仿 單 標 籤 粘 貼 表

98. 12. 2 3

產品中文名稱	“費森尤斯” 和膜流人工腎臟	申請廠商	臺灣費森尤斯醫藥股份有限公司
衛生署給證號碼	衛署醫器輸字第 020729 號		

Hemoflow™ **F80A**

Fresenius Polysulfone®

89-700-30 REV 04/08

Capillary dialyzer
Refer to instructions. Ethylene oxide sterilized.

Blood pathway is sterile and non-pyrogenic if the blood port caps are in place and undamaged. Recommended storage temperature between + 5° C and + 30° C. Use only on machines with controlled ultrafiltration.

Dialyseur capillaire
Se référer aux instructions. Circuit sanguin stérilisé à l'oxyde d'éthylène.

Le circuit sanguin est stérile et non pyrogéne si les capuchons des orifices pour connections sanguines sont bien en place et intacts. Conditions de stockage recommandées entre + 5° C et + 30° C. A n'utilliser qu'avec des maîtriseurs volumétriques d'ultrafiltration.

Dializador capilar
Utilicese de acuerdo con las instrucciones. Esterilizado con óxido de etileno.

El recorrido de la sangre es estéril y no pirogénico si la tapas de los puntos de acceso a la sangre están colocadas e intactas. Temperatura de almacenamiento recomendada entre 5° C y 30° C. Use sólo en aparatos con ultrafiltración controlada.

12 Units / Pièces / Unidades

Intended for Multiple Use

製造廠名稱：Fresenius Medical Care North America
製造廠地址：475 West 13th Street Ogden, UT 84404, U.S.A

Made in U.S.A.

Fresenius Medical Care

FRESENIUS MEDICAL CARE NORTH AMERICA
WALTHAM, MA 02451
1-800-323-5188

Batch no. / Lot no. / No de lote

Date of expiration / Date de péremption / Fecha de caducidad

Product Code / Code Produit / Código de producto

0500154A

署生衛院政行 章縫騎 輸 藥 政

F80A

Hemoflow™

Fresenius Polysulfone®

Caution: Federal (US) law restricts this device to sale by or on the order of a physician.
Surface Area/Superficie/Área superficial = 1.8 m^2
Max TMP/TMP (pression transmembranique) Max/TMP máxima = 600 mmHg
Priming Volume Blood/Volume d'amorçage - sang/Volumen de cebado de sangre = 110 mL

製造廠名稱：Fresenius Medical Care North America
製造廠地址：475 West 13th Street Ogden, UT 84404, U.S.A

Capillary dialyzer. Ethylene oxide sterilized. Blood pathway is sterile and non-pyrogenic. Use only on machines with controlled ultrafiltration. Refer to instructions.
Dialyseur capillaire. Stérilisé à l'oxyde d'éthylène. Le circuit sanguin est stérile et non pyrogène. A n'utiliser qu'avec des maîtriseurs volumétriques d'ultrafiltration. Se référer aux instructions.
Dializador capilar. Esterilizado por óxido de etileno. El recorrido de la sangre es estéril y no pirogénico. Uso exclusivo en aparatos automáticos con control de ultrafiltración. Utilícese según instrucciones.

Batch no. / Lot no. / No de lote

Date of expiration / Date de péremption / Fecha de caducidad

0500154A

Multiple-use High-Flux

Fresenius Medical Care

FRESENIUS MEDICAL CARE NORTH AMERICA
WALTHAM, MA 02451
1-800-323-5188

89-701-09 REV 12/08

署生衛院政行 章縫騎 輸 藥 政

費森尤斯 和膜流人工腎臟

Fresenius Hemoflow Dialyzer

許可字號：衛署醫器輸字第 020729 號
保存期限：見標籤
製造批號：見標籤
製造廠名稱：Fresenius Medical Care North America
製造廠地址：475 West 13th Street Ogden, UT 84404, U.S.A.
藥商名稱：臺灣費森尤斯醫藥股份有限公司
藥商地址：台北市信義區基隆路二段 51 號 11 樓之一

註銷規格
103. 10. -2

註 (1)報核標籤說明書以粘貼全型實物為原則。
(2)標籤說明書等實物過大或印於玻璃金屬容器等不便於粘貼時得附送現品並將彩色照片代替粘貼報核。

Fresenius Hemoflow™

F80A/ F80B

Hollow Fiber Dialyzer

	80B, 80A	
Priming volume blood	110	mL
Maximum TMP	600 80	mmHg kPa
Maximum blood flow	600	mL/min
Maximum dialysate flow	1000	mL/min
Surface area	1.8	m^2

TECHNICAL DATA

Membrane material:	Fresenius Polysulfone® polymer
Inner diameter (nominal):	200 µm
Wall thickness (nominal):	40 µm
Housing:	Polycarbonate
Potting compound:	Polyurethane
O-ring:	Silicone
Blood connectors:	DIN 13090 Part 3
Dialysis fluid connectors:	DIN 58352 Part 2

Manufacturer: Fresenius Medical Care North America
Office: 920 Winter Street, Waltham, MA 02451, USA
Site: 475 West 13th Street Ogden, UT 84404, U.S.A.
1-800-323-5188

"費森尤斯" 和膜流人工腎臟

"Fresenius" Hemoflow Dialyzer

98. 12. 2 3

注意：使用前請務必詳閱原廠之使用說明書並遵照指示使用。

衛署醫器輸字第 020729 號

騎縫章 註銷規格 103. 10. -2

產品規格	F80A/ F80B	單位
啟始血液體積	110	Ml
最大 TMP	600 80	mmHg kPa
最大血流	600	ml/min
最大透析液流速	1000	ml/min
表面積	1.8	m2

技術資料

膜材料：	Fresenius Polysulfone polymer
內徑（標定）：	200µm
壁厚（標定）：	40µm
外殼：	Polycarbonate
Potting 材質：	Polyurethane
O-環：	Silicone
血液連接器：	DIN 13090 Part 3
透析液連接器：	DIN 58352 Part 3

1. 依規定，透析器再生流程需依循 AAMI/ANSI Guideline 操作再生流程步驟及再生監控檢測，且每一次操作均需記錄所有相關監測數據，並留存於病歷中。
2. 重複使用規則及對有肝炎或 HIV 感染的患者的透析器進行重複使用有關的事宜，請遵循當地醫療管理機構對重複使用血液透析器的規定。

製造廠名稱：Fresenius Medical Care North America
地址：475 West 13th Street Ogden, UT 84404, U.S.A.
藥商名稱：臺灣費森尤斯醫藥股份有限公司
藥商地址：台北市信義區基隆路二段 51 號 11 樓之一
電話：02-27398800

GENERAL INFORMATION

Indications: Hemoflow dialyzers are designed for acute and chronic hemodialysis and are appropriate for single and multiple use when reprocessed utilizing the methods described or referenced in this package insert. Each reprocessed hemodialyzer shall be used for only one patient.

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

Contraindications: Specific contraindications for the dialyzer are unknown. Generally, the contraindications for hemodialysis are applicable. The dialyzer should only be used as directed by a physician.

Warning: Hypochlorite-based germicides should not be used for disinfection of the reprocessed dialyzer. Bleach should not be used as a blood path cleaning agent with F80A dialyzers unless Glutaraldehyde is used as the germicide.

Precautions: In the event of a blood leak during dialysis, the health care provider should respond according to the facility's established protocol.

Warning: Air entering the extracorporeal circuit during dialysis can result in serious injury or death. Check the integrity of all blood lines prior to the initiation of dialysis and periodically during the treatment. The venous return line or drip chamber should be continuously monitored with an air detector.

Warning: Due to the high water flux capability of dialyzer membrane with an ultrafiltration coefficient (Kuf) ≥ 8 mL/hr/mmhg, it is necessary to use such dialyzers only in conjunction with dialysis machines that are equipped with precise ultrafiltration control. Dialyzer models F80B and F80A must only be used with such UF control machines. In any case, the safety instructions of the manufacturer of the hemodialysis machine must be followed.

The user is cautioned to regularly monitor the patient's chemistry values using quantitative measurements and analysis to insure that the expected therapy is delivered. The clinical parameters monitored should, at least, include: urea, hematocrit, and serum albumin.

Dialyzers may leak, resulting in patient blood loss or contamination with dialysate. Each reprocessed dialyzer should be subjected to an air pressure leak test prior to use on a patient. Significant blood loss may require blood transfusion at the discretion of the physician.

一般資訊

適應症：
費森尤斯和膜流系列人工腎臟設計用於急性和慢性血液透析，適合單次和多次使用。經由再處理過程時，請依本產品說明書內所描述或推薦的方法。只限同一位病患多次使用。

注意事項：美國聯邦法律禁止此儀器由醫生和以醫生的名義銷售。

禁忌症：人工腎臟未知有特別的禁忌症。通常與一般作血液透析的禁忌症相同。人工腎臟只能在醫生指示下使用。

警告：次氯酸鹽類的殺菌劑不能用於人工腎臟再處理時的消毒程序。漂白粉不能作為 **F80A** 等型號人工腎臟的血液迴路的清洗劑，除非使用戊二醛作為殺菌劑。

預防措施：透析過程中出現血液滲漏情況時，醫護人員應當按照儀器設備生產廠商提供的方案採取相應的措施。

警告：透析過程中，若空氣進入體外循環可能導致嚴重損傷甚至死亡。透析啟始前檢查所有血液迴路的完整性，透析過程中也應當定期做此項檢查。靜脈回流管路或滴注腔應當持續使用空氣偵測器監控。

警告：由於透析膜的高流量能力（超濾系數**(Kuf)≧8ml/hr/mmhg**），此人工腎臟必須配合帶有精確超過濾控制的透析機器裝置。以下型號的人工腎臟必需只能在具有超過濾控制裝置的透析機器上使用，包括 **F80B** 和 **F80A**。無論任何情況，請遵循血液透析機器的製造廠商所提供的安全使用指示操作。

使用者必需謹記：使用定量分析方法定期監測患者的化學指標，以確保獲得預期的療效。臨床監測參數至少應包括尿素、血比容和血清白蛋白。

人工腎臟可能出現滲漏，導致患者血液流失或被透析液污染。每個再處理的人工腎臟用於患者之前，必需進行氣壓滲漏檢測。當血液顯著流失時，醫生可能要求輸血。

Dialysate: The dialysate must meet the Association for the Advancement of Medical Instrumentation's (AAMI) standards for dialysis. The use of bicarbonate dialysate is recommended for short dialysis.

Side effects: In rare cases hypersensitivity reactions may occur during hemodialysis treatment. A history of allergies is an indication for careful monitoring of hypersensitivity reactions. Dialyzers of this type should not be used again on any patient exhibiting a hypersensitivity reaction. With severe reactions, dialysis must be discontinued and aggressive, first line therapy for anaphylactic reactions must be initiated. The decision to return the blood to the patient must be made by a physician. The complete battery of tests necessary to demonstrate the carcinogenic potential of the material after reprocessing has not been performed. The AMES assay, for mutagenic potential was performed and it was negative (no indication of mutagenic potential).

Heparinization: It is recommended that the patient be systemically heparinized by allowing the heparin to circulate for 3 to 5 minutes before beginning extracorporeal circulation. In addition, the extracorporeal circuit may be heparinized taking care that the total amount of heparin to be delivered does not exceed the prescription. During dialysis, the dosage of heparin and the mode of administration are the responsibility of the attending physician. The coagulation time should be checked regularly.

Sterile/Non-pyrogenic: The dialyzer blood pathway is sterile and non-pyrogenic if the blood port caps are in place and undamaged. The dialyzer is sterilized with ethylene oxide gas. Do not use if the dialyzer is damaged in any way. Use aseptic technique for all blood side connections. Structural integrity of the hemodialyzer is warranted for the first use only when prepared as directed.

