



U.S. Department of Health & Human Services

Food and Drug Administration

SAVE REQUEST

USER: (Idt)
FOLDER: K030974 - 93 pages
COMPANY: BAXTER HEALTHCARE CORP. (BAXTHEAL)
PRODUCT: DIALYZER, HIGH PERMEABILITY WITH OR WITHOUT SEALED DIALYSATE SYSTEM (KDI)
SUMMARY: Product: EXELTRA HIGH FLUX DIALYZER, MODELS 150 & 170

DATE REQUESTED: Oct 8, 2014

DATE PRINTED: Oct 8, 2014

Note: Printed



APR 25 2003

K030974

510(K) SUMMARY

Submitter's Name: David E. Curtin, RAC

Address: 1620 Waukegan Rd. MPGR-A2E

Phone: (847) 473-6079

Fax: (847) 473-6952

Contact: David E. Curtin

Date Prepared: 3/27/03

Trade Name: EXELTRA™ Dialyzer, Single Use

Common Name: Dialyzer

Classification Name: High Permeability Hemodialysis System per 21 CFR 876.5860

Equivalent Predicate: Baxter CT Dialyzer, Single Use (K890315, K926568, K970663)

Device Description: Model EXELTRA™ 150 and 170 Single Use Dialyzers

Intended Use: Hemodialysis with EXELTRA™ dialyzers is indicated for patients with renal failure when conservative therapy is judged to be inadequate. It also may be indicated in the treatment of patients intoxicated with poisons or drugs.

Summary of the Technological Characteristics Compared to the The general design and material of the EXELTRA™ 150 and 170 single use dialyzers are similar to the CT 110 and CT190G dialyzers cleared under K890315, K926568 and K970663, and do not raise any new types of safety and effectiveness issues, when compared to the predicate product.

K030974

510(k) Premarket Notification
EXELTRA™ 150 and 170 Single Use Dialyzers
Page 2 of 2

Predicate Device: Baxter CT Dialyzers

Clinical Data: N/A

Conclusions Drawn Components of the subject EXELTRA™ dialyzers have met the biological requirements of ISO 10993-1: Biological Evaluation of Medical devices – Part: Guidance on selection of tests.

The validation of the gamma sterilization cycle for the EXELTRA™ dialyzer is based upon the AAMI/ISO 11137:1994 “Sterilization of Healthcare Products – Requirements for Validation and Routine Control – Radiation Sterilization”.

Functional testing for blood side integrity and conformance to manufacturing specifications are performed as in-process and/or final inspections prior to product release to ensure a quality product.

Additional Information Requested by FDA: None to date

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 25 2003

David E. Curtin, RAC
Associate Director, Regulatory Affairs
Renal Division
Baxter Healthcare Corporation
1620 Waukegan Road
MCGAW PARK IL 60085

Re: K030974

Trade/Device Name: EXELTRA™ Dialyzer, Single Use, Models 150 and 170
Regulation Number: 21 CFR §876.5860
Regulation Name: High permeability hemodialysis system
Regulatory Class: II
Product Code: 78 KDI
Dated: March 27, 2003
Received: March 28, 2003

Dear Mr. Curtin:

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.

Page 2

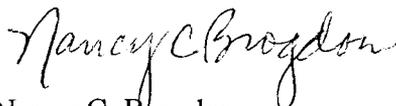
This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

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
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): K030974

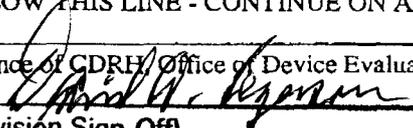
Device Name: EXELTRA™ Dialyzer

Indications For Use:

Hemodialysis with the EXELTRA™ Dialyzer is indicated for patients with acute or chronic renal failure when conservative therapy is judged to be inadequate. It also may be indicated in the treatment of patients intoxicated with poisons or drugs.

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

Concurrence of CDRH/Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of Reproductive, Abdominal,
and Radiological Devices

510(k) Number K030974

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

G:\510k\Exeltra 170 Single Use Dialyzers\submission\Indications for Use Statement



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

Jesse K. Seidman, MS, RAC
Director, Global Regulatory Affairs
Medical Products - Renal
Baxter Healthcare Corporation
32650 N. Wilson Road, WG2-3S
Round Lake, IL 60073

NOV 15 2012

Re: Please see enclosed list

Dear Mr. Seidman:

We have reviewed your letter, dated October 31, 2012, stating that you have changed your address and/or contact information for the above referenced premarket notifications (510(k)s). Consequently, we cannot change the original address of the 510(k) submitter in our database. It will remain as it was listed when the final decision was rendered on your 510(k)s. We suggest that you update your address through the Establishment Registration website <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/default.htm>. You may contact the Center for Devices and Radiological Health's Office of Compliance at (301) 796-5500 if you have any questions regarding your change of address.

If you have any other questions regarding this letter, please contact the 510(k) Staff at (301) 796-5640.

Sincerely yours,

Marjorie Shulman
Director, Premarket Notification Section
Program Operations Staff
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Services
Food and Drug Administration

Memorandum

Date: 11/5/12

From: DMC (HFZ-401)

Subject: Premarket Notification Number(s): K030974 / A001

To: Division Director: _____

The attached information has been received by the 510(k) DMC on the above referenced 510(k) submission(s). Since a final decision has been rendered, this record is officially closed.

Please review the attached document and return it to the DMC, with one of the statements checked below.

_____ Information does not change the status of the 510(k); no other action required by the DMC; please add to image file. (Prepare K-25) THIS DOES NOT APPLY TO TRANSFER OF OWNERSHIP. PLEASE BRING ANY TRANSFER OF OWNERSHIP TO POS.

_____ Additional information requires a new 510(k); however, the information submitted is incomplete; (Notify company to submit a new 510(k); [Prepare the K30 Letter on the LAN]

_____ No response necessary (e.g., hard copy of fax for the truthful and accuracy statement, 510(k) statement, change of address, phone number, or fax number).

CLIA CATEGORIZATION refers to laboratory test system devices reviewed by the Division of Clinical Laboratory Devices (HFZ-440)

_____ Information requires a **CLIA CATEGORIZATION**; the complexity may remain the same as the original 510(k) or may change as a result of the additional information (Prepare a CAT letter)

_____ Additional information requires a **CLIA CATEGORIZATION**; however, the information submitted is incomplete; (call or fax firm)

_____ No response necessary

This information should be returned to the DMC within 10 working days from the date of this Memorandum.

Reviewed by: _____

Date: _____

Baxter

FDA CDRH DMC

NOV 02 2012

Received

RIS

October 31, 2012

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center - W066-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002
Attn: Division of Reproductive, Gastro-Renal and Urological Devices

**Re: Change of Official Correspondent
Change of Address of Official Correspondent**
For the attached list of 510(k) Premarket Notifications

Dear Colleague:

This letter is to advise you of the change to the Official Correspondent and the change of address for the Official Correspondent for the 510(k) Premarket Notifications listed in the attached table. Effective immediately, please address all official correspondence to:

Jesse Seidman
Director, Global Regulatory Affairs
Medical Products - Renal
Baxter Healthcare Corporation
32650 N. Wilson Road, WG2-3S
Round Lake, IL 60073
Telephone: 224.270.4412
Fax: 224.270.4119

Thank you for making this change to our files. Please contact me at 224.270.4412 or via email at jesse_seidman@baxter.com with any questions regarding this request.

Sincerely,



Jesse K. Seidman, MS, RAC
Director, Global Regulatory Affairs
Baxter Healthcare Corporation

List of 510(k)s Effected by Correspondent / Address Change

510(k) NUMBER	DEVICE NAME	CLEARANCE DATE
K102936	HOMECHOICE/HOMECHOICE PRO AUTOMATED PERSONAL CYCLER PERITONEAL DIALYSIS SYSTEM MODEL 5C4471 5C8310 5C4471R AND 5C8310R	3/30/2011
K093120	XENIUM XPM 110 XENIUM XPM 130 MODELS M25649A M25650A XENIUM XPM 150 XENIUM XPM 170	2/17/2010
K090002	ACID CONCENTRATE 45X (2.0K 3.1CA) MODEL 5M8001A ACID CONCENTRATE 45X (2.0K 2.5CA) MODEL 5M8002A	8/7/2009
K083778	XENIUM XPH MODELS 110 130 150 170 190 AND 210	2/20/2009
K070320	AQUARIUS HEMOFILTRATION SYSTEM	6/7/2007
K063293	AQUARIUS BLOOD TUBING, AQUASPIKE MANIFOLD, AQUASAFE PRESSURE RELEASE DEVICE	3/23/2007
K062079	XENIUM DIALYZER MODELS 110 130 150 170 190 AND 210	10/19/2006
K061515	RENALSOFT	9/11/2006
K053539	MERIDIAN HEMODIALYSIS MACHINE MODEL 5M5576	5/24/2006
K053512	HOMECHOICE/HOMECHOICE PRO PERSONAL CYCLER PERITONEAL DIALYSIS SYSTEM MODELS 5C4471 AND 5C8310	2/16/2006
K041428	ACCUSOL DIALYSIS SOLUTION	8/27/2004
K031676	HOMECHOICE APD SET WITH LINEO CONNECTOR MODELS 5C4469Q 5C4468Q 5C4531Q 5C8302Q 5C4599Q	11/20/2003
K030099	BAXTER ARENA HEMODIALYSIS DELIVERY SYSTEM MODEL 1571278000	6/17/2003
K030974	EXELTRA HIGH FLUX DIALYZER MODELS 150 & 170	4/25/2003
K030975	EXELTRA PLUS HIGH FLUX DIALYZER MODEL 210	4/25/2003
K023664	SYNTRA + DIALYZER MODEL 200	2/21/2003
K013562	AURORA SYSTEM 1000 SERIES HOME SELF-CARE SINGLE PATIENT DELIVERY SYSTEM; MODELS- SYS 1000 L3 WITH N100 ARM 4B SOFTWARE	12/12/2002
K021615	BAXTER ACCURA SYSTEM MODEL 5M5660	11/18/2002
K012988	HOMECHOICE PERSONAL CYCLER PERITONEAL DIALYSIS SYSTEM MODELS 5C8310 5C8302 5C4471 5C4469	12/5/2001
K002210	SYNTRA DIALYZER MODEL SYNTRA 120 160	2/14/2001
K001685	PSN HEMODIALYZER MODEL PSN 130 150 170 210	11/15/2000
K001422	PSN HEMODIALYZER MODELS PSN 170 PSN 210	6/2/2000
K990643	PS 15 POLYSULFONE HOLLOW FIBER MEMBRANE HEMODIALYZER MODEL 239-015	12/7/1999
K992894	MERIDIAN HEMODIALYSIS MACHINE MODEL 5M5576	11/24/1999
K990953	RENAL LINK	6/18/1999
K970679	ALTRA FLUX 200 HEMODIALYZER	7/23/1998
K970681	ALTRA NOVA 200 HEMODIALYZER	7/23/1998
K974652	BLOOD MONITOR PUMP WITH ULTRAFILTRATION CONTROLLER	7/10/1998

List of 510(k)s Effected by Correspondent / Address Change

510(k) NUMBER	DEVICE NAME	CLEARANCE DATE
K980656	PSN DIALYZER MODEL PSN-170/R5M4235 PSN-210/R5M236	5/19/1998
K980658	PSN DIALYZER MODEL PSN 130/R5M4233 MODEL PSN-150/R5M4234	5/19/1998
K970653	CAHP HIGH PERFORMANCE CELLULOSE DIACETATE (CAPILLARY HOLLOW FIBER)	3/11/1998
K970662	CA CELLULOSE ACETATE HOLLOW FIBER DIALYZER (CA-170/CA-210)	3/11/1998
K970663	CT CELLULOSE TRIACETATE HOLLOW FIBER DIALYZER (CT-110G/CT-190G)	1/11/1998
K963933	PSN-120 HOLLOW FIBER DIALYZER AND PSN-140 HOLLOW FIBER DIALYZER	11/24/1997
K970654	CAHP HIGH PERFORMANCE CELLULOSE DIACETATE (CAPILLARY HOLLOW FIBER)	11/12/1997
K970661	CA CELLULOSE ACETATE HOLLOW FIBER DIALYZER (CA-90)	11/12/1997
K972579	HIGH DOSE DISCONNECT CAP AND MINICAP WITH POVIDONE-IODINE HIGH DOSE DISCONNECT CAP WITH POVIDONE-IODINE	10/1/1997
K970591	BLOOD MONITOR PUMP	9/9/1997
K970446	DRAKE WILLOCK SYSTEM & ALTRA TOUCH 1000 DIALYSIS DELIVERY SYSTEM	6/2/1997
K964922	DRAKE WILLOCK SYSTEM 1000 DIALYSATE DELIVERY SYSTEM ALTRATOUCH 1000 DIALYSATE DELIVERY SYSTEM	5/21/1997
K963203	BENTLEY QUICK-PRIME HEMOCONCENTRATOR WITH DURAFLO TREATMENT	3/25/1997
K955384	DRAKE WILLOCK SYSTEM 1000 DIALYSATE DELIVERY SYSTEM W/SINGLE NEEDLE SINGLE LUMEN OPTION	1/10/1997
K970446	SYSTEM 1000 DIALYSIS DELIEVERY SYSTEM	6/2/1997
K962309	ALTERNATE ENCAPSULATING RESIN SYSTEM FOR MCA HEMODIALYZERS	12/27/1996
K962907	SKINNYFRANSEENWESCOTT NEEDLES	10/23/1996
K963390	BIOPSY INTRODUCER NEEDLE	10/10/1996
K954987	ALTRATOUCH 1000 HEMODIALYSIS DELIVERY SYSTEM	8/8/1996
K961825	ULTRASET/3L CAPD DISPOSABLE DISCONNECT Y-SET MODELS 5C4366 & 5C4493	8/6/1996
K960787	TURARTHROSCOPICCYSTOSCOPY IRRIGATION SETS	5/14/1996
K960509	18 GAUGE TRU-CUT BIOPSY NEEDLE	4/4/1996
K955277	ARTERIAL BLOOD TUBING SET FOR SINGLE NEEDLE HEMODIALYSIS	2/16/1996
K954529	AUTOMATED TRU-CUT BIOPSY DEVICE	12/29/1995
K954218	STERILE FEEDING TUBE	11/3/1995
K952978	ALTRA FLUX 110 HEMODIALYZER	10/5/1995
K952982	ALTREX 110 HEMODIALYZER	10/5/1995

List of 510(k)s Effected by Correspondent / Address Change

510(k) NUMBER	DEVICE NAME	CLEARANCE DATE
K952983	ALTR NOVA 110 HEMODIALYZER	10/5/1995
K944007	EUROPHILIC SLIPPERY COATED FOLEY CATHETER	6/29/1995
K945621	ALTRA NOVA(TM) 170 HEMODIALYZER	5/30/1995
K945625	ALTRA NOVA(TM) 140 HEMODIALYZER	5/30/1995
K945622	MCA(TM) 180 HEMODIALYZER	5/25/1995
K945542	ALTRA FLUX(TM) 170 HEMODIALYZER	5/23/1995
K945620	ALTRA FLUX(TM) 140 HEMODIALYZER	5/18/1995
K945623	MCA(TM) 130 HEMODIALYZER	5/18/1995
K945624	MCA(TM) 160 HEMODIALYZER	5/18/1995
K945631	155 SCE(TM) HEMODIALYZER	5/18/1995
K925581	BAXTER BIostat 1000 UREA MONITOR	5/3/1995
K950454	CAHP HIGH PERFORMANCE CELLULOSE DIACETATE HOLLOW FIBER DIALYZER	4/27/1995
K950522	CAHP HIGH PERFORMANCE CELLULOSE DIACETATE HOLLOW FIBER DIALYZER	4/27/1995
K945595	ALTREX(R) 200 HEMODIALYZER	3/8/1995
K945596	ALTRES(R) 140 HEMODIALYZER	3/8/1995
K945597	ALTRES(R) 170 HEMODIALYZER	3/8/1995
K922757	SPS 1550 SINGLE NEEDLE PATIENT SYSTEM	2/13/1995
K926372	MCA 200 HEMODIALYZER	2/13/1995
K926373	ALTRA FLUX 200 HEMODIALYZER	2/13/1995
K926379	ALTRA NOVA 200 HEMODIALYZER	2/13/1995
K926567	BAXTER CA DIALYZER	1/11/1995
K926568	BAXTER CT DIALYZER	9/30/1994
K935659	BAXTER NIGHT EXCH DEVICE(NXD) PERITONEAL DIALY SYST	7/7/1994
K923065	BAXTER PERSONAL CYCLER AUTOMMATED PERITONEAL DIAL	3/4/1994
K925403	BAXTER APD 12' EXTENSION LINE	2/22/1994
K923312	HF 1200 HEMOFILTER 1.25m ²	2/18/1994
K934803	ARTERIAL & VENOUS BLOOD TUBING SETS FOR HEMODIALYSIS	12/17/1993
K932408	AMBULATORY INFUSION PUMP SYSTEM AND SOLUTION SETS	9/28/1993
K931340	GRASP FORCEPS/SCISSORS/NEEDLE HOLDER/DISSECTOR	7/1/1993
K905552	LAPAROLITH	12/17/1991
K913526	SERAFLO ARTERIAL AND VENOUS BLOODLINE SETS	11/1/1991
K913950	DUO-FLUX(R) ULTRA HIGH PERFORM ARTIFICIAL KIDNEY	11/1/1991
K911315	EXTRACORPOREAL BLOOD PUMPING SYST FOR HEMOFILTRAT	10/30/1991
K911630	LAPAROSCOPIC CHOLANGIOGRAPHY CATHETER WITH BALLOON	9/27/1991
K912839	LAPAROOPTX(TM) INTRAOPER DEFLECT CHOLEDOCHOSCOPE	9/25/1991

List of 510(k)s Effected by Correspondent / Address Change

510(k) NUMBER	DEVICE NAME	CLEARANCE DATE
K911106	MODEL BAXTER ULTRAFILTRATE METER AND DRAIN BAG	5/28/1991
K910270	PREMIXED DIALYSATE FOR HEMODIAFILTRATION	4/18/1991
K905707	BAXTER LAPAROSCOPIC CHOLANGIOGRAPHY CATHETERS	2/13/1991
K905228	MODEL CA.150 CELLULOSE ACETATE HOLLOW FIBER DIALYZ	12/10/1990
K904734	PHARMASEAL DISPOSABLE ABDOMINAL TROCAR	11/21/1990
K902526	CAPD DISPOSABLE DISCONNECT Y-SET CODE: 5C4481	11/20/1990
K901038	SPS 550-IPS (INTEGRATED PATIENT STATION)	4/19/1990
K900086	HEMORRHOIDAL LIGATOR WITH SUCTION	3/19/1990
K900125	ARTERIOVENOUS FISTULA SETS	1/31/1990
K895631	DISCONNECT CAPS PRODUCT CODES 5C4212 AND 5C4466	1/29/1990
K895673	CONNECTION SHIELDS CODES 5C4213 AND 5C4215	1/29/1990
K896006	DIALYSIS PRIMING SETS CODES 5C4094 AND 5C4095	12/27/1989
K895199	BIASOL LIQUID CONCENTRATES ADD'L ACID CONCENTRATE	12/13/1989
K894783	PERITONEAL DIAL. TITA. CATH ADAPTER & LOCKING CAP	9/7/1989
K894838	HEMODIALYSIS SINGLE PATIENT SYSTEM (SPS) 550 VSB	9/7/1989
K883111	HEOMDIALYSIS SINGLE PATIENT SYSTEM (SPS) MODEL 650	2/8/1989
K890315	CAPILLARY FLOW DIALYZERS MODELS CT110G & CT190G	2/8/1989
K884554	PERITONEAL CATHETER STABILIZATION DEVICE 5C4381	1/31/1989
K884725	BIASOL POWDER CONCENTRATES FOR BICARB. DIALYSIS	1/30/1989
K883239	CAPD ULTRAVIOLET(U.V.) GERMICIDAL EXCHANGE DEV SYS	10/21/1988
K883534	CAPILLARY FLOW DIALYZERS MODELS HT.80 & HT.100	10/21/1988
K883644	CAPILLARY FLOW DIALYZERS MODELS HT. 130 & 170	10/21/1988
K881469	ANGIOSCOPE W/INTEGRATED IRRIGATING CHANNEL	9/12/1988
K881781	CATHETER STRAP	8/2/1988
K882680	ALTERNATE BLOOD PORT DESIGN FOR ADDIT. MEMB. OF CA	7/22/1988
K882455	EXTENDED LIFE CAPD SOLUTION TRANSFER SET IC4373	7/13/1988
K882498	EXTENDED LIFE CAPD TRANSFER SET 5C4444	7/13/1988
K880102	BIASOL CONCENTRATES FOR BICARBONATE DIALYSIS	5/26/1988
K881332	DIAFLEX GRASP FORCEPS/RETRIEVAL LOOP & CYTO BRUSH	4/27/1988
K874728	CAPILLARY FLOW DIALYZERS	1/29/1988
K860230	CAPD TRANSFER SET SPIKE	2/5/1986
K851208	COMPACT EXCHANGE DEVICE	4/8/1985
K833065	APD CYCLER	11/28/1983
K830021	AVF NEEDLE	1/14/1983
K812802	CAPD SOLN TRANSFER SET WITH LOCKING CONNECTOR	3/2/1982
K791899	APD CYCLER SETS	11/13/1979
K771302	PFISTER-SCHWARTZ STONE RETRIEVER	8/2/1977
K770280	CORD ELECTROSURGICAL-STERILE & DISPOS.	4/15/1977
K770489	CATHETER WITH HARD VALVE	3/21/1977
K770490	DRAINAGE BAG IMPROVED FLAT	3/21/1977

List of 510(k)s Effected by Correspondent / Address Change

510(k) NUMBER	DEVICE NAME	CLEARANCE DATE
K770256	CATHETERS SILICONE COATED	2/17/1977
K761242	TEFLON COATED RESECTOSCOPE SHEATH	12/16/1976
K760273	LITHOTRITE	12/6/1976
K760172	OBTURATOR VISUAL	12/2/1976
K760173	BRIDGE SHORT DEFLECTING	12/2/1976
K760179	SHEATH CYSTOURETHROSCOPE W/ OBTURATOR	12/2/1976
K760180	FORCEPS GRASPING	12/2/1976
K760182	SHEATH RESECTOSCOPE	12/2/1976
K760183	OBTURATOR DEFLECTING	12/2/1976
K760184	ELEMENT WORKING	12/2/1976
K760189	STOPCOCK WATERLINE	12/2/1976
K761039	URINARY LEG BAG DRAINAGE TUBE	12/2/1976
K760715	FLEXIBLE CUTTING SCISSORS	10/21/1976
K760717	FLEXIBLE BIOPSY FORCEPS	10/21/1976
K760069	BAG LEG URINE COLLECTING DEVICE	10/20/1976
K760178	ELECTRODE CUTTING LOOP	10/15/1976
K760716	FLEXIBLE FOREIGN BODY FORCEPS	10/15/1976
K760793	ADAPTER FOR ELLIK EVACUATOR	10/15/1976
K760174	ADAPTER RESECTOSCOPE	8/30/1976
K760176	FLOORSTAND FIBER OPTIC LIGHT SOURCE	8/30/1976
K760177	TELESCOPE RIGID ENDOSCOPE	8/30/1976
K760274	TIP RUBBER PERFORATED	8/30/1976



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 25 2003

David E. Curtin, RAC
Associate Director, Regulatory Affairs
Renal Division
Baxter Healthcare Corporation
1620 Waukegan Road
MCGAW PARK IL 60085

Re: K030974

Trade/Device Name: EXELTRA™ Dialyzer, Single Use, Models 150 and 170
Regulation Number: 21 CFR §876.5860
Regulation Name: High permeability hemodialysis system
Regulatory Class: II
Product Code: 78 KDI
Dated: March 27, 2003
Received: March 28, 2003

Dear Mr. Curtin:

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.

