the blood compartment of the filter after priming is started. If a large amount of air enters, the set must be replaced.
5. Since drugs can pass through the membrane of the filter, the dosage of associated drug treatments must be adjusted for patients on continuous renal replacement therapy.
6. To assure adequate filter performance, it is recommended that the set be changed every 24 hours of use. However, the set must be changed after 3 days (72 hours) of use. Continued use beyond 72 hours could result in rupture of the pump segments, with patient injury or death.

SPECIFICATIONS

See Tables at end of document.

FILTER MATERIALS

PAES hollow fiber	: PolyArylEtherSulfone
Housing and headers	: Polycarbonate
Potting compound	: Polyurethane
Tubing material	: Plasticized polyvinyl chloride (PVC)
Cartridge plate and filter bracket	: Acrylonitrile-butadiene-styrene (ABS)

Note : *The following information is available from the manufacturer upon request :*

- *information about test methods used to obtain performance characteristics ;*
- *the number and range of particles in the effluent from the dialyzer prepared as recommended for clinical use ;*
- *the types and amounts of residue from the sterilization process.*

INSTRUCTIONS FOR USE

Note : *Use the set by following the detailed on-line instructions provided by the PRISMA Control Unit. Additional information is available in the PRISMA Control Unit Operator's Manual.*

Note : *a TMP > 40 kPa (300 mmHg) does not allow a higher ultrafiltration.*

Perform the following procedures when the appropriate instructions appear on the display of the PRISMA Control Unit.

Load Set

1. Remove the set from the tray. Holding filter vertically (so that the label is the right way up), carefully snap set cartridge into cartridge carrier (center of front panel).
2. Attach the 4 pressure pods to their proper pressure housings. Route appropriate lines through tubing guides, air bubble detector, return line clamp, and blood leak detector.
3. Connect the effluent bag securely to the effluent line (yellow-striped). Hang effluent bag on yellow scale hook.
4. Check that the prime collection bag is securely pre-connected to the access line (red-striped). Hang prime collection bag on left corner hook (bottom of front panel). See diagrams in the Prisma System Operator's Manual.

Prepare Solutions

1. Hang a 1-liter bag of priming solution (saline or alkaline solution (pH ≥ 7.3) with added 5000IU heparin/liter) on right corner hook (bottom of front panel).
2. Connect anticoagulant line to filled anticoagulant syringe. Install syringe in pump.
3. Hang replacement solution (CVVH, CVVHDF) on purple scale hook. Hang dialysate (CVVHD, CVVHDF) on green scale hook. (Bags of up to 5 liters can be placed on scale hooks.)

Note : *see Caution no. 8.*

Connect Lines to Solutions

⚠ **Caution :** The blood return line (blue-striped) is equipped with a Luer-lock connection near the blue sample site.

This connection joins the Prismatherm II Extension Line to the PRISMA Set when the Prismatherm II Blood Warmer is used. Refer to the Prismatherm II Extension Line Instructions For Use and strictly follow detailed instructions for set up of this line. Do not use this connection for any other purpose.

Using spike or Luer connector on applicable lines, connect :

- Return line (blue) to priming solution bag.
- Replacement solution line (purple) to replacement solution bag.
- Dialysate line (green) to dialysate bag.

Prime Set

Note : *see Cautions no. 10 through 13, cautions no. 23 and 24, and Warning no. 4.*

Priming includes multiple self-tests and takes approximately 8 minutes. After the cycle is complete :

1. Examine set carefully to be certain all connections are secure, all lines are unobstructed, and there are no leaks in the tubing.
2. Leave priming solution and prime collection bags attached until ready to connect patient.
3. Continue chosen treatment by following the instructions on the display of the PRISMA Control Unit.

The PRISMA Set must be carefully deaerated.

Anticoagulation Considerations

Note : *See Cautions no. 16 through 19 and Warning no. 6.*

Initiate anticoagulation of the blood flowpath, as prescribed by the physician. During use, monitor the patient's clotting parameters; adjust the anticoagulation settings on the PRISMA Control Unit, according to the physician's prescription. If prescribed, do not forget to infuse a loading dose of anticoagulant immediately after patient connection.

Anticoagulation plays an important part in extending filter life by retarding plugging and clotting.

Clinical experience* has demonstrated that, when standard heparin is used, a bolus of 5 to 10 U/kg and continuous infusion (pre-filter) of 3 to 12 U/kg/h provide adequate anticoagulation for all forms of continuous renal replacement therapy.

Change Set Procedure

To remove this set, load a new set and continue with present treatment :

Press "STOP" from the Status screen, then press "CHANGE SET" and follow the on-line instructions.

Note : *Operator can return blood to the patient prior to disconnecting, if desired (see Caution no. 20).*

* MEHTA R. L. Anticoagulation for continuous renal replacement therapies. In : RONCO C. & BELLOMO R. (eds). Critical Care Nephrology. Dordrecht : Kluwer Academic Publishers ; 1998. p. 1199-1211.

Temporary Disconnection Procedure

To temporarily disconnect the patient from the set :

Press "STOP" from the Status screen, then press "TEMP DISCON" and follow the on-line instructions.

Note : *Operator must return blood in the set to the patient and immediately reprime the set via on-line instructions. (see Cautions no. 20 and 21.)*

End Treatment Procedure

To end the present treatment and remove this set :

Press "STOP" from the Status screen, then press "END TREATMENT" and follow the on-line instructions.

Note : *Operator can return blood to the patient prior to disconnecting, if desired. (See Caution no. 20.)*

MANUAL TERMINATION

Manual termination may be necessary due to power loss or an alarm of the PRISMA Control Unit. The alarm screen tells the operator if a manual termination is required.

Note : *The following instructions are also found in "Troubleshooting" in the PRISMA Control Unit Operator's Manual.*

A. With Blood Return

Note : *See Caution no. 20.*

⚠ **Warning : The alarm system is inactivated. Visually check for air in blood return line until the patient is disconnected.**

1. Turn off power switch. Clamp access line (red) and disconnect from patient. Attach access line to a 1-liter bag of sterile saline. (Use spike connector if needed.) Unclamp access line.
2. Remove return line (blue) from return line clamp of the PRISMA Control Unit.
3. Manually turn blood pump counterclockwise until sufficient blood is returned to the patient.
4. Clamp return line (blue) and disconnect from patient. Clamp lines to all bags.
5. Press clip at left side of cartridge carrier. Tug on cartridge assembly while manually turning each pump counterclockwise.
6. When pump segments are free from pump raceways, remove set and discard as usual.

B. Without Blood Return

1. Turn off power switch. Clamp access line (red) and return line (blue) and disconnect from patient.
2. Clamp lines to all bags.
3. Follow Steps 5 and 6 above.

SPECIAL PROCEDURES IN CASE OF COMPLICATION

Filter Membrane Blood Leaks

Blood leaks through the filter membrane are automatically detected by the PRISMA Control Unit alarm system. A warning alarm is generated and blood loss is limited by immediate stoppage of all pumps.

To return blood to the patient, press STOP from the alarm screen, then press CHANGE SET from the Stop screen and follow the on-line instructions.

External Blood Leaks

Note : *See Cautions no. 14, 15 and 19.*

External blood leakage may not be immediately identified by monitoring equipment and could result in significant blood loss. Check the filter and all connections of the disposable tubings during treatment to minimize the risk of leakage. If an external blood leakage is observed, immediately stop the blood pump. Initiate corrective action by securing connections or replacing the Prisma Set.

If necessary, administer adequate replacement solution to the patient to compensate for blood loss.

Adverse reactions

Adverse reactions may occur due to the complex interaction between blood and the artificial surfaces of the entire extracorporeal circuit. These reactions may also be precipitated and/or exacerbated by other external factors involved with the individual patient's specific disease process and the treatment of renal insufficiency. Certain types of adverse reaction may occur due to operational factors associated with the treatment. Therefore, proper management of the fluid removal, electrolyte balance, anticoagulation and blood flow rate as well as monitoring of the overall treatment parameters are essential to avoid side-effects which may be associated with hemodialysis / hemofiltration therapies.

Hypersensitivity reactions have been observed during dialysis. Symptoms of a hypersensitivity reaction may be gastrointestinal, mucocutaneous, respiratory, cardiovascular or systemic in nature and range from very mild to severe. Such symptoms have been described as anaphylactic-like reactions within the first few minutes. Manifestations include nausea, malaise, weakness, a sensation of burning or heat throughout the body, profuse perspiration, respiratory distress and in some instances hypotension and cardiopulmonary arrest. Should a combination of such symptoms appear, particularly at the start of the treatment session, it is important to react immediately by discontinuing the session and administering appropriate treatment. Blood in the extracorporeal circuit must not be returned to the patient.

Extra care must be taken when treating patients who have exhibited possible hypersensitivity symptoms during previous treatments, or patients who have a history of being highly sensitive and allergic to a variety of substances. A physician must be consulted to evaluate the risk and prescribe the appropriate precautions if a possible sensitivity is suspected.

The following factors are considered essential to minimize the risk of a hypersensitivity reaction and other side-effects.

1. Strict adherence to the set-up, priming and rinsing procedures detailed in the manufacturer's Instructions for Use.
2. Setting and monitoring the treatment operating parameters according to the manufacturer's recommendations specified for each type of PRISMA Set and to the patient's needs and tolerance.
3. Strict adherence to all WARNINGS and CAUTIONS given by the manufacturer in the "Instructions for Use".

WARRANTY AND LIMITATION OF LIABILITY

a) The manufacturer warrants that the PRISMA Set has been manufactured in accordance with its specifications and in compliance with good manufacturing practices, other applicable industry standards and regulatory requirements.

It provided with the lot/serial number of the defective product, the manufacturer will, by replacement or credit, remedy manufacturing defects in the PRISMA Set becoming apparent before the expiration date.

b) The warranty under paragraph a) above is in lieu of, and to the exclusion of, any other warranty, whether written or oral, express or implied, statutory or otherwise, and there are no warranties of merchantability or other warranties, which extend beyond those described in paragraph a) above. The remedy set out above for manufacturing defects is the sole remedy available to any person due to defects in the PRISMA Set and the manufacturer shall not be liable for any consequential or incidental loss, damage, injury or expense arising directly or indirectly from the use of the PRISMA Set, whether as a result of any defect therein or otherwise.

c) The manufacturer shall not be liable for any misuse, improper handling, non-compliance with warnings and instructions, damage arising from events after the manufacturer's release of the PRISMA Set, failure or omission to inspect the PRISMA Set before use in order to ensure that the PRISMA Set is in proper condition, or any warranty given by independent distributors or dealers.

d) The manufacturer is HOSPAL Industrie, Meyzieu, France.

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FRANÇAIS

Ce produit est distribué par :

- **BELGIQUE :** HOSPAL RENAL INTENSIVE CARE, 11 Groenveldstraat, BE - 3001, Heverlee
- **CANADA :** HOSPAL-GAMBRO Inc, 9157 Champ d'Eau, CDN St Léonard, Québec H1P 3M3
- **FRANCE :** HOSPAL S.A, 61 Avenue Tony Garnier, 69007 Lyon
- **SUISSE :** GAMBRO HOSPAL SCHWEIZ AG, Sägereistrasse 24, CH - 8152 Glattbrugg

DEFINITION DES TERMES UTILISES DANS CE MANUEL

Dans ce document :

« **Avertissement** » est utilisé pour avertir l'opérateur **de ne pas faire** une action spécifique pouvant causer un risque potentiel qui, s'il est ignoré, peut provoquer une réaction indésirable, des lésions ou la mort ;

« **Attention** » est utilisé pour avertir l'opérateur **d'agir** spécifiquement pour protéger le patient contre un risque possible qui, s'il était ignoré, pourrait avoir un effet indésirable sur le patient ou sur le produit ;

« ***Note*** » est utilisé pour rappeler à l'opérateur les fonctions normales du traitement et la conduite à tenir dans une situation particulière.

DESCRIPTION DU PRODUIT

- Le Set PRISMA est un circuit extracorporel à usage unique destiné à être utilisé avec le moniteur PRISMA.
- Le Set PRISMA HF1000 est constitué d'un hémofiltre/dialyseur* à fibres creuses PAES et de lignes.
- Le filtre est en permanence connecté à une ligne d'entrée sang (liseré rouge), à une ligne de retour sang (liseré bleu), à une ligne dialysat (liseré vert) et à une ligne de liquide effluent (liseré jaune).
- Les autres lignes du Set se composent d'une ligne de solution de réinjection (liseré violet) et d'une ligne d'anticoagulant.
- Une poche est connectée à l'extrémité de la ligne d'entrée sang et sert à recueillir le liquide d'amorçage ; une poche de 5 litres est prévue pour être connectée à l'extrémité de la ligne de liquide effluent et sert à recueillir l'ultrafiltrat et/ou le dialysat usé. D'autres poches de 5 litres stériles et des perforateurs stériles et apyrogènes peuvent être fournis séparément.
- Tous les connecteurs des lignes sont compatibles avec les normes internationales ISO 594/1 & 2 concernant les raccords coniques.
- 2 types de Sets PRISMA HF1000 sont disponibles :
  - Set post dilution : permet l'ajout de solution de réinjection *après* le passage du sang dans le filtre.
  - Set pre dilution : permet l'ajout de solution de réinjection *avant* le passage du sang dans le filtre.
- Les compartiments sang et dialysat du Set PRISMA sont garantis stériles et apyrogènes.
- Le Set PRISMA HF1000 est stérilisé à l'oxyde d'éthylène (EtO). La désorption est conduite de façon que le taux d'EtO résiduel soit conforme à celui prescrit dans la norme ISO 10993-7.
- Date de péremption : se référer à l'étiquette unitaire.
- Le Set PRISMA est fabriqué par HOSPAL Industrie, Meyzieu, France.