- **Recommended storage:** Between 5 and 30 °C (41 and 86 °F).
- Dialyzers disinfected with 1.5% formaldehyde @ 40°C or with 4.0% formaldehyde may be stored for a maximum of 30 days. After 30 days the dialyzers must be reprocessed.
- Dialyzers disinfected with Glutaraldehyde shall be stored according to the germicide manufacturer's instructions.
- Dialyzers disinfected with Puristeril 340™ solution shall be stored according to the germicide manufacturer's instructions.

Note: Puristeril 340™ concentrate are commercial germicides intended for the disinfection of hemodialyzers, and the manufacturer's instructions should be followed when using any of these germicides. Puristeril 340™ is Peracetic acid based germicides.

透析液：透析液必須符合醫療儀器促進委員會（AAMI）的透析標準。短期透析，建議使用重碳酸鹽類的透析液。

副作用：血液透析治療過程中，極少數病例可能發生敏感反應。過敏史是仔細監測敏感反應的指標。對於出現敏感反應的病患，不應該再次使用相同類型的人工腎臟。當出現嚴重反應時，透析必須中止，並且針對過敏反應的第一線救治方案必需立即啟動。血液是否輸回患者必須由醫生決定。對於人工腎臟所用材質，經再處理後所可能潛藏致癌性的完整評估尚未實施。但以 AMES 方法分析，顯示其致突變性為陰性（無誘導突變情形）。

肝素化：建議開始體外循環之前，讓患者透過使用肝素 3-5 分鐘，完成系統肝素化。此外，體外循環裝置也要肝素化，注意肝素的總劑量不要超過處方劑量。透析時，肝素的劑量和給藥模式由醫生負責決定。血液凝集時間應當定時檢測。

滅菌/無熱源：若連接血液端的滅菌帽蓋有蓋好且未毀損時，本人工腎臟是無菌且無熱源的。本人工腎臟使用環氧乙烷氣體滅菌。任何損壞的人工腎臟，都不得使用。所有血液端的連接，需使用無菌技術處理。當初次使用時，請遵照以下指示，人工腎臟的結構完整性才能有保證。

- 建議儲藏方法：5-30℃（41－86℉）
- 用 40℃1.5%或 4.0%的甲醛消毒過的人工腎臟，存放時間最多不超過 30 天。超過 30 天以後，人工腎臟需重新再消毒處理。
- 以戊二醛消毒的人工腎臟應當根據該殺菌劑的說明存放。
- 以 Puristeril 340™液體消毒的人工腎臟應當根據該殺菌劑的說明存放。

注意：Puristeril 340™ 濃縮液為商用殺菌劑，用於血液人工腎臟的消毒。使用任何一種殺菌劑，都應當遵照廠商的說明書使用。Puristeril 340™ 是過氧乙酸類的殺菌劑。

Dialyzer reuse: Reuse of these devices is a clinical decision. The Medical Director is responsible for the choice to reuse dialyzers and the procedures and safety of the reuse program. If dialyzer reuse is chosen, dialyzers must be reused in a carefully monitored program that complies with the AAMI Recommended Practice for the Reuse of Hemodialyzers, Centers for Medicare and Medicaid Services (CMS) requirements and other applicable Federal, State and local laws and regulations. Reprocessed dialyzers should not be used on patients with sepsis, excessive clotting problems, or known hypersensitivity. Follow recommendations of the Centers for Disease Control regarding reuse practices and the reuse of dialyzers on patients with hepatitis or HIV.
Follow universal precautions when handling used dialyzers.

Warning: The choice of cleaning agents, germicides, processing conditions, and reprocessing protocol must be carefully selected to avoid significant degradation of the dialyzer components. Certain sanitizing agents used for exterior cleaning, such as quaternary ammonium compounds, phenol-containing compounds, bleach (≥0.06%) or Puristeril 340™ solution (> 1.0%) may damage the plastic components when exposed for extended periods of time.

Warning: Pyrogenic reactions may occur with reused dialyzers. The water used to reprocess the dialyzer must meet AAMI standards for water for dialyzer reprocessing.

Dialyzers may clot after a variable number of uses. Any dialyzer that does not retain at least 80% of its original total cell volume (TCV) should be discarded. It is recommended that the original TCV be determined for each dialyzer prior to use.
In rare cases, dialysate may channel, resulting in reduced clearance. This condition is not identified by the TCV test.
Follow AAMI standards and the germicide manufacturer's instructions to assure that the disinfection process was carried out as intended.

Warning: Any chemical germicide in the dialyzer must be rinsed out prior to clinical use of the dialyzer.

The concentration of residual germicide must be measured and determined to be acceptable before clinical use. Use a test recommended by the germicide manufacturer or a test that is intended for measurement of residual levels of the germicide. Follow the instructions of the residual test manufacturer. Germicide concentration may increase (rebound) if the rinsing process is interrupted prior to connection to the patient. Additional rinsing and residual retesting are required in this event. Discard the prime solution when starting blood flow through the dialyzer. If the prime solution must be given to the patient for volume enhancement, replace the fluid in the circuit with fresh saline just before attachment to the patient. It is the responsibility of the medical director to assure that the residual levels of the germicide are acceptable.

人工腎臟的重複使用：是否再次使用這些器材應當由醫生決定。醫療指導者（The Medical Director）負責決定是否再次使用人工腎臟，以及重複使用方案的步驟和安全性。如果決定再次使用，人工腎臟的重複使用必需有嚴格監控方案，且必須符合 AAMI 建議的血液透析用人工腎臟重複使用綱要、Medicare 和 Medicaid 服務中心（CMS）的要求和其他適用的聯邦、州、地方的法律規範。再處理後的人工腎臟不應當用於膿血症、血液過度凝集或已知有過敏反應的患者。遵照疾病管制中心對於人工腎臟重複使用的規範，以及對於 B 肝和 HIV 患者使用再處理後人工腎臟的建議。
處理使用過的人工腎臟時，遵照通用的注意事項。

警告：清洗劑、殺菌劑、處理條件和再處理方案必須慎重選擇，以避免人工腎臟的零件發生嚴重降解。某些外部清洗用的殺菌劑，如第四氨類化合物，含酚類的化合物、漂白劑(≥0.06%)或 Puristeril 340™溶液（>1.0%），如果接觸時間太長，可能損壞人工腎臟的某些塑膠零件。

警告：重複使用人工腎臟可能產生熱源反應。用於人工腎臟再處理的水必須符合 AAMI 製定的人工腎臟處理水的標準。

人工腎臟經多次重覆使用後，可能會堵塞。當總血室容量（TCV）不及初始總血室容量（TCV）的 80%時，則此人工腎臟應當棄用。建議每一個人工腎臟在被使用前，均應檢測其 TCV。

極少數情況下，透析液可以傳送，導致廓清率減少。TCV 檢測不能發現此類問題。

遵照 AAMI 標準和殺菌劑生產商的說明書，確保消毒過程正確實施。

警告：經再處理的人工腎臟，必須將在人工腎臟內的化學殺菌劑沖洗乾淨才能用於臨床治療。

人工腎臟使用前必須做殺菌劑殘留的濃度檢測，以保證符合臨床使用規定。使用殺菌劑生產廠商提供的檢測方法或專門檢測殺菌劑殘留量的檢測方法，來檢測殘留的殺菌劑。遵照檢測廠商指示檢測殺菌劑殘留。在人工腎臟連接到患者身上之前，若其清洗過程被干擾時，可能引發殺菌劑含量增高（反彈）的現象。此時，必須再次清洗並作殺菌劑殘留濃度檢測。血液透過人工腎臟開始流動時，丟棄人工腎臟中的最初注入的液體。如果此初始液體必須用於提升患者的血容量，在人工腎臟連接到患者之前，用乾淨的生理鹽水替換初始液體。醫療指導者將負責將殺菌劑的殘餘水準控制在可接受的範圍之內。

Warning: These are suggested rinse procedures that contain many elements that are necessary in order to obtain fully rinsed dialyzers. However, Fresenius does not take responsibility for the rinsing procedures used at the dialysis facility. In addition, Fresenius makes no representations nor is assurance given that following these procedures will prevent patient reactions. It is necessary to follow AAMI guidelines, validate the rinse procedure, and be sure that it is followed, and properly test each dialyzer for residual chemical.

PREPARATION FOR DIALYSIS - DRY PACK

- If the dialysate delivery system was chemically disinfected or sterilized prior to patient use, be sure to test the dialysis machine for the absence of germicide residuals with a test intended for this application, according to the manufacturers' instructions.
- Place the dry dialyzer in a vertical position, arterial end down.
- Install the arterial and venous bloodlines on the hemodialysis machine.

Note: Refer to the manufacturer's instructions for the dialysate delivery machine.

- Remove any dialyzer blood port caps and aseptically connect the arterial and venous blood lines to the dialyzer.
- Aseptically spike a 1 liter bag of 0.9% sterile normal saline with a clamped IV administration set. Attach the IV administration set to the patient end of the arterial bloodline.
- Open the clamp on the IV set. Prime the arterial bloodline, dialyzer, and venous bloodline using a blood pump speed of approximately 150 mL/min. Discard the first 500 mL of solution. The drip chambers should be maintained about 3/4 full.
- Stop the blood pump. Clamp the arterial and venous bloodlines. **Turn the dialyzer so that the venous end is downward.** Aseptically connect the patient ends of the arterial and venous lines together in preparation for recirculation. Open the clamps on the bloodlines.
- Verify that the dialysate is within the prescribed conductivity limits with a calibrated external conductivity meter. To identify situations where the acetate or acid and bicarbonate concentrates are not properly matched, use pH paper or a meter to verify that the approximate pH is in the physiologic range.
- Attach the dialysate lines to the dialyzer. Fill the dialysate compartment. In order to maximize the efficiency of the dialyzer, the dialysate flow must be countercurrent to the blood flow.
- Rotate the dialyzer so that the arterial end is downward. Recirculate the blood side at a flow rate of 300 - 400 mL/min and a dialysate flow of 500 mL/min for a minimum of ten to fifteen minutes. Recirculate until all the air has been purged from the system before connecting to the patient. Continue recirculation and dialysate flow until patient connection.
- Ultrafilter or flush an additional 500 mL of 0.9% sterile normal saline so that the extracorporeal circuit has been flushed with a minimum of 1 liter of saline to minimize sterilization residues.
- Discard the prime solution when starting blood flow through the dialyzer. If the prime solution must be given to the patient for volume enhancement, replace the fluid in the circuit with fresh saline just before attachment to the patient.
- It is the responsibility of the Medical Director to assure that the residual levels are acceptable.