Page 2

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
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): K030974

Device Name: EXELTRA™ Dialyzer

Indications For Use:

Hemodialysis with the EXELTRA™ Dialyzer is indicated for patients with acute or chronic renal failure when conservative therapy is judged to be inadequate. It also may be indicated in the treatment of patients intoxicated with poisons or drugs.

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

Concurrence of CDRH/Office of Device Evaluation (ODE)

David W. Johnson
(Division Sign-Off)

Division of Reproductive, Abdominal,
and Radiological Devices

510(k) Number K030974

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

G:\510k\Exeltra 170 Single Use Dialyzers\submission\Indications for Use Statement

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

March 28, 2003

BAXTER HEALTHCARE CORP.
RENAL DIVISION
1620 WAUKEGAN RD., MPR-D1
MCGAW PARK, IL 60085
ATTN: DAVID E. CURTIN

510(k) Number: K030974
Received: 28-MAR-2003
Product: EXELTRA HIGH FLUX
DIALYZER, MODELS 150
& 170

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.

The Act, as amended by the Medical Device User Fee and Modernization Act of 2002 (MDUFMA)(Public Law 107-250), authorizes FDA to collect user fees for premarket notification submissions. (For more information on MDUFMA, you may refer to our website at <http://www.fda.gov/oc/mdufma>).

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 manual entitled, "Premarket Notification 510(k) Regulatory Requirements for Medical Devices" available from DSMICA. 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/dsmmain.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

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K030974

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

510(k) Number: _____

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

RECEIVED 10/15/14 11:32

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

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

* - 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.

5/15/17 28
i GED

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

	Present	Inadequate or Missing
Name and 510(k) number of the sponsor's own, unmodified predicate device.	<input checked="" type="checkbox"/>	<input type="checkbox"/>
A description of the modified device and a comparison to the sponsor's predicate device.	<input checked="" type="checkbox"/>	<input type="checkbox"/>
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 sponsor's unmodified predicate device	<input checked="" type="checkbox"/>	<input type="checkbox"/>
A statement that the modification has not altered the fundamental technology of the sponsor's predicate device.	<input checked="" type="checkbox"/>	<input type="checkbox"/>
A Design Control Activities Summary that includes the following elements (a-e):		
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.	<input checked="" type="checkbox"/>	<input type="checkbox"/>
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.	<input checked="" type="checkbox"/>	<input type="checkbox"/>
c. A Declaration of Conformity with design controls that includes the following statements:	<input checked="" type="checkbox"/>	<input type="checkbox"/>
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.	<input checked="" type="checkbox"/>	<input type="checkbox"/>
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.	<input checked="" type="checkbox"/>	<input type="checkbox"/>

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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.)	<input type="checkbox"/>	<input type="checkbox"/>
For 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 .]	<input type="checkbox"/>	<input type="checkbox"/>
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.	<input type="checkbox"/>	<input type="checkbox"/>
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.	<input type="checkbox"/>	<input type="checkbox"/>
For a submission, which relies on a non-recognized standard that has <u>not</u> been historically accepted by the FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device <u>and</u> any additional information requested by the reviewer in order to determine substantial equivalence.	<input type="checkbox"/>	<input type="checkbox"/>
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.	<input type="checkbox"/>	<input type="checkbox"/>

- * - 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:	<input type="checkbox"/>	<input type="checkbox"/>
b) Sterilization and expiration dating information:	<input type="checkbox"/>	<input type="checkbox"/>
i.) sterilization process	<input type="checkbox"/>	<input type="checkbox"/>
ii.) validation method of sterilization process	<input type="checkbox"/>	<input type="checkbox"/>
iii.) SAL	<input type="checkbox"/>	<input type="checkbox"/>
iv.) packaging	<input type="checkbox"/>	<input type="checkbox"/>
v.) specify pyrogen free	<input type="checkbox"/>	<input type="checkbox"/>
vi.) ETO residues	<input type="checkbox"/>	<input type="checkbox"/>
vii.) radiation dose	<input type="checkbox"/>	<input type="checkbox"/>
c) Software Documentation:	<input type="checkbox"/>	<input type="checkbox"/>

Items with checks in the "Present but Deficient" column require additional information from the sponsor. Items with checks in the "Missing" column must be submitted before substantive review of the document.

Passed Screening Yes No

Reviewer: _____

Concurrence by Review Branch: _____

Date: _____

The deficiencies identified above represent the issues 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>

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**510(k) Premarket Notification
EXELTRA™ 150 and 170 Dialyzer, Single Use**

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Date of Submission: March 27, 2003 FDA Document Number:

Section A Type of Submission				
PMA <input type="checkbox"/> Original Submission <input type="checkbox"/> Modular Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment	PMA Supplement <input type="checkbox"/> Regular <input type="checkbox"/> Special <input type="checkbox"/> Panel Track <input type="checkbox"/> 30-Day Supplement <input type="checkbox"/> 30-Day Notice <input type="checkbox"/> 135-Day Supplement <input type="checkbox"/> Real-Time Review <input type="checkbox"/> Amendment to PMA Supplement	PDP <input type="checkbox"/> Pre-submission Summary <input type="checkbox"/> Original PDP <input type="checkbox"/> Notice of intent to Start clinical trials <input type="checkbox"/> Intention to Submit Notice of Completion <input type="checkbox"/> Notice of Completion <input type="checkbox"/> Amendment to PFP <input type="checkbox"/> Report	510(k) <input checked="" type="checkbox"/> Original Submission: <input type="checkbox"/> Traditional <input checked="" type="checkbox"/> Special <input type="checkbox"/> Abbreviated <input type="checkbox"/> Additional Information: <input type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Abbreviated	Meeting <input type="checkbox"/> Pre-IDE Meeting <input type="checkbox"/> Pre-PMA Meeting <input type="checkbox"/> Pre-PDP Meeting <input type="checkbox"/> 180-Day Meeting <input type="checkbox"/> Other (Specify):
IDE <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement	Humanitarian Device Exemption <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement <input type="checkbox"/> Report	Class II Exemption <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	Evaluation of Automatic Class III Designation <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	Other Submissions Describe Submission:

Section B Applicant or Sponsor	
Company / Institution Name: Baxter Healthcare Corporation	Establishment Registration Number: 1417572
Division Name (if applicable): Renal Division, MPGR-A2E	Phone Number (Include Area Code): (847) 473-6079
Street Address: 1620 Waukegan Road	FAX Number (Include Area Code): (847) 473-6952
City: McGaw Park	State / Province: IL 60085
	Country: USA
Contact Name: David E. Curtin, RAC	
Contact Title: Associate Director, Regulatory Affairs	Contact E-Mail Address: curtind@baxter.com

Section C Submitter Correspondent (if different from above)	
Company / Institution Name:	Establishment Registration Number:
Division Name (if applicable):	Phone Number (Include Area Code): ()
Street Address:	FAX Number (Include Area Code): ()
City:	State / Province:
	Country:
Contact Name:	
Contact Title:	Contact E-Mail Address:

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Reason for Submission - PMA, IDE or IDE

<input type="checkbox"/> New Device	<input type="checkbox"/> Change in Design, Component, or Specification:	<input type="checkbox"/> Location Change:
<input type="checkbox"/> Withdrawal	<input type="checkbox"/> Software	<input type="checkbox"/> Manufacturer
<input type="checkbox"/> Additional or Expanded Indications	<input type="checkbox"/> Color Additive	<input type="checkbox"/> Sterilizer
<input type="checkbox"/> Licensing Agreement	<input type="checkbox"/> Material	<input type="checkbox"/> Packager
	<input type="checkbox"/> Specifications	<input type="checkbox"/> Distributor
<input type="checkbox"/> Process Change	<input type="checkbox"/> Other (Specify Below)	
<input type="checkbox"/> Manufacturing		<input type="checkbox"/> Report Submission:
<input type="checkbox"/> Sterilization	<input type="checkbox"/> Labeling Change:	<input type="checkbox"/> Annual or Periodic
<input type="checkbox"/> Packaging	<input type="checkbox"/> Indications	<input type="checkbox"/> Post-Approval Study
<input type="checkbox"/> Other (Specify Below)	<input type="checkbox"/> Instructions	<input type="checkbox"/> Adverse Reaction
	<input type="checkbox"/> Performance Characteristics	<input type="checkbox"/> Device Defect
<input type="checkbox"/> Response to FDA Correspondence:	<input type="checkbox"/> Shelf Life	<input type="checkbox"/> Amendment
<input type="checkbox"/> Request for Applicant Hold	<input type="checkbox"/> Trade Name	
<input type="checkbox"/> Request for Removal of Applicant Hold	<input type="checkbox"/> Other (Specify Below)	<input type="checkbox"/> Change in Ownership
<input type="checkbox"/> Request Extension		<input type="checkbox"/> Change in Correspondent
<input type="checkbox"/> Request to Remove or Add Manufacturing Site		
<input type="checkbox"/> Other Reason (Specify):		

Reason for Submission - IDE

<input type="checkbox"/> New Device	<input type="checkbox"/> Change In:	<input type="checkbox"/> Response to FDA Letter Concerning:
<input type="checkbox"/> Addition of Institution	<input type="checkbox"/> Correspondent	<input type="checkbox"/> Conditional Approval
<input type="checkbox"/> Expansion / Extension of Study	<input type="checkbox"/> Design	<input type="checkbox"/> Deemed Approved
<input type="checkbox"/> IRB Certification	<input type="checkbox"/> Informed Consent	<input type="checkbox"/> Deficient Final Report
<input type="checkbox"/> Request Hearing	<input type="checkbox"/> Manufacturer	<input type="checkbox"/> Deficient Progress Report
<input type="checkbox"/> Request Waiver	<input type="checkbox"/> Manufacturing Process	<input type="checkbox"/> Deficient Investigator Report
<input type="checkbox"/> Termination of Study	<input type="checkbox"/> Protocol - Feasibility	<input type="checkbox"/> Disapproval
<input type="checkbox"/> Withdrawal of Application	<input type="checkbox"/> Protocol - Other	<input type="checkbox"/> Request Extension of Time to Respond to FDA
<input type="checkbox"/> Unanticipated Adverse Effect	<input type="checkbox"/> Sponsor	<input type="checkbox"/> Request Meeting
<input type="checkbox"/> Notification of Emergency Use		
<input type="checkbox"/> Compassionate Use Request	<input type="checkbox"/> Report Submission:	
<input type="checkbox"/> Treatment IDE	<input type="checkbox"/> Current Investigator	
<input type="checkbox"/> Continuing Availability Request	<input type="checkbox"/> Annual Progress	
	<input type="checkbox"/> Site Waiver Limit Reached	
	<input type="checkbox"/> Final	
<input type="checkbox"/> Other Reason (Specify):		

Section D3 Reason for Submission - 510(k)

<input type="checkbox"/> New Device	<input type="checkbox"/> Change in Technology	<input type="checkbox"/> Change in Materials
<input type="checkbox"/> Additional or Expanded Indications	<input type="checkbox"/> Change in Design	<input type="checkbox"/> Change in Manufacturing Process
<input checked="" type="checkbox"/> Other Reason (Specify):		

Device modification adding new code consisting of different fiber count and fiber surface area.

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Section E Additional Information on 510(k) Submissions

Product codes of devices to which substantial equivalence is claimed:				Summary of, or statement concerning safety and effectiveness data: <input checked="" type="checkbox"/> 510(k) Summary Attached <input type="checkbox"/> 510(k) Statement
1 78 KDI	2	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 K890315	1 Capillary Flow Dialyzer, Models CT110G and CT190G	1 Baxter Healthcare Corporation
2 K926568	2 Baxter CT Dialyzer	2 Baxter Healthcare Corporation
3 K970663	3 Baxter CT Dialyzer	3 Baxter Healthcare Corporation
4	4	4
5	5	5
6	6	6

Section F Product Information - Applicable to All Applications

Common or Usual Name or Classification Name:
 High Permeability Hemodialysis System

Trade or Proprietary or Model Name	Model Number
1 Exeltra™ Dialyzer, Single Use	1 Exeltra 150 Dialyzer
2 Exeltra™ Dialyzer, Single Use	2 Exeltra 170 Dialyzer
3	3
4	4
5	5

FDA Document Numbers of All Prior Related Submissions (Regardless of Outcome):

1 K890315	2 K926568	3 K970663	4	5	6
7	8	9	10	11	12

Data Included in Submission: Laboratory Testing Animal Trials Human Trials

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4

Section G Product Classification – Applicable to All Applications

Product Code: 78KDI	C.F.R. Section: 21 CFR 876.5860	Device Class: <input type="checkbox"/> Class I <input type="checkbox"/> Class II	<input checked="" type="checkbox"/> Class II <input type="checkbox"/> Unclassified
Classification Panel: Gastroenterology and Urology			
Indications (From Labeling): Hemodialysis with Exeltra™ Dialyzers is indicated for patients with renal failure when conservative therapy is judged to be inadequate. It also may be indicated in the treatment of patients intoxicated with poisons or drugs.			

Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Registration Form.

Section H Manufacturing / Packaging / Sterilization Sites Relating to a Submission

<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add	<input type="checkbox"/> Delete	FDA Establishment Registration Number: 8030376	<input checked="" type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Manufacturer	<input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Repackager / Relabeler
Company / Institution Name: Nipro Corporation		Establishment Registration Number: 8030376		
Division Name (If Applicable): International Division		Phone Number (Include Area Code)Ⓢ (011 81) 66 375 6713		
Street Address: 8 - 7 Hanukiyachi Nijda		FAX Number (Include Area Code): (011 81) 66 371 7422		

City: Odate City	State / Province: Akita Pref.	Country: Japan
---------------------	----------------------------------	-------------------

Contact Name: Mr. Nori Watanabe

Contact Title: Director International Division	Contact E-Mail Address:
---	-------------------------

<input type="checkbox"/> Original <input checked="" type="checkbox"/> Add	<input type="checkbox"/> Delete	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Manufacturer	<input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Repackager / Relabeler
--	---------------------------------	---	---

Company / Institution Name:	Establishment Registration Number:
Division Name (If Applicable):	Phone Number (Include Area Code):
Street Address:	FAX Number (Include Area Code):

City:	State / Province:	Country:
-------	-------------------	----------

Contact Name:

Contact Title:	Contact E-Mail Address:
----------------	-------------------------

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Baxter

March 27, 2003

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

2003 MAR 28 A 11:32
FOIA/CDRH/OCE/DID

**RE: 510(k) Premarket Notification
EXELTRA™ 150 and EXELTRA™ 170 Dialyzers, Single Use**

Special 510(k): Device Modification

Ladies/Gentlemen:

As required by Section 510(k) of the Medical Device Amendments of 1976, and in conformance with 21 CFR, Part 807, we are providing you with prior notice that we propose to market the EXELTRA™ 150 and EXELTRA™ 170 Dialyzers, Single Use.

The EXELTRA™ 150 and 170 Dialyzers are cellulose triacetate dialyzers and are exactly the same as the CT110G and CT190G single use dialyzers cleared under Baxter's premarket notification applications K890315, K926568 and K970663. The only difference between the previously cleared cellulose triacetate dialyzers and the proposed dialyzers is in the amount of fibers contained within the dialyzer case. The predicate dialyzers consist of 1.1 m² of fibers (CT110G) and 1.9 m² of fibers (CT190G). The proposed dialyzer consists of 1.5 m² of fibers (EXELTRA 150) and 1.7 m² of fibers (EXELTRA 170). Additionally, we are introducing the trademark EXELTRA to identify our family of single use cellulose triacetate dialyzers. All other aspects of the proposed dialyzers are exactly the same as the predicate dialyzers including the materials of construction, manufacturing process and site, sterilization process (gamma sterilization) and packaging. The proposed dialyzers are intended for single use only.

The proposed dialyzers are substantially equivalent to the predicate dialyzers currently marketed by Baxter and cleared under K890315, K926568 and K970663. Substantial equivalence is as described in the attached tab entitled **Substantial Equivalence**.

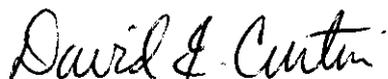
6 37

510(k) Premarket Notification
Exeltra™ 150 and 170 Single Use Dialyzer
Page 2

Any questions regarding the preparation and content of this submission or requests for additional information may be addressed to me at the phone number listed below. In the event I am not available, please contact Mr. Robert Wilkinson at 847-473-6335.

Sincerely,

Baxter Healthcare Corporation



David E. Curtin, RAC
Associate Director, Regulatory Affairs
Renal Division
(847) 473-6079
(847) 473-6952 FAX
curtind@baxter.com

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**510(K) Premarket Notification Checklist
EXELTRA™ 150 and 170 Dialyzer, Single Use**

Device Trade or Proprietary Name: EXELTRA™ High Flux Dialyzer

Device Common Usual Name: High Permeability Hemodialysis System

Class into which Device is Classified Under Section 513: Class II

Device Classification Name: High Permeability Hemodialysis System
21 CFR 876.5860

Classification Panel: Gastroenterology and Urology

Product Code: 78 KDI

Owner Operator Number and Address: 1417572
Baxter Healthcare Corporation
1 Baxter Parkway
Deerfield, IL 60015, USA

Establishment Registration Number and Manufacturing Facilities **Manufacturing Facility:**
(b) (4)

Action taken to comply with §514 of the ACT, Performance. High Permeability Hemodialysis Systems were reclassified into Class II (special controls), pursuant to a final rule published in the Federal Register Vol. 65, No. 63, March 31, 2000.

Standards or §513 Special Controls: We are in compliance with the performance standards established under Section 514 of the Food, Drug and Cosmetic Act including “Biological Evaluation of Medical Devices Part I: Evaluation and Testing” per ISO 10993-1 and “Guidance for the Content of 510(k)s for Conventional and High Permeability Hemodialyzers.”

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510(k) Premarket Notification

EXELTRA™ 150 and 170 Single Use Dialyzers

Page 2

**Reason for 510(k)
Premarket
Notification:**

Device Modification. The EXELTRA™ 150 and 170 dialyzers are an addition to Baxter's Cellulose Triacetate (CT) Dialyzer product line and represents additional fiber surface areas to the currently marketed products. The EXELTRA™ 150 and 170 dialyzes are intended for Single Use Only, and are not validated or labeled for multiple use.

**Equivalence to
Marketed Predicate:**

The EXELTRA™ 150 and 170 single use dialyzers are substantially equivalent to the CT 110G and CT 190G dialyzers previously cleared under K890315, K926568 and K970663. The indication for use, components, materials of construction, manufacturing process, sterilization process and packaging of the EXELTRA™ 150 and 170 single use dialyzers are the same as the predicate CT 110G and CT 190G dialyzers. The trademark EXELTRA will be used to identify Baxter's family of single use cellulose triacetate dialyzers.

The only difference between the proposed dialyzers and the predicate dialyzers is the number of fibers contained within the dialyzer case. The proposed dialyzer contains 1.5 m² of fibers (EXELTRA™ 150) and 1.7 m² of fibers (EXELTRA™ 170). The predicate dialyzers contain 1.1 m² of fibers (CT 110G) and 1.9 m² of fibers (CT 190G). The dialyzer case for the proposed dialyzers has been sized appropriately to accommodate the number of fibers.

Proposed Labeling:

Draft labeling, including Unit label Pouch Label, Carton Label, Performance Data Sheets and Directions for Use for the EXELTRA™ 150 and 170 dialyzers are provided in **TAB 1**.

These products are intended for distribution in the US and Canada, including territories where French is the predominant language. As such, the labeling and labels include both English and French language, the French being an exact translation of the English text.

We are pursuing Canadian regulatory approval separately.

**Equivalent Device
Labeling:**

Copies of the labeling for the predicate CT 110G and CT 190G dialyzers are provided in **TAB 2**.

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510(k) Premarket Notification

EXELTRA™ 150 and 170 Single Use Dialyzers

Page 3

Description of Device:

A product drawing of the EXELTRA™ dialyzer is provided in **TAB 3**.

The EXELTRA™ 150 and 170 dialyzers are cellulose triacetate dialyzer and will be labeled for single use only.

These dialyzers are exactly the same as the predicate cellulose triacetate CT 110G and CT 190G dialyzers currently cleared under K890315, K926568 and K970663.

A list of components comparing the predicate dialyzers to the proposed dialyzers is provided in **TAB 4**.

The indication for use, components, materials of construction, manufacturing process, sterilization process and packaging of the EXELTRA™ 150 and 170 dialyzers are the same as the predicate CT 110G and CT 190G dialyzers. A description of the fiber material and manufacturing process is provided in **TAB 5**.

The only difference between the proposed dialyzer and the predicate dialyzers is the number of fibers contained within the dialyzer case. The proposed dialyzers contain 1.5 m² of fibers (EXELTRA™ 150) and 1.7 m² of fibers (EXELTRA™ 170). The predicate dialyzers contain 1.1 m² of fibers (CT 110G) and 1.9 m² of fibers (CT 190G).

Intended Use Statement:

Hemodialysis with EXELTRA™ dialyzer is indicated for patients with renal failure when conservative therapy is judged to be inadequate. It also may be indicated in the treatment of patients intoxicated with poisons or drugs.

This intended use statement is exactly the same as the intended use statement for the predicate products, with the exception that we have added the trade name EXELTRA™ to describe this family of dialyzers.

Intended Use Statement for Predicate Product:

Hemodialysis with these dialyzers is indicated for patients with acute or chronic renal failure when conservative therapy is judged to be inadequate. It may also be indicated in the treatment of patients intoxicated with poisons or drugs.

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EXELTRA™ 150 and 170 Single Use Dialyzers

Page 4

Summary of the Technological Characteristics and Physical Comparison to the Predicate Device:

The EXELTRA™ dialyzer is a High Flux, gamma sterilized single use product that provides 1.5 m² and 1.7 m² of fiber surface area. The EXELTRA™ dialyzer is identical to the CT dialyzer in all aspects including indication for use, components, materials of construction, manufacturing process, sterilization process and packaging. The proposed dialyzers represent the addition of new fiber surface areas. This modification does not alter the fundamental technology represented by the predicate products. A summary of the technological characteristics and physical comparison between the EXELTRA™ dialyzer and the CT dialyzers is provided in **TAB 4**.

Biocompatibility

The proposed dialyzers consist of the exact same materials of construction as the predicate products. As such, biocompatibility has been established via the predicate product 510(k)s K890315, K926568 and K970663.