* Dans ce document, le mot "filtre" est utilisé pour désigner l'hémofiltre/dialyseur.

INDICATIONS

Le Set Prisma doit être utilisé uniquement avec le moniteur Prisma pour la mise en oeuvre de techniques continues d'assistance rénale et de maîtrise des fluides. Le système est indiqué pour les patients atteints d'insuffisance rénale aiguë, de surchage hydrique, ou des deux.

Ce Set permet de réaliser les traitements veino-veineux suivants : Ultrafiltration continue lente (SCUF), Hémofiltration veino-veineuse continue (CVVH), Hémodialyse veino-veineuse continue (CVVHD), Hémodiafiltration veino-veineuse continue (CVVHDF

Tous les traitements administrés à l'aide du Set PRISMA doivent être prescrits par un médecin. Avant chaque traitement le médecin prescripteur devra évaluer la taille, le poids, l'état urémique et cardiaque et la condition physique générale du patient.

Les Sets PRISMA HF1000 et HF1000 PRE doivent être utilisés sur des patients de poids supérieur à 30 kg.

CONTRE-INDICATIONS

Il n'y a pas de contre-indications connues aux techniques continues d'assistance rénale.

AVERTISSEMENTS ET PRECAUTIONS

***Note** : des avertissements et précautions supplémentaires relatifs au système PRISMA figurent dans le Manuel d'Utilisation du Moniteur PRISMA.*

⚠ **Attention**

1. Avant d'utiliser le produit, lire attentivement la présente Notice d'Utilisation, ainsi que le Manuel d'Utilisation du Moniteur PRISMA.
2. Le Set PRISMA doit être stocké dans un endroit sec, entre 0°C et 30°C.
3. Certains solvants ou autres produits chimiques au contact du Set PRISMA peuvent l'endommager. Pour toute utilisation de produits de cette nature l'accord d'HOSPAL est indispensable. Sont notamment à prohiber :
   a) les solvants aromatiques et aliphatiques halogénés ;
   b) les solvants cétoniques.
4. Afin d'éviter toute contamination, le Set PRISMA doit être utilisé immédiatement après avoir été extrait de son emballage et après que l'on ait ôté ses protecteurs de stérilité.
5. Ne pas utiliser ce Set si l'emballage unitaire est endommagé, si les protecteurs de stérilité sont manquants ou mal fixés, ou si les lignes à sang sont plicaturées.
6. Ce Set est à usage unique et doit être détruit après usage, en utilisant des techniques aseptiques pour le matériel potentiellement contaminé. Il ne doit pas être restérilisé.
7. Utiliser une technique aseptique lors de la manipulation des lignes du Set.
8. Utiliser uniquement avec le système PRISMA la solution de réinjection et le liquide de dialyse stériles et isotoniques prescrits. En cas d'utilisation d'une solution d'épuration du commerce, elle doit porter des indications précisant qu'elle est destinée à une utilisation en injection intraveineuse. Ces solutions devront être de densité voisine des solutions salines (proches de 1) afin d'éviter les erreurs de volumes mis en oeuvre pour les échanges.
   L'utilisation d'un dialysat non stérile exposerait le patient à des risques de contamination bactérienne ou pyrogénique.
9. Connecter le Set PRISMA au patient en utilisant des dispositifs d'accès et de retour sang veineux. Nous recommandons d'utiliser un cathéter veineux à double lumière ou deux cathéters veineux à simple lumière. Lors des traitements réalisés avec le système PRISMA, il est possible d'utiliser trois accès : la veine sous-clavière, jugulaire ou fémorale.
10. Lors de l'amorçage et de l'utilisation de l'appareil, vérifier soigneusement l'absence de fuites au niveau des points d'assemblage et des connexions du Set, en particulier au niveau des poches et des embouts dialysat/filtrat du filtre. Les fuites risquent de causer des pertes de sang ou des embolies gazeuses. Si la fuite persiste après le resserrage des connexions, remplacer le Set.
11. Avant de connecter la ligne de retour sang au patient, vérifier l'absence d'air entre le segment de ligne inséré dans le détecteur d'air et l'extrémité patient de la ligne de retour sang.
    En cas de présence d'air dans cette partie de la ligne de retour, connecter la ligne d'entrée sang au patient, mettre en route la pompe à sang en laissant la ligne de retour connectée à la poche de solution saline. Purger l'air présent dans l'extrémité de la ligne de retour puis arrêter la pompe à sang. Déconnecter la ligne de retour de la poche de solution saline et la connecter au patient.
    En cas de présence d'une grande quantité d'air dans le circuit sang, refaire un amorçage complet du circuit avant de brancher le patient.
12. A la fin de l'amorçage, ne pas retirer les prises de pression des logements des capteurs de pression. En cas de retrait des prises, il est nécessaire de procéder au changement du Set ou au repositionnement du diaphragme de la prise de pression (voir le Manuel d'Utilisation du Moniteur PRISMA).
13. Si le patient ne peut être connecté immédiatement au Set PRISMA après que l'amorçage du filtre ait été effectué, il est recommandé de remplir/rincer à nouveau le Set avec au moins 500 ml de solution saline ou alcaline (pH ≥ 7.3) héparinè, immédiatement avant le branchement du patient. Pour cela, il est nécessaire d'utiliser une nouvelle poche de solution.
14. Utiliser une aiguille 20 G (ou d'un diamètre plus petit) pour prélever des échantillons de sang et/ou de fluide du Set PRISMA ou pour ôter des bulles d'air. L'utilisation d'aiguilles de plus gros calibre peut compromettre l'étanchéité du Set aux sites de prélèvement et provoquer ainsi des pertes de sang ou des embolies gazeuses.
15. Il est possible que le moniteur PRISMA ne détecte pas les déconnexions survenant entre le Set et le cathéter du patient. Surveiller attentivement le Set et le déroulement du traitement lors de l'utilisation du système PRISMA.
16. En raison du type d'utilisation de ce produit (débits sang faibles, longue durée de traitement et autres facteurs particuliers), les risques de coagulation du circuit sang sont augmentés. Les risques médicaux associés à la coagulation

totale ou partielle du circuit sang existent donc. Il est nécessaire d'accorder une attention toute particulière aux instructions concernant l'anticoagulation de ce produit et de respecter les débits sang minimum spécifiques de chaque type de filtre (voir tableau « Caractéristiques de Fonctionnement du Filtre »).

17. Les spécifications de performances du filtre imposent d'utiliser un débit sang minimum, afin d'éviter tout risque d'hémoconcentration (voir tableau « Caractéristiques de Fonctionnement du Filtre »).

18. Pendant l'utilisation, surveiller attentivement les paramètres d'anticoagulation du patient, en particulier si la dose d'anticoagulant administré est augmentée ou après avoir changé la seringue de l'anticoagulant.

19. Pour obtenir un débit d'anticoagulant adéquat, n'utiliser que des seringues Luer-lock de 20 cc, de marque BD, Braun, Monoject (Sherwood Medical) ou Terumo. L'utilisation de seringues d'un autre type peut compromettre la sécurité du patient. En particulier, en cas d'absence de Luer-lock sur la seringue, l'étanchéité de la connexion entre la seringue et la ligne à héparine n'est plus garantie.

20. Toujours vérifier que le circuit sang n'est pas coagulé avant de procéder à la restitution. Si le circuit est coagulé, ne pas réinfuser le sang au patient.

21. Lors d'un débranchement temporaire, **si le patient ne peut être branché à nouveau dans les minutes qui suivent,** il est impératif de remplacer le Set.
Si la restitution ou l'élimination du sang n'est pas de très bonne qualité, le Set devra être remplacé.
Dans tous les cas, il est impératif d'amorcer à nouveau le Set avec du sérum physiologique frais immédiatement avant le branchement du patient.

22. Le Set PRISMA n'est pas configuré pour accepter le branchement d'un réchauffeur sur la ligne de solution de réinjection. Le branchement d'un réchauffeur sur cette ligne engendrerait une accumulation de bulles d'air dans la ligne de retour sang au niveau de la prise de pression.
Il est donc **déconseillé** d'utiliser un réchauffeur sur la ligne de solution de réinjection.
Néanmoins, en traitement CVVH, pour résoudre les problèmes d'hypothermie, il pourra être nécessaire de réchauffer le patient.

23. En cas d'utilisation d'un réchauffeur sur le circuit entrée dialysat, la procédure d'amorçage automatique du moniteur PRISMA n'intègre pas l'amorçage du segment de ligne supplémentaire. Il sera donc nécessaire de purger ce segment de ligne associé au réchauffeur avant de le connecter au Set PRISMA (pour cela suivre les instructions d'utilisation fournies avec cet accessoire).

24. Ne pas brancher un réchauffeur de sang sur la ligne de retour sang en aval du détecteur de bulles d'air car le système PRISMA ne peut pas détecter l'air introduit dans la ligne en aval du détecteur d'air.

25. La ligne de retour sang (liseré bleu) est équipée d'un connecteur luer-lock situé près du site de prélèvement.
Ce connecteur permet de relier la ligne d'extension Prismatherm II au Set PRISMA lors de l'utilisation du réchauffeur de sang Prismatherm II. Se référer à la Notice d'utilisation de la ligne d'extension Prismatherm II et suivre scrupuleusement les instructions détaillées lors de l'installation de cette ligne. Ne pas utiliser ce connecteur à d'autres fins.

⚠ Avertissements

1. Toute procédure d'utilisation autre que celles publiées par le fabricant, ainsi que l'utilisation d'accessoires non recommandés par ce dernier, risquent de compromettre la santé du patient ou de mettre sa vie en danger.
2. Utiliser exclusivement les Sets PRISMA avec le moniteur PRISMA. L'utilisation de Sets d'autre provenance risque de compromettre la santé du patient ou de mettre sa vie en danger.
3. Au cas où des réactions allergiques aiguës (syndrome de première utilisation) apparaitraient pendant les toutes premières minutes du traitement, **il faut réagir immédiatement en arrêtant la séance** et en administrant un traitement approprié. (Voir le chapitre "Réactions indésirables".)
4. Il est impératif de ne pas laisser entrer d'air après avoir initié l'amorçage. En cas d'entrée d'air importante, remplacer le Set.
5. Du fait d'un transfert possible des drogues ou médicaments à travers la membrane du filtre, le traitement des patients par épuration extra rénale continue implique une adaptation de la posologie des traitements médicamenteux associés.
6. Pour s'assurer d'une bonne performance du filtre, il est recommandé de remplacer le Set après 24 heures d'utilisation ; toutefois, ce changement devient obligatoire après 3 jours (72 heures) d'utilisation. La poursuite de l'utilisation au delà de 72h peut conduire à la rupture des corps de pompe, compromettant ainsi la santé du patient ou mettant sa vie en danger.

SPECIFICATIONS

Voir tableaux à la fin du document.

MATERIAUX DU FILTRE

Fibre creuse PAES	PolyArylEtherSulfone
Coquille et couvercles	Polycarbonate
Colle	Polyuréthane
Matériau des lignes	PVC (chlorure de polyvinyle plastifié
Cassette et support de filtre	ABS (acrylonitrile-butadiène-styrène

Note : *Les informations suivantes sont disponibles sur demande auprès d'HOSPAL.*

- *les méthodes d'essais utilisées pour obtenir les caractéristiques de performances*
- *le nombre et la taille des particules obtenues dans l'extrait de l'hémodialyseur préparé selon les recommandations pour usage clinique ;*
- *le type et la quantité de résidus du procédé de stérilisation.*

PROCEDURE D'UTILISATION

Note : *l'utilisation du Set doit être conforme aux instructions détaillées affichées sur l'écran du moniteur PRISMA à chacune des phases. Des informations complémentaires sont disponibles dans le Manuel d'Utilisation du Moniteur PRISMA.*

Note : *Une PTM > 40 kPa (300 mmHg) ne permet pas d'obtenir une ultrafiltration plus élevée.*

Exécuter les procédures ci-dessous lorsque les instructions appropriées apparaissent sur l'écran du moniteur PRISMA.

Mise en place du Set

1. Retirer le Set de son étui. Tout en maintenant le filtre à la verticale (de façon que l'étiquette soit lisible), engager avec précaution la cassette du Set sur son support (situé au centre du panneau avant).
2. Connecter les quatre prises de pression dans les logements appropriés. Acheminer les lignes dans leurs guides, à travers le détecteur d'air, le clamp de la ligne de retour et le détecteur de fuite sang.
3. Connecter soigneusement le sac de recueil du liquide effluent à la ligne de liquide effluent (liseré jaune). Accrocher le sac de recueil du liquide effluent au crochet du peson (jaune).
4. Vérifier la pré-connexion du sac de recueil du liquide d'amorçage à la ligne d'entrée (liseré rouge). Accrocher le sac de recueil du liquide d'amorçage au crochet du coin gauche (au bas du panneau avant). Voir figures dans le Manuel d'Utilisation du Moniteur PRISMA.

Préparation des solutions

1. Suspendre une poche d'un litre de liquide d'amorçage (solution saline ou alcaline (pH ≥ 7.3) stérile hépariné) (dose d'héparine : 5000 UI/l) au crochet du coin droit (au bas du panneau avant).
2. Connecter la ligne d'anticoagulant à la seringue remplie d'anticoagulant. Installer la seringue dans le pousse-seringue.
3. Suspendre la poche de solution de réinjection (CVVH ou CVVHDF) au crochet du peson violet. Suspendre la poche de dialysat (CVVHD ou CVVHDF) au crochet du peson vert. (Les crochets de pesons acceptent les poches d'une capacité maximale de 5 litres.)

Note : *voir Attention n° 6.*

Connexion des lignes aux solutions

⚠ **Attention :** La ligne de retour sang (liseré bleu) est équipée d'un connecteur luer-lock situé près du site de prélèvement.