警告：以上的清洗程序是保證人工腎臟獲得徹底漂洗的建議方案，許多步驟是必要的。但是，費森尤斯公司並不會對透析場所中的清洗過程負責。而且，費森尤斯公司不做這樣的聲明也不會保證遵照這些步驟會防止患者出現各種反應。請務必遵照 AMMI 的指南，確認清洗程序的有效性，確實執行，並對每一個人工腎臟進行正確的化學殘留物檢測。

透析準備——乾燥包裝

- 如果透析液輸送系統在用於患者前，使用化學消毒或滅菌法，務必根據殺菌劑生產廠商提供的指示，對透析機器作測試以確認無殺菌劑殘留。
- 將乾燥的人工腎臟垂直擺放，動脈端朝下。
- 將動脈、靜脈血液管路安裝到血液透析機器

注意：參照透析液輸送設備廠商的指示使用。

- 去掉人工腎臟的所有血液埠蓋，以無菌技術連接動、靜脈血液管路於人工腎臟。
- 使用夾緊的靜脈輸液工具套件，以無菌技術開啟 1 升裝的 0.9%普通滅菌生理鹽水。將靜脈輸液工具套件連接到動脈血液管路的患者端。
- 打開靜脈輸液套件的夾子。使用血液幫浦灌注動脈血液管路、人工腎臟、靜脈血液管路，灌注速率約為 150ml/min。丟棄首次灌注的 500ml 液體。滴注腔應當保持 3/4 滿的容積。
- 關閉血液幫浦。夾住動、靜脈血液管路。**轉動人工腎臟使靜脈端朝下**。以無菌技術連接患者端的動、靜脈血液管路，為再循環做準備。 打開血液管路的夾子。
- 確保透析液的傳導性符合處方醫生的要求，並用外部的傳導性能檢測儀來校正。發現乙酸鹽、酸和重碳酸鹽濃度未能正確配比的情況，使用 PH 試紙或 PH 計調節，使近似 PH 值位於生理範圍。
- 將透析液管路連接到人工腎臟，將透析液腔填滿。為了讓人工腎臟發揮最佳的效率，透析液的流向必須與血液流向相反。
- 旋轉人工腎臟使動脈端朝下。重複環流血液端，流速為 300-400ml/min，透析液流速為 500ml/min，至少 10-15 分鐘。在連接到患者之前，重複環流直至所有空氣自系統中清除乾淨。保持重複環流和透析液的流動，直到連接到患者身上。
- 再用 500ml 0.9%普通滅菌生理鹽水過濾或沖洗，確保體外循環系統至少以 1 升生理鹽水沖洗，以使殺菌劑殘留降到最低。
- 當血流開始流過人工腎臟時，丟棄初始液體。如果此液體必須用於增加患者血容量，在連接到患者之前，用生理食鹽水更換迴路中的液體。
- 醫學指導者需負責確認殺菌劑殘留量在可接受的範圍之內。

PREPARATION FOR DIALYSIS – FORMALDEHYDE OR GLUTARALDEHYDE FILLED DIALYZERS

- If the dialysate delivery system was chemically disinfected or sterilized prior to patient use, be sure to test the dialysis machine for the absence of germicide residuals with a test intended for this application, according to the manufacturers' instructions.
- Check the dialyzer and label. Verify that the dialyzer is properly capped and has been filled with the dialyzer disinfecting solution. **Verify that the correct dialyzer has been selected for the patient.**
- Place the dialyzer in a vertical position.
- Install the arterial and venous bloodlines on the hemodialysis machine.

Note: Refer to the manufacturer's instructions for the dialysate delivery machine.

- Verify that the dialysate is at the conductivity required by the prescribing physician with a calibrated external conductivity meter. To identify situations where the acetate or acid and bicarbonate concentrates are not properly matched, use pH paper or a meter to verify that the approximate pH is in the physiologic range.
- Connect the dialysate lines to the dialyzer and establish dialysate flow (> 500 mL/min). Place the dialyzer so that the dialysate flow is upward and all the air bubbles are flushed from the dialysate compartment. This step must precede the attachment of the bloodlines and priming of the bloodside of the dialyzer. Verify that dialysate is flowing through the dialyzer.
- If a heparin pump is to be used, fill the heparin syringe with the prescribed medication and prime the heparin infusion line to the arterial line. Clamp the infusion line as close as possible to the arterial line.
- Spike a 1 liter bag of 0.9% sterile normal saline with a clamped IV administration set.
- Attach the IV administration set to the patient end of the arterial bloodline.
- Aseptically prime the arterial line with saline. If not already done, insert the blood pump segment into the blood pump. Connect the arterial and venous lines to the dialyzer only after the dialysate side has flushed for a couple of minutes. Connect the arterial and venous drip chamber monitor lines to the machine with new transducer protectors.
- Rotate the dialyzer so that the arterial end is down and the venous end is up. Flush 500 mL of sterile saline through the blood side of dialyzer at a flow rate of 150 mL/min. Adjust the fluid levels in the drip chambers. Insure the monitor lines are cleared of any fluid. Fluid contamination of the transducer protectors can cause false pressure readings.

透析準備——甲醛或戊二醛充填的人工腎臟

- 如果透析液輸送系統在用於患者之前以化學試劑消毒或滅菌，必須確認透析機器無殺菌劑殘留。請依據殺菌劑生產廠商提供專用於此類設備的方法，對透析設備進行殺菌劑殘留量檢測。
- 檢查人工腎臟和標籤。確認人工腎臟的蓋子已正確蓋好，並且已於人工腎臟內部充填殺菌劑。並為病人確認將正確的人工腎臟用於患者。
- 將人工腎臟垂直擺放。
- 將動脈、靜脈血液管路安裝到血液透析機器

注意：參照透析液輸送設備廠商的指示使用。

- 使用校正過的外部傳導性檢測儀，以確認透析液的傳導性符合處方醫生的要求。若要確認醋酸鹽、醋酸和重碳酸鹽濃度是否未能正確配比的情況，可使用 PH 試紙或 PH 計，以確保 PH 值位於生理範圍。
- 連接透析液管路與人工腎臟，使透析液流動起來（流速>500ml/min）。調整人工腎臟使透析液的流向朝上，將所有的氣泡從透析液室沖走。這一步驟必須在與血液管路連接，以及灌注人工腎臟血液腔之前。務使透析液在人工腎臟中流動。
- 如果要使用肝素幫浦，將處方用藥肝素充填於注射器，並注入肝素傳輸管路，連接到動脈管線。儘可能夾緊肝素傳輸管路和動脈管線。
- 使用夾緊的靜脈輸液工具套件開啟 1 升裝的 0.9%普通滅菌生理鹽水。
- 將靜脈輸液工具套件連接到動脈血液管路的患者端。
- 以無菌技術將生理食鹽水注入動脈管路。如果還沒準備好，將血液幫浦段插入血液幫浦。只有當透析液腔一側已經沖洗幾分鐘以後，才能將動、靜脈管路連接到人工腎臟。以新的感測器保護裝置將動、靜脈滴注腔的監測管路連接到血液透析機器。
- 旋轉人工腎臟使動脈端朝下，靜脈端朝上。以流速為 150ml/min 的速率，將 500ml 滅菌過的生理食鹽水沖洗人工腎臟的血液腔。調節滴注腔中的液體水平。保證監測管路中無任何液體。感測器保護裝置如果沾染流體，會導致壓力錯誤判讀。

- Clamp the saline administration line. Connect the arterial and venous blood lines together and recirculate the blood side at a high rate (400 - 500 mL/min). Alternately clamp and unclamp the venous line (below the drip chamber) to help remove air from the dialyzer. Do not exceed 500 mmHg venous pressure.
- Set an ultrafiltration rate of about 2 liters/hour and turn the UF on. When the TMP begins to rise, unclamp the saline administration line. Be sure there is sufficient sterile saline left in the bag to complete the rinsing process.

Note: If there are TMP alarms, Air Fill programs, or similar programs where the UF control system is bypassed or the TMP is relieved, clamp the saline administration line until the condition is cleared.

- About half-way through the recirculation procedure, rotate the dialyzer so that the flow directions are reversed. At this point the arterial end should be up and the venous end down.
- After an appropriate rinse time, test for residual germicide solution. Aseptically remove a sample from the venous bloodline and test for the absence of germicide residuals with a test intended for this application, according to the manufacturer's instructions.

Note: Acceptable residual levels for formaldehyde as stated in the AAMI guidelines for dialyzer reuse (RD47 1993) are less than 5 ppm.
Acceptable residual levels for Glutaraldehyde are less than 3 ppm as stated by the manufacturer.

- The test used for determining residual levels of Formaldehyde and Glutaraldehyde should be performed according to the manufacturer's instructions.
- Adjust the level of fluid in the arterial and venous drip chambers. The arterial blood port of the dialyzer should be up for the dialysis treatment (blood flow down, dialysate flow up).
- After an acceptable residual test has been obtained, the dialyzer must not be allowed to sit without blood side recirculation and dialysate flow unless the dialyzer is re-rinsed and tested again for residual germicide. Inadequate rinsing of the dialyzer may cause the patient to experience reactions to the residual germicide.
- If dialysis is not to be initiated now, turn down the blood pump flow rate to about 100 mL/min. Turn down the UF rate to 70 - 300 mL/hr. The dialysate flow may be turned down to 300 mL/min.

- 夾緊生理食鹽水傳輸管路。同時連接動、靜脈血液管路，以高流速（400-500ml/min）重複回流血液端。交替使用夾子，夾緊及鬆開靜脈管路（位於滴注腔下方），以此幫助從人工腎臟中排出空氣。靜脈壓力不要超過 500mmHg.
- 將超過濾速度設定在大約 2 升/小時，並打開 UF 開關。當 TMP 開始上升時，鬆開生理食鹽水輸送管路。袋子中應當保留有足夠的滅菌生理食鹽水以完成漂洗過程。

注意：當超過濾控制系統被忽略或 TMP 被釋放，如出現 TMP 警報，空氣充填等類似的程式，請先夾住生理鹽水輸注管路，直至情況解除。

- 在再循環程式完成接近一半左右，旋轉人工腎臟以逆轉液體的流向。這時，動脈端應當朝上，而靜脈端應當朝下。
- 經過適當的漂洗過程之後，需做殺菌劑殘留檢測。用無菌技術從靜脈血液管路取出測試樣品，根據殺菌劑生產廠商提供的說明，對殺菌劑的殘留量，按照專用於此用途的方法進行檢測。

注意：AAMI 關於重複使用的人工腎臟（RD47 1993）的指南規定：可接受的甲醛殘留量應當小於 5ppm。
依殺菌劑製造廠商規定，可接受的戊二醛殘留量應當小於 3ppm。

- 用於確定甲醛和戊二醛殘留量的檢測方法，應當參照殺菌劑生產廠商提供的說明。
- 調節動靜脈滴注腔內的液體量。為了便於透析治療，人工腎臟的動脈血部分應當朝上（血流向下，透析液流向朝上）。
- 當殘留物檢測在可接受的範圍，除非人工腎臟再次漂洗並再次作殺菌劑殘留檢測，否則人工腎臟不得在沒有血液再循環和透析液流動的情形下運作。人工腎臟漂洗不充分可能引起患者對殘留殺菌劑出現不良反應。
- 如果透析還沒啟動，降低血液幫浦的流速到約 100ml/min。降低 UF 速率為 70-300ml/hr。透析液的流量可降到 300ml/min。

PREPARATION FOR DIALYSIS - Puristeril 340™

- If the dialysate delivery system was chemically disinfected or sterilized prior to patient use, be sure to test the dialysis machine for the absence of germicide residuals with a test intended for this application, according to the manufacturers' instructions.
- Check the dialyzer and label. Verify that the dialyzer has been filled with germicide solution for the period specified by the manufacturer. **Verify that the correct dialyzer has been selected for the patient.**
- Place the dialyzer in a vertical position.
- Install the arterial and venous bloodlines on the hemodialysis machine.

Note: Refer to the manufacturer's instructions for the dialysate delivery machine.

- Verify that the dialysate is at the conductivity required by the prescribing physician with a calibrated external conductivity meter. To identify situations where the acetate or acid and bicarbonate concentrates are not properly matched, use pH paper or a meter to verify that the approximate pH is in the physiologic range.
- Check the dialyzer for presence of germicide according to the germicide manufacturer's instructions.
- If a heparin pump is to be used, aseptically fill the heparin syringe with the prescribed medication and prime the heparin infusion line to the arterial line. Clamp the infusion line as close as possible to the arterial line.
- Aseptically prime the arterial line with saline. Connect the arterial and venous lines to the dialyzer. Clamp and connect the arterial and venous drip chamber monitor lines to the machine with new transducer protectors.
- With the arterial end down and the venous end up, flush about 500 mL of sterile saline through the blood side of dialyzer at a flow rate of about 150 mL/min.
- Clamp the saline administration line. Connect the dialysate lines to the dialyzer and establish dialysate flow (> 500 mL/min). Rotate the dialyzer so that the dialysate flow is upward and all the air bubbles are flushed from the dialysate compartment.
- When the dialysate side is filled, again, rotate the dialyzer so that the blood side flow will be upward (arterial blood port on the bottom).
- Connect the arterial and venous blood lines together and recirculate the blood side at a high rate (400 - 500 mL/min). Alternately clamp and unclamp the venous line (below the drip chamber) to flush all remaining bubbles from the fibers (do not exceed 500 mmHg venous pressure).
- Unclamp the arterial and venous monitor lines and set an ultrafiltration rate of about 2 liters/hour and turn the UF on. Be sure there is sufficient sterile saline left in the bag. When the TMP begins to rise, unclamp the saline administration line.