Design Control Activities:

The risk analysis methods used to assess the impact of the modifications were a Clinical and Hazard Analysis, Failure Modes and Effects Analysis (FMEA) and a review of the product complaint database. These analyses concluded that no additional verification and validation testing for the change in fiber surface area is required. The modified hemodialyzers were performance tested for bovine blood ultrafiltration rate and clearances of urea, creatinine, phosphate, vitamin B12 and myoglobin. The data has been included in the product data sheet.

A declaration of conformity statement that all verification and validation activities were performed by the designated individuals and results met acceptance criteria, and that the manufacturing facility is in compliance with design controls is provided in **TAB 6**.

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EXELTRA™ 150 and 170 Single Use Dialyzers
Page 5

- Sterilization** Sterilization remains unchanged from that which was cleared for the predicate devices under K890315, K926568 and K970663. Sterilization dose setting is based on ANSI/AAMI/ISO-11137 Method 2B. The Sterility Assurance Level is 10⁻⁶.
- Packaging** Packaging remains unchanged from that which was cleared for the predicate devices under K970663.
- Expiration Dating** The EXELTRA™ dialyzer will be labeled with an expiration date of three years from the production date. Expiration dating of 3 years has been previously established for the predicate devices. Since the materials of construction and manufacturing process for the proposed dialyzers are exactly the same as the predicate devices, the expiration dating will remain at 3 years.
- 510(k) Summary of Safety and Effectiveness** Refer to the **Tab** titled **510(k) Summary** following this Checklist

Official Correspondent:

Robert L. Wilkinson DC
 Robert L. Wilkinson, RAC
 Director, Regulatory Affairs
 Renal Division

3-26-03
 Date

Prepared By:

David E. Curtin
 David E. Curtin, RAC
 Associate Director, Regulatory Affairs
 Renal Division

3-26-03
 Date

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Baxter 510(k) Substantial Equivalence Determination

Question#

1. Does the New Device Have the Same Indications Statements?

Yes. The Exeltra™ Dialyzer has the same indications for use as the equivalent predicate device.

3. Does the New Device Have the Same Intended Use and is the Device “Substantially Equivalent?”

Yes. The Exeltra™ Dialyzer has the same intended use as the predicate device, which is indicated for hemodialysis in patients with renal failure when conservative therapy is judged to be inadequate. They may also be indicated in the treatment of patients intoxicated with poisons or drugs.

Based on the intended use of the products the Exeltra™ Dialyzer is “substantially equivalent” to the predicate device.

4. Does the New Device Have the Same Technological Characteristics, eg. Design, Materials, etc.?

Yes. The EXELTRA™ Dialyzer has the same technological characteristics as the predicate device. The EXELTRA™ dialyzer and the predicate product are designed to filter substances from the blood. The materials of the EXELTRA™ dialyzer are exactly the same as the predicate product.

Are the Descriptive Characteristics Precise Enough to Ensure Equivalence?

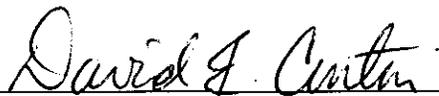
Yes. The descriptive characteristics are precise enough to ensure equivalence. A comparison of the proposed product to the predicate product is provided in **TAB 4**.

Decision: Substantially Equivalent

**Premarket Notification
Truthful and Accurate Statement
[21CFR 807.87(k)]**

Pursuant to 21 CFR 807.87(j), I, David E. Curtin certify, in my capacity as Associate Director, Regulatory Affairs of Baxter Healthcare Corporation, that to the best of my knowledge and belief the data and information submitted in this Premarket Notification are truthful and accurate and that no facts material to the review of the substantial equivalence of the Exeltra™ Dialyzer have been knowingly omitted from this submission.

Baxter Healthcare Corporation



David E. Curtin
Associate Director, Regulatory Affairs
Renal Division

Premarket Notification [510(k)] Number

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15

510(K) SUMMARY

Submitter's Name: David E. Curtin, RAC

Address: 1620 Waukegan Rd. MPGR-A2E

Phone: (847) 473-6079

Fax: (847) 473-6952

Contact: David E. Curtin

Date Prepared: 3/27/03

Trade Name: EXELTRA™ Dialyzer, Single Use

Common Name: Dialyzer

Classification Name: High Permeability Hemodialysis System per 21 CFR 876.5860

Equivalent Predicate: Baxter CT Dialyzer, Single Use (K890315, K926568, K970663)

Device Description: Model EXELTRA™ 150 and 170 Single Use Dialyzers

Intended Use: Hemodialysis with EXELTRA™ dialyzers is indicated for patients with renal failure when conservative therapy is judged to be inadequate. It also may be indicated in the treatment of patients intoxicated with poisons or drugs.

Summary of the Technological Characteristics Compared to the The general design and material of the EXELTRA™ 150 and 170 single use dialyzers are similar to the CT 110 and CT190G dialyzers cleared under K890315, K926568 and K970663, and do not raise any new types of safety and effectiveness issues, when compared to the predicate product.

510(k) Premarket Notification

EXELTRA™ 150 and 170 Single Use Dialyzers

Page 2 of 2

Predicate Device: Baxter CT Dialyzers

Clinical Data: N/A

Conclusions Drawn Components of the subject EXELTRA™ dialyzers have met the biological requirements of ISO 10993-1: Biological Evaluation of Medical devices – Part: Guidance on selection of tests.

The validation of the gamma sterilization cycle for the EXELTRA™ dialyzer is based upon the AAMI/ISO 11137:1994 “Sterilization of Healthcare Products – Requirements for Validation and Routine Control – Radiation Sterilization”.

Functional testing for blood side integrity and conformance to manufacturing specifications are performed as in-process and/or final inspections prior to product release to ensure a quality product.

Additional Information

Requested by FDA: None to date

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Indications for Use Statement

510(k) Number (if known): _____

Device Name: EXELTRA™ Dialyzer

Indications For Use:

Hemodialysis with the EXELTRA™ Dialyzer is indicated for patients with renal failure when conservative therapy is judged to be inadequate. It also may be indicated in the treatment of patients intoxicated with poisons or drugs.

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

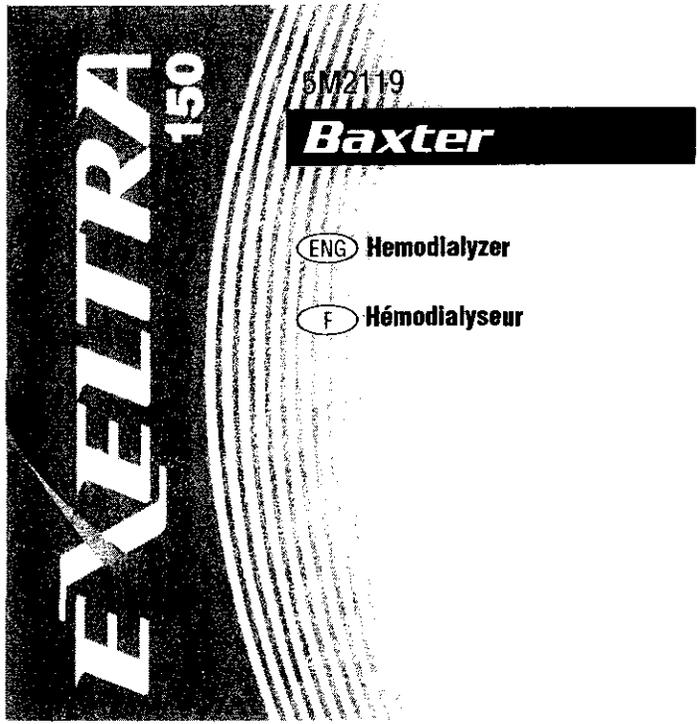
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

18 49



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



For Single Use Only



See Instructions For Use



500 mmHg
66 kPa
Max TMP



Sterilized By
Gamma Irradiation

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Baxter International Inc.

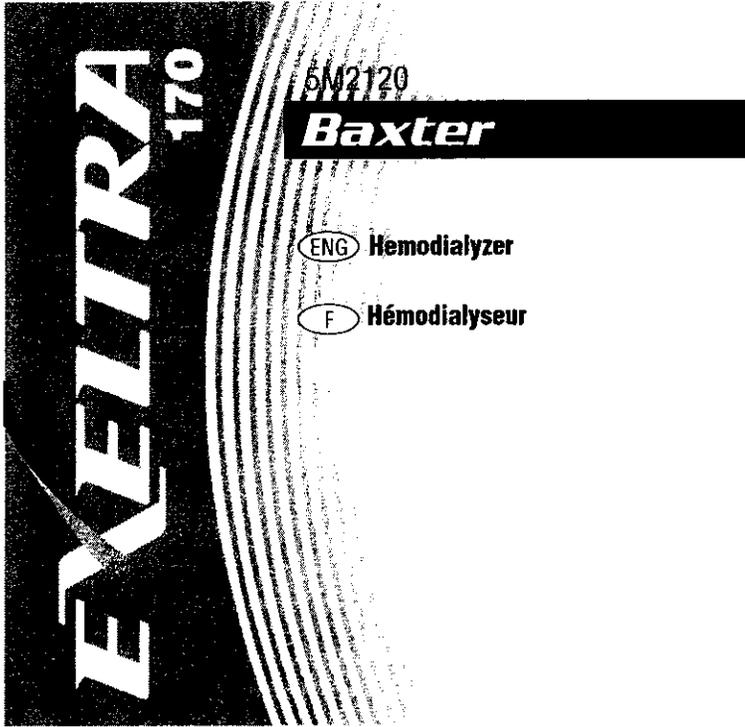
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2003/03

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



For Single Use Only



See Instructions For Use



500 mmHg
66 kPa
Max TMP



Sterilized By
Gamma Irradiation

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2003/03

Lot



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5M2119

Baxter

**EXELTRA High Flux Dialyzer/Dialyseur EXELTRA
Model EXELTRA 150/Modèle EXELTRA 150**

ⓘ Do not use if blood port tip protectors are not in place.
Do not use if package has been previously opened or damaged.
Do not store above 40°C (104°F). Avoid excessive changes in relative humidity.
Avoid direct exposure to sunlight and vibrations.

Warning: This device must be used on dialysis machines equipped with an ultrafiltration controller or an accurate fluid balancing system.

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

Baxter and EXELTRA are trademarks of Baxter International Inc.

Baxter et EXELTRA sont des marques de commerce de Baxter International Inc.

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Baxter Healthcare Corporation

Deerfield, IL 60015 USA

Made in Japan/Fabrique au Japon

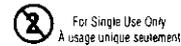
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2003/03

ⓘ Ne pas utiliser si les protecteurs de stérilité des connecteurs sanguins ne sont pas à leur place.
Ne pas utiliser si l'emballage a été ouvert auparavant ou endommagé.
Ne pas stocker à plus de 40 °C (104 °F). Éviter les changements excessifs en humidité relative.
Éviter l'exposition directe à la lumière et aux vibrations.

Attention : ce dispositif ne doit être utilisé qu'avec des générateurs de dialyse équipés d'un maîtreur d'ultrafiltration ou d'un système précis de contrôle de l'équilibre des liquides.

Attention : En vertu de la loi fédérale américaine, cet appareil ne peut être vendu que par un médecin ou sur la demande d'un médecin.



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5M2120

Baxter

EXELTRA High Flux Dialyzer/Dialyseur EXELTRA
Model EXELTRA 170/Modèle EXELTRA 170

Ⓢ Do not use if blood port tip protectors are not in place.
Do not use if package has been previously opened or damaged.
Do not store above 40°C (104°F). Avoid excessive changes in relative humidity.
Avoid direct exposure to sunlight and vibrations.

Warning: This device must be used on dialysis machines equipped with an ultrafiltration controller or an accurate fluid balancing system.

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

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Baxter et EXELTRA sont des marques de commerce de Baxter International Inc.

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Baxter Healthcare Corporation
Deerfield, IL 60015 USA

Made in Japan/Fabriqué au Japon
07-07-35-345 2003/03

Ⓢ Ne pas utiliser si les protecteurs de stérilité des connecteurs sanguins ne sont pas à leur place.
Ne pas utiliser si l'emballage a été ouvert auparavant ou endommagé.
Ne pas stocker à plus de 40 °C (104 °F). Éviter les changements excessifs en humidité relative.
Éviter l'exposition directe à la lumière et aux vibrations.

Attention : ce dispositif ne doit être utilisé qu'avec des générateurs de dialyse équipés d'un maltriseur d'ultrafiltration ou d'un système précis de contrôle de l'équilibre des liquides.

Attention : En vertu de la loi fédérale américaine, cet appareil ne peut être vendu que par un médecin ou sur la demande d'un médecin.



See Instructions For Use
Voir mode d'emploi



For Single Use Only
À usage unique seulement



Sterilized By Gamma Irradiation
Stérilisé par rayonnement gamma



Lot



Exp/Péremp.

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Baxter**ENG EXELTRA High Flux Dialyzers**
Directions for Use

Baxter cannot warrant the sterility, nonpyrogenicity, mechanical integrity or performance of this dialyzer when reused. Deviation from described method should be undertaken only under the supervision or with the approval of a physician. See specific data sheet for performance characteristics.

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

Caution for Storage

Store at 0°C to 40°C, avoiding direct exposure to sunlight and vibrations. Avoid excessive changes in relative humidity.

Indications

Hemodialysis with **EXELTRA** dialyzers is indicated for patients with renal failure when conservative therapy is judged to be inadequate. It also may be indicated in the treatment of patients intoxicated with poisons or drugs.

The device should be used only on the direction of a physician.

Contraindications

There are no special contraindications for use of this dialyzer for the hemodialysis procedure. Patients with a history of allergic reactions to Cellulose Triacetate should not be treated using this product.

Adverse Reactions

Patients may experience hypersensitivity (allergic) reactions during treatment. Symptoms and signs have included asthmatic reactions, respiratory arrest, pruritus, urticaria, erythema, peripheral and facial edema, hypertension, hypotension, and cardiac arrhythmia. A history of allergic responses, including asthma is an indication for careful monitoring for such signs or symptoms during treatment.

Side effects such as hypotension, hypertension, headache and nausea, which may be associated with hypovolemia or hypervolemia, can usually be avoided by careful management of the patient's fluid, electrolyte balance, blood flow rate and ultrafiltration rate.

Warnings and Precautions

Refer to specific procedures for additional warnings and precautions.

WARNING: The performance properties of reused EXELTRA dialyzers have not been established and processes for disinfectant procedures have not been validated. Ineffective removal of residual disinfectant may lead to adverse patient reactions.

Air Embolism

Air in the extracorporeal circuit during treatment must be avoided. If air gets into the system, the treatment must be discontinued and the blood must not be returned to the patient.

Hypersensitivity Reactions

It is recommended that treatment be discontinued in any patient exhibiting signs or symptoms of a hypersensitivity reaction. **The blood contained in the extracorporeal circuit at the time of the reaction should not be returned to the patient.**

High Permeability Dialyzers

EXELTRA dialyzers must be used only in conjunction with dialysis machines equipped with an ultrafiltration controller or an accurate fluid balancing system.

Use of the **EXELTRA** dialyzer under clinical conditions of high transmembrane pressure may result in net ultrafiltration rates that greatly exceed the ultrafiltration requirements of some patients. Under these conditions, the use of sterile reinfusion fluid is mandatory.

Dialysate Fluid

Use of an in-line conductivity monitor is recommended. To avoid hemolysis, dialysate temperature should never exceed 42°C (107.6°F).

Treatment Procedure

1. Aseptic technique must be employed.
2. All connections should be checked carefully before and during treatment.
3. The inlet (arterial) and outlet (venous) air bubble traps must be 3/4 full at all times. Since air may be drawn into the extracorporeal circuit on the negative pressure side of the blood pump, the use of an air bubble detector on the venous line is recommended.
4. To preserve fiber integrity, do not exceed 500 mmHg (66 kPa) transmembrane pressure.
5. Weighing the patient before and after treatment is recommended to verify the extent of ultrafiltration.
6. Many dialysis products available from other manufacturers are used with equipment or disposables from Baxter Healthcare Corporation. Baxter has no control over variability, tolerances, mechanical strength or changes in these products which may be made from time to time. Therefore, Baxter cannot ensure that the dialysis products of other manufacturers, when connected with its products, will function in a satisfactory manner.
7. If the patient is under drug therapy, blood levels must be monitored to assure appropriate therapeutic levels are maintained.

Set Up Procedure

Refer to **Warnings and Precautions** section for additional statements.

Do not use if blood port tip protectors are not in place.

Do not use if package has been previously opened or damaged.

Initial Assembly

Connect the inlet (arterial) set, outlet (venous) set, monitoring lines, saline administration line, and heparin line (where applicable) to the dialysis machine and dialyzer.

Air Testing

Although this dialyzer has been tested for mechanical integrity, a rupture or leak leading to blood loss can occur during treatment. Therefore, air leak testing before use, constant monitoring by a blood leak detector on the dialysate fluid line, and visual inspection of the system is recommended.

1. Air testing should be completed prior to wetting either the blood or dialysate sides of the dialyzer.
2. Clamp the outlet (venous) set below the bubble trap and any other tubes necessary to create a closed system on the venous side.
3. Prior to turning on the blood pump, make sure there is an open port through which air can be drawn into the inlet (arterial) set through a bacterial barrier such as a sterile pressure transducer isolator. Turn on the blood pump and slowly increase the pressure in the extracorporeal circuit to 300 mmHg (39.9 kPa) as measured on the venous pressure monitor.
4. Turn off the blood pump and clamp off the inlet (arterial) set between the pump and the dialyzer.
5. If a pressure drop greater than 10 mmHg within 30 seconds occurs, check for a faulty clamp or connection before assuming a dialyzer leak exists. A confirmed drop in pressure greater than 10 mmHg within 30 seconds is not acceptable and the dialyzer should be replaced.
6. Release air slowly by unclamping the outlet (venous) set. Release clamp on the inlet (arterial) set.

Priming

Adherence to rinsing instructions is essential for removal of air and residues within the device.

1. Position the dialyzer in the holder with the venous blood port directed upwards. Note: It is important to keep the dialyzer in this position during priming of the blood compartment. Close or plug both dialysate ports using the blood port tip protectors. (Refer to Figure 1)
2. Attach an IV Administration Set to a one liter container of sterile isotonic saline (0.9% saline) and connect it as follows:
 - a. In a set equipped with a saline administration port, the isotonic saline can be introduced by gravity flow at the saline administration port. When the section between the port and cannula connector is free of air, cross-clamp near the cannula connector.
 - b. When using a set equipped with an inlet priming port with cap over the patient connection, attach the administration set directly into the port.
3. Run the isotonic saline through the extracorporeal circuit at a flow rate of approximately 200 mL/min.
4. After approximately 500 mL of isotonic saline has been run through the dialyzer, and the dialyzer has been purged of all air, stop the blood pump and rotate the dialyzer 180 degrees so the arterial blood port (red) is directed upwards.
5. Remove tip protectors from the dialysate ports. Attach the dialysate connectors so that the dialysate fluid inlet line is near the venous blood port. Blood and dialysate fluid should flow countercurrently. Start the blood pump and initiate dialysate flow at a rate of approximately 500 mL/min. Set the ultrafiltration rate as low as possible. Do not allow the dialysate-side pressure to become greater than the blood-side pressure. Do not run the saline bag empty to prevent air from entering the system.
6. Turn off the blood pump after the extracorporeal circuit has been rinsed with 1000 mL of sterile isotonic saline. Make sure the blood compartment is filled with isotonic saline.
7. Continue to run dialysate for another 5 minutes, then proceed to clamp the arterial and venous lines near the cannula connector. Discard the spent priming fluid. The venous bubble trap should be 3/4 full.

action: When the priming procedure has been completed, and the extracorporeal circuit is free of air, set the ultrafiltration rate as low as possible. Do not allow the dialysate-side pressure to become greater than the blood-side pressure. This will minimize the ultrafiltration of priming solution from the dialyzer between the time when the circuit is primed and treatment is to commence. If for any reason the treatment procedure is not started immediately following the completion of priming, the isotonic saline solution in the circuit should be replaced with fresh solution immediately prior to the initiation of treatment.

Treatment Procedure

Refer to the **Warnings and Precautions** section for additional statements.

Specific directions should be given by the attending physician.

Caution: Operation of the dialyzer at a zero net UF rate or at extremely low net UF rates may cause the dialysate-side pressure to exceed the blood-side pressure in a portion of the dialyzer. Because the likelihood of reverse UF of nonsterile dialysate into the blood is increased under these conditions, the UF rate must be carefully adjusted as directed by a physician.

Administration of Heparin

Systemic or regionalized heparinization may need to be administered based on instructions from attending physician.

Initiation of Treatment

For extracorporeal circuit configuration, refer to Figure 2.

Warning: Carefully observe the outlet (venous) bubble trap chamber as blood enters. If blood appears hemolyzed, clamp off the outlet (venous) set and simultaneously shut off the blood pump. Clamp off the inlet (arterial) set. Verify that the dialysate mixture is proportioned correctly and properly formulated, then explore other causes (e.g. dialysate over-temperature, improper priming fluids). Purge all incompatible fluid from the dialyzing fluid path. **The blood must not be returned to the patient.** When cause has been determined and corrected, discard the dialyzer and sets. Set up a new dialyzer and sets and prepare the circuit in the normal way for starting treatment.

1. Connect the arterial cannula to the inlet (arterial) set and the venous cannula to the outlet (venous) set. Secure fittings before proceeding.
2. Remove the clamps from the patient's cannula or fistula needles and the inlet (arterial) set, then remove the outlet (venous) set clamp. Coordinate the starting of the blood pump with this action. Start the blood pump slowly and adjust the speed to at least 80 mL/min. Do not allow the level in the arterial and venous bubble traps to drop below the manufacturer's recommended full level.
3. Check to make sure there is no air present in the arterial or venous headers. If air is present, run blood at a flow rate of 200 mL/min for five to ten minutes through the dialyzer to remove any air bubbles.
4. Ensure that the appropriate treatment parameters are properly set, e.g. blood flow rate, dialysate flow rate, ultrafiltration rate.

Treatment Monitoring

It is recommended to monitor the post-pump inlet (arterial) pressures during treatment. A continuing rise in inlet arterial pressure may indicate an obstruction in the dialyzer or lines leading to the patient.

Although this dialyzer has been tested for mechanical integrity, a rupture or leak leading to blood loss can occur during treatment. Therefore, constant monitoring by a blood leak detector on the dialysate fluid line and visual inspection of the system is recommended.

If a blood leak occurs, an attempt may be made (at the discretion of the attending physician) to return blood from the extracorporeal system to the patient (see Termination of Treatment). If the decision is made not to return the blood to the patient, clamp off the outlet (venous) set and simultaneously shut off the blood pump. Clamp off the inlet (arterial) set. Discard the dialyzer and sets.

Termination of Treatment

Warning: Any air that was trapped inadvertently in the dialyzer during priming and treatment may be dislodged. Carefully monitor the level of the venous bubble trap at all times. Air rinsing of blood at the termination of treatment is not recommended.