Ce connecteur permet de relier la ligne d'extension Prismatherm II au Set PRISMA lors de l'utilisation du réchauffeur de sang Prismatherm II. Se référer à la Notice d'utilisation de la ligne d'extension Prismatherm II et suivre scrupuleusement les instructions détaillées lors de l'installation de cette ligne. Ne pas utiliser ce connecteur à d'autres fins.

Effectuer les connexions suivantes, en utilisant soit le connecteur perforateur soit le connecteur Luer-lock :

- Ligne de retour (liseré bleu) à la poche de liquide d'amorçage
- Ligne de solution de réinjection (liseré violet) à la poche de solution de réinjection.
- Ligne de dialysat (liseré vert) à la poche de dialysat

Amorçage du Set

Note : *voir Attention n° 10 à 13, Attention n° 23 et 24, et Avertissement n° 4.*

La procédure d'amorçage comporte une série d'auto-tests et dure environ 8 minutes. Une fois le cycle d'amorçage terminé, procéder comme suit :

1. Inspecter attentivement le Set pour vérifier l'intégrité de toutes les connexions, et s'assurer que les lignes ne sont pas obstruées et qu'elles ne fuient pas.
2. Ne déconnecter la poche de solution saline / alcaline et le sac de recueil du liquide d'amorçage que lorsque le patient est prêt à être connecté.
3. Reprendre le traitement choisi, conformément aux instructions affichées sur l'écran du moniteur PRISMA.

Le Set PRISMA doit être bien dégazé.

Anticoagulation

Note : *voir Attention n° 16 à 19 et Avertissement n° 6.*

La procédure d'anticoagulation du patient doit être conforme à la prescription du médecin. Il est nécessaire de contrôler périodiquement les paramètres de la coagulation du patient. Procéder aux réglages de l'anticoagulation sur le moniteur PRISMA, selon la prescription du médecin. Si cela est prescrit, ne pas oublier d'injecter un bolus d'anticoagulant, immédiatement après avoir branché le patient.

L'anticoagulation associée au débit sanguin de la circulation extracorporelle a un effet important sur la durée de vie du filtre (colmatage et coagulation progressifs).

L'expérience clinique* a montré que, pour l'héparine standard, un bolus de 5 à 10 UI/kg et une dose de maintien (pré-filtre) de 3 à 12 UI/kg procurent une anticoagulation adéquate pour toutes les modalités d'épuration continue.

Procédure de changement du Set

Pour retirer le Set, charger un nouveau Set et continuer le traitement en cours, procéder comme suit :

Appuyer sur la touche-programme "ARRET" de l'écran "SITUATION", puis sur la touche-programme "CHANGER SET" et suivre les instructions affichées.

Note : *l'opérateur peut procéder le cas échéant à la restitution du sang au patient avant le débranchement de ce dernier (voir Attention n° 20).*

Procédure de débranchement temporaire

Pour débrancher le Set temporairement, procéder comme suit :

Appuyer sur la touche-programme "ARRET" de l'écran "SITUATION", puis sur la touche-programme "DEBRANCH. TEMPORAIRE" et suivre les instructions affichées.

Note : *l'opérateur doit procéder à la restitution du sang présent dans le circuit au patient, puis réamorcer immédiatement le Set, conformément aux instructions affichées (voir Attention n° 20 et 21).*

Procédure pour terminer le traitement

Pour terminer le traitement en cours et retirer le Set, procéder comme suit :

Appuyer sur la touche-programme "ARRET" de l'écran "SITUATION", puis sur la touche-programme "TERMINER TRAITEMENT" et suivre les instructions affichées.

Note : *l'opérateur peut procéder le cas échéant à la restitution du sang au patient avant le débranchement de ce dernier (voir Attention n° 20).*

ARRET MANUEL DU TRAITEMENT

L'arrêt manuel du traitement peut s'avérer nécessaire suite à une panne de courant ou à une alarme déclenchée par le moniteur PRISMA. L'écran d'alarme avertit l'opérateur de la nécessité de procéder à un arrêt manuel du traitement.

Note : *les instructions ci-dessous se trouvent également dans le chapitre "Dépannage" du Manuel d'Utilisation du moniteur PRISMA.*

A. Avec restitution du sang au patient

Note : *voir Attention n° 20.*

⚠ **Attention: Le système d'alarme est inactivé. S'assurer visuellement de l'absence d'air dans la ligne de retour sang jusqu'à ce que le patient soit débranché.**

1. Mettre l'interrupteur I/O en position hors tension. Clamper la ligne d'entrée (liseré rouge) et la déconnecter du patient. Connecter la ligne d'entrée à une poche d'un litre de sérum physiologique stérile (au besoin, utiliser un connecteur perforateur). Déclamper la ligne d'entrée.
2. Retirer la ligne de retour (liseré bleu) du clamp de la ligne de retour du moniteur PRISMA.
3. Faire tourner la pompe à sang manuellement dans le sens contraire des aiguilles d'une montre, jusqu'à ce qu'un volume suffisant de sang ait été restitué au patient.
4. Clamper la ligne de retour (liseré bleu) et la déconnecter du patient. Clamper les lignes de toutes les poches.
5. Appuyer sur le clip situé du côté gauche du support de cassette. Tirer sur l'ensemble "cassette" tout en faisant tourner chaque pompe manuellement dans le sens contraire des aiguilles d'une montre.
6. Une fois les corps de pompe dégagés des gorges des pompes, retirer le Set et le jeter en suivant les procédures en usage dans l'hôpital.

B. Sans restitution du sang au patient

1. Mettre l'interrupteur I/O en position hors tension. Clamper la ligne d'entrée (liseré rouge) et la ligne de retour (liseré bleu) et les déconnecter du patient.
2. Clamper les lignes de toutes les poches.
3. Suivre les points 5 et 6 ci-dessus.

PROCEDURES SPECIALES EN CAS DE COMPLICATIONS

Fuites sang internes

Les fuites sang à travers la membrane sont automatiquement détectées par le système d'alarme du moniteur PRISMA. Une alarme se déclenche et la fuite sang est immédiatement limitée par l'arrêt de toutes les pompes.

Pour restituer du sang au patient, appuyer sur la touche-programme "ARRET" de l'écran d'alarme, puis sur la touche-programme "CHANGER SET" de l'écran "ARRET" et suivre les instructions affichées.

Fuites sang externes

Note : *voir Attention n° 14, 15 et 19.*

Celle-ci peut ne pas être immédiatement détectée par le moniteur PRISMA et conduire à une perte de sang importante. Pour minimiser le risque de fuite, vérifier le filtre et toutes les connexions du circuit pendant le traitement. Si une fuite se manifeste, arrêter immédiatement la pompe à sang. Commencer à corriger la situation en s'assurant que toutes les connexions sont correctes ou en remplaçant le Set.

Si nécessaire, administrer au patient une solution de remplacement adéquate pour compenser la perte de sang.

Réactions indésirables

L'interaction complexe entre le sang et les surfaces artificielles du circuit extracorporel peut être à l'origine de réactions indésirables. Celles-ci peuvent également être déclenchées et/ou exacerbées par d'autres facteurs externes liés au processus pathologique d'un patient et au traitement de l'insuffisance rénale. Certains types de réactions indésirables peuvent être causés par des facteurs spécifiques associés au traitement. Une bonne maîtrise de l'élimination du liquide, de l'équilibre électrolytique, de l'anticoagulation, du débit sang, ainsi qu'une surveillance rigoureuse de tous les paramètres du traitement, permettront d'éviter les effets secondaires pouvant être associés aux thérapies d'hémodialyse / hémofiltration.

Des réactions d'hypersensibilité ont été observées durant la dialyse. Leurs symptômes peuvent être de nature gastro-intestinale, cutanéo-muqueuse, respiratoire, cardio-vasculaire ou systémique, et leur intensité peut être légère à sévère. De tels symptômes ont été décrits comme des réactions de type anaphylactique au cours des premières minutes: nausées, malaise, faiblesse, sensation de brûlure ou de chaleur envahissant tout le corps, transpiration excessive, détresse respiratoire et, dans certains cas, hypotension et arrêt cardio-respiratoire. Si plusieurs de ces symptômes sont observés, en particulier au début du traitement, réagir immédiatement en interrompant la dialyse et en administrant un traitement approprié au patient. Le sang du circuit extracorporel ne doit pas être réinjecté au patient.

Une attention particulière est nécessaire lors du traitement des patients ayant présenté des éventuels symptômes d'hypersensibilité au cours des traitements précédents, ou les patients présentant des antécédents de haute sensibilité ou d'allergie à diverses substances. Si une sensibilité du patient est suspectée, le risque doit être évalué par un médecin, qui établira les précautions spécifiques devant être prises.

Les facteurs suivants sont considérés comme essentiels pour minimiser le risque de réaction d'hypersensibilité ou autre effet secondaire.

1. Respect minutieux des procédures de mise en place, d'amorçage et de rinçage décrites dans la "Notice d'utilisation" fourni par le fabricant.
2. Définition des paramètres de traitement en fonction des recommandations fournies par le fabricant pour chaque type de Set PRISMA, ainsi que des besoins et de la tolérance du patient, et surveillance de ces paramètres.
3. Respect de toutes les précautions (AVERTISSEMENT et ATTENTION) fournies par le fabricant dans la "Notice d'utilisation".

GARANTIES ET LIMITES DE RESPONSABILITE

a) Le fabricant garantit que le Set PRISMA a été fabriqué conformément aux spécifications techniques, aux bonnes pratiques de fabrication (GMP -Good Manufacturing Practices) et autres normes industrielles ainsi qu'aux règles en vigueur.

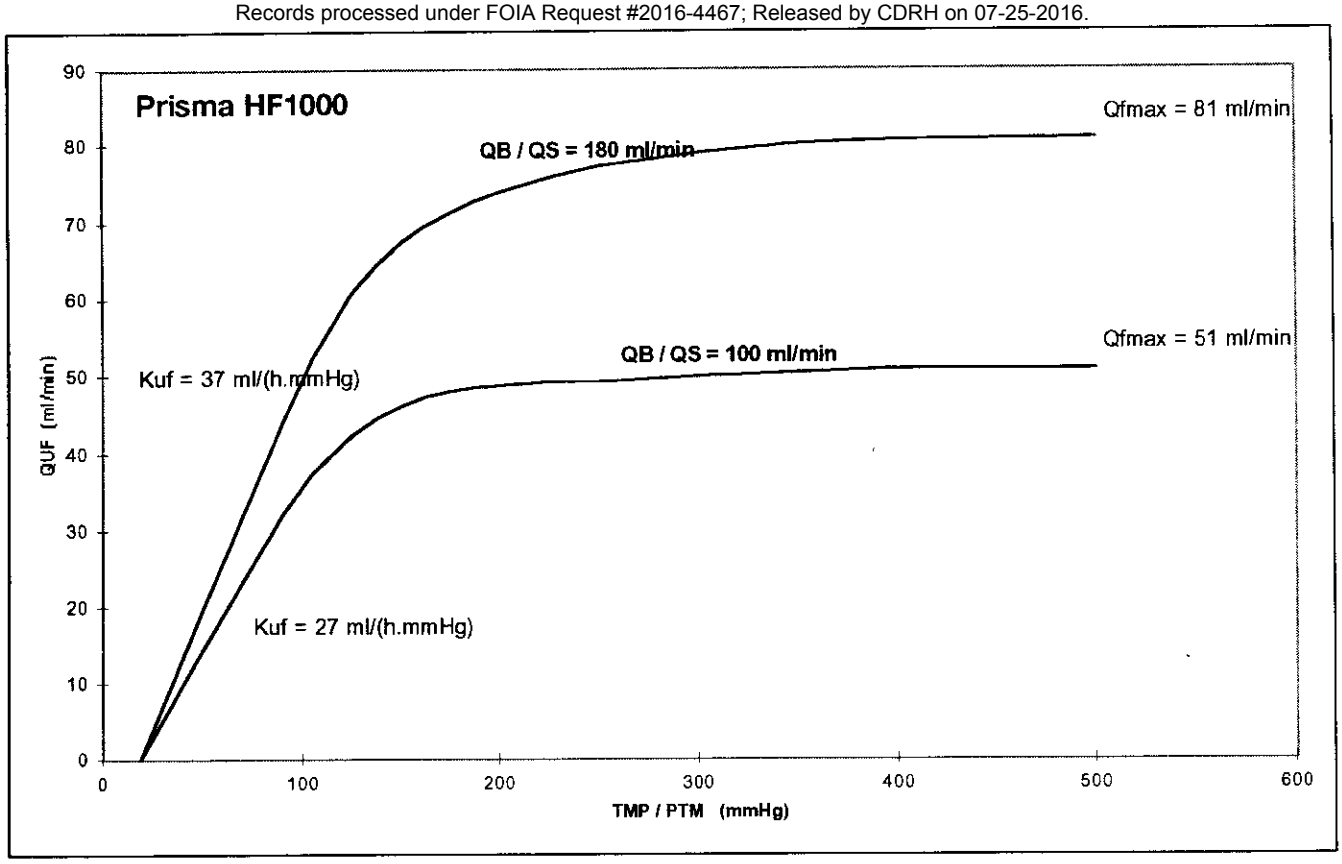
Sous réserve de notification du numéro de lot du produit défectueux, le fabricant s'engage à remplacer ou rembourser tout Set PRISMA présentant des vices avant la date de péremption.

b) La garantie du paragraphe a) ci-dessus s'applique en lieu et place de toute autre garantie, écrite ou orale, expresse ou implicite, statutaire ou autre, et aucune garantie, commerciale ou autre, différente de celle spécifiée au paragraphe a) ne saurait être prise en compte. Le seul recours légal en présence de vices de forme est la garantie prévue par le paragraphe a) ci-dessus. Cette garantie n'engage pas le fabricant en cas de perte, dommage, blessure ou dépenses directement ou indirectement liés à l'utilisation du Set PRISMA.

c) Le fabricant est dégagé de toute responsabilité en cas de mauvaise utilisation ou mauvaise manipulation, de non-respect des avertissements et des instructions, de dommages survenant après la mise en vente du Set PRISMA, en cas d'oubli de contrôle du Set PRISMA avant utilisation pour s'assurer que le Set PRISMA est en état de fonctionner, ou pour toute autre garantie donnée par les distributeurs ou négociants indépendants.

d) Le fabricant est HOSPAL Industrie, Meyzieu, France.