透析準備——Puristeril 340™ 消毒液充填的人工腎臟

- 如果透析液輸送系統在用於患者之前以化學試劑消毒或滅菌，必須確認透析機器無殺菌劑殘留，請依據殺菌劑生產廠商提供專用於此類設備的方法，對透析設備進行殺菌劑殘留檢測。
- 檢查人工腎臟和標籤。確認已於人工腎臟內部充填消毒液，時程長短依殺菌劑製造廠規定。**務必為患者選擇正確的人工腎臟。**
- 垂直擺放人工腎臟。
- 連接動、靜脈血液管線於血液透析機器上。

注意：參照透析液輸送設備廠商的指示使用。

- 使用校正後的外部傳導性檢測儀來確認透析液的傳導性符合處方醫生的要求。欲確認醋酸鹽、醋酸和重碳酸鹽濃度是否正確配比的情況，可使用 PH 試紙或 PH 計已確認 PH 值位於生理範圍內。
- 根據殺菌劑製造廠提供的說明，檢測人工腎臟是否留有殺菌劑。
- 如果要使用肝素幫浦，將處方用藥肝素以無菌技術充填於注射器，並注入肝素傳輸管路，連接到動脈管線。儘可能夾緊肝素傳輸管路和動脈管線。
- 以無菌技術將生理食鹽水注入動脈管路。連接動、靜脈管路與人工腎臟。以新的感測器保護裝置將動、靜脈滴注腔的監測管路連接到血液透析機器並夾緊。
- 旋轉人工腎臟使動脈端朝下，靜脈端朝上。以流速為 150ml/min 的速率，將 500ml 滅菌過的生理食鹽水沖洗人工腎臟的血液腔。
- 夾緊生理食鹽水傳輸管路。連接透析液管路與人工腎臟，使透析液流動起來（流速 >500ml/min）。旋轉人工腎臟使透析液的流向朝上，並將所有的氣泡從人工腎臟沖走。
- 當透析液一側被充填時，再次旋轉人工腎臟使血液端的液體流向朝上（動脈血的部分在底部）。
- 共同連接動、靜脈血液管路，以高流速（400-500ml/min）再循環血液端。交替使用夾子，鬆開靜脈管路（位於滴注腔下方），將所有殘餘的氣泡從纖維膜沖洗排出（靜脈管路的壓力勿超過 500mmHg）。
- 鬆開動靜脈監測管路，將超過濾速度設定在 2 升/小時，並打開 UF 開關。袋子中應當保留有足量的滅菌生理鹽水。當 TMP 開始上升時，鬆開生理鹽水輸送管路。

Note: If there are TMP alarms, Air Fill programs, or similar programs where the UF control system is bypassed or the TMP is relieved, clamp the saline administration line until the condition is cleared.

- About half-way through the recirculation procedure, rotate the dialyzer so that the flow directions are reversed. At this point the arterial end should be up and the venous end down.
- After an appropriate rinse time, test for residual germicide. Aseptically remove a sample from the venous bloodline and check the dialyzer for an acceptable residual level of germicide according to the germicide manufacturer's instructions.

Note: Acceptable residual levels for Puristeril 340™ solution is less than 3 ppm hydrogen peroxide as stated by the manufacturers.

- The test used for determining residual levels of Puristeril 340™ solution should be performed according to the manufacturers' instructions.
- Adjust the level of fluid in the arterial and venous drip chambers. The arterial blood port of the dialyzer should be up for the dialysis treatment (blood flow down, dialysate flow up). Ensure the monitor lines are cleared of any fluid. Fluid contamination of the transducer protectors can cause false pressure readings.
- After an acceptable residual test has been obtained, the dialyzer should not be allowed to sit without recirculation unless the dialyzer is re-rinsed and tested again for residual germicide. Inadequate rinsing of the dialyzer may cause the patient to experience reactions to the residual germicide.
- If dialysis is not to be initiated at this time, turn down the blood pump flow rate to about 100 mL/min. Turn down the UF rate to 70 - 300 mL/hr. The dialysate flow may be turned down to 300 mL/min, if desired to conserve concentrate for the treatment.

INITIATION OF DIALYSIS TREATMENT

- Turn the blood pump off. Clamp the saline line and the arterial and venous bloodlines.
- Do not infuse the recirculated saline prime into the patient. If saline is required for volume enhancement, discard the recirculated saline and fill the bloodlines with fresh saline.
- Aseptically attach the arterial bloodline to the patient's arterial access. Open the arterial bloodline clamp.
- Place the venous bloodline in a drain container, making sure not to contaminate the end of the bloodline. Open the clamp on the venous bloodline.
- Turn the blood pump speed up to 100 - 150 mL/min and fill the extracorporeal circuit with the patient's blood.

Warning: This step must be carefully monitored to prevent any possibility of blood loss.

- 注意：當超過濾控制系統被忽略或 TMP 被釋放，如出現 TMP 警報，空氣充填等類似的程式，請先夾住生理鹽水輸注管路，直至情況解除。

- 當再循環程序進行到接近一半左右，旋轉人工腎臟以逆轉液體的流向。這時，動脈端應當朝上，而靜脈端朝下。
- 在適當的漂洗流程之後，需做殺菌劑殘留檢測。用無菌技術從靜脈血液管路取出測試樣品，根據殺菌劑生產廠商提供的說明，檢測人工腎臟的殺菌劑殘留量，確定是否在可接受的殺菌劑範圍。

注意：根據 Puristeril 340™ 生產製造廠規定：過氧化氫可接受殘留範圍應當小於 3ppm。

- 用於確定 Puristeril 340™ 的殘留量的檢測方法，應當參照殺菌劑製造廠所提供的指示來實施。
- 調節動、靜脈滴注腔內的液體高度。當透析治療時，人工腎臟的動脈血路連接埠應當朝上（血流向下，透析液流向朝上）。確認任何在監測管路中的液體是乾淨的。轉換器保護裝置如果受到液體污染，會導致壓力值誤判。
- 當殘留物檢測在可接受的範圍，除非人工腎臟再次漂洗並再次作殺菌劑殘留檢測，否則人工腎臟不得在沒有血液再循環的情形下運作。人工腎臟漂洗不充分可能引起患者對殘留殺菌劑出現不良反應。
- 如果透析還沒啟動，降低血液幫浦的流速到約 100ml/min。降低 UF 速率為 70-300ml/hr。如果想要節省治療期間濃度時，透析液的流量可降到 300ml/min。

透析治療的啟動

- 關閉血液幫浦。夾住生理食鹽水管路和動、靜脈血液管路。
- 勿將再循環過的生理鹽水灌注液輸給患者。如果要用生理食鹽水提升血液容量，丟棄再循環過的生理食鹽水，並以新鮮的生理食鹽水注入血液管路。
- 無菌連接動脈血液管路與患者的動脈入口。打開血液管路夾子。
- 將靜脈血液管路放在引流的容器中，切勿污染血液管路末端。打開靜脈血液管路夾。
- 升高血液幫浦速度到 100-150ml/min，將患者的血液注入體外循環迴路。

警告：這個步驟必須謹慎監控，以防止出現任何的血液流失。

- Turn off the blood pump and clamp the venous bloodline.
- Aseptically attach the patient end of the venous bloodline to the patient's venous access. Open the clamp to the venous access.
- Unclamp the venous bloodline and set the blood flow to the prescribed rate. Rotate the dialyzer so that the venous end is downward.
- Set the prescribed ultrafiltration rate. A minimum ultrafiltration rate of 300 mL/hr during dialysis treatment is recommended with Fresenius Hemoflow High Flux dialyzers.

DURING DIALYSIS TREATMENT

- If a blood leak should occur during the treatment, the decision to attempt to allow the leak to clot off by reducing the blood flow and ultrafiltration rate to minimum values is a clinical decision. The decision whether or not to return the blood to the patient must be made by a medical professional.
- Air entering the extracorporeal circuit during dialysis may be very serious and should be avoided. A routine check of all connections prior to initiation of dialysis and periodically throughout the treatment is recommended. Constant monitoring of the venous return line with an air detector is essential. Should air get into the venous line during treatment, the dialysis treatment must be discontinued without returning any of the patient's blood that is mixed with air.
- All blood tubing connections must be checked for security or obstruction to prevent damage or loss of blood or entry of air. Dialysate circuit leaks allowing air entry or fluid loss may cause significant ultrafiltration errors.

TERMINATION OF DIALYSIS TREATMENT

- When the dialysis treatment is completed, turn the blood flow rate to zero and UF rate to recommended minimum.
- Clamp arterial bloodline and aseptically disconnect from the patient's arterial access.
- Using the blood pump, rinse the patient's blood back using sterile 0.9% saline solution at a slow rate. **Do not allow air to enter the extracorporeal circuit.**
- Once the blood has been returned, turn the blood pump flow rate to zero.
- Clamp the venous bloodline.
- Clamp the patient's venous access and aseptically disconnect the venous bloodline from the patient's access.

- **If the dialyzer is to be discarded, place the extracorporeal circuit in an appropriate biohazard waste receptacle.** References: 29CFR 1910.145, 1910.1030 (Code of Federal Regulations) and appropriate state or local codes.
- If the dialyzer is to be reused, infuse any remaining heparin and recirculate for 1 to 2 minutes. After recirculation, cap the blood and dialysate ports being sure to keep both compartments full of fluid. **Insure that the dialyzer is marked in indelible ink with the patient's name.** Pre-clean and reprocess the dialyzer as soon as possible or refrigerate.

- 關閉血液幫浦，夾住靜脈血液管路。
- 無菌連接靜脈血液管路的患者端與患者的靜脈入口。打開靜脈入口的夾子。
- 鬆開靜脈血液管路的夾子，將血流設定在規定的流速。旋轉人工腎臟使靜脈端朝下。
- 設定規定的超過濾速率。在使用 Fresenius 和膜流系列高流量人工腎臟作透析治療時，建議最小超過濾速率為 300ml/hr。

透析治療過程中

- 如果治療過程中發生漏血，應當由臨床醫生決定：是否可藉由將血流和超過濾速率降至最低的方法，來去除滲漏的血液凝集。至於是否將血液回流至患者也應當由專業醫療人員決定。
- 透析時空氣進入體外循環是非常嚴重的情況，應當盡量避免。建議透析啟動之前對所有連結部位做常規檢查，並且治療期間全程應做定期檢查。使用空氣檢測儀經常監控靜脈回流管路是必要的。萬一治療過程空氣進入靜脈管路，透析治療必須中止，與空氣混合的患者血液不能回流給患者。
- 所有血液通路的連接必須做安全檢查，或者封閉管路以防止損壞、血液流失或空氣進入。透析液迴路滲漏會發生空氣進入或液體流失，因而導致明顯的超過濾錯誤。

透析治療中止

- 透析治療完成時，將血液流速調到零，UF 速率調到建議的最低值。
- 夾住動脈血液管路，以無菌技術中斷與患者動脈入口的連接。
- 用血液幫浦以 0.9%無菌生理鹽水在緩慢流速下回沖患者的血液。**切勿使空氣進入體外循環迴路。**
- 一旦血液回收到患者體內，將血液幫浦的速度調節至零。
- 夾住靜脈血液管路。
- 夾住患者的靜脈入口，以無菌技術中斷靜脈血液管路與患者靜脈入口處的連接。

- 如果人工腎臟棄置不用，將體外循環裝置放到適當的生物危害性廢物容器中。參照：29CFR 1910.145， 1910.1030(聯邦法規條例)和相應的州及地方條例。

- 如果要重複使用人工腎臟，輸入一些剩下的肝素，環流 1-2 分鐘。環流後，將血液室和透析液室蓋上蓋子，務使血液室和透析液室充滿液體。**確保人工腎臟用不可擦除的墨水標記患者的姓名。**應當儘快預清洗並再處理人工腎臟，否則需置於低溫冷藏。

DIALYZER PRE-CLEANING

- The water used to pre-clean dialyzers must meet AAMI standards for water for dialyzer reprocessing.