1. Set ultrafiltration rate as low as possible. Do not allow the dialysate-side pressure to become greater than the blood-side pressure.
2. Stop dialysate flow.
3. Reduce blood pump speed to zero and sequentially clamp outlet (venous) and inlet (arterial) sets and arterial cannula.
4. Separate the inlet (arterial) set from the arterial cannula and connect the (arterial) set to a source of sterile isotonic saline.
5. Open the clamps on the fluid administration set, the inlet (arterial) set, and the outlet (venous) set and turn up the blood pump slowly to 100 mL/min to return the blood to the patient.
6. Intermittently clamp and unclamp the tubing beneath the venous bubble trap with a line clamp. This will increase and decrease the pressure within the dialyzer which will help reduce the amount of blood retained in the dialyzer. Do not exceed the dialysis machine pressure limits.
7. Pump the fluid through the blood tubing until the fluid in the outlet (venous) set is as clear as desired.
8. Shut off the blood pump and clamp off the outlet (venous) set and the venous cannula. Separate the outlet (venous) set from the venous cannula.
9. Discard dialyzer and all other disposable equipment. Clean dialyzing equipment following manufacturer's instruction manual.
10. Provide appropriate care to the patient's vascular access as prescribed by the physician.

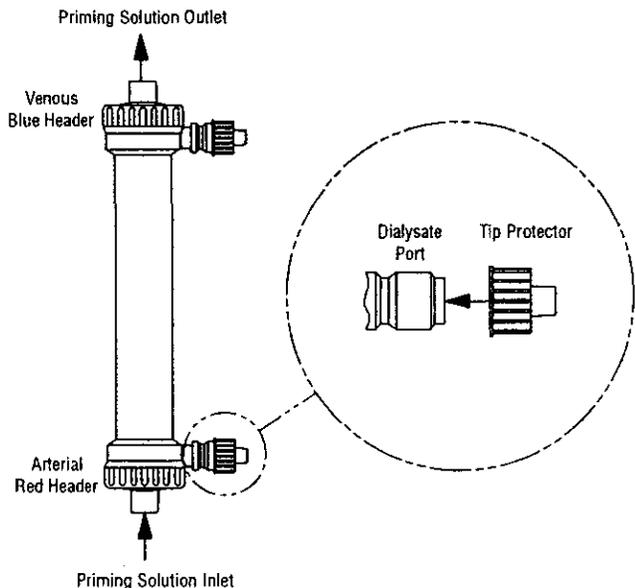


Figure 1 - Dialyzer Orientation During Blood Compartment Priming.

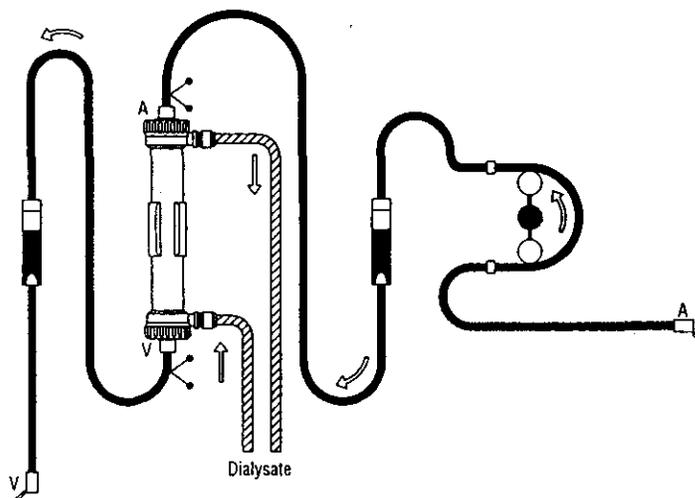


Figure 2 - Extracorporeal Circuit for Hemodialysis Treatment.

	R	Blood path is sterile and nonpyrogenic. Sterilized by gamma irradiation.
	500 mmHg 66 kPa	To preserve fiber integrity, do not exceed 500 mmHg (66 kPa) transmembrane pressure.
		For single use only.

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Baxter

F Dialyseurs EXELTRA Mode d'emploi

Baxter ne peut garantir la stérilité, l'apyrogénicité, l'intégrité mécanique ou la performance du dialyseur si ce dernier a déjà été utilisé. Les modifications par rapport à la méthode indiquée doivent être effectuées seulement sous le contrôle ou avec l'accord d'un médecin. Consultez la fiche technique spécifique pour les performances.

Attention : En vertu de la loi fédérale américaine, cet appareil ne peut être vendu que par un médecin ou sur la demande d'un médecin.

Précautions de stockage

Stocker à une température de 0 °C à 40 °C, éviter les vibrations et l'exposition directe au soleil. Éviter les variations excessives d'humidité relative.

Indications

L'utilisation du dialyseur **EXELTRA** est indiquée pour l'hémodialyse chez les patients souffrant d'insuffisance rénale pour lesquels le traitement classique est jugé inadéquat, ou en cas d'intoxication médicamenteuse due à l'ingestion de médicament ou de poison.

Ce dispositif ne doit être utilisé que sous la stricte surveillance d'un médecin.

Contre-indications

Il n'existe aucune contre-indication spécifique en rapport avec l'utilisation de ce dialyseur lors d'une procédure d'hémodialyse. Les patients présentant des antécédents de réaction allergique au triacétate de cellulose ne doivent pas être dialysés avec ce produit.

Effets indésirables

Des réactions d'hypersensibilité (type allergique) peuvent se présenter durant le traitement. Des symptômes et des signes de réactions asthmatiques, d'arrêt respiratoire, de prurit, d'urticaire, d'érythème, d'œdèmes périphérique et facial, d'hypertension, d'hypotension, et d'arythmie cardiaque ont été signalés. Chez les patients présentant des antécédents de réactions allergiques, y compris l'asthme, il est nécessaire de surveiller ces signes et les symptômes pendant le traitement.

Les effets secondaires souvent associés à une hypovolémie ou une hypervolémie, tels que l'hypotension, l'hypertension, les maux de tête et les nausées peuvent généralement être évités par une surveillance stricte de l'équilibre hydroélectrolytique du patient et par le contrôle du débit sanguin et du taux d'ultrafiltration.

Recommandations et précautions

Se reporter aux procédures spécifiques pour d'autres recommandations et précautions.

AVERTISSEMENT : dans le cas d'une réutilisation, les propriétés de performance des dialyseurs EXELTRA n'ont pas été établies et les procédures de désinfection n'ont pas été validées. La persistance de résidus de désinfectant peut provoquer des réactions indésirables chez les patients.

Embolie gazeuse

Éviter la présence d'air dans le circuit extracorporel pendant le traitement. Si de l'air s'introduit dans le système, le traitement doit être interrompu et le sang ne doit pas être restitué au patient.

Réactions d'hypersensibilité

Il est recommandé d'interrompre le traitement si le patient présente des signes ou des symptômes de réactions d'hypersensibilité. **Il est impératif de ne pas restituer au patient le sang contenu dans le circuit extracorporel au moment où la réaction a eu lieu.**

Dialyseurs à haute perméabilité

Les dialyseurs **EXELTRA** ne doivent être utilisés qu'avec des générateurs de dialyse équipés d'un maîtreur d'ultrafiltration ou d'un système précis de contrôle de l'équilibre de liquides.

L'utilisation du dialyseur **EXELTRA** dans des conditions cliniques de pression transmembranaire élevée peut entraîner un taux d'ultrafiltration net pouvant largement dépasser les besoins d'ultrafiltration de certains patients. Dans ces conditions, l'utilisation d'une solution de réinjection stérile est obligatoire.

Dialysat

L'utilisation d'un contrôleur de conductivité en ligne est recommandée. Afin d'éviter une hémolyse, la température du dialysat ne doit jamais dépasser les 42 °C.

Procédure

1. S'astreindre à une asepsie rigoureuse.
2. Tous les raccordements doivent être soigneusement contrôlés avant et pendant le traitement.
3. Les pièges à bulles d'entrée (artériel) et de sortie (veineux) doivent toujours être aux 3/4 pleins. De l'air pouvant s'introduire à l'intérieur du circuit extracorporel en amont de la pompe à sang, l'utilisation d'un détecteur de bulles d'air sur la ligne veineuse est recommandée.
4. Afin de préserver l'intégrité des fibres, ne pas dépasser une pression transmembranaire de 500 mmHg (66 kPa).
5. Il est recommandé de peser le patient avant et après le traitement afin de vérifier l'importance de l'ultrafiltration.
6. Différents produits de dialyse distribués par d'autres firmes peuvent être utilisés avec le matériel ou les produits de Baxter Healthcare Corporation. Comme Baxter n'est pas responsable des variations, des tolérances, de la résistance mécanique ou des modifications pouvant survenir à ces produits, Baxter ne peut garantir le bon fonctionnement des produits de dialyse des autres firmes lorsqu'ils sont connectés aux produits Baxter.
7. Si le patient est sous traitement médicamenteux, vérifier régulièrement les niveaux sanguins pour assurer le maintien de niveaux thérapeutiques appropriés.

Procédure de mise en route

Consultez la section **Recommandations et précautions** pour des instructions supplémentaires.

Ne pas utiliser si les protecteurs de stérilité des connecteurs sanguins ne sont pas à leur place.

Ne pas utiliser si l'emballage a été ouvert auparavant ou endommagé.

Montage initial

Connecter la ligne d'entrée (artérielle), la ligne de sortie (veineuse), les lignes de contrôle, la ligne d'administration de soluté et la ligne d'héparine (le cas échéant) au générateur de dialyse et au dialyseur.

Test à la pression du dialyseur

Bien que l'intégrité mécanique de ce dialyseur ait été testée, il peut toujours se produire en cours de traitement une rupture ou une fuite entraînant une perte de sang. C'est pourquoi il est recommandé de faire préalablement à l'utilisation un essai à la pression et d'exercer ensuite un contrôle permanent à l'aide d'un détecteur de fuite de sang placé sur la ligne du dialysat. Une inspection visuelle du système est également recommandée.

1. Le test à la pression doit être achevé avant le rinçage du compartiment sang et dialysat du dialyseur.
2. Clamper la ligne de sortie (veineuse) en aval du piège à bulles, ainsi que toutes les autres tubulures nécessaires à la mise en place d'un système clos sur la ligne veineuse.
3. Avant d'actionner la pompe à sang, s'assurer qu'il existe un orifice ouvert par lequel de l'air peut être aspiré dans la ligne d'entrée (artérielle) au travers d'un filtre bactérien tel qu'un isolateur de pression stérile. Actionner la pompe et augmenter lentement la pression dans le circuit extracorporel jusqu'à 300 mmHg (39,9 kPa) comme mesuré par le manomètre de pression veineuse.
4. Arrêter la pompe et clamper la ligne artérielle entre le dialyseur et la pompe.
5. Si la chute de pression est supérieure à 10 mmHg dans un délai de 30 secondes, vérifier qu'il n'y a pas d'erreur de clampage ou de raccordement avant de conclure à une fuite dans le dialyseur. Une chute de pression supérieure à 10 mmHg dans un délai de 30 secondes n'est pas acceptable et le dialyseur doit être remplacé.
6. Faire éventer l'air lentement en déclamant la ligne d'entrée (veineuse). Retirer le clamp de la ligne de sortie (artérielle).

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Amorçage

" est indispensable de bien suivre les instructions de rinçage pour éliminer l'air et les sidus de l'intérieur du dispositif.

- Placer le dialyseur dans son support, l'embout veineux du sang dirigé vers le haut. Remarque : il est important de maintenir le dialyseur dans cette position pendant l'amorçage du compartiment sang. Fermer les sorties du dialysat à l'aide des protecteurs de stérilité des connecteurs sanguins (se référer à la figure 1).
- Raccorder un nécessaire pour perfusion i.v. à une poche d'un litre de solution saline isotonique stérile à 0,9 % comme suit :
 - Dans le cas d'une ligne comportant un site d'injection de solution saline isotonique, la solution peut être administrée par gravité au niveau de ce site. Lorsque la section entre le site et le connecteur de canule est purgée d'air, clamber à proximité de ce connecteur.
 - Si la ligne comporte un site d'amorçage avec capuchon sur la connexion patient, raccorder le nécessaire pour perfusion directement sur le site.
- Faire circuler la solution saline isotonique à travers le circuit extracorporel à un débit d'environ 200 mL/min.
- Après avoir fait circuler environ 500 mL de solution saline isotonique à 0,9 % dans le dialyseur et éliminé l'air, arrêter la pompe à sang et tourner le dialyseur de 180 ° pour que la sortie artérielle (rouge) se trouve vers le haut.
- Retirer les protecteurs de stérilité des sorties dialysat. Fixer les connecteurs dialysat pour que la ligne d'entrée du dialysat se trouve près de l'embout du sang veineux. Le sang et le dialysat doivent circuler en sens inverse. Mettre la pompe à sang en marche et faire couler le dialysat à un débit d'environ 500 mL/min. Régler le taux d'ultrafiltration au minimum. Ne pas laisser la pression dans le compartiment dialysat dépasser celle du compartiment sang. Ne pas faire fonctionner le sac de solution saline à vide pour éviter l'entrée d'air dans le système.
- Arrêter la pompe à sang après avoir rincé le circuit extracorporel avec 1000 mL de solution saline isotonique stérile à 0,9 %. S'assurer que le compartiment sang est rempli de solution saline isotonique.
- Continuer à faire circuler le dialysat pendant 5 minutes puis clamber les lignes artérielle et veineuse près du connecteur de la canule. Jeter le liquide d'amorçage utilisé. Le piège à bulles de la ligne veineuse devrait être aux 3/4 plein.

Attention : une fois le dialyseur amorcé et le circuit extracorporel purgé, régler le taux d'ultrafiltration au minimum. Ne pas laisser la pression du compartiment dialysat dépasser celle du sang. Ceci permet de minimiser l'ultrafiltration du liquide d'amorçage du dialyseur entre le moment où le circuit est amorcé et le début du traitement. Si pour une raison quelconque la procédure ne commence pas immédiatement après l'amorçage, la solution saline isotonique du circuit doit être immédiatement remplacée avec une nouvelle solution avant le début du traitement.

Procédure

Se référer à la section **Recommandations et précautions** pour des instructions supplémentaires.

Des instructions spécifiques seront données par le médecin traitant.

Précautions : l'utilisation du dialyseur avec taux d'UF (ultrafiltration) net nul ou à des taux d'UF nets extrêmement bas peut entraîner une pression dans le compartiment dialysat supérieure à la pression du compartiment sang dans une partie du dialyseur. Comme la probabilité d'ultrafiltration inverse de dialysat non stérile dans le sang augmente dans ces conditions, le taux d'ultrafiltration doit être soigneusement réglé selon les indications d'un médecin.

Injection d'héparine

Une héparinisation systémique ou locale peut être réalisée selon les instructions du médecin traitant.

Démarrage du traitement

Pour la configuration du circuit extracorporel, se référer à la figure 2.

Attention : observer attentivement le piège à bulles de sortie (veineux) au moment où pénètre le sang. Si ce dernier semble hémolysé, clamber la ligne de sortie (veineuse) et arrêter simultanément la pompe à sang. Clamber la ligne d'entrée (artérielle). Vérifier la formulation et les proportions du mélange puis chercher les autres causes possibles (surchauffe du dialysat, utilisation d'un liquide d'amorçage inadéquat). Purger tout liquide incompatible du circuit de dialyse. **Le sang ne doit pas être titulé au patient.** Une fois la cause identifiée et corrigée, mettre le dialyseur et les lignes au rebut. Installer un nouveau dialyseur et des lignes et préparer le circuit selon la procédure normale pour commencer le traitement.

- Raccorder la canule artérielle sur la ligne d'entrée (artérielle) et la canule veineuse sur la ligne de sortie (veineuse) sur les lignes appropriées. Bien serrer les raccords avant de continuer.
- Retirer les clamps de la connexion patient ou des aiguilles à fistules et de la ligne d'entrée (artérielle), puis retirer le clamp de la ligne de retour (veineuse). Coordonner cette action avec le démarrage de la pompe à sang. Démarrer la pompe à sang lentement et régler la vitesse à un minimum de 80 mL/min. Le niveau des pièges à bulles artériel et veineux ne doit pas descendre au-dessous du niveau recommandé par le fabricant.
- Vérifier qu'il n'y a pas d'air dans les têtes de sortie artérielle et veineuse. Si de l'air est présent, faire circuler le sang à un débit de 200 mL/min pendant 5 à 10 minutes dans le dialyseur pour retirer toute bulle d'air.
- Vérifier que les paramètres du traitement sont bien réglés : le débit de sang, le débit de dialysat, le taux d'ultrafiltration.

Surveillance au cours du traitement

Il est recommandé de contrôler les pressions en aval de la pompe artérielle pendant le traitement. Une augmentation continue de la pression artérielle peut indiquer une obstruction du dialyseur ou des lignes menant au patient.

Bien que l'intégrité mécanique de ce dialyseur ait été testée, il peut toujours se produire en cours de traitement une rupture ou une fuite entraînant une perte de sang. C'est pourquoi il est recommandé de réaliser un contrôle permanent au moyen d'un détecteur de fuite de sang sur la ligne de dialysat et une inspection visuelle de l'ensemble du système.

Si une fuite de sang se produit, il faut essayer (selon l'avis du médecin traitant) de restituer le sang du circuit extracorporel au patient (voir Fin du traitement). Si le médecin décide de ne pas restituer le sang au patient, clamber la ligne de sortie (veineuse) et en même temps arrêter la pompe à sang. Clamber la ligne d'entrée (artérielle). Mettre le dialyseur et les lignes au rebut.

Fin du traitement

Attention : l'air qui aurait pu être emprisonné dans le dialyseur lors de l'amorçage et du traitement risque d'être entraîné dans le système. Surveiller constamment et attentivement le niveau du piège à bulles de la ligne veineuse. Le rinçage du sang à l'air à la fin du traitement n'est pas recommandé.

- Régler le taux d'ultrafiltration au minimum. Ne pas laisser la pression du compartiment dialysat dépasser la pression du compartiment sang.
- Arrêter la circulation du dialysat.
- Diminuer la vitesse de la pompe à sang jusqu'à zéro et clamber successivement les lignes de sortie (veineuse) et d'entrée (artérielle) puis la canule artérielle.
- Déconnecter la ligne d'entrée (artérielle) de la canule artérielle et raccorder la ligne artérielle à un récipient de solution saline isotonique stérile.
- Déclamber la ligne d'administration du perfuseur, la ligne d'entrée (artérielle) et la ligne de sortie (veineuse) et démarrer la pompe à sang lentement jusqu'à un débit de 100 mL/min pour restituer le sang au patient.
- Clamber et déclamber alternativement la tubulure sous le piège à bulles de la ligne veineuse. Ceci provoquera, par des augmentations et réductions de pression dans le dialyseur, l'évacuation du sang présent dans le dialyseur. Ne pas dépasser les limites de pression du générateur de dialyse.
- Pomper le liquide de rinçage au travers de la tubulure sanguine, jusqu'à ce que le liquide dans la ligne de sortie (veineuse) soit considéré suffisamment clair.
- Arrêter la pompe à sang et clamber la ligne de sortie (veineuse) et la canule veineuse. Séparer la ligne de sortie (veineuse) de la canule veineuse.
- Mettre le dialyseur et le matériel jetable au rebut. Nettoyer le matériel de dialyse en suivant les instructions du fabricant.
- Effectuer les soins appropriés sur le site d'accès vasculaire du patient comme indiqué par le médecin.

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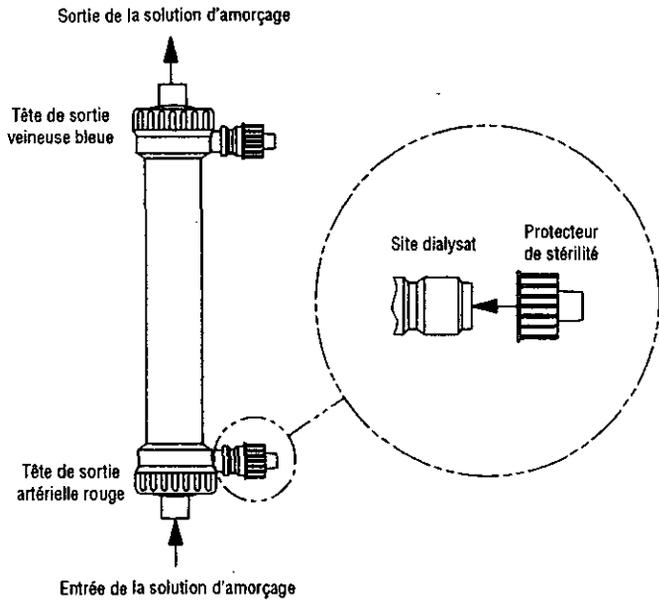


Figure 1 - Orientation du dialyseur pendant l'amorçage du compartiment sanguin.

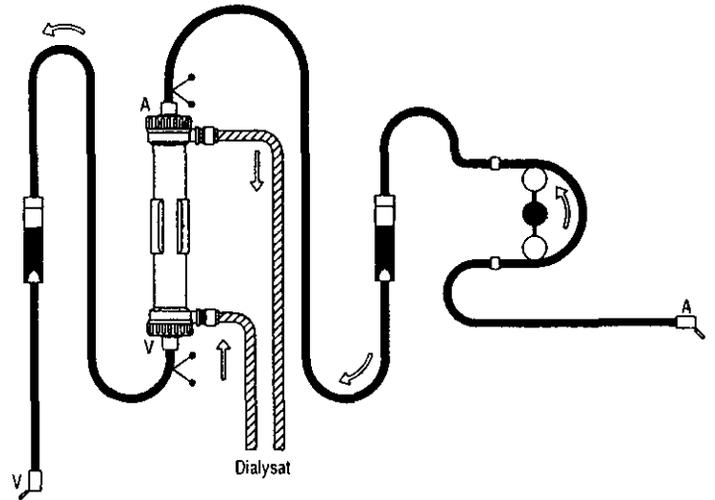


Figure 2 - Circuit extracorporel pour l'hémodialyse.

	R	Trajet extracorporel stérile et apyrogène. Stérilisé par rayonnement gamma.
	500 mmHg 66 kPa	Afin de préserver l'intégrité des fibres, ne pas laisser la pression transmembranaire excéder 66 kPa (500 mmHg) durant la dialyse.
		À usage unique seulement.

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5M2119

07-19-36-769

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EXELTRA 150 Data Sheet

Approximate Performance Characteristics

Note: Operation of the dialyzer under clinical conditions may produce values different from those illustrated because of the variables involved in the clinical dialysis procedure, in the cellulose triacetate membrane, and in the manufacture of the device. Therefore, the values given are for approximation only. See in-vitro test conditions for explanatory materials relating to the test conditions from which the data were derived.

Warning: These devices must be used on dialysis machines equipped with an ultrafiltration controller or an accurate fluid balancing system.