* MEHTA R.L., Anticoagulation for continuous renal replacement therapies. In: RONCO C. & BELLOMO R. (eds.), Critical Care Nephrology. Dordrecht: Kluwer Academic Publishers, 1998, p.1199-1211.



"In vitro" ultrafiltration with blood (values ± 15%)
(Bovine blood at 37°C, Hct 32 %, Protein concentration 60 g/l)
Ultrafiltration is controlled by the PRISMA System and is independent of the ultrafiltration coefficicent (KUF)

Ultrafiltration au sang "in vitro" (valeurs à ± 15%)
(Sang de bœuf à 37°C, Hématocrite = 32 %, Concentration protéique = 60 g/l)
L'ultrafiltration est maîtrisée par le système PRISMA et est indépendante du coefficient d'ultrafiltration (KUF)

Ultrafiltration mit Blut "in vitro" (Werte bei ± 15 %)
(Rinderblut bei 37°C, Hkt 32 %, Protein-Konzentration 60 g/l)

Die Ultrafiltration wird von der PRISMA Maschine auf dem richtingen Wert gehalten und hängt nicht vom Ultrafitrationskoeffizienten (KUF) ab.

Ultrafiltración con sangre "in vitro" (valores a ± 15%)
(Sangre bovina a 37°C, Hematocrito = 32 %, Concentración protéica = 60 g/l)
La ultrafiltración controlada por el sistema PRISMA, es independiente del coeficiente de ultrafiltración (KUF)

Ultrafiltrazione con sangue "in vitro" (valori a ± 15%)
(Sangue bovino a 37°C, ematocrito = 32 %, Concentrazione proteica = 60 g/l)
L'ultrafiltrazione è controllata dal Sistema PRISMA ed è indipendente dal coefficiente di ultrafiltrazione (KUF)

"In vitro" ultrafiltration med blod (värden ± 15%)
(Bovint blod vid 37°C, Hct 32 %, Proteinkoncentration 60 g/l)
Ultrafiltrationen kontrolleras av PRISMA systemet och är oberoende av koefficienten för ultrafiltration (KUF)

Ultrafiltratie met "In vitro"-bloed (waarden op ± 15%)
(Runderbloed 37°C, Hematocrietwaarde = 32 %, Eiwitgehalte = 60 g/l)
Ultrafiltratie wordt gecontroleerd door het PRISMA Systeem en is onafhankelijk van de ultrafiltratie coefficiënt.

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FILTER DATA	CARACTERISTIQUES DU FILTRE	FILTER-DATEN	CARACTERISTICAS DEL FILTRO
NOMINAL PHYSICAL CHARACTERISTICS Effective surface area Fiber internal diameter Fiber wall thickness	**CARACTERISTIQUES PHYSIQUES** Surface efficace Ø interne de la fibre Epaisseur de paroi de la fibre	**PHYSIKALISCHE EIGENSCHAFTEN** Effektive Oberfläche Innendurchmesser Wandstärke	**CARACTERISTICAS FISICAS** Superficie efectiva Ø interno de la fibra Espesor de la pared de la fibra
IN VITRO PERFORMANCES ≠ **Blood priming volume**	**PERFORMANCES IN VITRO ≠** **Volume de remplissage sang**	**IN VITRO LEISTUNGEN ≠** **Blutfüllvolumen**	**RENDIMIENTOS IN VITRO ≠** **Volumen de cebado sanguíneo**
Blood pressure drop (post dilution) (bovine blood, Htc****32%, Cp***** 60 g/l, 37°C) QB** = 100 ml/min, QUF*** = 1 L/h QB** = 180 ml/min, QUF*** = 2 L/h QB** = 180 ml/min, QUF*** = 4 L/h	**Perte de charge sang (post dilution)** (sang de bœuf, Htc****32%, Cp***** 60 g/l, 37°C) QS** = 100 ml/min, QUF*** = 1 L/h QS** = 180 ml/min, QUF*** = 2 L/h QS** = 180 ml/min, QUF*** = 4 L/h	**Blut druckabfall (Postdilution)** (Rinderblut, Hkt****32%, Pt***** 60 g/l, 37°C) QB** = 100 ml/min, QUF*** = 1 L/h QB** = 180 ml/min, QUF*** = 2 L/h QB** = 180 ml/min, QUF*** = 4 L/h	**Caídas de presión sangre (post-dilución)** (sangre bovina, Htc****32%, Cp***** 60 g/l, 37°C) QS** = 100 ml/min, QUF*** = 1 L/h QS** = 180 ml/min, QUF*** = 2 L/h QS** = 180 ml/min, QUF*** = 4 L/h
Sieving coefficient (bovine plasma, Cp***** 60 g/l, 37° C) QB** = 100 ml/min, QUF*** = 20 ml/min - Urea - Creatinine - Vitamin B12 - Inulin - Myoglobin - Albumin	**Transmittance** (plasma de bœuf, Cp***** 60 g/l, 37° C) QS** = 100 ml/min, QUF*** = 20 ml/min - Urée - Créatinine - Vitamine B12 - Inuline - Myoglobine - Albumine	**Siebkoeffizient** (Rinderplasma, Pt***** 60 g/l, 37° C) QB** = 100 ml/min, QUF*** = 20 ml/min - Harnstoff - Kreatinin - Vitamin B12 - Inulin - Myoglobin - Albumin	**Transmitancia** (plasma bovino, Cp***** 60 g/l, 37° C) QS** = 100 ml/min, QUF*** = 20 ml/min - Urea - Creatinina - Vitamina B12 - Inulina - Mioglobina - Albúmina

≠ Typical mean values obtained from laboratory testing of post-sterilization sample lots. Results may vary depending on patient and clinical conditions. / Valeurs moyennes caractéristiques mesurées au laboratoire sur un échantillonnage de lots stérilisés. Les résultats sont susceptibles de varier en fonction du patient et de son état clinique. / Typische Mittelwerte, die an strilen Produkten im Labor ermittelt wurden. Die angegebenen Werte können abhängig vom Patienten und den klinischen Bedingungen schwanken.
Valores medios característicos medidos en laboratorio sobre un muestreo de lotes esterilizados. Los valores pueden variar en función del paciente, así como de su estado clínico.

GENERAL DATA / CARACTERISTIQUES GENERALES / ALLGEMEINE DATEN / CARACTERISTICAS GENERALES / CARATTERISTICHE GENERALI / ALLMÄN DATA / ALGEMENE TECHNISCHE GEGEVENS

Weight / Poids / Gewicht / Peso / Peso / Vikt / Gewicht	590 g
Overall dimensions / Dimensions totales / Außenmaße / Dimensiones totales / Dimensioni / Storlek / Total afmetingen	
length / longueur / Länge / largo / lunghezza / längd / lengte	40 cm
width / largeur / Breite / ancho / larghezza / bredd / breedte	27 cm
height / hauteur / Höhe / altura / altezza / höjd / hoogte	12 cm
Blood volume in set / Volume sang dans le set / Blutvolumen im Set / Volumen de sangre en el set / Volume ematico nel set / Blodvolym i setet / Hoeveelheid bloed in set (± 10%)	128 ml

FILTER OPERATING SPECIFICATIONS / CARACTERISTIQUES DE FONCTIONNEMENT DU FILTRE / BETRIEBSPEZIFIKATIONEN FÜR DEN FILTER / CARACTERISTICAS DE FUNCIONAMIENTO DEL FILTRO / CARATTERISTICHE DI FUNZIONAMENTO DEL FILTRO / ANVÄNDNINGSSPECIFIKATIONER FÖR FILTER / FILTERPRESTATIES

Maximum TMP* / PTM* Maximum / Maximum TMP* / PTM* máxima / PTM* massima / Maximalt TMP* / Maximum TMP*	500 mmHg 66.6 kPa
Maximum blood pressure / Pression sang maximum / Maximum Filter-Blutdruck / Presión sanguínea máxima / Pressione ematica massima / Maximalt blodtryck / Maximum bloeddruk	500 mmHg 66.6 kPa
Minimum blood flow rate / Débit sang minimum / Mindest-Blutflußrate / Flujo sanguíneo mínimo / Flusso ematico minimo / Minimalt Blodflöde / Minimum Bloedsnelheid	75 ml/min

CARATTERISTICHE DEL FILTRO	FILTERDATA	FILTER DATA	PRISMA HF1000 SET
CARATTERISTICHE FISICHE	**NOMINELLA FYSISKA KARAKTÄRISTIKA**	**NOMINALE FYSIEKE EIGENSCHAPPEN**	
Superficie effettiva	Effektiv yta	Effectiev oppervlak	1.15 m²
Ø interno della fibra	Inre kapillärdiameter	Inw. vezeldiam.	215 µm
Spessore parete della fibra	Tjocklek av kapillärvägg	Wanddikte vezel	50 µm
PRESTAZIONI IN VITRO ≠	**IN VITRO PRESTANDA ≠**	**IN VITRO PRESTATIES ≠**	
Volume di priming ematico	**Blodvolym**	**Bloed priming volume**	81 ml ± 10 %
Perdita di carico ematico (postdiluizione)	**Blod tryckfall (postdilution)**	**Bloed drukdaling (Post-dilutie)**	
(sangue bovino, Hct****32%, Cp***** 60 g/l, 37°C)	(bovint blod, Htc****32%, Cp*****60 g/l, 37°C)	(bovine bloed, Htc****32%, Cp*****60 g/l, 37°C)	
QS** = 100 ml/min, QUF*** = 1 L/h	QB** = 100 ml/min, QUF*** = 1 L/h	QB** = 100 ml/min, QUF*** = 1 L/h	34 mmHg
QS** = 180 ml/min, QUF*** = 2 L/h	QB** = 180 ml/min, QUF*** = 2 L/h	QB** = 180 ml/min, QUF*** = 2 L/h	60 mmHg
QS** = 180 ml/min, QUF*** = 4 L/h	QB** = 180 ml/min, QUF*** = 4 L/h	QB** = 180 ml/min, QUF*** = 4 L/h	73 mmHg
Trasmittanza	**Sievingkoefficient**	**Sieving coëfficient**	
(plasma bovino, Cp***** 60 g/l, 37° C)	(bovin plasma, Cp***** 60 g/l, 37 °C)	(bovine plasma, Cp***** 60 g/l, 37 °C)	
QS** = 100 ml/min, QUF*** = 20 ml/min	QB** = 100 ml/min, QUF*** = 20 ml/min	QB** = 100 ml/min, QUF*** = 20 ml/min	
- Urea	- Urea	- Ureum	1
- Creatinina	- Kreatinin	- Creatinine	1
- Vitamina B12	- Vitamin B12	- Vitamine B12	1
- Inulina	- Inulin	- Inuline	1
- Mioglobina	- Myoglobin	- Myoglobine	0.12
- Albumina	- Albumin	- Albumine	0.01

≠ Tipici valori medi ottenuti da test di laboratorio su campioni di lotti sterili. I risultati possono variare a seconda del paziente e delle diverse condizioni cliniche. / Vanliga medelvärden erhållna vid laboratorietest av post-steriliserade prov-partier. Resultaten kan variera beroende på patient och kliniska förutsättningar. / Typisch gemiddelde waarden verkregen na het testen van stalen na sterilisatie. Resultaten kunnen verschillen afhankelijk van de patiënt en de klinische situatie.