- **Warning: Header caps and O-rings must remain with their respective dialyzers.**

- Wear protective clothing, gloves, goggles, and mask.
- Step 1: Unscrew the header on dialyzers with substantial clots.
- Step 2: Clean all residual blood and protein from the header and tubesheet surface under running (AAMI quality) water.
- Step 3: Disinfect the header, header cap, and O-ring, prior to reassembly.

- If Puristeril 340™ solution is used as the dialyzer germicide, dip the header, header cap, and O-ring in 1% Puristeril 340™ solution.
- If Formaldehyde or Glutaraldehyde is used as the dialyzer germicide, dip the header, header cap, and O-ring in a 100 to 1 diluted solution of 5.25% bleach.
- Some germicides may attack the plastic used in dialyzers, so if cracking of the dialyzer occurs with extended use, this procedure must be evaluated.

- Step 4: Carefully reseat the header O-ring and hand tighten the header cap. If too loose, the header may leak when tested and if over-tightened the header, header cap, or O-ring may be damaged.
- Step 5: Rinse the blood compartment of the dialyzer with treated water until the effluent is clear.
- Step 6: The dialyzer may also be pre-cleaned by applying a reverse UF flush using AAMI quality water. If a vacuum is used on the blood side, the vacuum should not exceed 725 mmHg. If a positive pressure is used on the dialysate side, the pressure should not exceed 750 mmHg.

REPROCESSING PROCEDURES

- Reprocessing of hemodialyzers should be performed according to the AAMI guidelines for Reprocessing of Hemodialyzers.

Warning: The only reuse methods tested for these dialyzers were 4% Formaldehyde, 1.5% Formaldehyde @ 40°C, 3.5% Puristeril 340™ solution and 0.8% Glutaraldehyde as germicides. The only cleaning agents tested were bleach and Puristeril 340™ solution. All dialyzers reprocessed in the *in vitro* testing were reprocessed using the proper machine. Refer to the Operator's Manual for these complete instructions for use.

- **Warning: CMS regulations require that once a dialyzer has been reprocessed with one type of chemical germicide, it may not be reprocessed using any other method.**

人工腎臟的預清洗

- 預清洗人工腎臟的水質必須符合 AAMI 關於人工腎臟再處理用水的標準。

- 警告：每個人工腎臟的頂蓋和 O 型環必須同各自的人工腎臟一起處理。

- 穿防護衣，戴手套、護目鏡、面罩。
- 第一步：將有大量血塊的人工腎臟的頂蓋旋轉開來
- 第二步：在流水下（符合 AAMI 的品質標準）從頂蓋和管板表面清洗殘留的血液和蛋白質
- 第三步：重新裝配之前，對頂蓋、頂蓋罩、O 型環進行消毒。

- 如果用 Puristeril 340™ 作為人工腎臟的殺菌劑，則頂蓋、頂蓋罩、O 型環也用 1% 濃度的相同殺菌劑浸泡。
- 如果用甲醛或戊二醛作為人工腎臟的殺菌劑，則頂蓋、頂蓋罩、O 型環用 5.25%漂白粉以 100：1 的稀釋液浸泡。
- 某些殺菌劑可能會破壞人工腎臟的塑膠配件。如果在長時間使用下引起人工腎臟產生裂縫，則此預清洗程序應被重新評估。

- 第四步：仔細重新安裝頂蓋、O 型環，用手上緊頂蓋罩。如果太鬆，檢測時頂蓋可能會發生滲漏；如果太緊，頂蓋、O 型環、頂蓋罩可能被損壞。
- 第五步：用處理過的水漂洗人工腎臟的血液室，直至流出物變得清澈、乾淨。
- 第六步：人工腎臟也可以用 AAMI 標準的水，使用反超過濾沖洗。血液室如果要抽真空，壓力不得超過 725mmHg。如果透析液室用正壓，壓力不得超過 750mmHg。

再處理步驟

- 血液人工腎臟的再處理應當根據 AAMI 對於血液人工腎臟再處理的指南來實施。

警告：經測試用於本人工腎臟重複使用的再處理方法為：以 4%的甲醛、40℃1.5%的甲醛、3.5%Puristeril 340TM 溶液、0.8%的戊二醛作為殺菌劑。經測試的唯一清洗劑是漂白粉和 Puristeril 340™ 溶液。所有用於本次體外測試的人工腎臟，皆使用特定裝置進行再處理程序。使用時，請參考操作手冊中的完整使用指示。

- **警告：根據 CMS 規定，一旦人工腎臟用某個類型的化學殺菌劑實施再處理，則此人工腎臟不可再用其他殺菌劑實施再處理。**

Warning: Dialyzers which will be disinfected using 4% Formaldehyde and 0.8% Glutaraldehyde should be reprocessed with specific machine. Dialyzers which will be disinfected using Peracetic acid should be reprocessed with the Renatron® machine. Dialyzers which will be disinfected using 1.5% formaldehyde should be reprocessed with specific machine and heated to 40°C in an incubator with the following characteristics:

- **Use an incubator capable of delivering 45°C +/- 4°C for 24 hours.**
- As much residual blood as possible should be removed during the reprocessing procedure. When cleaning the dialyzer, pressures should not exceed 750 mmHg.
- Reverse ultrafiltration may also be used to aid in the removal of residual blood from the dialyzer. If reverse ultrafiltration is used, positive pressures should not exceed 750 mmHg and negative pressures should not exceed 725 mmHg.
- Reprocessed dialyzers must always be tested according to the AAMI guidelines for performance and membrane integrity prior to disinfection.
- *In vitro* Ultrafiltration test results may not be used to establish TMP treatment parameters.
- A total cell volume (TCV) test must be performed each time the dialyzer is reprocessed to insure it has at least 80% of its original volume. Dialyzers with less than 80% of original volume should not be used. For dialyzers with a high coefficient of ultrafiltration (Kuf > 8), when performing the TCV test by blowing out the blood compartment, the dialysate compartment must be filled with water and sealed to prevent fluid transfer from the blood to dialysate compartment.
- A membrane integrity test must be performed each time the dialyzer is reprocessed prior to disinfection.
- Bleach and Puristeril 340™ solution may be used as cleaning agents during reprocessing. If cleaning agents are used, dialyzer performance may be altered. See dialyzer performance characteristic information.
- If bleach is used as the cleaning agent, the concentration in the dialyzer should not exceed 1.0%.
- If Puristeril 340™ solution is used as cleaning agents the concentration in the dialyzer should not exceed 2.0%. Puristeril 340™ solution may only be used as a cleaning agent if Puristeril 340™ solution is used as the dialyzer germicide.

REUSE DIALYZER LABELING

- All reused dialyzers must be labeled according to the AAMI guidelines, each time they are reprocessed. These reprocessing labels must not obscure the manufacturer's label.

- 警告：使用 4%甲醛和 0.8%戊二醛消毒的人工腎臟應當用適合的儀器進行再處理。使用過醋酸消毒的人工腎臟應當用 Renatron®或其它適合的儀器進行再處理。使用 1.5%甲醛消毒的人工腎臟應當用適合的儀器進行再處理，並且在孵育箱中加熱到 40℃，此孵育箱具有以下特性：
- 請使用能夠連續 24 小時維持 45±4℃溫度的孵育箱。
- 人工腎臟再處理時，殘留的血液應儘可能去除。清洗人工腎臟時，壓力勿超過 750mmHg。
- 反超過濾可用於幫助除去人工腎臟中的殘留血液。如果使用反超過濾，正壓不得超過 750mmHg，負壓不得超過 725mmHg。
- 根據 AAMI 的指示，經再處理的人工腎臟必須於消毒前檢測產品效能和膜的完整性。
- 超過濾體外測試結果不應當用於建立 TMP 治療參數。
- 總血室容量（TCV）必須要在每次人工腎臟再處理後進行測試，經再處理後的人工腎臟必須至少保有 80%的初始容量，否則不能再使用。具有較高超過濾系數的人工腎臟（Kuf>8），用排空血液貯室的方法來實施 TCV 檢測時，透析液室必須用水充填並密封，以防止液體從血液室轉移到透析液室。
- 每次人工腎臟再處理消毒前，必須進行膜完整性檢測。
- 漂白粉和 Puristeril 340™ 溶液可以作為再處理人工腎臟時的清洗劑。如果使用清洗劑，人工腎臟的效能可能會改變。參考人工腎臟操作特點說明。
- 如果用漂白粉作為清洗劑，其在人工腎臟中的濃度不應超過 1.0%。
- 如果用 Puristeril 340™ 溶液作為清洗劑，其在人工腎臟中的濃度不應超過 2.0%。如果使用 Puristeril 340™ 溶液作為人工腎臟殺菌劑，則只能用 Puristeril 340™ 作清洗劑。

標記重複使用的人工腎臟

根據 AMMI 的指示，所有重複使用的人工腎臟，在每次再處理時必須做標記。這些再處理的標記不得掩蓋製造者的標籤。

TECHNICAL DATA

The Kuf and clearance characteristics of the dialyzers may change after repeated exposure to the reprocessing procedure. For example, the *in vitro* Kuf will usually rise with exposure to reuse processes. The use of volume ultrafiltration control dialysis equipment is mandatory when these dialyzers are reused.

Note: All dialyzers reprocessed using Formaldehyde (4% and 1.5%), and 0.8% Glutaraldehyde in the *in vivo* testing were reprocessed using the Seratronics® DRS-4 machine. Dialyzers tested with Peracetic acid were reprocessed with the Renatron® machine. All dialyzers reprocessed using Puristeril 340™ solution in the *in vivo* testing were reprocessed using the Renatron®. All *in vitro* testing was performed at a dialysate flow rate of 500 mL/min @ 37°C.

Note: The methodology used to generate all of the *in vitro* and *in vivo* data presented below, is based on testing requirements outlined in the FDA "Guidance for Hemodialyzer Reuse Labeling". Clearance tests were performed using aqueous solutions of urea, creatinine, phosphate and Vitamin B_{12}.

SUMMARY OF *IN VIVO* TESTING METHODS 4.0% FORMALDEHYDE

In vivo testing of Fresenius Hemoflow Dialyzers was performed according to the "Guidance for Hemodialyzer Reuse Labeling" testing protocol. At least 12 patients were started in the study that utilized F80B high flux dialyzers. Clinical testing of the F80B dialyzer was performed with 14 patients (9 males, 5 females), average age 61, average blood flow of 439 mL/min and average dialysis time of 3.25 hours. *In vivo* Kuf for the different hemodialyzers were calculated from pressure determinations available from the Fresenius 2008H hemodialysis machine. Blood samples were taken at predetermined times pre and post dialysis session on the 0, 1, 5 and 15th reuse. Blood samples were analyzed for urea, albumin and Beta2-Microglobulin (B2M for high flux hemodialyzers only). Equilibrated single pool Kt/V urea (spKt/V), urea reduction ratio, (URR = %) and pre/post serum albumin values were calculated.