SPECIFICATIONS/PERFORMANCE						
Model	EXELTRA 150					
Code Number	5M2119					
Effective Surface Area (m ²)	1.5					
Effective Length (mm)	230					
Priming Volume (mL)	95					
Clearances (mL/min)	Q _b	100	200	300	400	500
	Q _d	500	500	500	500	500
	Urea	100	193	262	305	332
	Creatinine	100	186	242	274	297
	Phosphate	99	179	227	255	274
	Vitamin B ₁₂	90	132	152	163	170
	Myoglobin	30	33	33	34	34
Ultrafiltration Rate (mL/hr/100mmHg)	3150					
Hollow Fiber	Materials	Cellulose Triacetate				
	Inner Diameter	200 microns				
	Membrane Thickness	15 microns				
Sterilization	Gamma Irradiation					

IN-VITRO TEST CONDITIONS

- Clearance in compliance with the evaluation standards for dialyzer performances called for by the Japan Society of Artificial Organs.
 Solute Concentration: Test Solution: Dialysate
 Urea 100 mg/dL Temperature: 37°C
 Creatinine 10 mg/dL UFR: 0 mL/hr
 Phosphate 5 mEq/L Dialysate Flow: 500 mL/min
 Vitamin B₁₂ 2 mg/dL
 Myoglobin 10 mg/dL
- Ultrafiltration rates were determined using bovine blood.
 HCT: 25% Blood Flow: 200 mL/min
- Priming Volumes were determined using an aqueous solution.

SPECIFICATIONS OF MODULE	
Header:	Polycarbonate
Housing:	Polycarbonate
Potting Compound:	Polyurethane

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07-19-36-769 2003/03



Sterilized By Gamma Irradiation
 Stérilisé par rayonnement gamma



For Single Use Only
 À usage unique seulement



See Instructions For Use
 Voir mode d'emploi

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5M2120

07-19-36-770



ENG EXELTRA 170 Data Sheet

Approximate Performance Characteristics

Note: Operation of the dialyzer under clinical conditions may produce values different from those illustrated because of the variables involved in the clinical dialysis procedure, in the cellulose triacetate membrane, and in the manufacture of the device. Therefore, the values given are for approximation only. See in-vitro test conditions for explanatory materials relating to the test conditions from which the data were derived.

Warning: These devices must be used on dialysis machines equipped with an ultrafiltration controller or an accurate fluid balancing system.

SPECIFICATIONS/PERFORMANCE						
Model	EXELTRA 170					
Code Number	5M2120					
Effective Surface Area (m ²)	1.7					
Effective Length (mm)	239					
Priming Volume (mL)	105					
Clearances (mL/min)	Q _d	100	200	300	400	500
	Q _d	500	500	500	500	500
	Urea	100	196	268	310	341
	Creatinine	100	190	252	286	307
	Phosphate	98	179	232	261	280
	Vitamin B ₁₂	92	138	160	172	180
	Myoglobin	34	39	45	46	48
Ultrafiltration Rate (mL/hr/100mmHg)	3380					
Hollow Fiber	Materials	Cellulose Triacetate				
	Inner Diameter	200 microns				
	Membrane Thickness	15 microns				
Sterilization	Gamma Irradiation					

IN-VITRO TEST CONDITIONS

1. Clearance in compliance with the evaluation standards for dialyzer performances called for by the Japan Society of Artificial Organs.

Solute Concentration:	Test Solution:	Dialysate
Urea 100 mg/dL	Temperature:	37°C
Creatinine 10 mg/dL	UFR:	0 mL/hr
Phosphate 5 mEq/L	Dialysate Flow:	500 mL/min
Vitamin B ₁₂ 2 mg/dL		
Myoglobin 10 mg/dL		

- 2. Ultrafiltration rates were determined using bovine blood.
HCT: 25% Blood Flow: 200 mL/min
- 3. Priming Volumes were determined using an aqueous solution.

SPECIFICATIONS OF MODULE	
Header:	Polycarbonate
Housing:	Polycarbonate
Potting Compound:	Polyurethane

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Sterilized By Gamma Irradiation
 Stérilisé par rayonnement gamma



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See Instructions For Use
 Voir mode d'emploi

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<p>07-05-36-765</p> <p style="text-align: right;"></p>		

<p>07-05-35-342</p> 	<p>Distributed by/Distribué par Baxter Healthcare Corporation Deerfield, IL 60015 USA</p> <p>Baxter and EXELTRA are trademarks of Baxter International Inc./ Baxter et EXELTRA sont des marques de commerce de Baxter International Inc. Made in Japan/Fabrique au Japon</p> <p>The End Up Here  Fragile</p> <h1>Baxter</h1>	
	<p>5M2120 EXELTRA 170</p> <p>24 Units/Unités</p> <p>EXELTRA 170, The Dependable EXELTRA also in the same form as EXELTRA, used to treat patients with acute renal failure. Each unit contains 170 mg of EXELTRA. Each unit is individually sealed in a plastic bag. Each unit is individually sealed in a plastic bag. Each unit is individually sealed in a plastic bag. Each unit is individually sealed in a plastic bag.</p> <p> R</p> <p>MADE IN JAPAN</p> <p>EXELTRA 170 Lot Cap/Volume</p> <h1>Baxter</h1>	
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Cellulose Triacetate Hollow Fiber Dialyzer

Introduction

This direction sheet is intended for use with the CT™ Cellulose Triacetate Hollow Fiber Dialyzer. See data sheet for performance characteristics of accompanying dialyzer model. Deviation from described methods should be undertaken only under the supervision or with the approval of a physician.

Note: This dialyzer is recommended for one time use only.

Much of the original medical literature regarding dialyzer reuse describes risks and hazards associated with the practice. These include an increase in morbidity (Wing et al. 1978); septicemia (Neff 1972); febrile reactions (Neff 1972); anaphylactoid reactions (Ceslero et al. 1975); reduced solute clearances (Raja et al. 1974); formation of anti-H-like antibodies (Kaehny et al. 1975; Harrison et al. 1975; Fassbinder et al. 1979; Lynen et al. 1983); infections with *Mycobacterium chelonae* (Bolan et al. 1985); risk of cross use between patients; an increased risk of hepatitis (Stamm 1978) and a deleterious effect on mechanical integrity (Favero and Bland 1986). Acute toxic (Reveffand et al. 1977; Ogden et al. 1973) or allergic reactions (Siemsen et al. 1974) related to the use of formaldehyde in patients are also cited.

Since these early reports, some of the cited risks and hazards have been shown to be related to the specific methods of rinsing, cleaning and sterilization employed. In addition, the inadequacy of the Cliniflex™ method of demonstrating an acceptable residual level of formaldehyde has been reported and a substitute, more sensitive test proposed (Nash 1953; Keshaviah 1980). One study showed that the risk of hepatitis in reuse centers was not higher than in single use centers (Favero et al. 1981). When reuse is properly carried out, medical benefits during dialysis have been claimed, e.g., reduction of signs and symptoms of fever, chest pain, respiratory distress, hypotension, nausea and vomiting (Kant and Poliak 1980; Smith et al. 1980; Robson et al. 1986).

Reduction in dialyzer induced leukopenia and hemolytic complement activation has also been noted to be associated with dialyzer reuse (Saudie et al. 1977; Hakim et al. 1980; Hakim and Lowrie 1980; Nakamura et al. 1980) although the clinical significance of this finding is not clear. There have been studies that report reduction in mortality for patients treated in dialysis units that were long term reusers (Heid et al. 1987). New concerns, however, have been raised regarding the risk of carcinogenicity as related to long term exposure of patients and staff to formaldehyde (U.S. Regulatory Council 1980) or other effects due to long term administration of small amounts of this agent. Reuse is also contraindicated for patients who are sensitive to disinfection solution residuals and bacteremic patients (Kaiser 1987). A consensus regarding the medical acceptability of reuse has not been reached. It has been suggested that standard procedures for rinsing, cleaning and sterilization be developed and evaluated in prospective, randomized trials. AAMI has developed guidelines (Recommended Practice for Reuse of Hemodialyzers 1986) which could be used in preparing protocols for these trials, but to date the trials have not been performed. Until such trials have been accomplished and the results analyzed, or a medical consensus regarding the acceptability of specific techniques otherwise developed, Baxter Healthcare Corporation recommends that this dialyzer be discarded after a single use.

Since conditions of cleaning and reesterilization after the first use are the responsibility of the attending physician or institution ordering dialyzer reuse, Baxter cannot warrant the sterility, nonpyrogenicity, chemical integrity or performance of this dialyzer when reused.

Description

See data sheet for materials of construction and sterilization method of the accompanying dialyzer model.

Dialyzing fluid is distributed around each hollow fiber. Blood enters one end of the dialyzer through the blood inlet port, passes through the hollow fibers and exits at the opposite end through the blood outlet port. Dialyzing fluid enters and exits in countercurrent fashion to the blood flow through separate dialysate ports (Figure 1). See data sheet for approximate surface area of the accompanying dialyzer model. The surface area may vary due to the variables involved in the manufacture of the device.

High Permeability Dialyzers

High permeability dialyzers must be used only in conjunction with dialysis machines equipped with an ultrafiltration controller. An ultrafiltration controller provides continuous and automatic control of fluid removal from the patient during dialysis according to a preset fluid removal goal.

Actions

Some performance characteristics of the dialyzer are depicted on the accompanying data sheet. Performance data has been developed under indicated specific test conditions *in vitro*, in accordance with the evaluation standards for dialyzer performances called for by the Japan Society of Artificial Organs. Ultrafiltration characteristics have been measured using *in vitro* or *ex vivo* blood containing systems. Operation of the dialyzer under clinical conditions may produce different performance characteristics from those illustrated because of the variables involved in the clinical dialysis procedure, the cellulose triacetate membrane fibers and the manufacture of the device.

Indications

Dialysis with these dialyzers is indicated for patients with acute or chronic renal failure when alternative therapy is judged to be inadequate. It may also be indicated in the treatment of patients associated with poisons or drugs (Winchester et al. 1977).

Selection of patients as candidates for such procedures is a medical responsibility, with the outcome dependent on many factors. The device should be used only on the direction of a physician who has evaluated all of the pertinent features of the patient's illness.

Adverse Reactions

Some patients have experienced apparent hypersensitivity (allergic) reactions during dialysis. Symptoms and signs have included asthmatic reaction, respiratory arrest, pruritus, urticaria, erythema, peripheral and facial edema, hypertension, hypotension and cardiac arrhythmia. The reactions have ranged from very mild to very severe and deaths have been reported.

Side effects such as hypervolemia, hypotension, headache and nausea, which may be associated with hypotension or hypervolemia, can usually be avoided by careful management of the patient's fluid, electrolyte balance, blood flow rate and dialyzing fluid negative pressure. Other complications of dialysis such as blood loss, blood overheating, hemolysis, excessive ultrafiltration and electrolyte imbalance have been associated with equipment malfunction, defect or procedural error.

Warnings and Precautions

A. Hypersensitivity Reactions

It is recommended that dialysis be discontinued in any patient exhibiting signs or symptoms of a hypersensitivity reaction (see section on adverse reactions) and the appropriate treatment be undertaken (Kelly and Patterson 1974). It is also recommended that blood contained in the extracorporeal circuit at the time of the reaction should not be returned to the patient. It further is recommended that the CT™ Cellulose Triacetate Hollow Fiber Dialyzer not be used again for such patients unless a particular medical indication exists and that the dialyzer should be used only in the presence of a physician. A history of hypersensitivity reaction or asthma is an indication for careful monitoring for such signs or symptoms during dialysis.

B. High Permeability Dialyzers

High permeability devices are defined as those devices with *in vivo* ultrafiltration rates greater than 8.0 ml/hr/mmHg. Such devices must be used only in conjunction with dialysis machines equipped with an ultrafiltration controller.

Patients being dialyzed on high permeability dialyzers should be monitored more frequently to avoid complications related to excessive fluid removal and electrolyte balance.

C. Dialyzing Fluid

1. A dialyzing fluid of the appropriate composition should be selected by a physician to suit the patient's needs.
2. Use of a conductivity meter to confirm proper mixing is recommended.
3. To avoid hemolysis, dialyzing fluid temperature should never exceed 42°C (107.6°F).

D. Dialysis Procedure

1. Aseptic technique must be employed to avoid contamination of the blood path when connecting the patient to the inlet (arterial) and outlet (venous) sets.
2. All connections should be checked carefully before and during the first minutes of operation. At several times during dialysis, there should be visual inspections of the connections to detect leaks and avoid blood loss.
3. The outlet (venous) bubble trap must be 3/4 full at all times to optimize bubble trapping capability. See instructions accompanying sets. Since the possibility exists that air may be drawn into the extracorporeal circuit on the negative pressure side of the pump, the use of an air bubble detector device on the venous line is recommended.
4. To avoid unnecessary blood trauma, the blood pump must be adjusted for proper occlusion of the pump segment tubing. Refer to instructions accompanying the blood pump and dialyzer tubing set for proper occlusion procedures.
5. Use heavy duty tubing clamps or hemostats placed at right angles when clamping tubing. The use of heavy duty clamps minimizes the possibility of their falling off and insures complete tubing occlusion.
6. Although this dialyzer has been tested for mechanical integrity, a rupture or leak leading to blood loss can occur during dialysis. Therefore, both air testing before use (See Pressure Testing Section) and constant monitoring by means of a hemoglobin blood leak detector in the dialyzing fluid line of the dialysis machine and visual inspection of the system are recommended.
7. If blood appears in the dialyzing fluid, indicating a leak, an attempt may be made (at the discretion of the attending physician) to return blood from the extracorporeal system to the patient (See Terminating Dialysis Section). If the decision is made not to return the blood to the patient, immediately clamp the outlet (venous) and inlet (arterial) sets and turn off the blood pump and fluid delivery system. Sequentially clamp off the patient's cannulae and disconnect from the inlet (arterial) and outlet (venous) sets. Close the patient's cannulae and remove clamps to maintain blood flow. For patients with fistulae, maintain patency of the fistula sets by injecting approximately 5 ml. of heparinized priming fluid into each set. Remove the dialyzer and inlet sets from the machine and discard.
8. Carefully observe bubble trap chamber as blood enters. If blood appears hemolyzed, clamp off the outlet (venous) set and simultaneously shut off the blood pump. Clamp off the inlet (arterial) set. Sequentially clamp the patient's fistula sets and disconnect from the inlet (arterial) and outlet (venous) sets. Verify that the dialyzing fluid mixture is correct or that the mixing system is providing proper formulation, then explore other causes (e.g., dialyzing fluid overtemperature, improper priming fluids). Purge all incompatible fluid from the dialyzing fluid path. The blood must not be returned to the patient. When cause has been determined and corrected, discard the dialyzer and sets. Set up a new dialyzer and sets and prepare the circuit in the normal way for starting dialysis.
9. To preserve fiber integrity, do not exceed 500 mmHg transmembrane pressure.
10. Monitoring of the post-pump inlet (arterial) and outlet (venous) blood pressures should be done throughout dialysis. This will detect certain problems indicated by rising inlet pressure and allow calculation of TMP which is useful in the prediction of ultrafiltration. A continuing rise in inlet (arterial) pressure may indicate an obstruction in the dialyzer or lines leading to the patient. The increasing pressure may exceed the recommended TMP of 500 mmHg. To monitor the inlet pressure, an inlet (arterial) set with a post-pump monitoring chamber may be used. See directions accompanying set.
11. In order to achieve extremely low ultrafiltration rates, the dialysate pressure in a portion of the dialyzer may exceed the blood pressure. Under these circumstances, nonsterile dialysate could potentially be infused into the blood. Therefore, the ultrafiltration rate must be carefully adjusted as directed by a physician.
12. Due to the resulting increased residual blood volume, and the increased chance of air embolism to the patient, air rinsing of blood at the termination of dialysis is not recommended.
13. Many dialysis products available from other manufacturers are used with equipment or disposables from Baxter Healthcare Corporation. Baxter has no control over variability, tolerances, mechanical strength or changes in these products which may be made from time to time. Therefore, Baxter cannot ensure that the dialysis products of other manufacturers, when connected with its products, will function in a satisfactory manner.
14. Refer to manufacturer's directions accompanying drugs and products to obtain full information for use in this procedure.

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NOT FOR PRODUCTION USE**Preparing the Dialyzer****A. Pressure Testing**

Note: It is recommended that the following testing be completed prior to wetting either the blood or dialysate sides of the dialyzer.

To ensure that the dialyzer does not have a leak, perform the following procedure (Figure 2).

1. Place the dialyzer in the dialyzer holder.
2. Install pump segment of the inlet (arterial) set in the blood pump and adjust for proper occlusion. Refer to instructions accompanying sets.
3. Suspend the outlet (venous) set with the bubble trap in the vertical position.
4. Aseptically remove the protectors from the inlet (arterial) set and dialyzer inlet port and connect. Repeat with the outlet (venous) set.
5. Connect the monitoring line on the outlet (venous) set to the venous pressure monitor.
6. Clamp the outlet (venous) set below the bubble trap and any other tubes necessary to create a closed system on the venous side.
7. Prior to turning on the blood pump, make sure there is an open port through which air can be drawn into the set through a bacterial barrier such as a Sterile Pressure Transducer Isolator. Clamp any other air passages (e.g., heparin infusion line, pressure monitoring line) to create a closed system.
8. Turn on the blood pump and slowly increase the pressure in the extracorporeal circuit to 300 mmHg as measured on the venous pressure monitor.
9. Turn off the blood pump and clamp off the inlet (arterial) set between the pump and the dialyzer.
10. Observe the drop in pressure in the blood compartment; any drop in pressure greater than 10 mmHg within 30 seconds is not acceptable and the dialyzer should be replaced. If a pressure drop greater than 10 mmHg occurs, check for a faulty clamp or connection before assuming a dialyzer leak exists.
11. Release air slowly by unclamping the outlet (venous) set. Release clamp on the inlet (arterial) set.

B. Initial Assembly

1. Refer to Air Testing section above and perform steps 1 through 4.
2. Connect the remaining monitoring lines, saline administration line, and heparin line where applicable.

C. Priming the Dialyzer (Figure 3)

1. Position the dialyzer in the holder with the venous port directed upwards (Figure 3).
2. Close or plug the dialysate ports by clamping and connecting the dialysate lines to the dialyzer (the dialysate inlet line should be connected at the same end as the venous outlet).
3. Check to make sure the arterial and venous lines are connected securely to the dialyzer. Attach an IV Administration Set to a one liter container of heparinized saline and connect it to the saline administration port on the arterial set (Figure 4). An additional one liter of saline solution should be available for infusion during dialysis and for rinsing the extracorporeal circuit when terminating dialysis. Run the heparinized saline solution through the extracorporeal circuit at a flow rate of approximately 200 mL/min.
4. After approximately 500 mL of heparinized saline has been run through the dialyzer, unclamp the dialysate lines to the dialyzer and run dialysate at a flow rate of approximately 500 mL/min. under a pressure of approximately 0 mmHg.
5. Turn the blood pump off after the extracorporeal circuit has been rinsed with 1000 mL of the heparinized saline solution. Continue to run dialysate for another 5 minutes; then proceed to clamp the blood lines shown in Figure 5. Discard the spent priming fluid. The venous bubble trap should be 3/4 full.

Caution: When the priming procedure has been completed, and the extracorporeal circuit is free of air, set the dialysate outlet (negative) pressure to approximately zero (0 mmHg). This will minimize the ultrafiltration of priming solution from the dialyzer between the time when the circuit is primed and dialysis is to commence. Some ultrafiltration of the priming solution will occur (additional heparinized saline may need to be added to the circuit to prevent all of the priming solution from being ultrafiltered). If for any reason the dialysis procedure is not started immediately following the completion of priming, the priming solution in the circuit should be displaced with fresh solution immediately prior to the initiation of dialysis.

Administration of Heparin

Although heparin administration procedures vary, and are adjusted to the requirements of the individual patient by the attending physician, a proper heparinization schedule **must** be initiated before and maintained throughout dialysis to prevent clotting and subsequent blood path obstruction. The following are examples of heparinization schedules for hemodialysis (Gutch and Stoner 1979).

1. Priming fluid should contain the following amounts of heparin:
 - a. Blood should contain 1000 to 2000 USP Units of Heparin per 450 mL of blood.
 - b. Noncellular electrolyte priming fluid, (0.9% Sodium Chloride Injection, etc.) should contain 2000 USP Units of Heparin per 1000 mL of solution.
2. A.V. fistula sets, catheters, etc. should be primed with a solution containing at least 1000 USP Units of Heparin per 100 mL of solution.
3. Continuous Heparinization

Continuous heparinization is similar to intermittent heparinization except that following administration of the loading dose, a heparin pump is used to deliver heparin into the arterial line at the rate necessary to maintain the desired clotting time. Clotting time should be determined approximately at hourly intervals. A heparin pump delivery between 1000 - 3000 USP Units of Heparin per hour usually is sufficient.

Avoid negative pressure at the infusion site. Follow equipment manufacturer's operating directions carefully.
4. Intermittent Heparinization

Patient should be heparinized systemically at least five but not more than ten minutes before hemodialysis (unless contraindicated by factors requiring regional heparinization). The loading dose is typically 2000 to 4000 USP Units of Heparin intravenously for the average adult (70 kg). The loading dosage should be adjusted to the patient's weight in order to establish a clotting time equivalent to a Lee-White time of 25 to 30 minutes (determined by either the Lee-White or a phospholipid Activated Clotting Time [A.C.T.] technique). If longer clotting times (30 - 60 minutes) are preferred, larger amounts of heparin are given (5,000 - 10,000 USP Units of Heparin) as a loading dose. For patients with an internal A.V. fistula, do not give heparin until all needles are in place. Venipuncture after the patient is heparinized may result in oozing or hematoma formation.

Intermittent dosages of 1000 to 3000 USP Units of Heparin per hour into the arterial line are repeated during the procedure. This dosage again is adjusted to establish the preferred clotting time (at least 25 - 30 minutes). No additional heparin is administered to patients having A.V. fistulas during the last hour of dialysis unless clotting time falls below 20 minutes.

5. Regional Heparinization

If systemic heparinization would lead to danger from bleeding, regional heparinization may be indicated. During regional heparinization, heparin is administered to the blood flowing from the patient to the dialyzer and a neutralizing dose of protamine sulfate is administered simultaneously to the blood flowing from the dialyzer to the patient. A control clotting time should be obtained prior to starting. Clotting time of blood from the patient and of blood from the machine must be checked at least every 30 minutes, preferably using the A.C.T. method. More frequent monitoring may be desirable. Obtain blood samples proximal to the heparin and protamine infusion sites. The clotting time of blood from the machine should be 15 to 20 minutes, whereas the clotting time of blood from the patient should be normal.

Preparation of the Patient

This section is provided as a guide for connecting the patient to the dialyzer, conducting the treatment, and terminating dialysis. Specific directions should be given by the attending physician.

The inlet (arterial) and outlet (venous) sets are connected to the patient's blood vessels by one of the following methods: Cannulation by surgical cut down, permanent indwelling cannulae (A.V. shunts) or A.V. fistula cannulation via percutaneous puncture.

A. Dialysis Procedure

1. In patients with A.V. shunts, sequentially clamp arterial cannula and venous cannula prior to separating the cannulae at the shunt connector. Aseptically connect the arterial cannula to the inlet (arterial) set and the venous cannula to the outlet (venous) set. Secure fitting before proceeding.
2. Remove the clamps from the patient's cannulae or fistulae and the inlet (arterial) set, then remove the outlet (venous) set clamp. Coordinate the starting of the blood pump with the action. Start the blood pump slowly and adjust the speed to at least 50 mL/min. Do not allow the level in the bubble trap drop below the 3/4 full level.
3. Check to make sure there is no air present in the arterial or venous headers. If air is present, run blood at a normal flow rate for five (5) to ten (10) minutes through the dialyzer to remove any air bubbles. Finally, rotate the dialyzer 180 degrees so the arterial port (red) is directed upwards.