CVVHD CLEARANCES (Continuous veno-venous hemodialysis) Clearances versus inlet dialysate flow rate (37°C)
CLAIRANCES EN CVVHD (Hémodialyse veino-veineuse continue) Clairances au bain de dialyse, à débit entrée dialysat (37°C)
CVVHD CLEARANCES (Kontinuierliche veno-venöse Hämodialyse) Clearancewerte abhängig von der Dialysierflüssigkeit-Einlaßrate (37°C)
ACLARAMIENTOS EN CVVHD (Hemodiálisis veno-venosa contínua) Aclaramientos con baño de diálisis a 37°C
CVVHD CLEARANCE (Emodialisi veno-venosa continua) Clearance con dializzato a 37°C
CVVHD CLEARANCE (Kontinuerlig veno-venös hemodialys) Clearance mot dialysatflöde (37°C)
KLARINGEN IN CVVHD (Continue veno-veneuze hemodialyse) Klaringen, snelheid en de van de dialysaataanvoer (37°C)

QB/QS = 150 ml/min, QUF*** = 10 ml/min**

QD******	(l/h)	1	2	2.5
	(ml/min)	17	25	42
Urea / Urée / Harnstoff / Urea / Urea / Urea / Ureum	(± 10%)	27	43	51
Vit B12	(± 20%)	26	39	45
Inulin / Inuline / Inulin / inulina / inulina / Inulin / inuline	(± 20%)	25	37	40

* Transmembrane pressure / Pression transmembranaire / Transmembrandruck / Presión transmembránica / Pressione transmembrana / Transmembrantryck / Transmembraandruk

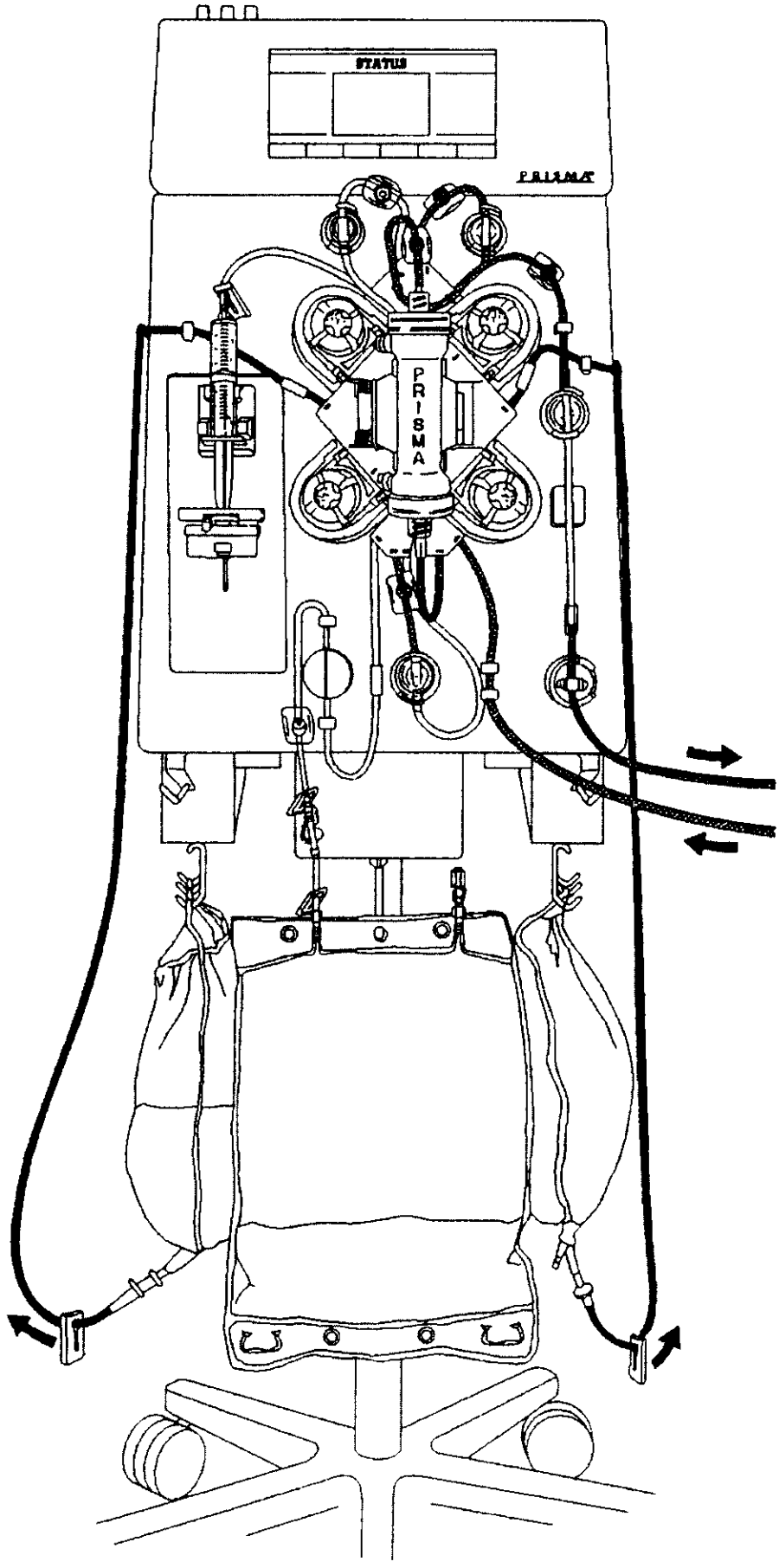
** Arterial blood flow rate / Débit sang / Arterieller Blutfluß / Flujo sanguíneo arterial / Flusso ematico arterioso / Arteriellt blodflöde / Arteriële bloedsnelheid

*** Ultrafiltration flow rate (on PRISMA system, the ultrafiltration flow rate = fluid removal flow rate + replacement flow rate) / Débit d'ultrafiltration (sur le système PRISMA, le débit d'ultrafiltration correspond au débit de prélèvement de liquide + débit de solution de réinjection) / Ultrafiltrationsflußrate (beim PRISMA-System ist die Ultrafiltrationsflußrates die Flussigkeitsentfernungsflußrate + Substitutionsflußrate) / Flujo de ultrafiltración (en el sistema PRISMA el flujo de ultrafiltración corresponde al flujo de extracción de líquido más el flujo de solución de reinyección) / Flusso di ultrafiltrazione (il sistema PRISMA calcola il flusso di ultrafiltrazione nel seguente modo : flusso di rimozione del fluido + flusso di reinfusione) / Ultrafiltrationshastighet (på PRISMA, ultrafiltrationshastighet = hastighet på vätskeborttag från patient + hastghet på ersättningslösning / Ultrafiltratie-snelheid (op PRISMA-systeem : de ultrafiltratie-snelheid = vochtverwijderings-snelheid + vervangings-snelheid)

**** Hematocrit / Hématocrite / Hämatokrit / Hematocrito / Ematocrito / Hematokrit / Hematocriet

***** Protein concentration / Concentration protéique / Protein-Konzentration / Concentración protéica / Concentrazione proteica / Proteinkoncentration / Proteïne concentratie

****** Dialysate flow rate / Débit dialysat / Dialysatflußrate / Flujo de líquido de diálisis / Flusso dialisato / Dialysatflöde / Dialysaatsnelheid



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HOSPAL
Renal Intensive Care

SACIPrint - 12/00 - Tél. 04 72 45 27 27

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 31 2001

Mr. Michael Homs
Regulatory Affairs Specialist
GAMBRO® Renal Products
10810 W. Collins Avenue
LAKEWOOD CO 80215

Re: K011221
Trade/Device Name: Prisma HF 1000 Set and
Prisma HF 1000 Pre-Set
Regulation Number: 21 CFR §876.5860
Regulation Name: High permeability hemodialysis system
Regulatory Class: II
Product Code: 78 KDI
Dated: August 1, 2001
Received: August 3, 2001

Dear Mr. Homs:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K011221
Page 1 of 1

GAMBRO Renal Products

510(k) Number K011221

Device Name: Prisma HF 1000

Indications for Use:

"The Prisma Set is indicated for use only with the Prisma Control Unit in providing continuous fluid management and renal replacement therapies. The system is intended for patients who have acute renal failure, fluid overload, or both.

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K011221

Prescription Use ✓

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 18 2004

Mr. Thomas B. Dowell
Manager Regulatory Affairs
Gambro® Renal Products
10810 W. Collins Avenue
LAKEWOOD CO 80215

received
10/18/04

Re: K041005
Trade/Device Name: Gambro Prismaflex™ System with M60 and M100 Sets
Regulation Number: 21 CFR §876.5860
Regulation Name: High permeability hemodialysis system
Regulatory Class: II
Product Code: 78 KDI
Dated: August 10, 2004
Received: August 11, 2004

Dear Mr. Dowell:

This letter corrects our substantially equivalent letter of October 7, 2004 regarding the incorrect product code listed for the Gambro Prismaflex™ System.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent [(for the indications for use stated in the enclosure)] to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other

requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications For Use

510(k) Number (if known): K041005

Device Name:

Prismaflex™ System
Prismaflex™ M60 Set
Prismaflex™ M100 Set

Indications For Use:

The Prismaflex is indicated for the following use:

- continuous solute and/or fluid removal in patients with acute renal failure or fluid overload

All treatments administered by the Prismaflex must be prescribed by a physician.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C. Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K041005

108

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Memorandum

From: Reviewer(s) - Name(s) Joshua C. Nipper

Subject: 510(k) Number K042938/S1

To: The Record - It is my recommendation that the subject 510(k) Notification:

- ☐ Refused to accept.
- ☐ Requires additional information (other than refuse to accept).
- ☑ Is substantially equivalent to marketed devices.
- ☐ NOT substantially equivalent to marketed devices.
- ☐ Other (e.g., exempt by regulation, not a device, duplicate, etc.).

Is this device subject to Section 522 Postmarket Surveillance?	☐ YES	☑ NO
Is this device subject to the Tracking Regulation?	☐ YES	☑ NO
Was clinical data necessary to support the review of this 510(k)?	☐ YES	☑ NO
Is this a prescription device?	☑ YES	☐ NO
Was this 510(k) reviewed by a Third Party?	☐ YES	☑ NO
Special 510(k)?	☑ YES	☐ NO
Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers	☐ YES	☑ NO

Truthful and Accurate Statement ☐ Requested ☑ Enclosed

☑ A 510(k) summary OR ☐ A 510(k) statement

~~☐ The required certification and summary for class III devices~~ N/A

☑ The indication for use form

Combination Product Category (Please see algorithm on H drive 510k/Boilers) N

Animal Tissue Source ☐ YES ☑ NO Material of Biological Origin ☐ YES ☑

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

☐ No Confidentiality ☐ Confidentiality for 90 days ☐ Continued Confidentiality exceeding 9(

Predicate Product Code with class: Additional Product Code(s) with panel (optional):

21 CFR §876.5860, Class II, 78-KDT

Review: Carolyn A. Neuland (Branch Chief) GRDB (Branch Code) 1/5/05 (Date)

Final Review: Daniel A. Lippman (Division Director) 1/6 (Date)

4

SPECIAL 510(k): Device Modification

ODE Review Memorandum (Decision Making Document is Attached)

To: THE FILE **RE:** DOCUMENT NUMBER K042938

This 510(k) submission contains information/data on modifications made to the SUBMITTER'S own Class II, Class III or Class I devices requiring 510(k). The following items are present and acceptable (delete/add items as necessary):

1. The name and 510(k) number of the SUBMITTER'S previously cleared device. (For a preamendments device, a statement to this effect has been provided.)
2. Submitter's statement that the **INDICATION/INTENDED USE** of the modified device as described in its labeling **HAS NOT CHANGED** along with the proposed labeling which includes instructions for use, package labeling, and, if available, advertisements or promotional materials.
3. A description of the device **MODIFICATION(S),** including clearly labeled diagrams, engineering drawings, photographs, user's and/or service manuals in sufficient detail to demonstrate that the **FUNDAMENTAL SCIENTIFIC TECHNOLOGY** of the modified device **has not changed**.

   The changes made were the addition of a new line of dialyzers to the PrismaflexTM system.
4. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device including, labeling, intended use, physical characteristics, materials, design, and performance characteristics.
5. A **Design Control Activities Summary** which includes:
   a) Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis
   b) Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria to be applied
   c) A declaration of conformity with design controls. The declaration of conformity should include:
      i) A statement signed by the individual responsible, that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met, and
      ii) A statement signed by the individual responsible, that the manufacturing facility is in conformance with design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review.
6. **A Truthful and Accurate Statement**, a **510(k) Summary** and the **Indications for Use Enclosure.**

The labeling for this modified subject device has been reviewed to verify that the indication/intended use for the device is unaffected by the modification. In addition, the submitter's description of the particular modification(s) and the comparative information between the modified and unmodified devices demonstrate that the fundamental scientific technology has not changed. The submitter has provided the design control information as specified in The New 510(k) Paradigm and on this basis, I recommend the device be determined substantially equivalent to the previously cleared (or their preamendment) device.

[signature] (Reviewer's Signature) 1/3/05 (Date)

Comments

revised:3/27/98

C. Newland
1/5/05

REVISED:3/14/95

THE 510(K) DOCUMENTATION FORMS ARE AVAILABLE ON THE LAN UNDER 510(K) BOILERPLATES TITLED "DOCUMENTATION" AND MUST BE FILLED OUT WITH EVERY FINAL DECISION (SE, NSE, NOT A DEVICE, ETC.).

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

K042938

Reviewer: Joshua C. Nipper

Division/Branch: DRARD/ Gastroenterology and Renal Devices Branch (GRDB)

Device Name: Gambro Prismaflex™ HF1000 and HF1400 Sets

Product To Which Compared (510(K) Number If Known): K041005 and K011221 .

		YES	NO	
1.	Is Product A Device	✓		If **NO** = Stop
2.	Is Device Subject To 510(k)?	✓		If **NO** = Stop
3.	Same Indication Statement?	✓		If **YES** = Go To 5
4.	Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If **YES** = Stop **NE**
5.	Same Technological Characteristics?	✓		If **YES** = Go To 7
6.	Could The New Characteristics Affect Safety Or Effectiveness?			If **YES** = Go To 8
7.	Descriptive Characteristics Precise Enough?		✓	If **NO** = Go To 10 If **YES** = Stop **SE**
8.	New Types Of Safety Or Effectiveness Questions?			If **YES** = Stop **NE**
9.	Accepted Scientific Methods Exist?			If **NO** = Stop **NE**
10.	Performance Data Available?	✓		If **NO** = Request Data
11.	Data Demonstrate Equivalence?	✓ **SE**		Final Decision:

Note: In addition to completing the form on the LAN, "yes" responses to questions 4, 6, 8, and 11, and every "no" response requires an explanation.

1. Intended Use:

The Prismaflex Set is indicated for use only with the Prismaflex Control Unit in providing continuous fluid management and renal replacement therapies. The system is intended for patients who have acute renal failure, fluid overload, or both.

2. Device Description: Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement. Is the device life-supporting or life sustaining? Is the device implanted (short-term or long-term)? Does the device design use software? Is the device sterile? Is the device for single use? Is the device over-the-counter or prescription use? Does the device contain drug or biological product as a component? Is this device a kit? Provide a summary about the devices design, materials, physical properties and toxicology profile if important.

PRISMAFLEX DESCRIPTION

The Gambro Prismaflex™ System is a continuous renal replacement therapy (CRRT) device capable of delivering various treatment modalities to patients with acute renal failure or fluid overload.