***In vivo* Ultrafiltration Coefficient, Kuf of Dialyzers Reprocessed with 0.75% Bleach / 4.0% Foraldehyde (Kuf=mL/hr/mmHg)**

	0	1 use	5 use	15 use
F80B	53	53	71	71

技術性資料

人工腎臟的 Kuf 和廓清率特性可能在多次重複再處理程序之後發生改變。例如，在體外測試結果中，重複使用常常會導致 Kuf 升高。如果要重複使用人工腎臟，需強制使用具有超過濾容積控制的透析設備。

注意：在做體內測試時，所有以 **4%**和 **1.5%**的甲醛，以及 **0.8%**的戊二醛進行再處理的人工腎臟，皆使用 **Seratronics®DRS-4** 儀器進行再處理；以過醋酸做測試的人工腎臟使用 **Renatron®**儀器進行再處理；以 **Puristeril 340™** 做測試的人工腎臟使用 **Renatron®**儀器進行再處理。所有體內測試進行時，透析液的條件為 **37**℃，流速 **500 ml/min**。

注意：以下提供的所有體內和體外試驗數據，其測試方法是依據美國 FDA 在"重複使用人工腎臟標記指導規範"中，對於體內和體外試驗的要求所進行而得。人工腎臟的廓清率檢測，係採用尿素、肌酸酐、磷酸鹽和維生素 **B12** 的水溶液來進行。

體內測試方法總結，4.0%甲醛

費森尤斯和膜流系列人工腎臟的體內測試，係依據「重複使用人工腎臟標記指導規範」中所建議的測試方法進行。測試的人工腎臟為高流量的 F80B。測試開始時，參加的患者人數至少要達到 12 名。F80 B 型人工腎臟的臨床測試，共有 14 名患者參與(男性 9 名，女性 5 名)，平均年齡 61 歲，平均血流速為 439ml/min，平均透析時間為 3.25 小時。不同人工腎臟的 Kuf 體內測試值，是根據從 Fresenius 2008H 血液透析機器獲得的壓力測定資料來計算。血液樣品採集方法為：在第 0，1，5，15 次重複透析前、後的規定時間內採集。血液樣本的分析指標為尿素、白蛋白、β2 微球蛋白（β2 微球蛋白只在高流量的人工腎臟測試）。計算平衡單槽尿素的 Kt/V (Equilibrated single pool Kt/V urea)（sp Kt/V），尿素減少率（URR=%）、和透析前後血漿白蛋白值。

人工腎臟的體內測試，超過濾系數，Kuf
以 0.75%漂白粉/4.0%甲醛再處理
（Kuf=ml/hr/mmHg）

	0	1 次使用	5 次使用	15 次使用
F80B	53	53	71	71

In vivo spKt/V and URR of Dialyzers Reprocessed with 0.75% Bleach / 4.0% Formaldehyde (URR=%)

	0	1 use	5 use	15 use
F80B				
spKt/V	1.58	1.63	1.60	1.59
URR	73	74	73	73

In vivo Beta2-Microglobulin Clearance of Dialyzers Reprocessed with 0.75% Bleach / 4.0% Formaldehyde (B2M=mL/min)

	0	1 use	5 use	15 use
F80B	23	30	39	57

In vivo Pre and Post Serum Albumin Levels of Dialyzers Reprocessed with 0.75% Bleach / 4.0% Formaldehyde (Albumin=g/dl)

	0	1 use	5 use	15 use
F80B				
Pre Serum	3.89	4.01	3.91	3.65
Post Serum	4.40	4.24	4.26	4.05

IN VIVO RESULTS 4.0% FORMALDEHYDE

In vivo Kuf for all study dialyzers increased when exposed to multiple reprocessing with 0.75% Bleach / 4.0% Formaldehyde. The use of volume ultrafiltration control dialysis equipment is mandatory when these dialyzers are reused.

In vivo spKt/V and URR were unchanged with multiple exposure to the reprocessing procedure. Beta2-Microglobulin increased significantly with the F80B dialyzers with multiple exposure to the 0.75% Bleach / 4.0% Formaldehyde reprocessing procedure indicating a slight increase in hydraulic permeability and higher middle molecule removal rates. There was no change in serum albumin levels for any of the hemodialyzers tested.

人工腎臟的體內測試, sp Kt/V 和 URR 以 0.75%漂白粉/4.0%甲醛再處理（URR=%）

	0	1 次使用	5 次使用	15 次使用
F80B				
spKt/V	1.58	1.63	1.60	1.59
URR	73	74	73	73

人工腎臟的體內測試, β2 微球蛋白廓清率 以 0.75%漂白粉/4.0%甲醛再處理（β2 M = ml/min）

	0	1 次使用	5 次使用	15 次使用
F80B	23	30	39	57

人工腎臟的體內測試, 處理前後的體內血漿白蛋白濃度 以 0.75%漂白粉/4.0%甲醛再處理（Albumin=g/dl）

	0	1 次使用	5 次使用	15 次使用
F80B				
前血清	3.89	4.01	3.91	3.65
後血清	4.40	4.24	4.26	4.05

體內測試結果，4.0%的甲醛

多次重複使用以 0.75%的漂白粉/4.0%的甲醛再處理的人工腎臟，所有人工腎臟的 Kuf 體內檢測值均升高。如果要重複使用，需強制使用具有超過濾容積控制的透析機器。

體內測試 sp Kt/V 和 URR 的結果並未改變。F80B 型人工腎臟經多次重複使用 0.75%的漂白粉/4.0%的甲醛再處理後，其 β2 微球蛋白項的檢測值明顯增加，顯示該人工腎臟對水的通透性稍微增加，並且對中等分子量的物質具有較高的廓清率。所測試的任何型號的人工腎臟，其血漿白蛋白濃度皆無變化。

SUMMARY OF *IN VIVO* TESTING METHODS
1.5% FORMALDEHYDE @ 40°C

In vivo testing of Fresenius Hemoflow Dialyzers was performed according to the "Guidance for Hemodialyzer Reuse Labeling" testing protocol. At least 12 patients were started in the study that utilized F80B high flux dialyzers. Clinical testing of the F80B dialyzer was performed with 12 patients (9 males, 3 females), average age 62, average blood flow of 325 mL/min and average dialysis time of 2.68 hours. *In vivo* Kuf for the different hemodialyzers were calculated from pressure determinations available from the Fresenius 2008H hemodialysis machine. Blood samples were taken at predetermined times pre and post dialysis session on the 0, 1, 5 and 15th reuse. Blood samples were analyzed for urea, albumin and Beta2-Microglobulin (B2M for high flux hemodialyzers only). Equilibrated single pool Kt/V urea (spKt/V), urea reduction ratio, (URR = %) and pre/post serum albumin values were calculated.

***In vivo* Ultrafiltration Coefficient, Kuf of Dialyzers Reprocessed with 0.75% Bleach / 1.5% Formaldehyde @ 40°C (Kuf=mL/hr/mmHg)**

	0	1 use	5 use	15 use
F80B	35	34	39	49

***In vivo* spKt/V and URR of Dialyzers Reprocessed with 0.75% Bleach / 1.5% Formaldehyde @ 40°C (URR=%)**

	0	1 use	5 use	15 use
F80B				
spKt/V	1.28	1.31	1.29	1.32
URR	66	66	66	66

***In vivo* Beta2-Microglobulin Clearance of Dialyzers Reprocessed with 0.75% Bleach / 1.5% Formaldehyde @ 40° (B2M=mL/min)**

	0	1 use	5 use	15 use
F80B	26	25	40	68

***In vivo* Pre and Post Serum Albumin Levels of Dialyzers Reprocessed with 0.75% Bleach / 1.5% Formaldehyde (Albumin=g/dL)**

	0	1 use	5 use	15 use
F80B				
Pre Serum	3.61	3.63	3.59	3.49
Post Serum	4.14	4.08	4.02	4.11

體內測試方法總結，1.5%甲醛 40℃

費森尤斯和膜流系列人工腎臟的體內測試，係依據「重複使用人工腎臟標記指導規範」中所建議的測試方法進行。測試的人工腎臟為高流量的 F80B。測試開始時，參加的患者人數至少要達到 12 名。F80 B 型人工腎臟的臨床測試，共有 12 名患者參與(男性 9 名，女性 3 名)，平均年齡 62 歲，平均血流速為 325ml/min，平均透析時間為 2.68 小時。不同人工腎臟的 Kuf 體內測試值，是根據從 Fresenius 2008H 血液透析機器獲得的壓力測定資料來計算。血液樣品採集方法為：在第 0，1，5，15 次重複透析前、後的規定時間內採集。血液樣本的分析指標為尿素、白蛋白、β2 微球蛋白（β2 微球蛋白只在高流量的人工腎臟測試）。計算平衡單槽尿素的 Kt/V (Equilibrated single pool Kt/V urea)（sp Kt/V），尿素降低率（URR=%）和透析前後血漿白蛋白值。

人工腎臟的體內測試，超過濾系數，Kuf
以 0.75%漂白粉/1.5%甲醛 40℃再處理
（Kuf=ml/hr/mmHg）

	0	1 次使用	5 次使用	15 次使用
F80B	35	34	39	49

人工腎臟的體內測試，sp Kt/V 和 URR
以 0.75%漂白粉/4.0%甲醛 40℃再處理
（URR=%）

	0	1 次使用	5 次使用	15 次使用
F80B				
spKt/V	1.28	1.31	1.29	1.32
URR	66	66	66	66

人工腎臟的體內測試，β2 微球蛋白廓清率
以 0.75%漂白粉/1.5%甲醛 40℃再處理
（β2 M = ml/min）

	0	1 次使用	5 次使用	15 次使用
F80B	26	25	40	68

人工腎臟的體內測試，處理前後的體內血漿白蛋白濃度
以 0.75%漂白粉/1.5%甲醛 40℃再處理
（白蛋白=g/dl）

	0	1 次使用	5 次使用	15 次使用
F80B				
前血清	3.61	3.63	3.59	3.49
後血清	4.14	4.08	4.02	4.11

IN VIVO RESULTS 1.5% FORMALDEHYDE @ 40°C

In vivo Kuf for all study dialyzers increased when exposed to multiple reprocessing with 0.75% Bleach / 1.5% Formaldehyde @ 40°C. The use of volume ultrafiltration control dialysis equipment is mandatory when these dialyzers are reused.
In vivo spKt/V and URR were unchanged with multiple exposure to the reprocessing procedure. Beta2-Microglobulin increased significantly with the F80B dialyzers with multiple exposure to the 0.75% Bleach / 1.5% Formaldehyde @ 40°C reprocessing procedure indicating a slight increase in hydraulic permeability and higher middle molecule removal rates. There was no change in serum albumin levels for any of the hemodialyzers tested.

體內測試結果，1.5%的甲醛，40℃

多次重複使用以 0.75%的漂白粉/1.5%的甲醛 40℃再處理的人工腎臟，所有人工腎臟的 Kuf 體內檢測值均升高。如果要重複使用，需強制使用具有超過濾容積控制的透析機器。

體內測試 sp Kt/V 和 URR 的結果並未改變。F80B 型人工腎臟經多次重複使用 0.75%的漂白粉/1.5%的甲醛 40℃再處理後，其 β2 微球蛋白項的檢測值明顯增加，顯示該人工腎臟對水的通透性稍微增加，並且對中等分子量的物質具有較高的廓清率。所測試的任何型號的人工腎臟，其血漿白蛋白濃度皆無變化。

SUMMARY OF IN VITRO TESTING METHODS GLUTARALDEHYDE

In vitro testing of Fresenius Hemoflow Dialyzers was performed according to the "Guidance for Hemodialyzer Reuse Labeling" testing protocol. Where possible, three dialyzers from each of three different manufacturing lots were tested. Dialyzers were reprocessed a total of 15 times with the 0.75% Bleach / 0.8% Glutaraldehyde reprocessing procedure. Dialyzers were not exposed to blood between reprocessings. Dialyzers were stored for 24 hours before the subsequent reprocessing. Dialyzers were tested for in vitro Kuf using fresh whole beef blood and aqueous solute clearance using urea, creatinine and Vitamin B_{12} as the solute markers.