Warning: Carefully observe the outlet (venous) bubble trap chamber as blood enters. If blood appears hemolyzed, clamp off the outlet (venous) set and simultaneously shut off the blood pump. Clamp off the inlet (arterial) set. Sequentially clamp the patient's cannulae and disconnect from the inlet (arterial) and the outlet (venous) sets. Close the patient's cannulae and remove clamps to maintain blood flow. Verify that the dialyzing fluid mixture is correct or that the mixing system is providing proper formulation, then explore other causes (e.g., dialyzing fluid overtemperature, improper priming fluids). Purge all incompatible fluid from the dialyzing fluid path. The blood may not be returned to the patient. When cause has been determined and corrected, discard the dialyzer and sets. Set up a new dialyzer and sets and prepare the circuit in the normal way for starting dialysis.
4. As dialysis begins, frequently measure the patient's blood pressure and carefully observe the venous bubble trap pressure. When these pressures stabilize, the blood flow rate may be increased slowly.

Note: As blood flow rate increases, a concomitant rise in bubble trap pressure will be noted.
5. It is recommended that the patient be weighed before dialysis and after one hour of dialysis to verify the ultrafiltration rate being obtained. Then adjust the negative pressure on the dialyzing fluid to increase or decrease the ultrafiltration rate; dialysis machines equipped with an ultrafiltration controller, accomplish this automatically.

B. Control of Ultrafiltration

Ultrafiltration can be predicted as a function of transmembrane pressure. In order to calculate transmembrane pressure, it is necessary to measure the blood inlet and outlet pressures and dialyzing fluid inlet and outlet pressures. To measure blood inlet pressure, use an inlet (arterial) set with a post pump pressure monitoring chamber and monitoring line. To measure blood outlet pressure, use an c (venous) set equipped with a pressure monitoring line.

The following equation applies:

$$TMP = \frac{P_{bi} + P_{bo}}{2} - \frac{P_{di} + P_{do}}{2}$$

P_{bi} = pressure blood in
P_{bo} = pressure blood out

These readings can be obtained if a pressure monitoring chamber in the post-pump inlet (arterial) set, and a bubble trap in the outlet (venous) set, are used at the inlet and out of the dialyzer respectively.

P_{di} = pressure dialyzing fluid in

This pressure corresponds with the dialyzing fluid inlet negative pressure.

P_{do} = pressure dialyzing fluid out

This pressure corresponds with the dialyzing fluid outlet negative pressure.

To predict approximate ultrafiltration, refer to the data sheet.

Dialysis machines equipped with an ultrafiltration controller automatically control TMP to achieve the desired weight loss.

C. Terminating Dialysis

Warning: Any air that was trapped inadvertently in the dialyzer during priming and dialysis may be dislodged. Carefully monitor the level of venous bubble trap at all times.

Note: All disconnections should be made using aseptic techniques.

1. Replace heparinized priming fluid container with a one liter container of 0.9% Sodium Chloride Injection for rinsing the extracorporeal circuit.
2. Reduce dialyzing fluid compartment pressure to minimize ultrafiltration. Do not allow dialyzing fluid pressure to become positive.
3. Reduce blood pump speed to zero and sequentially clamp outlet (venous) and inlet (arterial) set arterial cannula.
4. Separate the inlet (arterial) set from the arterial cannula.
5. Remove the clamp from the outlet (venous) set and inlet (arterial) set and simultaneously turn up blood pump to slowly pump the blood in the tubing up to the priming port. An alternate method connect the inlet (arterial) set to a source of 0.9% Sodium Chloride Injection rinsing fluid.
6. Reduce the blood pump speed to zero and sequentially clamp the outlet (venous) and inlet (arterial) sets near the cannula. Do not clamp the inlet (arterial) set if the IV container is connected direct to the arterial connector for rinsing.
7. Open the clamps on the fluid administration set and the outlet (venous) set and turn up the blood pump.
8. Use 0.9% Sodium Chloride Injection rinsing fluid at a flow rate of 100 mL/min to return the blood to the dialyzer to the patient.
9. Intermittently clamp and unclamp the tubing beneath the venous bubble trap with a line clamp, will increase and decrease the pressure within the dialyzer which will help reduce the amount of retained in the dialyzer.
10. Pump the fluid through the blood tubing until the fluid in the outlet (venous) set is as clear as the volume of fluid infused and the effect on the patient's blood pressure should be monitored. Infusion may be stopped after the desired volume is infused or if excessive blood pressure elev occurs.
11. When a satisfactory rinse back has been completed, shut off the blood pump and clamp off the (venous) set and the venous cannula. Disconnect as previously done for the arterial cannula.
12. Prepare and reconnect the patient's A.V. shunt following physician's instructions. If the patient has A.V. fistula, withdraw needles and apply dressings as directed by a physician.
13. Discard dialyzer and all other disposable equipment. Clean dialyzing equipment following manufacturer's instruction manual. The dialyzer is recommended for one time use only.

References

Association for the Advancement of Medical Instrumentation. 1986. Recommended Practice for Reuse of Hemodialyzers.

Bolan, G. et al. 1985. Infections with Mycobacterium chelonae in patients receiving dialysis and using processed hemodialyzers. *J Infect Dis* 152:1013-1019.

Cestero, R.V.M. et al. 1975. Anaphylactoid reactions and eosinophilia in patients treated with hollow fiber artificial kidneys (HFAK). *Am Soc Artif Intern Organs Abstr* 4:9.

Fassbinder, W. et al. 1979. Haemolysis due to formaldehyde-induced anti-NI-like antibodies in haemolytic patients. *Blut Weissenhof* 57:673-679.

NOT FOR PRODUCTION USE

Favero, M. et al. 1981. Effect of multiple use of dialyzers on hepatitis B incidence in patients and staff. *JAMA* 245:166-167.

Favero, S. and Bland, L. 1986. Microbiologic principles applied to reprocessing hemodialyzers. *Guide To Reprocessing Of Hemodialyzers*.

Gutch, C.F. and Stoner, M.H. 1979. *Review of hemodialysis for nurses and dialysis personnel*. St. Louis: C.V. Mosby Co. 115-117.

Hakim, R.M. and Lowrie, E.G. 1980. Effect of dialyzer reuse on leukopenia, hypoxemia and total hemolytic complement system. *Trans Am Soc Artif Intern Organs* 26:159-164.

Hakim, R.M. et al. 1980. Chronic Renal Disease Conference (NANDO), 9-11 January 1980, at Bethesda, MD.

Harrison, P.B. et al. 1975. Cold agglutinin formation in patients undergoing hemodialysis: a possible relationship to dialyzer reuse. *Aust NZ J Med* 5:195-197.

Held P.J. et al. 1987. Survival analysis of patients undergoing dialysis. *JAMA* 257:645-650.

Ing, T.S. et al. 1983. First-use syndrome with cuprammonium cellulose dialyzers. *Int J Artif Organs* 6:235-239.

Kaehny, W.D. et al. 1975. Dialysis and anti-N. *Am Soc Nephrol Abstr* 8:31.

Kaizer, W. M.D., M.P.H. 1987. Notice of public availability of changes to proposed regulations regarding hemodialysis filters. *Department of Health Services*, pg. 27.

Kant, K. and Pollak, V. 1980. Dialyzer reuse: safety and efficacy. Paper read at Chronic Renal Disease Conference (NANDO), 9-11 January 1980, at Bethesda, MD.

Kant, K. et al. 1980. Multiple dialyzer use (MDU): a long-term study of safety and efficacy at one center. Paper read at National Kidney Foundation, 10th Annual Clin Dial and Trans, 19-23 November 1980, at Washington, D.C.

Kelly, J.F. and Patterson, R. 1974. Anaphylaxis: course, mechanism and treatment. *JAMA* 227:1431-1436.

Keshaviah, P. 1980. Reuse of dialyzers: investigation of the risks and hazards associated with hemodialysis devices. *MMRF 1979 Technical Report*. April, 1980.

Lynen, R. et al. 1983. Characterization of formaldehyde-related antibodies encountered in hemodialysis patients at different stages of immunization. *Vox Sang* 44:81-89.

Nakamura, Y. et al. 1980. Modified leukopenic response and complement activation during dialyzer reuse. *Proc Clin Dial Transplant Forum* 10:237-239.

Nash, T. 1953. The colorimetric estimation of formaldehyde by means of the Hantzsch reaction. *Biochem J* 55:416.

Neff, M.S. 1972. Reuse of dialysis coils. *JAMA* 219:1765.

Ogden, D. et al. 1973. Iatrogenic administration of formaldehyde to hemodialysis patients. *Trans Dial Trans Forum* 141-143.

Raja, R.M. et al. 1974. Solute transport in reused hollow fiber artificial kidney. *Nephron* 13:325-332.

Reveiland, R.J. et al. 1977. Risks of IV administration of formaldehyde to hemodialyzed patients. *Kidney Int* 11:292-293.

Robson, M.D. et al. 1986. Effect of first and subsequent use of hemo-dialyzers on patient well-being. *Am J Nephrol* 6:101-106.

Saudie, E. et al. 1977. Modified neutropenic response to re-used dialyzers in patients with chronic renal failure. *Clin Nephrol* 8:422-428.

Siemsen, A. et al. 1974. Clinical and laboratory evaluation of coil reuse. *Trans Am Soc Artif Intern Organs* 20:589-594.

Stamm, W.E. 1978. Stamm highlights device related infection. *Hosp Infect Contr*: 100.

U.S. Department of Health, Education and Welfare, Public Health Service. 1977. Evaluation of hemodialyzers and dialysis membranes. Report of the Study Group for the Artificial Kidney-Chronic Uremia Program (No. 77-1294).

U.S. Regulatory Council, Consumer Product Safety Act. 1980. *Chronic hazards associated with formaldehyde*, Fed. Reg. 45:77881-77883.

Winchester, J.F. et al. 1977. Dialysis and hemoperfusion of poisons and drugs-update. *Trans Am Soc Artif Intern Organs* 23:762-842.

Wing, A.J. et al. 1978. Mortality and morbidity of reusing dialyzers. *Br Med J* 2:853-855.

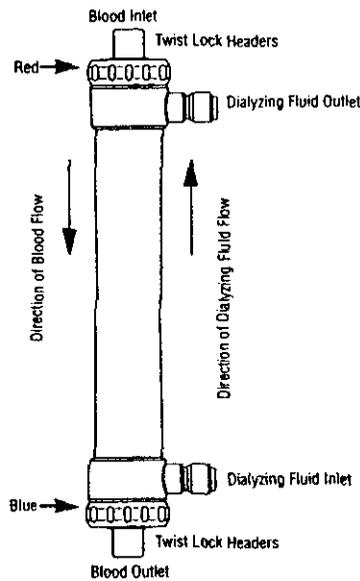


Figure 1 - Location of Blood Inlet and Outlet Ports, Dialyzing Fluid Inlet and Dialyzing Fluid Outlet Ports

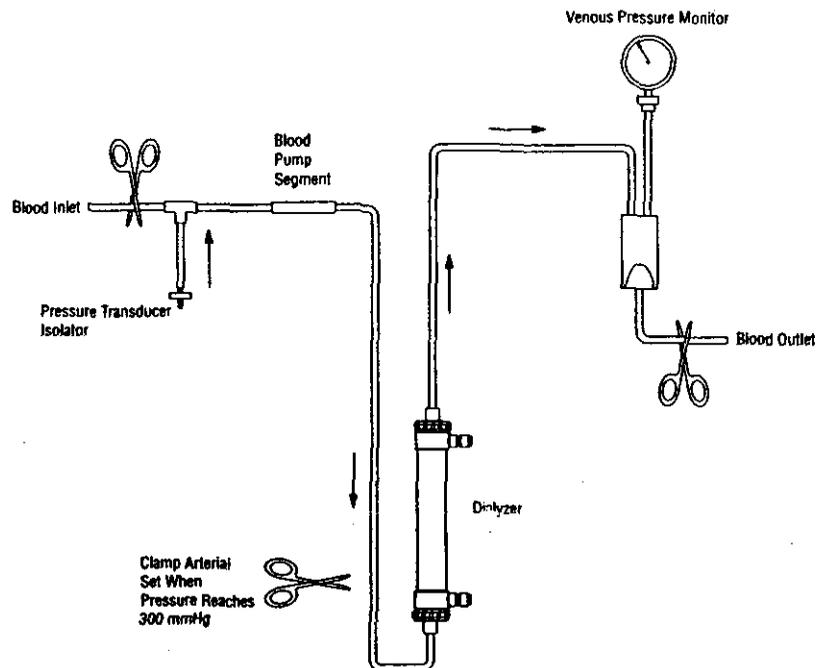


Figure 2 - Air Testing of Dialyzer

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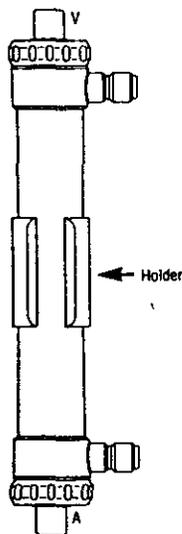


Figure 3 - Dialyzer in Holder for Priming

Note: It is extremely important to keep the dialyzer in this position during priming of blood compartment until all air is removed.

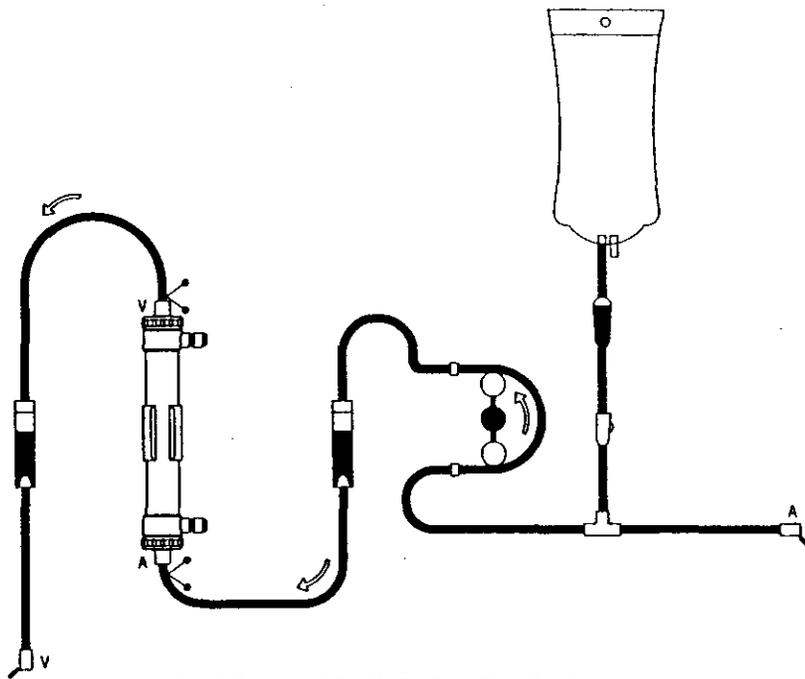


Figure 4 - Extracorporeal Circuit for First Step in Priming Procedure

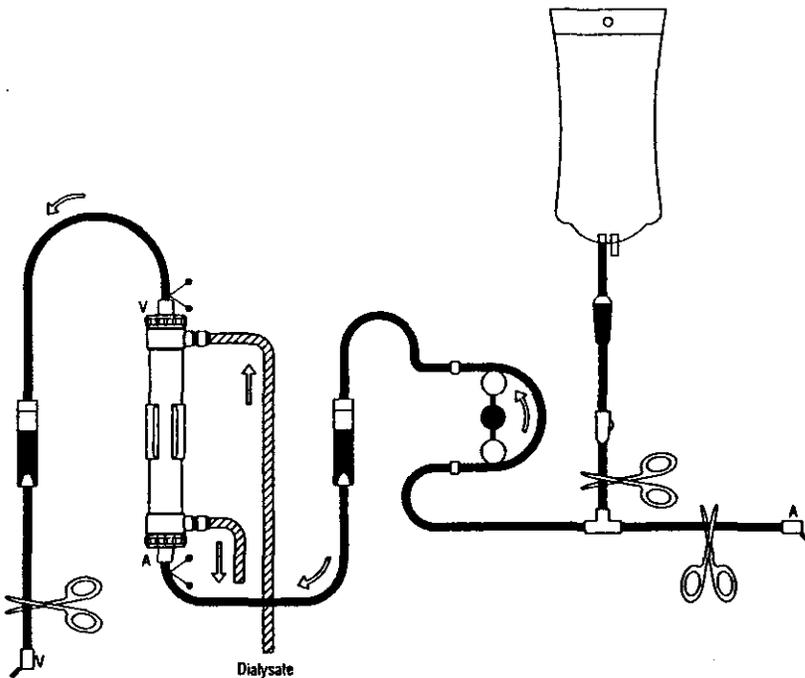


Figure 5 - Extracorporeal Circuit for Second Step in Priming Procedure

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Lot

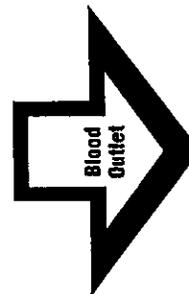
Sterile, nonpyrogenic blood path. Sterilized by gamma irradiation. Do not use if tip protectors are not in place. Blood and dialyzing fluid should flow countercurrently. See accompanying directions.

This dialyzer is recommended for one time use only.

Do not store above 40°C (104°F). Avoid excessive changes in relative humidity.

Warning: This device must be used on dialysis machines with an ultrafiltration controller.

7-26-1-288
93/1



Pantone 287 Blue

33 68



5M1546

Baxter

CT™

**Cellulose Triacetate
Hollow Fiber Dialyzer**

Model CT-190G

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

Distributed by
Baxter Healthcare Corporation
Deerfield, IL 60015 USA
Made in Japan

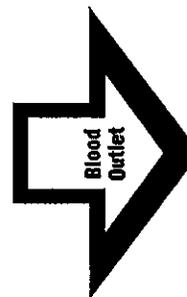
Lot

Sterile, nonpyrogenic blood path. Sterilized by gamma irradiation. Do not use if tip protectors are not in place. Blood and dialyzing fluid should flow countercurrently. See accompanying directions.

This dialyzer is recommended for one time use only. Do not store above 40°C (104°F). Avoid excessive changes in relative humidity.

Warning: This device must be used on dialysis machines with an ultrafiltration controller.

7-26-1-280
93/1



Pantone 287 Blue

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Tear Here

5M1542

Baxter

CT™ Cellulose Triacetate High Efficiency Hollow Fiber Dialyzer Model CT•110G

Sterile, nonpyrogenic blood path
Sterilized by gamma irradiation.
Do not use if tip protectors are not in place.
Blood and dialyzing fluid should flow countercurrently.
Do not store above 40°C (104°F). Avoid excessive changes in relative humidity.
See accompanying directions.

Distributed by
Baxter Healthcare Corporation
Deerfield, IL 60015 USA
Made in Japan
7-7-1-804 93/3

This dialyzer is recommended for one time use only.

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

Warning: This device must be used on dialysis machines equipped with an ultrafiltration controller.

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5M1546

Baxter

CT™ Cellulose Triacetate High Efficiency Hollow Fiber Dialyzer Model CT•190G

Sterile, nonpyrogenic blood path
Sterilized by gamma irradiation.
Do not use if tip protectors are not in place.
Blood and dialyzing fluid should flow countercurrently.
Do not store above 40°C (104°F). Avoid excessive changes in relative humidity.
See accompanying directions.

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Deerfield, IL 60015 USA
Made in Japan
7-7-1-806 93/3

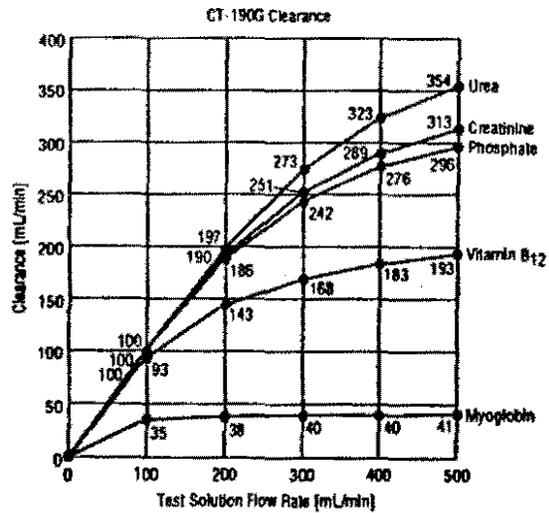
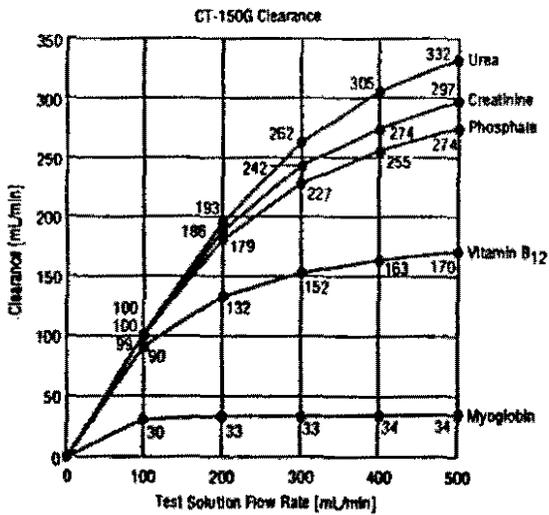
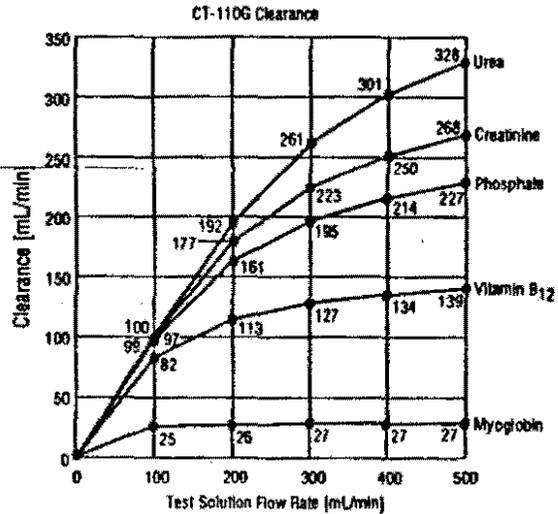
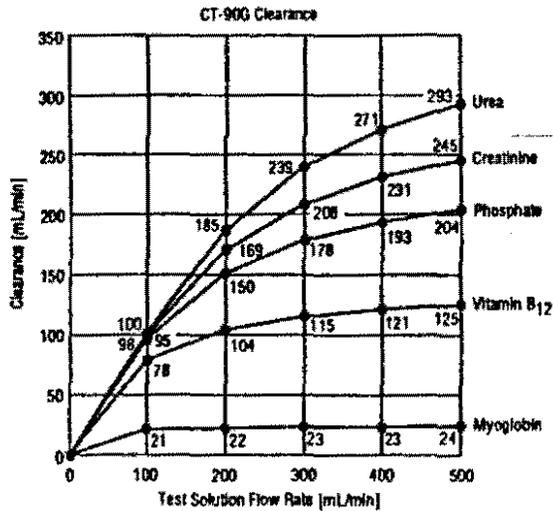
This dialyzer is recommended for one time use only.
Caution: Federal (USA) law restricts this device to sale by or on order of a physician.
Warning: This device must be used on dialysis machines equipped with an ultrafiltration controller.