Available therapies offered by the Prismaflex™ include:

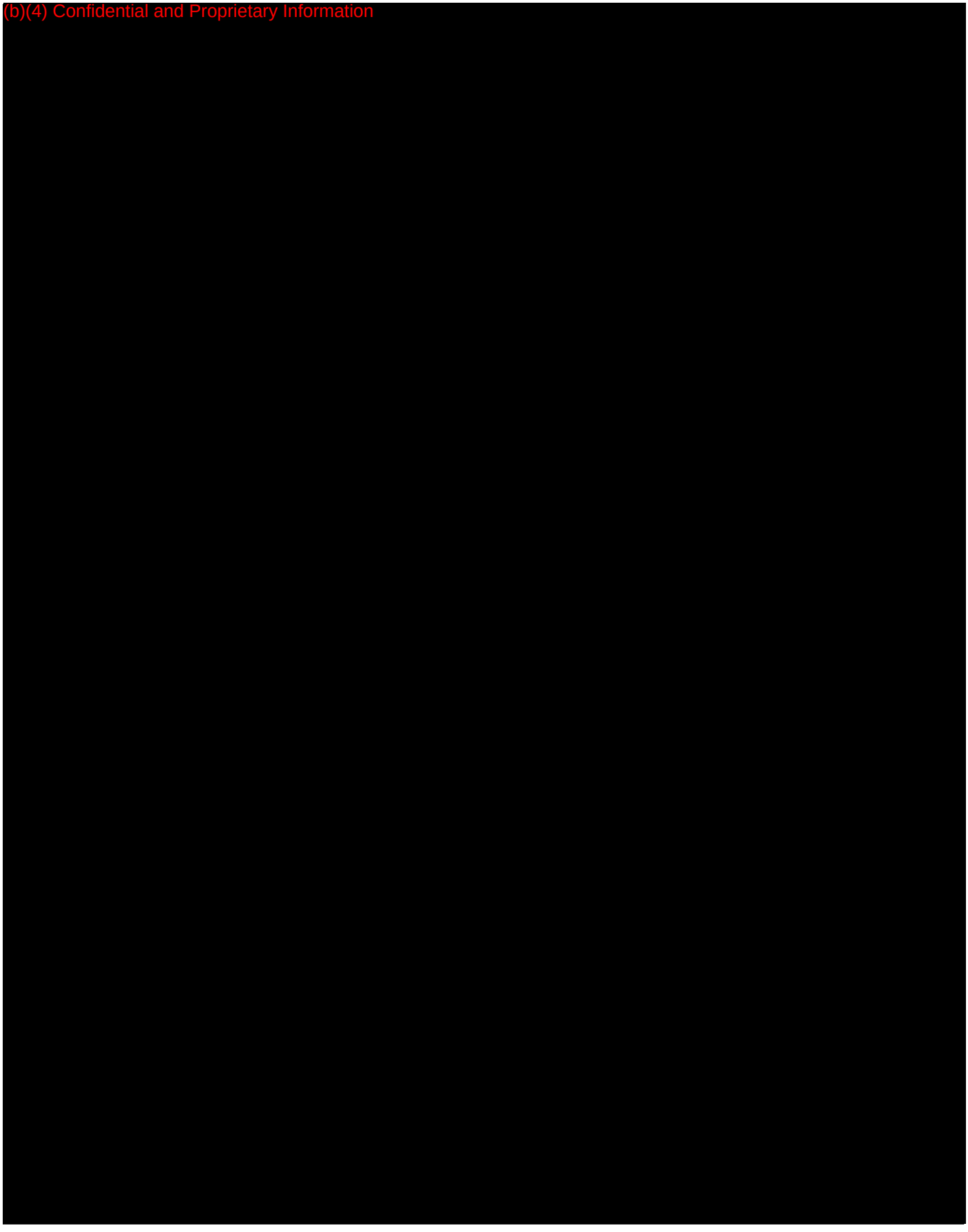
- Slow Continuous Ultrafiltration (SCUF): Provides fluid removal via ultrafiltration
- Continuous Veno-venous Hemofiltration (CVVH): Provides convective solute clearance by hemofiltration. Net fluid removal (ultrafiltration) can also be prescribed during CVVH. The Prismaflex™ system can provide either pre-dilution (pre-filter) hemofiltration, post-dilution (post-filter) hemofiltration, or a combination of pre and post dilution hemofiltration.
- Continuous Veno-venous Hemodialysis (CVVHD): Provides diffusive solute clearance by hemodialysis. Net fluid removal (ultrafiltration) can also be prescribed during CVVHD.
- Continuous Veno-venous Hemodiafiltration (CVVHDF): Provides solute clearance by both convection and diffusion. Net fluid removal (ultrafiltration) can also be prescribed during CVVHDF. The Prismaflex™ system can provide either pre-dilution (pre-filter) fluid infusion or post-dilution (post-filter) fluid infusion during CVVHDF, but not both.

The Prismaflex™ delivery system is loaded with a proprietary cartridge which contains all blood tubing and a preattached hemodialyzer/hemofilter. Currently, only the M60 and M100 sets have been cleared for use (K041005). The current submission seeks to add the HF1000 and HF1400 Sets to the product line. (b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information



(b)(4) Confidential and Proprietary Information

[redacted]

(b)(4) Confidential and Proprietary Information

[redacted]

(b)(4) Confidential and Proprietary Information

[redacted]

RECOMMENDATION

I recommend that the Gambro Prismaflex HF1000 and HF1400 Sets be found substantially equivalent (**SE**) to the predicate devices identified according to 21 CFR § 876.5860.

Joshua C. Nipper, M.E. — Date: 1/4/05

C. Neuland
1/5/05

EXPLANATIONS TO "YES" AND "NO" ANSWERS TO QUESTIONS ON PAGE 1 AS NEEDED

1. Explain why not a device: **N/A, is a device.**

2. Explain why not subject to 510(k): **N/A, is subject to 510(k) regulation.**

3. How does the new indication differ from the predicate device's indication: **N/A, indication for use is identical.**

4. Explain why there is or is not a new effect or safety or effectiveness issue:

5. Describe the new technological characteristics: **N/A, no new technological characteristics.**

6. Explain how new characteristics could or could not affect safety or effectiveness:

7. Explain how descriptive characteristics are not precise enough: **Performance testing is required for hemodialyzers / hemofilters in order to list their performance characteristics in the device labeling.**

8. Explain new types of safety or effectiveness questions raised or why the questions are not new:

9. Explain why existing scientific methods can not be used:

10. Explain what performance data is needed: **Performance testing in accordance with the FDA guidance document "Guidance for the Content of Premarket Notifications for Conventional and High Permeability Hemodialyzers" should be submitted.**

11. Explain how the performance data demonstrates that the device is or is not substantially equivalent: **Performance testing, including ultrafiltration rate, pressure drop, and in-vitro solute clearance has been provided which demonstrates that the proposed device is substantially equivalent to the predicate devices identified.**

ATTACH ADDITIONAL SUPPORTING INFORMATION

FOOD AND DRUG ADMINISTRATION

Memorandum

DATE: January 3, 2005

FROM: Joshua C. Nipper, Biomedical Engineer
Gastroenterology and Renal Devices Branch/DRARD, HFZ-470

SUBJECT: K042938/S1 – Special
Gambro Prismaflex™ HF1000 and HF1400 Sets
Gambro Renal Products

CONTACT: Thomas B. Dowell
Manager, Regulatory Affairs
Gambro Renal Products
10810 West Collins Avenue
Lakewood, CO 80215
Phone: (303) 231-4094
Fax: (303) 542-5138
Email: Tom.Dowell@us.gambro.com

TO: The Record

BACKGROUND

This is my second review of this special 510(k) submission. The first review resulted in the firm being sent an additional information (AI) letter dated November 16, 2004. This submission attempts to address the deficiencies that were identified during the first review. The firm has requested a special 510(k) because they feel that the proposed device represents a modification to their existing products. The proposed device is the Gambro Prismaflex™ HF1000 and HF1400 Sets to be used with the Gambro Prismaflex™ System, manufactured by Gambro Renal Products ("Gambro" or "the firm"). The device is regulated under **21 CFR §876.5860 High permeability hemodialysis system**, and is a **Class II** device. The product code for this device is **78-KDI**. The FDA guidance document "Guidance for the Content of Premarket Notifications for Conventional and High Permeability Hemodialyzers" is applicable for the proposed device.

INDICATIONS FOR USE

As stated by firm, "The Prismaflex Set is indicated for use only with the Prismaflex Control Unit in providing continuous fluid management and renal replacement therapies. The system is intended for patients who have acute renal failure, fluid overload, or both."

PRISMAFLEX DESCRIPTION

The Gambro Prismaflex™ System is a continuous renal replacement therapy (CRRT) device capable of delivering various treatment modalities to patients with acute renal failure or fluid overload. Available therapies offered by the Prismaflex™ include:

- Slow Continuous Ultrafiltration (SCUF): Provides fluid removal via ultrafiltration
- Continuous Veno-venous Hemofiltration (CVVH): Provides convective solute clearance by hemofiltration. Net fluid removal (ultrafiltration) can also be prescribed during CVVH. The Prismaflex™ system can provide either pre-dilution (pre-filter) hemofiltration, post-dilution (post-filter) hemofiltration, or a combination of pre and post dilution hemofiltration.
- Continuous Veno-venous Hemodialysis (CVVHD): Provides diffusive solute clearance by hemodialysis. Net fluid removal (ultrafiltration) can also be prescribed during CVVHD.
- Continuous Veno-venous Hemodiafiltration (CVVHDF): Provides solute clearance by both convection and diffusion. Net fluid removal (ultrafiltration) can also be prescribed during CVVHDF. The Prismaflex™ system can provide either pre-dilution (pre-filter) fluid infusion or post-dilution (post-filter) fluid infusion during CVVHDF, but not both.

The Prismaflex™ delivery system is loaded with a proprietary cartridge which contains all blood tubing and a preattached hemodialyzer/hemofilter. Currently, only the M60 and M100 sets have been cleared for use (K041005). The current submission seeks to add the HF1000 and HF1400 Sets to the product line. (b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information

15

(b)(4) Confidential and Proprietary Information

[redacted]

(b)(4) Confidential and Proprietary Information

[redacted]

(b)(4) Confidential and Proprietary Information

[redacted]

(b)(4) Confidential and Proprietary Information

[redacted]

(b)(4) Confidential and Proprietary Information

[redacted]

(b)(4) Confidential and Proprietary Information

[redacted]

(b)(4) Confidential and Proprietary Information

[redacted]

(b)(4) Confidential and Proprietary Information

[redacted]

COMMUNICATIONS LOG

I spoke with Mr. Dowell on December 21, 2004 and requested minor updates of the labeling. Originally, Gambro had not included the first page of the labeling revisions with the k_{uf} values added. Mr. Dowell told me that this omission was accidental, and faxed the updated page later that day. Mr. Dowell later submitted an updated in-vitro clearance table, with creatinine values "red-lined" into the labeling.

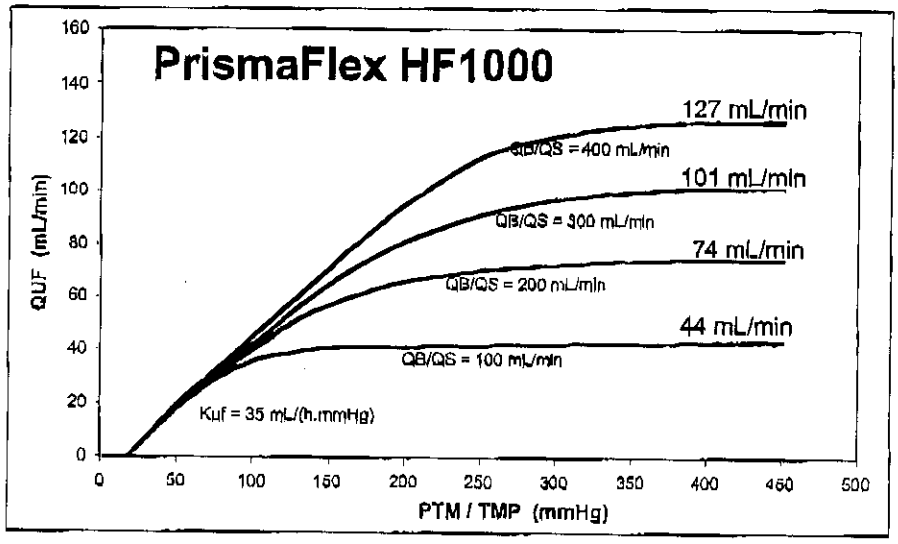
RECOMMENDATION

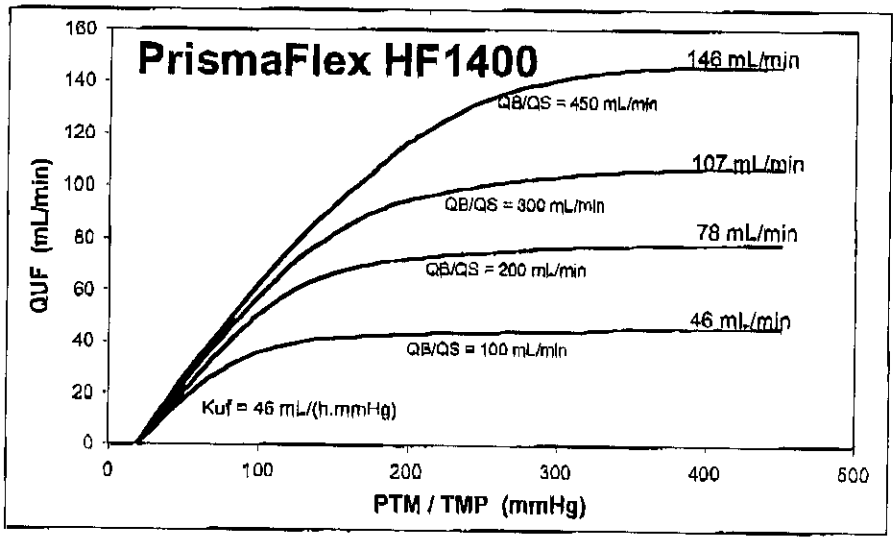
I recommend that the Gambro Prismaflex HF1000 and HF1400 Sets be found substantially equivalent (**SE**) to the predicate devices identified according to 21 CFR § 876.5860.