體外測試方法總結，戊二醛

費森尤斯和膜流系列人工腎臟的體外測試，係依據「重複使用人工腎臟標記指導規範」中所建議的測試方法進行。若可能的話，從三個不同生產批次抽出三個人工腎臟來做測試。人工腎臟總共需進行 15 次的再處理過程，且使用 0.75%漂白粉/0.8%的戊二醛進行再處理。在兩次再處理之間，人工腎臟不能接觸到血液。每次處理完後，在再次處理之前，人工腎臟需靜置存放 24 小時。人工腎臟在體外的 Kuf 檢測使用新鮮的小牛全血；尿素、肌酸酐、磷酸鹽和維生素 B12 作為溶質指標，用於人工腎臟的水溶液廓清率檢測。

In vitro Ultrafiltration Coefficient, Kuf of Dialyzers Reprocessed with 0.75% Bleach / 0.8% Glutaraldehyde Using Fresh Whole Beef Blood (Kuf=mL/hr/mmHg)

	0	1 use	5 use	15 use
F80A	50	47	36	33

人工腎臟的體外測試，超過濾系數，Kuf
以 0.75%漂白粉/0.8%的戊二醛再處理，使用新鮮小牛全血
（Kuf=ml/hr/mmHg）

	0	1 次使用	5 次使用	15 次使用
F80A	50	47	36	33

Aqueous _In vitro_ Urea Clearance of Dialyzers Reprocessed with 0.75% Bleach / 0.8% Glutaraldehyde (mL/min)

	QB	0	1 use	5 use	15 use
F80A	200	183	180	180	185
	300	246	251	249	248
	400	284	295	292	293
	500	306	321	322	319

人工腎臟的體外測試，水溶液尿素廓清率
以 0.75%漂白粉/ 0.8%戊二醛再處理
(ml/min)

	QB	0	1 次使用	5 次使用	15 次使用
F80A	200	183	180	180	185
	300	246	251	249	248
	400	284	295	292	293
	500	306	321	322	319

Aqueous In vitro Creatinine Clearance of Dialyzers Reprocessed with 0.75% Bleach / 0.8% Glutaraldehyde (mL/min)

	QB	0	1 use	5 use	15 use
F80A	200	175	173	173	173
	300	225	229	228	226
	400	254	263	261	258
	500	269	283	282	278

Aqueous *In vitro* Vitamin B_{12} Clearance of Dialyzers Reprocessed with 0.75% Bleach / 0.8% Glutaraldehyde (mL/min)

	QB	0	1 use	5 use	15 use
F80A	200	136	145	129	118
	300	161	177	156	144
	400	170	188	167	153
	500	176	194	175	158

IN VITRO RESULTS GLUTARALDEHYDE

In vitro Kuf decreased with multiple exposures 0.75% Bleach / 0.8% Glutaraldehyde reprocessing. Urea and creatinine clearance were unaffected by multiple exposures to the reuse process. Vitamin B_{12} decreased reflecting the same effect as that observed with *in vitro* ultrafiltration.

SUMMARY OF *IN VIVO* TESTING METHODS GLUTARALDEHYDE

In vivo testing of Fresenius Hemoflow Dialyzers was performed according to the "Guidance for Hemodialyzer Reuse Labeling" testing protocol. At least 12 patients were started in the study that utilized F80A high flux dialyzers. Clinical testing of the F80A dialyzer was performed with 15 patients (14 males, 1 female), average age 57, average blood flow of 373 mL/min and average dialysis time of 3.3 hours. *In vivo* Kuf for the different hemodialyzers were calculated from pressure determinations available from the Fresenius 2008H hemodialysis machine. Blood samples were taken at predetermined times pre and post dialysis session on the 0, 1, 5 and 15th reuse. Blood samples were analyzed for urea, albumin and Beta2-Microglobulin (B2M for high flux hemodialyzers only). Equilibrated single pool Kt/V urea (spKt/V), urea reduction ratio, (URR = %) and pre/post serum albumin values were calculated

人工腎臟的體外測試，水溶液肌酸酐廓清率 以 0.75%漂白粉/ 0.8%戊二醛再處理 (ml/min)

	QB	0	1 次使用	5 次使用	15 次使用
F80A	200	175	173	173	173
	300	225	229	228	226
	400	254	263	261	258
	500	269	283	282	278

人工腎臟的體外測試，水溶液維生素 B12 廓清率 以 0.75%漂白粉/0.8%的戊二醛再處理 (ml/min)

	QB	0	1 次使用	5 次使用	15 次使用
F80A	200	136	145	129	118
	300	161	177	156	144
	400	170	188	167	153
	500	176	194	175	158

體外測試結果，戊二醛

多次重複使用以 0.75%的漂白粉/0.8%的戊二醛再處理的人工腎臟，人工腎臟的體外測試 Kuf 檢測值降低。尿素和肌酸酐廓清率未受影響。多次重複使用後，維生素 B12 的廓清率降低，與體外超過濾觀察的結果一致。

體內測試方法總結，戊二醛

費森尤斯和膜流系列人工腎臟的體內測試，係依據「重複使用人工腎臟標記指導規範」中所建議的測試方法進行。測試的人工腎臟為高流量的 F80A。測試開始時，參加的患者人數至少要達到 12 名。F80 A 型人工腎臟的臨床測試，共有 15 名患者參與(男性 14 名，女性 1 名)，平均年齡 57 歲，平均血流速為 373ml/min，平均透析時間為 3.3 小時。不同人工腎臟的 Kuf 體內測試值，是根據從 Fresenius 2008H 血液透析機器獲得的壓力測定資料來計算。血液樣品採集方法為：在第 0，1，5，15 次重複透析前、後的規定時間內採集。血液樣本的分析指標為尿素、白蛋白、β2 微球蛋白（β2 微球蛋白只在高流量的人工腎臟測試)。計算平衡單槽尿素的 Kt/V (Equilibrated single pool Kt/V urea)（sp Kt/V)，尿素降低率（URR=%）和透析前後血漿白蛋白值。

In vivo ultrafiltration Coefficient, Kuf of Dialyzers Reprocessed with 0.75% Bleach / 0.8% Glutaraldehyde (Kuf=mL/hr/mmHg)

	0	1 use	5 use	15 use
F80A	73	69	67	71

In vivo spKt/V and URR of Dialyzers Reprocessed with 0.75% Bleach / 0.8% Glutaraldehyde (URR=%)

	0	1 use	5 use	15 use
F80A				
spKt/V	1.31	1.33	1.26	1.20
URR	66	67	64	63

In vivo Beta2-Microglobulin Clearance of Dialyzers Reprocessed with 0.75% Bleach / 0.8% Glutaraldehyde (B2M=mL/min)

	0	1 use	5 use	15use
F80A	39	36	45	47

In vivo Pre and Post Serum Albumin Levels of Dialyzers Reprocessed with 0.75% Bleach / 0.8% Glutaraldehyde (Albumin=g/dL)

	0	1 use	5 use	15 use
F80A				
Pre Serum	3.80	3.72	3.66	3.74
Post Serum	4.30	4.11	4.25	4.28

IN VIVO RESULTS GLUTARALDEHYDE

In vivo Kuf (mL/hr/mmHg) was unchanged in high flux hemodialyzers when exposed to multiple reprocessing with 0.75% Bleach / 0.8% Glutaraldehyde.

In vivo spKt/V and URR were unchanged with multiple exposures to the reprocessing procedure. Beta2-Microglobulin increased significantly with the F80A dialyzers with multiple exposures to the 0.75% Bleach / 0.8% Glutaraldehyde reprocessing procedure. There was no change in serum albumin levels for any of the hemodialyzers tested.

人工腎臟的體內測試，超過濾系數，Kuf
以 0.75%漂白粉/0.8%的戊二醛再處理
（Kuf=ml/hr/mmHg）

	0	1 次使用	5 次使用	15 次使用
F80A	73	69	67	71

人工腎臟的體內測試，sp Kt/V 和 URR
以 0.75%漂白粉/0.8%的戊二醛
（URR=%）

	0	1 次使用	5 次使用	15 次使用
F80A				
spKt/V	1.31	1.33	1.26	1.20
URR	66	67	64	63

人工腎臟的體內測試，β2 微球蛋白廓清率
以 0.75%漂白粉/0.8%的戊二醛再處理
（β2 M = ml/min）

	0	1 次使用	5 次使用	15 次使用
F80A	39	36	45	47

人工腎臟的體內測試，處理前後血漿白蛋白濃度
以 0.75%漂白粉/0.8%的戊二醛再處理
（Albumin=g/dl）

	0	1 次使用	5 次使用	15 次使用
F80A				
前血清	3.80	3.72	3.66	3.74
後血清	4.30	4.11	4.25	4.28

體內測試結果，戊二醛

多次重複使用以 0.75%的漂白粉/0.8%的戊二醛再處理的人工腎臟， Kuf 體內檢測值，高流量的人工腎臟無變化。

體內測試 sp Kt/V 和 URR 的結果並未改變。F80A 型人工腎臟經多次重複使用 0.75%的漂白粉/0.8%的戊二醛再處理後，其 β2 微球蛋白項的檢測值明顯增加。所測試的任何型號的人工腎臟，其血漿白蛋白濃度皆無變化。

SUMMARY OF *IN VITRO* TESTING METHODS
PERACETIC ACID

In vitro testing of Fresenius Hemoflow Dialyzers was performed according to the "Guidance for Hemodialyzer Reuse Labeling" testing protocol. Where possible, three dialyzers from each of three different manufacturing lots were tested. Dialyzers were reprocessed a total of 15 times with the Peracetic Acid reprocessing procedure. Dialyzers were not exposed to blood between reprocessings. Dialyzers were stored for 24 hours before the subsequent reprocessing. High flux F80A dialyzers were used in the *in vitro* testing. Dialyzers were tested for *in vitro* Kuf using fresh whole beef blood and aqueous solute clearance using urea, creatinine and Vitamin B_{12} as the solute markers.

In vitro Ultrafiltration Coefficient, Kuf of Dialyzers Reprocessed with 3.5% Peracetic Acid Using Fresh Whole Beef Blood (Kuf=mL/hr/mmHg)

	0	1 use	5 use	15 use
F80A	50	47	36	33

Aqueous _In vitro_ Urea Clearance of Dialyzers Reprocessed with 3.5% Peracetic Acid (mL/min)

	QB	0	1 use	5 use	15 use
F80A	200	183	186	188	187
	300	238	243	251	252
	400	278	285	288	293
	500	308	302	316	319

Aqueous _In vitro_ Creatinine Clearance of Dialyzers Reprocessed with 3.5% Peracetic Acid (mL/min)

	QB	0	1 use	5 use	15 use
F80A	200	169	177	177	177
	300	214	223	226	229
	400	246	254	257	260
	500	272	276	280	280

體外測試方法總結，過醋酸

費森尤斯和膜流系列人工腎臟的體外測試，係依據「重複使用人工腎臟標記指導規範」中所建議的測試方法進行。若可能的話，從三個不同生產批次抽出三個人工腎臟來做測試。人工腎臟總共需進行 15 次的再處理過程，且使用過醋酸進行再處理。在兩次再處理之間，人工腎臟不能接觸到血液。每次處理完後，在再次處理之前，人工腎臟需靜置存放 24 小時。高流量的 F80A 的人工腎臟做了體外測試。人工腎臟在體外的 Kuf 檢測使用新鮮的小牛全血；尿素、肌酸酐、磷酸鹽和維生素 B12 作為溶質指標，用於人工腎臟的水溶液廓清率檢測。

人工腎臟的體外測試，超過濾系數，Kuf
以 3.5%的過醋酸再處理，使用新鮮小牛全血
（Kuf=ml/hr/mmHg）

	0	1 次使用	5 次使用	15 次使用
F80A	50	47	36	33

人工腎臟的體外測試，尿素水溶液廓清率
以 3.5%的過醋酸再處理
（ml/min）

	QB	0	1 次使用	5 次使用	15 次使用
F80A	200	183	186	188	187
	300	238	243	251	252
	400	278	285	288	293
	500	308	302	316	319

人工腎臟的體外測試，肌酸酐水溶液廓清率
以 3.5%的過醋酸再處理
（ml/min）

	QB	0	1 次使用	5 次使用	15 次使用
F80A	200	169	177	177	177
	300	214	223	226	229
	400	246	254	257	260
	500	272	276	280	280

Aqueous *In vitro* Vitamin B_{12} Clearance of Dialyzers Reprocessed with **3.5% Peracetic Acid (mL/min)**

	QB	0	1 use	5 use	15 use
F80A	200	116	124	125	135
	300	134	141	144	159
	400	148	153	156	169
	500	159	163	165	176

IN VITRO RESULTS PERACETIC ACID

In vitro Kuf was decreased in high flux hemodialyzers with multiple exposures to Peracetic acid reprocessing. Urea, creatinine, and Vitamin B_{12} increased for some study hemodialyzers.