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CT™ Cellulose Triacetate Hollow Fiber Dialyzers

See accompanying directions for CT™ Cellulose Triacetate Dialyzers.



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SPECIFICATIONS/PERFORMANCE

Model	CT-90G	CT-110G	CT-150G	CT-190G
Effective Surface Area	0.9 m ²	1.1 m ²	1.5 m ²	1.9 m ²
Effective Length	194 mm	208 mm	230 mm	248 mm
Priming Volume	60 mL	70 mL	95 mL	115 mL
Clearances (mL/min)	Urea	185	192	193
	Creatinine	169	177	186
	Phosphate	150	161	179
	Vitamin B ₁₂	104	113	132
	Myoglobin	22	26	33
Ultrafiltration Rate mL/(100mmHg/hr)	2130	2454	3150	3642
Hollow Fiber	Materials	Cellulose Triacetate		
	Inner Diameter	200 microns		
	Membrane Thickness	15 microns		
Sterilization	Gamma Irradiation			

IN-VITRO TEST CONDITIONS

1. Clearance in compliance with the evaluation standards for dialyzer performances called for by the Japan Society of Artificial Organs
2. UFR: Bovine Blood
Hct = 25%

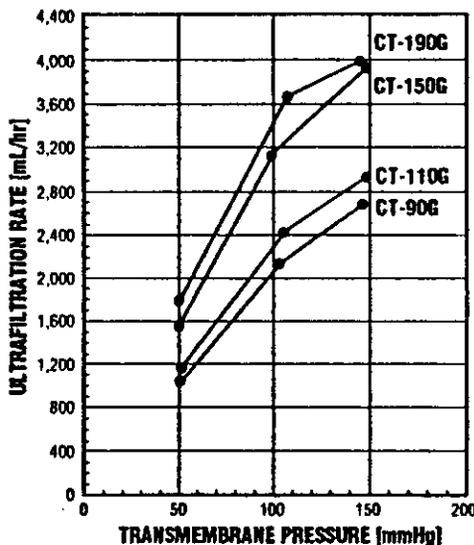
Solute Concentrations:

Urea	100 mg/dL
Creatinine	10 mg/dL
Vitamin B ₁₂	2 mg/dL
Myoglobin	10 mg/dL
Phosphate	5 mEq/L
Dialysate	
Temperature:	37°C
TMP:	0 mmHg
Blood Flow:	200 mL/min
Dialysate Flow:	500 mL/min

SPECIFICATIONS OF MODULE

Header:	Polycarbonate
Housing:	Polycarbonate
Potting compound:	Polyurethane
Max. Pressure:	500 mmHg

CT™ DIALYZER ULTRAFILTRATION DATA



Approximate Performance Characteristics

Note: Operation of the dialyzer under clinical conditions may produce values different from those illustrated because of the variables involved in the clinical dialysis procedure, in the cellulose triacetate membrane, and in the manufacture of the device. Therefore, the values given above are for approximation only. See further explanatory material in the text under each chart relating to the test conditions from which the data were derived.

Warning: High permeability dialyzers are defined as those devices with *in vivo* ultrafiltration rates greater than 8.0 mL/hr/mmHg. These devices must be used on dialysis machines equipped with an ultrafiltration controller.

Distributed by
Baxter Healthcare Corporation
Deerfield, IL 60015 USA

Made in Japan

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7-19-2-502
Iss. June 1994

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F.T 6/21/94

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EXELTRA™ HIGH FLUX DIALYZERS

MATERIAL LIST

EXELTRA™ High Flux Dialyzers – Single Use					Predicate Device
Component	Material	Trade Name	Additives	Supplier Name & Address	Material

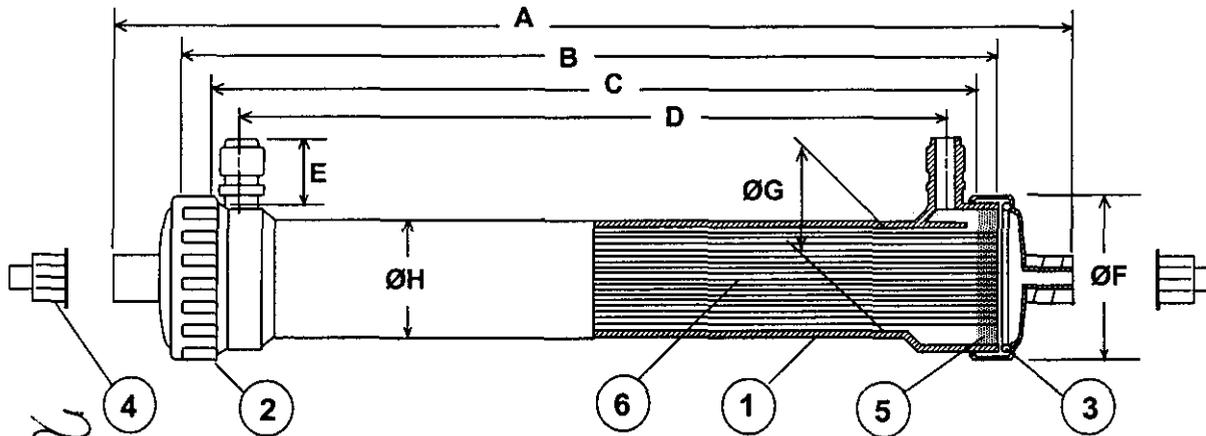
(b) (4)



EXELTRA™ HIGH FLUX DIALYZERS

PHYSICAL CHARACTERISTICS

Model Size	Predicate Devices		Modified Device	
	CT-110G	CT-190G	EXELTRA 150	EXELTRA 170
Number of Fibers	8,400	12,100	10,300	11,300
Effective Surface Area	1.1	1.9	1.5	1.7
Priming Volume	70	115	90	105
Device Weight	130	182	150	160
Overall Length (A)	265	305	287	296
Potted Length (B)	223	263	245	254
Effective Length (C)	208	248	230	239
Port to Port Length (D)	189	229	211	220
Dialysate Port Length (E)	24	24	26.5	26.5
Dialysate Port Inner Diameter	9	9	9	9
Header Outer Diameter (øF)	49.5	56.5	52.5	52.5
Case Inner Diameter (øG)	31	37	34	36
Case Outer Diameter (øH)	34	40	37	39
Hollow Fiber Inner Diameter	200	200	200	200
Hollow Fiber Wall Thickness	15	15	15	15
Sterilization	Gamma	Gamma	Gamma	Gamma

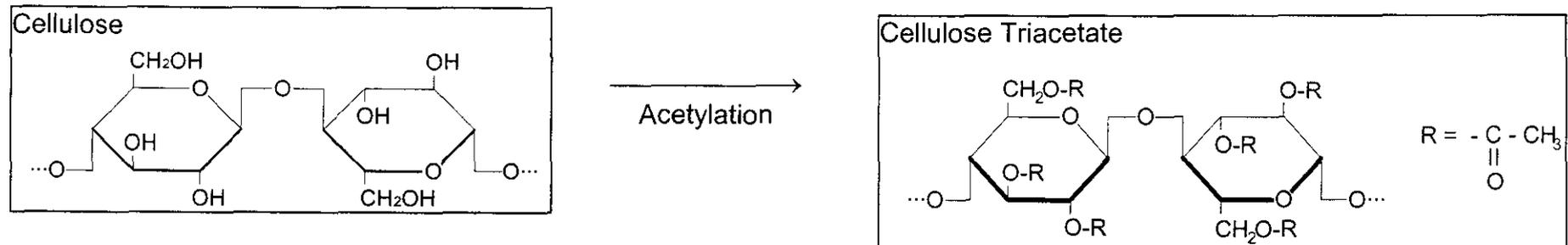


- ① CASE (HOUSING)
- ② HEADER
- ③ O-RING
- ④ HEADER CAP (TIP PROTECTOR)
- ⑤ POTTING COMPOUND
- ⑥ HOLLOW FIBER

EXELTRA™ HIGH FLUX DIALYZERS

CHEMICAL STRUCTURE

The membrane used in the Baxter EXELTRA™ dialyzers is manufactured using the same cellulose triacetate material as the previously cleared CT™ dialyzer membrane. This cellulose triacetate material is produced using an acetylation process which substitutes about 90% of the hydroxyl groups (-OH) in cellulose with acetyl groups (CH₃CO-). The resulting material (polymer) is then extruded into hollow fibers by the Toyobo Co., Ltd. The Nipro Corporation has calculated the pore size to be 70Å radius for the EXELTRA™ membrane.

42
m

EXELTRA™ HIGH FLUX DIALYZERS

MEMBRANE PRODUCTION PROCESS FLOW CHART

(b) (4)



78

43

EXELTRA 150 and EXELTRA 170, Single Use Dialyzers

Declaration of Conformity with Design Controls

**Verification
Activities**

To the best of my knowledge, the verification and validation activities, as required by the risk analysis, for the above referenced Medical Devices were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met.



Thomas Hiller
Director, Quality Assurance
Baxter Healthcare Corporation

3/25/03
Date

**Manufacturing
Facility**

(b) (4) [redacted] manufacturing facility in (b) (4) [redacted] has been audited by Baxter Healthcare Corporation and is in conformance with the design control requirements as specified in 21 CFR 820.30 and the records are available for review.

Allen T. Range
Manager, Supplier Quality Assessment
Baxter Healthcare Corporation

Date

44 79

MAR-13-2003 08:28 FROM:MU MARRIOTT

16196920769

TO: 8472704681

P. 2/3

HEMODIALYSIS ENGR

Fax: 8474736931

Mar 13 2003 8:49 P.02

EXELTRA 150 and EXELTRA 170, single Use Dialyzers

Declaration of Conformity with Design Controls

Verification Activities

To the best of my knowledge, the verification and validation activities, as required by the risk analysis, for the above referenced Medical Devices were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met.

Thomas Hiller
Director, Quality Assurance
Baxter Healthcare Corporation

Date

Manufacturing Facility

(b) (4) manufacturing facility in (b) (4)
(b) (4) has been audited by Baxter Healthcare Corporation and is in conformance with the design control requirements as specified in 21 CFR 820.30 and the records are available for review.

Allen T. Range
Allen T. Range
Manager, Supplier Quality Assessment
Baxter Healthcare Corporation

March 13, 2003
Date

45 80

MAR 13 2003 10:41 P.02

Fax: 8472704681

BAXTER HEALTHCARE

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

4/25/03

Memorandum

From: Reviewer(s) - Name(s) Gema Gonzalez

Subject: 510(k) Number K030974

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. *Per 510k Paradigm, Sponsor has reached SE determination for Special*
 - NOT substantially equivalent to marketed devices. *De Novo Classification Candidate?*
 - YES
 - NO *NA*
 - Other (e.g., exempt by regulation, not a device, duplicate, etc.)
- | | | |
|---|---|--|
| Is this device subject to Postmarket Surveillance? | <input type="checkbox"/> YES | <input checked="" type="checkbox"/> NO |
| Is this device subject to the Tracking Regulation? | <input type="checkbox"/> YES | <input checked="" type="checkbox"/> NO |
| Was clinical data necessary to support the review of this 510(k)? | <input type="checkbox"/> YES | <input checked="" type="checkbox"/> NO |
| Is this a prescription device? | <input checked="" type="checkbox"/> YES | <input type="checkbox"/> NO |
| Was this 510(k) reviewed by a Third Party? | <input type="checkbox"/> YES | <input checked="" type="checkbox"/> NO |
| Special 510(k)? | <input checked="" type="checkbox"/> YES | <input type="checkbox"/> NO |
| Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers | <input type="checkbox"/> YES | <input checked="" type="checkbox"/> NO |

This 510(k) contains:

- Truthful and Accurate Statement Requested Enclosed (required for originals received 3-14-95 and after)
- 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 (required for originals received 1-1-96 and after)
- Animal Tissue Source YES NO *NA*

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):

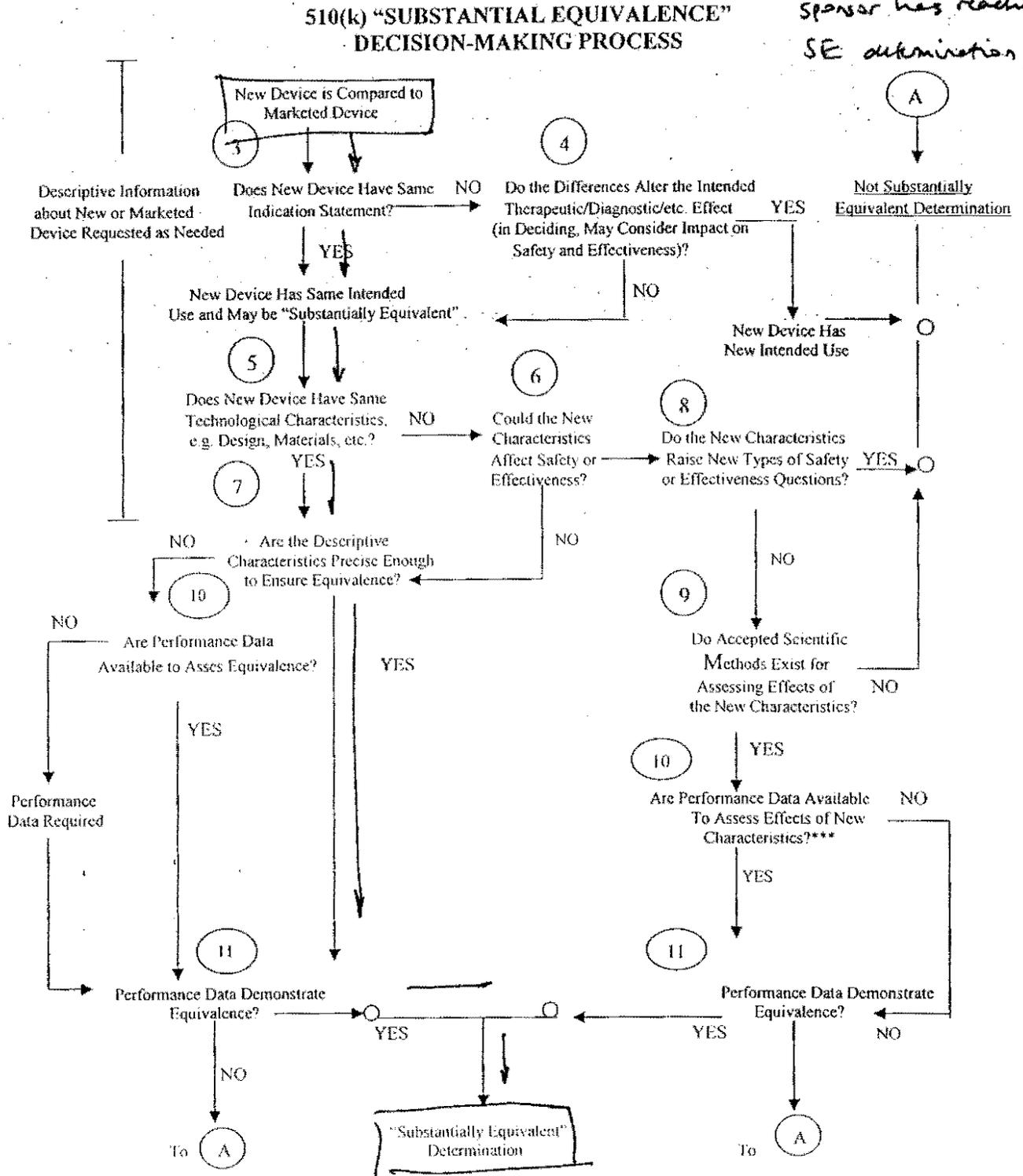
Class II, 78 RDI, 876.5860

Review: John M. [Signature] for CN GRDB 4/25/03
 (Branch Chief) (Branch Code) (Date)

Final Review: David A. [Signature] 4/25
 (Division Director) (Date)

4

*Per 510k Paradigm,
sponsor has reached
SE determination*



- ❖ 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 510(k)s, the Center's classification files, or the literature.

5

**SPECIAL 510(k): Device Modification
ODE Review Memorandum**

To: THE FILE

RE: DOCUMENT NUMBER K030974

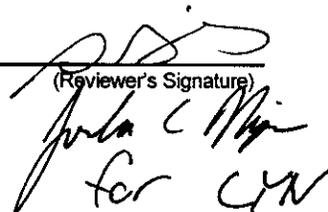
This 510(k) submission contains information/data on modifications made to the SUBMITTER'S own Class II, Class III or Reserved Class I device. The following items are present and acceptable (delete/add items as necessary):

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**.
4. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device including, labeling, intended use, and physical characteristics. – Addition of 1.5 m² and 1.7 m² dialyzers to dialyzer family (changes in numbers of fibers and fiber lengths).
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 weremet, 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 or Statement and the Indications for Use Enclosure (and Class III Summary for Class III devices).**

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 acknowledge the sponsor's determination of substantial equivalent to the previously cleared (or their preamendment) device.

See Attached Memorandum

revised:3/27/98


(Reviewer's Signature)
for CYN

4/25/03
(Date)

4/25/03

6

MEMORANDUM

**FOOD AND DRUG ADMINISTRATION
CENTER FOR DEVICES AND
RADIOLOGICAL HEALTH
OFFICE OF DEVICE EVALUATION**

DATE: April 24, 2003

FROM: Biomedical Engineer, GRDB/DRARD, HFZ-470

SUBJECT: K030974 – Baxter Healthcare Corporation
EXELTRA™ 150 and EXELTRA™ 170 Dialyzers, Single Use

Special 510(k)

TO: The Record

The proposed device is a single-use dialyzer, the EXELTRA™ Plus 210 dialyzer, which is a modification of the previously cleared CT110G and CT190G dialyzers (K890315, K926568, and K970663). The classification is Class II, 21 CFR §876.5860. The product code is 78KDI.

This document was submitted under the Special 510(k) program. Because it represents a slight change in the number of fibers, resulting in an increased surface area, it is my opinion that, through the use of appropriate design controls and design verification activities, a substantial equivalence determination may be reached by the sponsor. This submission, therefore, is eligible for review as a Special 510(k).]*

Intended Use:

The proposed devices are indicated for patients with acute and chronic renal failure when conservative therapy is judged to be inadequate. It also may be indicated in the treatment of patients with poisons or drug overdose.

Note: At the request of FDA, the sponsor has modified this statement to be consistent with that of the predicate device. As revised, the statement is adequate.

Device Description:

The sponsor has noted that the proposed EXELTRA™ 150 and 170 devices are cellulose triacetate hollow fiber dialyzers that will be labeled for single use. Their casing and header are fabricated of polycarbonate and they contain silicone O-rings, polyethylene header caps, and polyurethane potting compounds. In use, like other hollow fiber dialyzers, blood traverses through the hollow fibers while dialysate flows, typically in a counter-current fashion, in the dialysate compartment of the device, which encircles the hollow fiber bundle. With the flow of

**Page 2 – K030974 Baxter Healthcare Corporation
EXELTRA™ 150 and EXELTRA™ 170 Dialyzers**

blood and dialysate, diffusion occurs through the fiber membrane, thus enabling the clearance of solutes and toxins from the patient's blood. The sponsor has explained that the proposed devices' design, including the materials of construction, have not been altered from those of the predicate device. They both share the identical cellulose triacetate membrane. The differences introduced in the current submission consist of changes in the number of fibers used, resulting in increases in the proposed dialyzers' surface areas, and the introduction of the EXELTRA™ name.

The sponsor has presented the following device specifications throughout the submission:

Parameter	Proposed EXELTRA™ 150	Proposed EXELTRA™ 170	Predicate CT110G	Predicate CT190G
Surface Area, m ²	1.5	1.7	1.1	1.9
Effective Fiber Length, mm	230	239	206	248
Priming Volume, ml	95	105	70	115
Number of Fibers	<i>10,300</i>	<i>11,300</i>	<i>8,400</i>	<i>12,100</i>
Fiber Inner Diameter, μm	200	200	200	200
Fiber Thickness, μm	15	15	15	15
Fiber Material	Cellulose Triacetate	Same	Same	Same
Number of Fibers	10,300	11,300	8400	12,100
Ultrafiltration Rate, ml/hr/100 mm Hg *	3159	3380	2454	3642
Solute Clearances **				
Urea	193	196	192	197
Creatinine	186	190	177	190
Phosphate	179	179	161	186
Vitamin B ₁₂	132	138	113	143
Myoglobin	33	39	26	38
Sterilization	Gamma Irradiation	Gamma	Gamma	Gamma

* For the ultrafiltration data, the blood flow rate was 200 ml/min.

** Solute clearance data obtained with a dialysate of the following concentrations: 100 mg/dL urea, 10 mg/dL creatinine, 5 mEq/L phosphate, 2 mg/dL Vitamin B₁₂, and 10 mg/dL myoglobin. The UFR was set at 0 ml/hr. The solute clearance data reported in the table above were obtained at a blood flow rate of 200 ml/min and dialysate flow rate of 500 ml/min. Data obtained at Q_b of 100, 300, 400, and 500 ml/min were also reported.

It should be noted that the data described above were included in the proposed labeling. The data and information appear adequate.

As discussed above, no materials changes have been implemented. As a result, no biocompatibility issues remain at this time. However, in an effort to address the changes implemented, the sponsor performed a Clinical Hazard Analysis, Failure Modes and Effects

**Page 3 – K030974 Baxter Healthcare Corporation
EXELTRA™ 150 and EXELTRA™ 170 Dialyzers**

Analysis (FMEA). As a result of this analysis, the sponsor concluded that no additional verification and validation testing was required. When asked about this, the sponsor explained that no new types of tests were deemed necessary, however, functionality tests were performed, as they are for any Baxter dialyzer (i.e., ultrafiltration coefficients, solute clearances, priming volume, dimensional verifications, etc). Furthermore, the sponsor has indicated that all tests performed used the same acceptance criteria as those used for the predicate devices. Judging from the data provided in the proposed labeling, most of the required tests, as per FDA's guidance document for hemodialyzers, have been performed, with the exception of pressure drop tests for the dialyzer's blood and dialysate sides. This test is necessary, since the fibers' lengths have changed, and the dimensions of the dialyzer casing have also been modified to accommodate the increased numbers of fibers. Changes in these parameters may affect the flow characteristics within the dialyzer. This was brought to the attention of the sponsor, who provided a justification for why these data were deemed unnecessary. According to the sponsor, the fiber lengths and numbers of fibers used for the proposed EXELTRA™ 150 and 170 dialyzers are the same as those used for the Baxter CA-HP-150 and CA-HP-170 dialyzers (K950454 and K950522). Also, these dialyzers share the same casing dimensions, fiber inside diameters and fiber thicknesses. As a result, the pressure drop data obtained for the CA-HP-150 and CA-HP-170 dialyzers should also be applicable to the proposed EXELTRA™ dialyzers. This is adequate.