Joshua C. Nipper, M.E. — Date: 1/3/05

	YES	NO
Is the device life-supporting or life sustaining?	✓	
Is the device implanted (short-term or long-term)?		✓
Does the device design use software?		✓
Is the device sterile?	✓	
Is the device for single use?	✓	
Is the device for over the counter (OTC) use?		✓
Is the device for prescription use?	✓	
Does the device contain a drug or biological product as a component?		✓
Is this device a kit?		✓

C Newland
1/5/05





"In vitro" ultrafiltration with blood (values ± 15 %)
(Bovine blood at 37°C, Hct 32 %, Protein concentration 60 g/l)
Ultrafiltration is controlled by the PRISMAFLEX System and is independent of the ultrafiltration coefficient (KUF)

Ultrafiltration au sang "in vitro" (valeurs à ± 15 %)
(Sang de bœuf à 37°C, Hématocrite = 32 %, Concentration protéique = 60 g/l)
L'ultrafiltration est maîtrisée par le système PRISMAFLEX et est indépendante du coefficient d'ultrafiltration (KUF)

Ultrafiltration mit Blut "in vitro" (Werte bei ± 15 %)
(Rinderblut bei 37°C, Hkt 32 %, Protein-Konzentration 60 g/l)
Die Ultrafiltration wird von der PRISMAFLEX Maschine auf dem richtingen Wert gehalten und hängt nicht vom Ultrafiltrationskoeffizienten (KUF) ab.

Ultrafiltración con sangre "in vitro" (valores a ± 15 %)
(Sangre bovina a 37°C, Hematocrito = 32 %, Concentración proteica = 60 g/l)
La ultrafiltración controlada por el sistema PRISMAFLEX, es independiente del coeficiente de ultrafiltración (KUF)

Ultrafiltrazione con sangue "in vitro" (valori a ± 15 %)
(Sangue bovino a 37°C, ematocrito = 32 %, Concentrazione proteica = 60 g/l)
L'ultrafiltrazione è controllata dal Sistema PRISMAFLEX ed è indipendente dal coefficiente di ultrafiltrazione (KUF)

"In vitro" ultrafiltration med blod (värden ± 15 %)
(Bovint blod vid 37°C, Hct 32 %, Proteinkoncentration 60 g/l)
Ultrafiltrationen kontrolleras av PRISMAFLEX systemet och är obeorende av koefficienten för ultrafiltration (KUF)

-Ultrafiltratie met "in vitro"-blood (waarden op ± 15 %)
(Rundorbloed 37°C, Hematocrietwaarde = 32 %, Eiwitgehalte = 60 g/l)
Ultrafiltratie wordt gecontroleerd door het PRISMAFLEX Systeem en is onafhankelijk van de ultrafiltratie coefficient.

A ultrafiltração com sangue "in vitro" (valores a ± 15 %)
(Sangue bovino à temperatura de 37°C. Hematócrito = 32 %, Concentração proteica = 60 g/l)
A ultrafiltração controlada pelo sistema PRISMAFLEX e é independente do coeficiente de ultrafiltração (KUF)

"In vitro"-ultrafiltrasjon med blod (verdier ± 15 %)
(Bovint blod ved 37°C, Hct 32 %, proteinkonsentrasjon 60 g/l)
Ultrafiltrasjon kontrolleres av PRISMAFLEX-systemet, og er uavhengig av ultrafiltrasjonskoefficienten (KUF)

"In vitro"-ultrafiltrering med blod (værdier ± 15 %)
(Bovint blod ved 37°C, Hct 32 %, proteinkoncentration 60 g/l)
Ultrafiltreringen styres af PRISMAFLEX-systemet og er uafhængigt af koefficienten for ultrafiltrering (KUF)

Veren ultrafiltraatio "in vitro" (arvot ± 15 %)
(Naavaan 37°C verta, Hct 32 %, proteiinipitoisuus 60 g/l)
Ultrafiltraatio tapahtuu PRISMAFLEX-ohjausyksikön alaisena ja se on riippumaton ultrafiltration kertoimesta (KUF)

25

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Memorandum

From: Reviewer(s) - Name(s) Joshua C Nipper (JCN)

Subject: 510(k) Number K042938

To: The Record - It is my recommendation that the subject 510(k) Notification:

- ☐ Refused to accept.
- ☑ Requires additional information (other than refuse to accept).
- ☐ Is substantially equivalent to marketed devices.
- ☐ NOT substantially equivalent to marketed devices.
- ☐ Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Is this device subject to Section 522 Postmarket Surveillance?	☐ YES	☑ NO
Is this device subject to the Tracking Regulation?	☐ YES	☑ NO
Was clinical data necessary to support the review of this 510(k)?	☐ YES	☐ NO
Is this a prescription device?	☑ YES	☐ NO
Was this 510(k) reviewed by a Third Party?	☐ YES	☑ NO
Special 510(k)?	☑ YES	☐ NO
Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers	☐ YES	☑ NO

Truthful and Accurate Statement ☐ Requested ☑ Enclosed

☑ A 510(k) summary OR ☐ A 510(k) statement

☐ ~~The required certification and summary for class III devices~~

☑ The indication for use form

Combination Product Category (Please see algorithm on H drive 510k/Boilers) N

Animal Tissue Source ☐ YES ☑ NO Material of Biological Origin ☐ YES ☑ NO

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

☐ No Confidentiality ☐ Confidentiality for 90 days ☐ Continued Confidentiality exceeding 90 days

Predicate Product Code with class: Additional Product Code(s) with panel (optional):

21 CFR 876.5860, Class II, 78-KDI

Review: Carolyn Y Newland (Branch Chief) GRDB (Branch Code) 11/16/04 (Date)

Final Review: _____ (Division Director) _____ (Date)

Revised:4/2/03

FOOD AND DRUG ADMINISTRATION

Memorandum

DATE: November 12, 2004

FROM: Joshua C. Nipper, Biomedical Engineer
Gastroenterology and Renal Devices Branch/DRARD, HFZ-470

SUBJECT: K042938 – Special
Gambro Prismaflex™ HF1000 and HF1400 Sets
Gambro Renal Products

CONTACT: Thomas B. Dowell
Manager, Regulatory Affairs
Gambro Renal Products
10810 West Collins Avenue
Lakewood, CO 80215
Phone: (303) 231-4094
Fax: (303) 542-5138
Email: Tom.Dowell@us.gambro.com

TO: The Record

BACKGROUND

This is my first review of this special 510(k) submission. The firm has requested a special 510(k) because they feel that the proposed device represents a modification to their existing products. The proposed device is the Gambro Prismaflex™ HF1000 and HF1400 Sets to be used with the Gambro Prismaflex™ System, manufactured by Gambro Renal Products ("Gambro" or "the firm"). The device is regulated under **21 CFR §876.5860 High permeability hemodialysis system**, and is a **Class II** device. The product code for this device is **78-KDI**. The FDA guidance document "Guidance for the Content of Premarket Notifications for Conventional and High Permeability Hemodialyzers" is applicable for the proposed device.

INDICATIONS FOR USE

As stated by firm, "The Prismaflex Set is indicated for use only with the Prismaflex Control Unit in providing continuous fluid management and renal replacement therapies. The system is intended for patients who have acute renal failure, fluid overload, or both."

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dilution (post-filter) hemofiltration, or a combination of pre and post dilution hemofiltration.

- Continuous Veno-venous Hemodialysis (CVVHD): Provides diffusive solute clearance by hemodialysis. Net fluid removal (ultrafiltration) can also be prescribed during CVVHD.
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(b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information

[redacted]

(b)(4) Confidential and Proprietary Information

[redacted]

(b)(4) Confidential and Proprietary Information

[redacted]

(b)(4) Confidential and Proprietary Information

[redacted]

(b)(4) Confidential and Proprietary Information

[redacted]

(b)(4) Confidential and Proprietary Information

[redacted]

(b)(4) Confidential and Proprietary Information

RECOMMENDATION

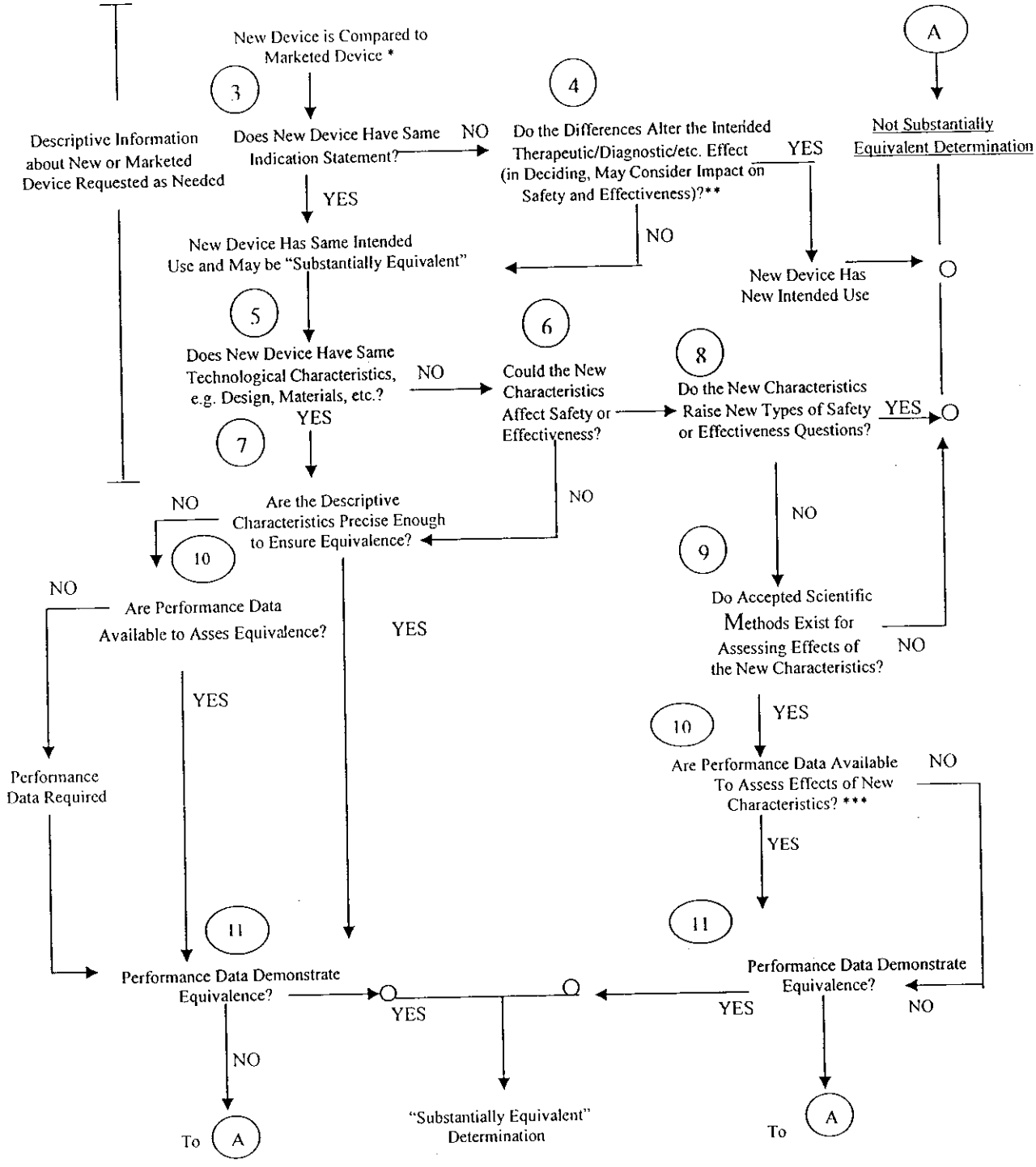
I recommend that the Gambro Prismaflex HF1000 and HF1400 Sets be placed on hold and that the firm be sent the aforementioned deficiencies in an additional information (**AI**) letter. Until these deficiencies are answered, the device cannot be found substantially equivalent to the predicate devices identified according to 21 CFR § 876.5860.

Joshua C. Nipper, M.E. — Date 11/12/04

C Neuland
11/15/04

K042938

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



* 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.

 K042938

Internal Administrative Form

	YES	NO
1. Did the firm request expedited review?		✓
2. Did we grant expedited review?		✓
3. Have you verified that the Document is labeled Class III for GMP purposes?	NA	
4. If, not, has POS been notified?		
5. Is the product a device?	✓	
6. Is the device exempt from 510(k) by regulation or policy?		✓
7. Is the device subject to review by CDRH?	✓	
8. Are you aware that this device has been the subject of a previous NSE decision?		✓
9. If yes, does this new 510(k) address the NSE issue(s), (e.g., performance data)?	NA	
10. Are you aware of the submitter being the subject of an integrity investigation?		✓
11. If, yes, consult the ODE Integrity Officer.		
12. Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #I91-2 and Federal Register 90N0332, September 10, 1991.	NA	

SCREENING CHECKLIST
FOR ALL PREMARKET NOTIFICATION [510(k)] SUBMISSIONS

510(k) Number: K042938

The cover letter clearly identifies the type of 510(k) submission as **(Check the appropriate box)**:

☑ Special 510(k) - Do Sections 1 and 2

☐ Abbreviated 510(k) - Do Sections 1, 3 and 4

☐ Traditional 510(k) or no identification provided - Do Sections 1 and 4

Section 1: Required Elements for All Types of 510(k) submissions:

	Present or Adequate	Missing or Inadequate
Cover letter, containing the elements listed on page 3-2 of the Premarket Notification [510)] Manual.	✓	
Table of Contents.	✓	
Truthful and Accurate Statement.	✓	
Device's Trade Name, Device's Classification Name and Establishment Registration Number.	✓	
Device Classification Regulation Number and Regulatory Status (Class I, Class II, Class III or Unclassified).	✓	
Proposed Labeling including the material listed on page 3-4 of the Premarket Notification [510)] Manual.	✓	
Statement of Indications for Use that is on a separate page in the premarket submission.	✓	
Substantial Equivalence Comparison, including comparisons of the new device with the predicate.	✓	
510(k) Summary ~~or 510(k) Statement~~	✓	
Description of the device (or modification of the device) including diagrams, engineering drawings, photographs or service manuals.	✓	
Identification of legally marketed predicate device. *	✓	
Compliance with performance standards. * [See Section 514 of the Act and 21 CFR 807.87 (d).]	NA	
Class III Certification and Summary. **	NA	
Financial Certification or Disclosure Statement for 510(k) notifications with a clinical study. * [Sec 21 CFR 807.87 (i)]	NA	
510(k) Kit Certification ***	NA	

* - May not be applicable for Special 510(k)s.