SUMMARY OF *IN VIVO* TESTING METHODS PERACETIC ACID

In vivo testing of Fresenius Hemoflow Dialyzers was performed according to the "Guidance for Hemodialyzer Reuse Labeling" testing protocol. At least 12 patients were started in the study that utilized F80A high flux dialyzers. Clinical testing of the F80A dialyzer was performed with 16 patients (9 males, 7 females), average age 50, average blood flow of 378 mL/min and average dialysis time of 3.04 hours. *In vivo* Kuf for the different hemodialyzers were calculated from pressure determinations available from the Fresenius 2008H hemodialysis machine. Blood samples were taken at predetermined times pre and post dialysis session on the 0, 1, 5 and 15th reuse. Blood samples were analyzed for urea, albumin and Beta2-Microglobulin (B2M for high flux hemodialyzers only). Equilibrated single pool Kt/V urea (spKt/V), urea reduction ratio, (URR = %) and pre/post serum albumin values were calculated.

***In vivo* Ultrafiltration Coefficient, Kuf of Dialyzers Reprocessed with 3.5% Peracetic Acid (Kuf=mL/hr/mmHg)**

	0	1 use	5 use	15 use
F80A	51	47	47	44

***In vivo* spKt/V and URR of Dialyzers Reprocessed with 3.5% Peracetic Acid (URR=%)**

	0	1 use	5 use	15 use
F80A				
spKt/V	1.62	1.56	1.54	1.69
URR	70	70	70	66

人工腎臟的體外測試，維生素 B12 水溶液廓清率
以 3.5%的過醋酸再處理
（ml/min）

	QB	0	1 次使用	5 次使用	15 次使用
F80A	200	116	124	125	135
	300	134	141	144	159
	400	148	153	156	169
	500	159	163	165	176

體外測試結果，過醋酸

多次重複使用以過醋酸再處理的人工腎臟，高流量人工腎臟 Kuf 檢測值降低。多次重複使用後，某些型號的人工腎臟，尿素、肌酸酐和維生素 B12 的廓清率增加。

體內測試方法總結，過醋酸

費森尤斯和膜流系列人工腎臟的體內測試，係依據「重複使用人工腎臟標記指導規範」中所建議的測試方法進行。測試的人工腎臟為高流量的 F80A。測試開始時，參加的患者人數至少要達到 12 名。F80A 型人工腎臟的臨床測試，共有 16 名患者參與(男性 9 名，女性 7 名)，平均年齡 50 歲，平均血流速為 378ml/min，平均透析時間為 3.04 小時。不同人工腎臟的 Kuf 體內測試值，是根據從 Fresenius 2008H 血液透析機器獲得的壓力測定資料來計算。血液樣品採集方法為：在第 0，1，5，15 次重複透析前、後的規定時間內採集。血液樣本的分析指標為尿素、白蛋白、β2 微球蛋白（β2 微球蛋白只在高流量的人工腎臟測試）。計算平衡單槽尿素的 Kt/V (Equilibrated single pool Kt/V urea)（sp Kt/V），尿素降低率（URR=%）和透析前後血漿白蛋白值。

人工腎臟的體內測試，超過濾系數，Kuf
以 3.5%的過醋酸再處理
（Kuf=ml/hr/mmHg）

	0	1 次使用	5 次使用	15 次使用
F80A	51	47	47	44

人工腎臟的體內測試，sp Kt/V 和 URR
以 3.5%的過醋酸再處理（URR=%）

	0	1 次使用	5 次使用	15 次使用
F80A				
spKt/v	1.62	1.56	1.54	1.69
URR	70	70	70	66

***In vivo* Beta2-Microglobulin Clearance of Dialyzers Reprocessed with Minimum 0.1% Peracetic Acid (B2M=mL/min)**

	0	1 use	5 use	15 use
F80A	43	57	50	38

***In vivo* Pre and Post Serum Albumin Levels of Dialyzers Reprocessed with 3.5% Peracetic Acid (Albumin=g/dL)**

	0	1 use	5 use	15 use
F80A				
Pre Serum	4.02	4.06	4.09	4.11
Post Serum	4.86	4.67	4.57	5.20

***IN VIVO* RESULTS PERACETIC ACID**

In vivo Kuf was decreased for high flux hemodialyzers when exposed to multiple reprocessing with Peracetic acid.

In vivo spKt/V and URR were unchanged with multiple exposure to the reprocessing procedure. Beta2-Microglobulin decreased with the F80A dialyzers with multiple exposure to the Peracetic acid reprocessing procedure. There was no change in serum albumin levels for any of the hemodialyzers tested.

人工腎臟的體內測試，β2 微球蛋白廓清率
以最小 **0.1%**的過醋酸再處理
（**β2 M = ml/min**）

	0	1 次使用	5 次使用	15 次使用
F80A	43	57	50	38

人工腎臟的體內測試，處理前後血漿白蛋白水準
以 **3.5%**的過醋酸再處理
（白蛋白=g/dl）

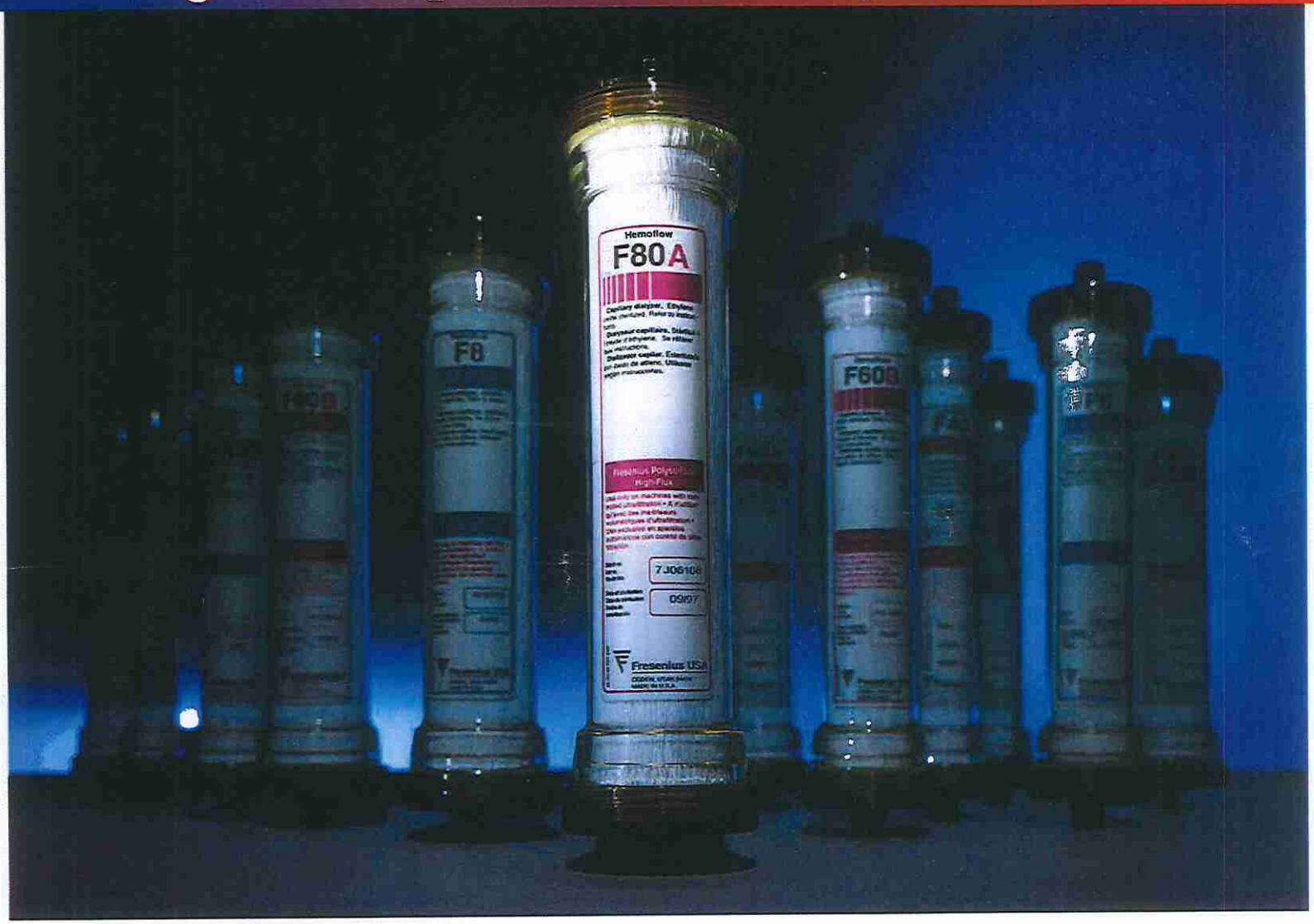
	0	1 次使用	5 次使用	15 次使用
F80A				
前血清	4.02	4.06	4.09	4.11
後血清	4.86	4.67	4.57	5.20

體內測試結果，過醋酸

多次重複使用以過醋酸再處理的人工腎臟，高流量人工腎臟的 Kuf 體內檢測值降低。體內測試 sp Kt/V 和 URR 的結果並未改變。F80A 型人工腎臟經多次重複使用過醋酸再處理後，其 β2 微球蛋白項的檢測值降低。所測試的任何型號的人工腎臟，其血漿白蛋白濃度皆無變化。

Fresenius *Polysulfone.*

Meeting the Complex Needs of Today's Dialysis Patient.



Fresenius Hemoflow Dialyzers

TYPICAL INVITRO DIALYZER PERFORMANCE

	PEDIATRIC	CONVENTIONAL THERAPY		HIGH EFFICIENCY THERAPY			MEDIUM FLUX		HIGH FLUX THERAPY					
	F3	F4	F5	F6	F7	F8	F60M	F80M	F40	F50	F60A	F60B	F80A	F80B
Surface Area (M^2)	0.4	0.7	1.0	1.3	1.6	1.8	1.3	1.8	0.7	1.0	1.3	1.3	1.8	1.8
Prime Volume(ml)	28	42	63	82	98	110	82	110	42	63	82	82	110	110
UFR (*Invivo*)	1.7	2.8	4.0	5.5	6.4	7.5	19	27	20	30	40	38	55	52
Membrane	PS	PS	PS	PS	PS	PS	PS	PS	PS	PS	PS	PS	PS	PS
Clearance Q_B 200, Q_D 500 ml/min														
Urea	125	155	170	180	184	186	185	190	165	178	185	185	190	190
Creatinine	95	128	149	164	169	172	170	177	140	160	172	172	180	177
Phosphate	50	78	103	123	132	138	162	170	138	158	170	168	177	173
Vitamin B_{12}	20	32	45	60	68	76	100	110	75	100	118	110	135	133
Clearance Q_B 300, Q_D 500 ml/min														
Urea		183	206	222	236	240	240	246	208	225	240	240	246	246
Creatinine		145	175	194	210	216	200	214	166	195	210	210	220	220
Phosphate		88	115	145	155	165	198	212	162	190	207	207	216	216
Vitamin B_{12}		34	47	62	72	82	112	130	87	112	130	130	150	150
Clearance Q_B 400, Q_D 500 ml/min														
Urea			225	244	265	275	280	292		252	280	280	292	292
Creatinine			186	208	235	245	222	246		215	244	244	270	270
Phosphate			120	156	168	180	220	244		206	239	239	265	265
Vitamin B_{12}			48	63	74	86	122	148		118	142	142	172	172
Clearance Q_B 400, Q_D 800 ml/min														
Urea				284	300	310	305	318			305	305	318	318
Creatinine				235	255	268	253	272			256	256	275	275
Phosphate				174	184	194	241	259			252	252	271	271
Vitamin B_{12}				69	84	98	132	151			153	153	175	175

Housing – Polycarbonate
Potting Compound – Polyurethane
PS – Fresenius Polysulfone
Inner Diameter – 200 microns
Membrane Wall Thickness – 40 microns
Clearance data is *Invitro* with Q_F 0 ml/min

Fresenius USA
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製造廠地址：475 West 13th Street Ogden, UT 84404, U.S.A

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