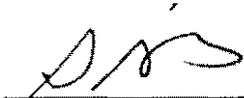
The sponsor has noted that the proposed dialyzer will be sterilized with gamma irradiation, just as the predicate devices. The sterilization dose is based on ANSI/AAMI/ISO-11137 Method 2B. The sterility assurance level (SAL) will be 10^{-6} . Regarding the packaging, the sponsor has also explained that it remains unchanged from that which was cleared for the predicate device under K970663. This information is adequate.

The sponsor has provided labeling for the proposed device in the form of package labels, carton labels, and package inserts. The package labels adequately identify the proposed device as a single-use dialyzer. They also have manufacturer information, maximum transmembrane pressure (TMP), the method of sterilization, lot number, surface area (through device's name), and an expiration date. The package inserts include the dialyzer's indications for use, a list of common adverse events, warnings and cautions, instructions for the priming of the dialyzers, as well as for running treatments, and diagrams of how the device is connected within the extracorporeal circuit. Among the warnings and cautions, the sponsor has noted that the proposed dialyzer should only be used with machines equipped with an ultrafiltration controller, and that sterile infusion fluid may be needed to replenish patients who become hypovolemic. The user is also warned against surpassing the maximum TMP, using aseptic techniques, waste disposal issues, and procedure problems which may lead to hemolysis. Finally, the package insert information contains a data sheet with a summary of the proposed dialyzer's performance specifications. In summary, the provided labeling is adequate and consistent with that of the predicate devices. At the request of FDA, the proposed package insert has been modified to reflect the predicate device's indications for use statement. This is adequate.

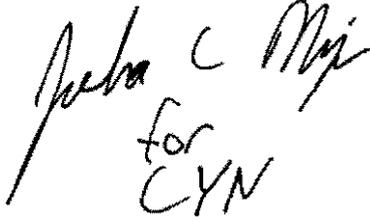
**Page 4 – K030974 Baxter Healthcare Corporation
EXELTRA™ 150 and EXELTRA™ 170 Dialyzers**

Regarding the proposed device's expiration date, the sponsor has noted that a three year shelf life will be specified. This is consistent with the predicate device's shelf life, therefore, no additional validation information is necessary at this time. However, it should be noted that accelerated and real time data have been provided for the EXELTRA™ Plus 210 Dialyzer, which is currently under review (K030975). In that submission, the dialyzer membrane's manufacturing has been changed slightly, however, that device's membrane chemical formulation is identical to that of the proposed dialyzers. In summary, the proposed three year shelf life is adequate.

Recommend: Submission be found substantially equivalent to the predicate devices and to devices under 876.5860, High permeability hemodialysis system.


Gemma González

4/25/03


for
CYN

4/25/03

10

BAXTER HEALTHCARE CORPORATION

FACSIMILE TRANSMITTAL SHEET

TO: Gema Gonzalez	FROM: David Curtin
COMPANY: FDA	DATE: 4/25/2003
FAX NUMBER: 301 594-2339	TOTAL NO. OF PAGES INCLUDING COVER: 11
PHONE NUMBER: 301-594-1220 x142	SENDER'S REFERENCE NUMBER: NA
RE: K030974/K030975	YOUR REFERENCE NUMBER: NA

URGENT FOR REVIEW PLEASE COMMENT PLEASE REPLY PLEASE RECYCLE

NOTES/COMMENTS:

Gema,

I am providing you with the information you requested via voice mail on April 24, 2003 and our phone conversation of April 25, 2003. Included in this FAX correspondence are revised Indications for Use sheets and revised draft package inserts incorporating the revised indications for use statement for both K030974 and K030975.

Regarding the pressure drop information, the subject Exeltra and Exeltra Plus dialyzers use the same case, the same case length, the same fiber count, the same fiber length, the same fiber internal diameter, the same effective length and the same priming volume as has been previously cleared for similar models (i.e., fiber surface area) of Baxter's CAHP dialyzers under K950454 and K950522. We have attached the data sheets and pressure drop performance data for the CAHP dialyzers cleared under those 510(k) premarket notification applications. The specific fiber counts for the subject dialyzers are as follows: Exeltra 150 - 10,300, Exeltra 170 - 11,300, Exeltra Plus 210 - 13,000. This information was provided in the original 510(k)s as page 41 in K030974 and page 42 in K030975. These are also the exact same fiber counts for the comparable CAHP dialyzer models.

All tests and acceptance criteria performed for the subject Exeltra and Exeltra Plus dialyzers submitted under K030974 and K030975 are the same as those tests and acceptance criteria for the predicate dialyzers.

If you have any questions, please contact me at 847-473-6079.

Sincerely,

David E. Curtin

David E. Curtin

11

K030974

Revised Indications for Use Sheet and Revised Draft Package Insert

Indications for Use Statement

510(k) Number (if known): _____

Device Name: EXELTRA™ Dialyzer

Indications For Use:

Hemodialysis with the EXELTRA™ Dialyzer is indicated for patients with acute or chronic renal failure when conservative therapy is judged to be inadequate. It also may be indicated in the treatment of patients intoxicated with poisons or drugs.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

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ENG EXELTRA High Flux Dialyzers Directions for Use

Baxter cannot warrant the sterility, nonpyrogenicity, mechanical integrity or performance of this dialyzer when reused. Deviation from described method should be undertaken only under the supervision or with the approval of a physician. See specific data sheet for performance characteristics.

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

Caution for Storage

Store at 0°C to 40°C, avoiding direct exposure to sunlight and vibrations.

Avoid excessive changes in relative humidity.

acute or chronic

Indications

Hemodialysis with EXELTRA dialyzers is indicated for patients with renal failure when conservative therapy is judged to be inadequate. It also may be indicated in the treatment of patients intoxicated with poisons or drugs.

The device should be used only on the direction of a physician.

Contraindications

There are no special contraindications for use of this dialyzer for the hemodialysis procedure. Patients with a history of allergic reactions to Cellulose Triacetate should not be treated using this product.

Adverse Reactions

Patients may experience hypersensitivity (allergic) reactions during treatment. Symptoms and signs have included asthmatic reactions, respiratory arrest, pruritus, urticaria, erythema, peripheral and facial edema, hypertension, hypotension, and cardiac arrhythmia. A history of allergic responses, including asthma is an indication for careful monitoring for such signs or symptoms during treatment.

Side effects such as hypotension, hypertension, headache and nausea, which may be associated with hypovolemia or hypervolemia, can usually be avoided by careful management of the patient's fluid, electrolyte balance, blood flow rate and ultrafiltration rate.

Warnings and Precautions

Refer to specific procedures for additional warnings and precautions.

WARNING: The performance properties of reused EXELTRA dialyzers have not been established and processes for disinfectant procedures have not been validated. Ineffective removal of residual disinfectant may lead to adverse patient reactions.

Air Embolism

Air in the extracorporeal circuit during treatment must be avoided. If air gets into the system, the treatment must be discontinued and the blood must not be returned to the patient.

Hypersensitivity Reactions

It is recommended that treatment be discontinued in any patient exhibiting signs or symptoms of a hypersensitivity reaction. The blood contained in the extracorporeal circuit at the time of the reaction should not be returned to the patient.

High Permeability Dialyzers

EXELTRA dialyzers must be used only in conjunction with dialysis machines equipped with an ultrafiltration controller or an accurate fluid balancing system.

Use of the EXELTRA dialyzer under clinical conditions of high transmembrane pressure may result in net ultrafiltration rates that greatly exceed the ultrafiltration requirements of some patients. Under these conditions, the use of sterile reinfusion fluid is mandatory.

Dialysate Fluid

Use of an in-line conductivity monitor is recommended. To avoid hemolysis, dialysate temperature should never exceed 42°C (107.6°F).

Treatment Procedure

1. Aseptic technique must be employed.
2. All connections should be checked carefully before and during treatment.
3. The inlet (arterial) and outlet (venous) air bubble traps must be 3/4 full at all times. Since air may be drawn into the extracorporeal circuit on the negative pressure side of the blood pump, the use of an air bubble detector on the venous line is recommended.
4. To preserve fiber integrity, do not exceed 500 mmHg (66 kPa) transmembrane pressure.
5. Weighing the patient before and after treatment is recommended to verify the extent of ultrafiltration.
6. Many dialysis products available from other manufacturers are used with equipment or disposables from Baxter Healthcare Corporation. Baxter has no control over variability, tolerances, mechanical strength or changes in these products which may be made from time to time. Therefore, Baxter cannot ensure that the dialysis products of other manufacturers, when connected with its products, will function in a satisfactory manner.
7. If the patient is under drug therapy, blood levels must be monitored to assure appropriate therapeutic levels are maintained.

Set Up Procedure

Refer to Warnings and Precautions section for additional statements.

Do not use if blood port tip protectors are not in place.

Do not use if package has been previously opened or damaged.

Initial Assembly

Connect the Inlet (arterial) set, outlet (venous) set, monitoring lines, saline administration line, and heparin line (where applicable) to the dialysis machine and dialyzer.

Air Testing

Although this dialyzer has been tested for mechanical integrity, a rupture or leak leading to blood loss can occur during treatment. Therefore, air leak testing before use, constant monitoring by a blood leak detector on the dialysate fluid line, and visual inspection of the system is recommended.

1. Air testing should be completed prior to wetting either the blood or dialysate sides of the dialyzer.
2. Clamp the outlet (venous) set below the bubble trap and any other tubes necessary to create a closed system on the venous side.
3. Prior to turning on the blood pump, make sure there is an open port through which air can be drawn into the inlet (arterial) set through a bacterial barrier such as a sterile pressure transducer isolator. Turn on the blood pump and slowly increase the pressure in the extracorporeal circuit to 300 mmHg (39.9 kPa) as measured on the venous pressure monitor.
4. Turn off the blood pump and clamp off the inlet (arterial) set between the pump and the dialyzer.
5. If a pressure drop greater than 10 mmHg within 30 seconds occurs, check for a faulty clamp or connection before assuming a dialyzer leak exists. A confirmed drop in pressure greater than 10 mmHg within 30 seconds is not acceptable and the dialyzer should be replaced.
6. Release air slowly by unclamping the outlet (venous) set. Release clamp on the inlet (arterial) set.

K030975

Revised Indications for Use Sheet and Revised Draft Package Insert

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Indications for Use Statement

510(k) Number (if known): _____

Device Name: **EXELTRA™ Plus Dialyzer**

Indications For Use:

Hemodialysis with the EXELTRA™ Plus Dialyzer is indicated for patients with acute or chronic renal failure when conservative therapy is judged to be inadequate. It also may be indicated in the treatment of patients intoxicated with poisons or drugs.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

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Baxter

(ENG) EXELTRA Plus High Flux Dialyzers Directions for Use

Baxter cannot warrant the sterility, nonpyrogenicity, mechanical integrity or performance of this dialyzer when reused. Deviation from described method should be undertaken only under the supervision or with the approval of a physician. See specific data sheet for performance characteristics.

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

Caution for Storage

Store at 0°C to 40°C, avoiding direct exposure to sunlight and vibrations.

Avoid excessive changes in relative humidity.

acute or chronic

Indications

Hemodialysis with **EXELTRA Plus** dialyzers is indicated for patients with renal failure when conservative therapy is judged to be inadequate. It also may be indicated in the treatment of patients intoxicated with poisons or drugs.

The device should be used only on the direction of a physician.

Contraindications

There are no special contraindications for use of this dialyzer for the hemodialysis procedure. Patients with a history of allergic reactions to Cellulose Triacetate should not be treated using this product.

Adverse Reactions

Patients may experience hypersensitivity (allergic) reactions during treatment. Symptoms and signs have included asthmatic reactions, respiratory arrest, pruritus, urticaria, erythema, peripheral and facial edema, hypertension, hypotension, and cardiac rhythmia. A history of allergic responses, including asthma is an indication for careful monitoring for such signs or symptoms during treatment.

Side effects such as hypotension, hypertension, headache and nausea, which may be associated with hypovolemia or hypervolemia, can usually be avoided by careful management of the patient's fluid, electrolyte balance, blood flow rate and ultrafiltration rate.

Warnings and Precautions

Refer to specific procedures for additional warnings and precautions.

WARNING: The performance properties of reused EXELTRA Plus dialyzers have not been established and processes for disinfectant procedures have not been validated. Ineffective removal of residual disinfectant may lead to adverse patient reactions.

Air Embolism

Air in the extracorporeal circuit during treatment must be avoided. If air gets into the system, the treatment must be discontinued and the blood must not be returned to the patient.

Hypersensitivity Reactions

It is recommended that treatment be discontinued in any patient exhibiting signs or symptoms of a hypersensitivity reaction. **The blood contained in the extracorporeal circuit at the time of the reaction should not be returned to the patient.**

High Permeability Dialyzers

EXELTRA Plus dialyzers must be used only in conjunction with dialysis machines equipped with an ultrafiltration controller or an accurate fluid balancing system.

Use of the **EXELTRA Plus** dialyzer under clinical conditions of high transmembrane pressure may result in net ultrafiltration rates that greatly exceed the ultrafiltration requirements of some patients. Under these conditions, the use of sterile reinfusion fluid is mandatory.

Dialysate Fluid

Use of an in-line conductivity monitor is recommended. To avoid hemolysis, dialysate temperature should never exceed 42°C (107.6°F).

Treatment Procedure

1. Aseptic technique must be employed.
2. All connections should be checked carefully before and during treatment.
3. The inlet (arterial) and outlet (venous) air bubble traps must be 3/4 full at all times. Since air may be drawn into the extracorporeal circuit on the negative pressure side of the blood pump, the use of an air bubble detector on the venous line is recommended.
4. To preserve fiber integrity, do not exceed 500 mmHg (66 kPa) transmembrane pressure.
5. Weighing the patient before and after treatment is recommended to verify the extent of ultrafiltration.
6. Many dialysis products available from other manufacturers are used with equipment or disposables from Baxter Healthcare Corporation. Baxter has no control over variability, tolerances, mechanical strength or changes in these products which may be made from time to time. Therefore, Baxter cannot ensure that the dialysis products of other manufacturers, when connected with its products, will function in a satisfactory manner.
7. If the patient is under drug therapy, blood levels must be monitored to assure appropriate therapeutic levels are maintained.

Set Up Procedure

Refer to **Warnings and Precautions** section for additional statements.

Do not use if blood port tip protectors are not in place.

Do not use if package has been previously opened or damaged.

Initial Assembly

Connect the inlet (arterial) set, outlet (venous) set, monitoring lines, saline administration line and heparin line (where applicable) to the dialysis machine and dialyzer.

Air Testing

Although this dialyzer has been tested for mechanical integrity, a rupture or leak leading to blood loss can occur during treatment. Therefore, air leak testing before use, constant monitoring by a blood leak detector on the dialysate fluid line, and visual inspection of the system is recommended.

1. Air testing should be completed prior to wetting either the blood or dialysate sides of the dialyzer.
2. Clamp the outlet (venous) set below the bubble trap and any other tubes necessary to create a closed system on the venous side.
3. Prior to turning on the blood pump, make sure there is an open port through which air can be drawn into the inlet (arterial) set through a bacterial barrier such as a sterile pressure transducer isolator. Turn on the blood pump and slowly increase the pressure in the extracorporeal circuit to 300 mmHg (39.9 kPa) as measured on the venous pressure monitor.
4. Turn off the blood pump and clamp off the inlet (arterial) set between the pump and the dialyzer.
5. If a pressure drop greater than 10 mmHg within 30 seconds occurs, check for a faulty clamp or connection before assuming a dialyzer leak exists. A confirmed drop in pressure greater than 10 mmHg within 30 seconds is not acceptable and the dialyzer should be replaced.
6. Release air slowly by unclamping the outlet (venous) set. Release clamp on the inlet (arterial) set.

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CAHP Dialyzer Data Sheets and Pressure Drop Information

SPECIFICATIONS/PERFORMANCE

Model	CA-HP-90	CA-HP-110	CA-HP-150	CA-HP-170	CA-HP-210
Code Number	5M2731	5M2732	5M2734	5M2735	5M2735
Effective Surface Area	0.9 m ²	1.1 m ²	1.5 m ²	1.7 m ²	2.1 m ²
Effective Length	194 mm	208 mm	230 mm	238 mm	257 mm
Priming Volume	80 mL	70 mL	85 mL	105 mL	125 mL
Clearances (mL/min)	Urea	172	177	187	192
	Creatinine	148	155	174	181
	Phosphate	115	128	147	158
	Vitamin B ₁₂	90	70	88	94
Ultrafiltration Rate (mL/hr/mmHg)	6.6	8.8	11.1	12.8	16.4
Hollow Fiber	Materials	Cellulose Diacetate			
	Inner Diameter	200 microns			
	Membrane Thickness	15 microns			
Sterilization	Ethylene Oxide				

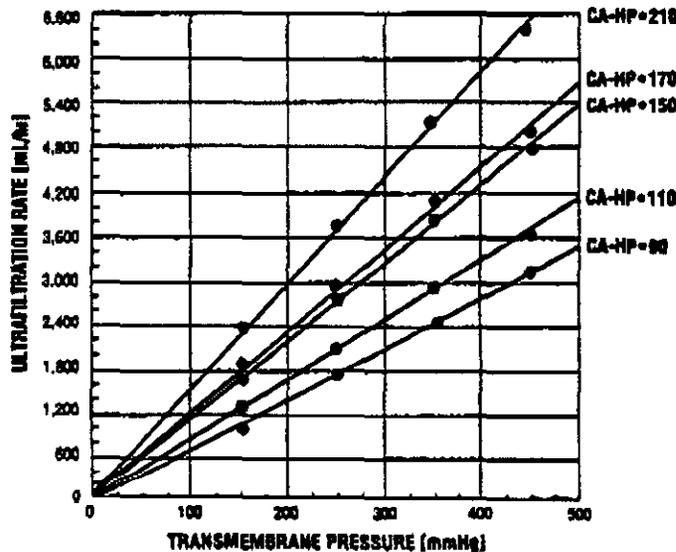
IN-VITRO TEST CONDITIONS

1. Clearance in compliance with the evaluation standards for dialyzer performances called for by the Japan Society of Artificial Organs.
 Solute Concentration: Urea 100 mg/dL, Creatinine 10 mg/dL, Phosphate 5 mEq/L, Vitamin B₁₂ 2 mg/dL
 Test Solution: Dialysate
 Temperature: 37°C
 TMP: 0 mmHg
 Blood Flow: 200 mL/min
 Dialysate Flow: 500 mL/min
2. Ultrafiltration Rates were determined using Bovine Blood.
 HCT: 25% TMP: 150 mmHg
3. Priming Volumes were determined using an Aqueous Solution.

SPECIFICATIONS OF MODULE

Housing: Polycarbonate
 Posing Compound: Polyurethane
 Maximum Pressure: 500 mmHg

CA-HP DIALYZER ULTRAFILTRATION DATA



Approximate Performance Characteristics

Note: Operation of the dialyzer under clinical conditions may produce different values from those illustrated because of the variables involved in the clinical dialysis procedure, in the cellulose diacetate membrane, and in the manufacture of the device. Therefore, the values given above are for approximation only. See further explanatory material in the IN-VITRO TEST CONDITIONS section as to the test conditions from which the data were derived.

Warning: High permeability dialyzers are defined as those devices with *in-vivo* ultrafiltration rates greater than 8.0 mL/hr/mmHg. These devices must be used on dialysis machines equipped with an ultrafiltration controller.

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 Deerfield, IL 60015 USA
 In Japan

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PERFORMANCE COMPARISONS
CAHP High Performance Cellulose Diacetate Hollow Fiber Dialyzers

Model Number Code Number	CAHP-110 5M2732	CA-110 5M1732	CAHP-130 5M2733	CA-130 5M1733	CAHP-150 5M2734	CA-150 5M1734
Pressure Drop (mmHg)						
Blood Side	41	41	37	37	36	36
Dialysate Side	12	12	12	12	12	12
Clearances (mL/min)						
Urea (BUN)	177	172	186	179	187	183
Creatinine	156	145	165	153	174	162
Vitamin B12	70	50	79	57	88	63
Ultrafiltration Rate (mL/hr/mmHg)	8.8	4.9	10.1	5.7	11.1	7.1

Note: Performance Data reported here are *In Vitro* results.

Clearance Data reported here were determined at Transmembrane Pressure = 0 mmHg,
Blood Flow Rate = 200 mL/min, and Dialysate Flow Rate = 500 mL/min.

Ultrafiltration Rate Data reported here were determined using Bovine Blood diluted to 25% HCT with Bovine Plasma.
Blood Flow Rate = 200 mL/min, Dialysate Flow Rate = 0 mL/min, and Transmembrane Pressure = 150 mmHg.

PERFORMANCE COMPARISONS
CAHP High Performance Cellulose Diacetate Hollow Fiber Dialyzers

Model Number Code Number	CAHP-170 5M2735	CA-170 5M1735	CAHP-210 5M2736	CA-210 5M1736
Pressure Drop (mmHg)				
Blood Side	35	35	32	32
Dialysate Side	12	12	12	12
Clearances (mL/min)				
Urea (BUN)	192	188	194	193
Creatinine	181	167	184	177
Vitamin B12	94	69	106	82
Ultrafiltration Rate (mL/hr/mmHg)	12.6	8.1	16.4	9.8

Note: Performance Data reported here are *In Vitro* results.

Clearance Data reported here were determined at Transmembrane Pressure = 0 mmHg,
 Blood Flow Rate = 200 mL/min, and Dialysate Flow Rate = 500 mL/min.

Ultrafiltration Rate Data reported here were determined using Bovine Blood diluted to 25% HCT with Bovine Plasma.
 Blood Flow Rate = 200 mL/min, Dialysate Flow Rate = 0 mL/min, and Transmembrane Pressure = 150 mmHg.

RENAL REG AFFAIRS

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

510(k) Number: K030974

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	Inadequate or Missing
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 in areas that are listed on page 3-4 of the Premarket Notification [510] Manual.	✓	
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).]		
Class III Certification and Summary. **		
Financial Certification or Disclosure Statement for 510(k) notifications with a clinical study. * [See 21 CFR 807.87 (i)]		
510(k) Kit Certification ***		

- * - 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.

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

	Present	Inadequate or Missing
Name and 510(k) number of the sponsor'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 sponsor's unmodified predicate device.	✓	
A statement that the modification has not altered the fundamental technology of the sponsor's predicate device.	✓	
A Design Control Activities Summary that includes the following elements (a-e):		
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.	✓	

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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 <u>not</u> 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 <u>and</u> 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:	N/A	
b) Sterilization and expiration dating information:	✓	
i) sterilization process		
ii) validation method of sterilization process		
iii) SAL		
iv) packaging		
v) specify pyrogen free		
vi) ETO residues		
vii) radiation dose		
c) Software Documentation:	N/A	

Items with checks in the "Present but Deficient" column require additional information from the sponsor. Items with checks in the "Missing" column must be submitted before substantive review of the document.

Passed Screening Yes No
 Reviewer: DTB
 Concurrence by Review Branch: _____
 Date: 4/25/23

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>

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Internal Administrative Form

K030974

	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?	✓	
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)?		
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.		

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