** - Required for Class III devices, only.

*** - See pages 3-12 and 3-13 in the Premarket Notification [510)] Manual and the Convenience Kits Interim Regulatory Guidance.

Section 2: Required Elements for a SPECIAL 510(k) submission:

	Present	Inadequate or Missing
Name and 510(k) number of the submitter's own, unmodified predicate device.	✓	
A description of the modified device and a comparison to the sponsor's predicate device.	✓	
A statement that the intended use(s) and indications of the modified device, as described in its labeling are the same as the intended uses and indications for the submitter's unmodified predicate device.	✓	
Reviewer's confirmation that the modification has not altered the fundamental scientific technology of the submitter's predicate device.	✓	
A Design Control Activities Summary that includes the following elements (a-c):	✓	
a. Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis.		✓
b. Based on the Risk Analysis, an identification of the required verification and validation activities, including the methods or tests used and the acceptance criteria to be applied.	✓	
c. A Declaration of Conformity with design controls that includes the following statements:	✓	
A statement that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results of the activities demonstrated that the predetermined acceptance criteria were met. This statement is signed by the individual responsible for those particular activities.	✓	
A statement that the manufacturing facility is in conformance with the design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review. This statement is signed by the individual responsible for those particular activities.	✓	

Section 3: Required Elements for an ABBREVIATED 510(k)* submission:

	Present	Inadequate or Missing
For a submission, which relies on a guidance document and/or special control(s), a summary report that describes how the guidance and/or special control(s) was used to address the risks associated with the particular device type. (If a manufacturer elects to use an alternate approach to address a particular risk, sufficient detail should be provided to justify that approach.)		
For a submission, which relies on a recognized standard, a declaration of conformity [For a listing of the required elements of a declaration of conformity, **SEE Required Elements for a Declaration of Conformity to a Recognized Standard,** which is posted with the 510(k) boilers on the **H drive.**]		

For a submission, which relies on a recognized standard without a declaration of conformity, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		
For a submission, which relies on a non-recognized standard that has been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		
For a submission, which relies on a non-recognized standard that has not been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device and any additional information requested by the reviewer in order to determine substantial equivalence.		
Any additional information, which is not covered by the guidance document, special control, recognized standard and/or non-recognized standard, in order to determine substantial equivalence.		

* - When completing the review of an abbreviated 510(k), please fill out an Abbreviated Standards Data Form (located on the H drive) and list all the guidance documents, special controls, recognized standards and/or non-recognized standards, which were noted by the sponsor.

Section 4: Additional Requirements for ABBREVIATED and TRADITIONAL 510(k) submissions (If Applicable):

	Present	Inadequate or Missing
a) Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation:		✓
b) Sterilization and expiration dating information:	✓	
i) sterilization process	EtO	
ii) validation method of sterilization process	✓	
iii) SAL	10-6	
iv) packaging	✓	
v) specify pyrogen free	✓	
vi) ETO residues	NA	
vii) radiation dose	T	
viii) Traditional Method or Non-Traditional Method	NA	
c) Software Documentation:		

Items with checks in the "Present or Adequate" column do not require e additional information from the sponsor. Items with checks in the "Missing or Inadequate" column must be submitted before substantive review of the document.

Passed Screening ✓ Yes ____ No

Reviewer: [signature] 11/2/04

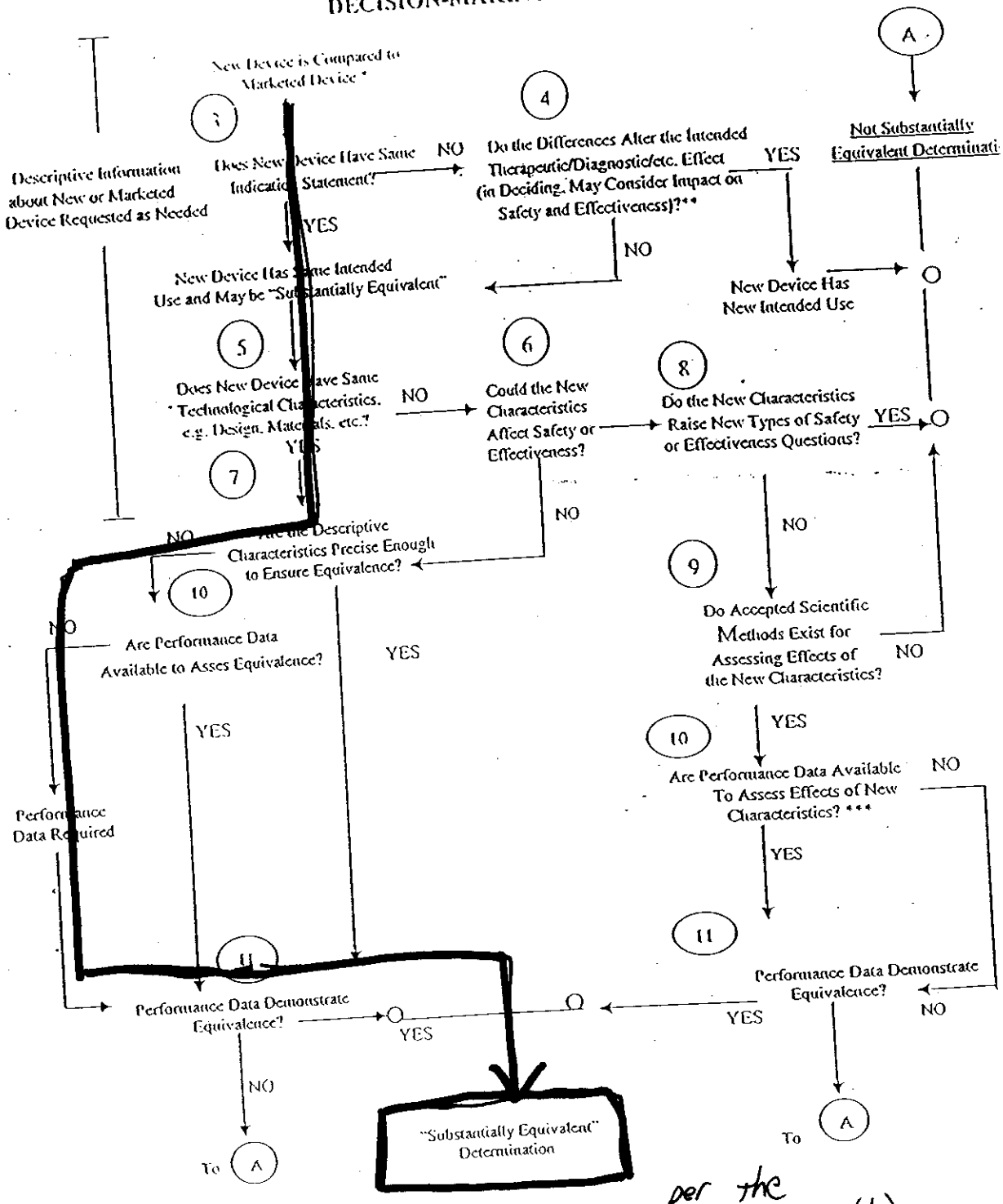
Concurrence by Review Branch: C. Newland

Date: 11/16/04

The deficiencies identified above represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: http://www.fda.gov/cdrh/modact/leastburdensome.html

K042938

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



per the Special 510(k) paradigm

* 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Data may be in the 510(k), other submissions, reclassification files, or the literature.

5

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

December 17, 2004

GAMBRO RENAL PRODUCTS
10810 WEST COLLINS AVE.
LAKEWOOD, CO 80215
ATTN: THOMAS B. DOWELL

510(k) Number: K042938
Product: GAMBRO
PRISMAFLEX
HF1000 AND
HF1400 SETS

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html.

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

If you have procedural or policy questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

 K042938 1 of 51

GAMBRO Renal Products

December 16, 2004

10810 W. Collins Avenue
Lakewood, Colorado 80215 USA
Tel 303-232-6800

Joshua Nipper, (Biomedical Engineer) Gastroenterology and Renal Devices Branch
Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd
Rockville, Maryland 20850

Subject: **K042938**
GamCath® High Flow Catheter

Dear Mr. Nipper,

Enclosed is the official response to your questions related to 510(k) submission K042938.

If you have any additional questions please call me at 303-231-4094.

Attachments:

Revised Pages of the Instructions for Use

Sincerely,

Thomas B. Dowell
Manager Regulatory Affairs
Gambro Renal Products

5k 26

(b)(4) Confidential and Proprietary Information

[redacted]

GAMBRO Renal Products

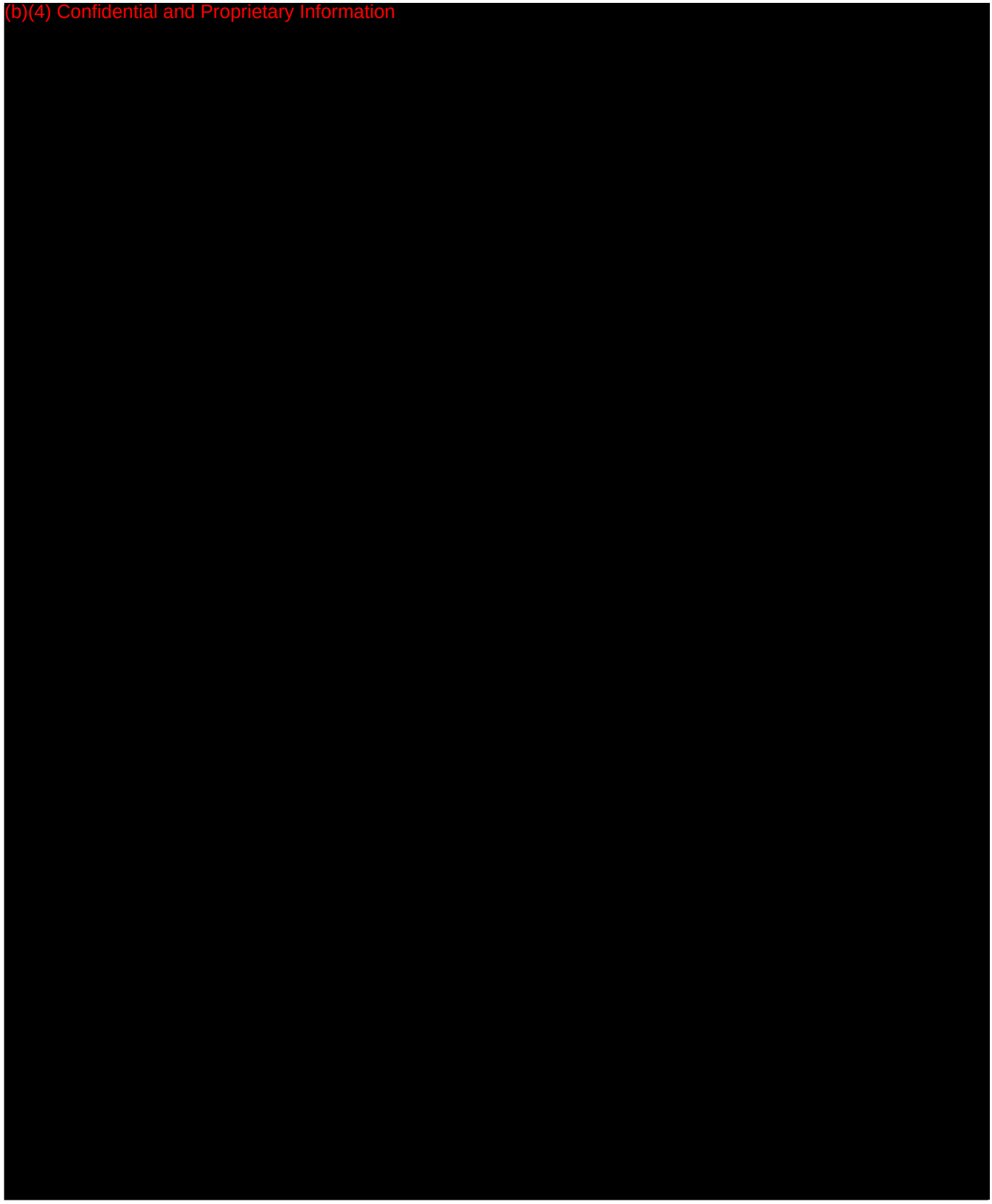
(b)(4) Confidential and Proprietary Information

[redacted]

(b)(4) Confidential and Proprietary Information

[redacted]

(b)(4) Confidential and Proprietary Information



(b)(4) Confidential and Proprietary Information

[redacted]

GAMBRO Renal Products

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(b)(4) Confidential and Proprietary Information

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