IFU Insert

Prismaflex ST Set

Emergency Use Authorization for the United States

The Prismaflex ST Set has been Authorized by the FDA to provide continuous renal replacement therapy (CRRT) to treat patients in an acute care environment during the Coronavirus Disease 2019 (COVID-19) pandemic.

The Prismaflex ST Set has neither been cleared or approved to provide CRRT in an acute care environment.

The Prismaflex ST Set has been authorized by FDA under EUA200704.

The Prismaflex ST Set is Authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of the Prismaflex ST Set under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

Intended Use for Patients with COVID-19

The Prismaflex ST Set is indicated for use only with the Prismaflex control unit or with the PrisMax control unit in providing continuous fluid management and renal replacement therapies in an acute care environment during the Coronavirus Disease 2019 (COVID-19) pandemic. The system is intended for patients who have acute renal failure, fluid overload, or both.

Relative contraindications (individual risk/benefit to be determined by treating physician) for the use of Prismaflex ST Sets include:

- The inability to establish vascular access
- Severe hemodynamic instability
- Known hypersensitivity to any component of the Prismaflex ST Set

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

All treatments administered with the Prismaflex ST Set must be prescribed by a physician. The size, weight, metabolic and fluid balance, cardiac status, and general clinical condition of the patient must be carefully evaluated by the prescribing physician before each treatment.

Additional Product Information for the United States

The tubing contained in the following product codes are labeled as DEHP-free in the IFU, this means that the product was not made with DEHP plasticizer: 107643, 115308, 107636, 115309, 107640 and 115310.

The tubing contained in the following product codes were made using DEHP plasticizer: 955468 and 955596.

The following codes do not include reference to the PrisMax control unit; however, all Prismaflex ST Sets may be used with the Prismaflex control unit or with the PrisMax control unit: 115308, 115309, 115310, 955468 and 955596.

To access COVID-19 Resources, product details, product use information, and the comprehensive Prismaflex Control Unit Operator's Manual and PrisMax Control Unit Operator's Manual please visit the Baxter Healthcare Acute Therapies website at http://www.renalacute.com

prismaflex

ST60 SET / ST100 SET / ST150 SET

AN69 ST
MEMBRANE

- eng **Instructions for use**
- fre **Notice d'utilisation**
- ger **Gebrauchsanweisung**
- spa **Folleto de utilización**
- ita **Istruzioni per l'uso**
- swe **Handhavandeninstruktioner**
- dut **Gebruiksaanwijzing**
- por **Instruções de use**
- nor **Bruksanvisning**
- dan **Bruksanvisning**
- fin **Käyttöä opas**
- pol **Instrukcja stosowania**
- tur **Kullanma talimatları**
- rus **Инструкция по применению**
- gre **Οδηγίες χρήσης**
- cze **Návod k použití**
- srp **Uputstvo za upotrebu**
- ukr **Інструкції з використання**
- slk **Návod na použitie**
- slv **Navodila za uporabo**
- hun **Használati utasítás**
- hrv **Upute za uporabu**
- est **Kasutusjuhend**
- lav **Lietošanas instrukcijas**
- lit **Naudojimo instrukcijos**
- bul **Инструкции за употреба**
- rum **Instrucțiuni de utilizare**

REF 107643
REF 107636
REF 107640

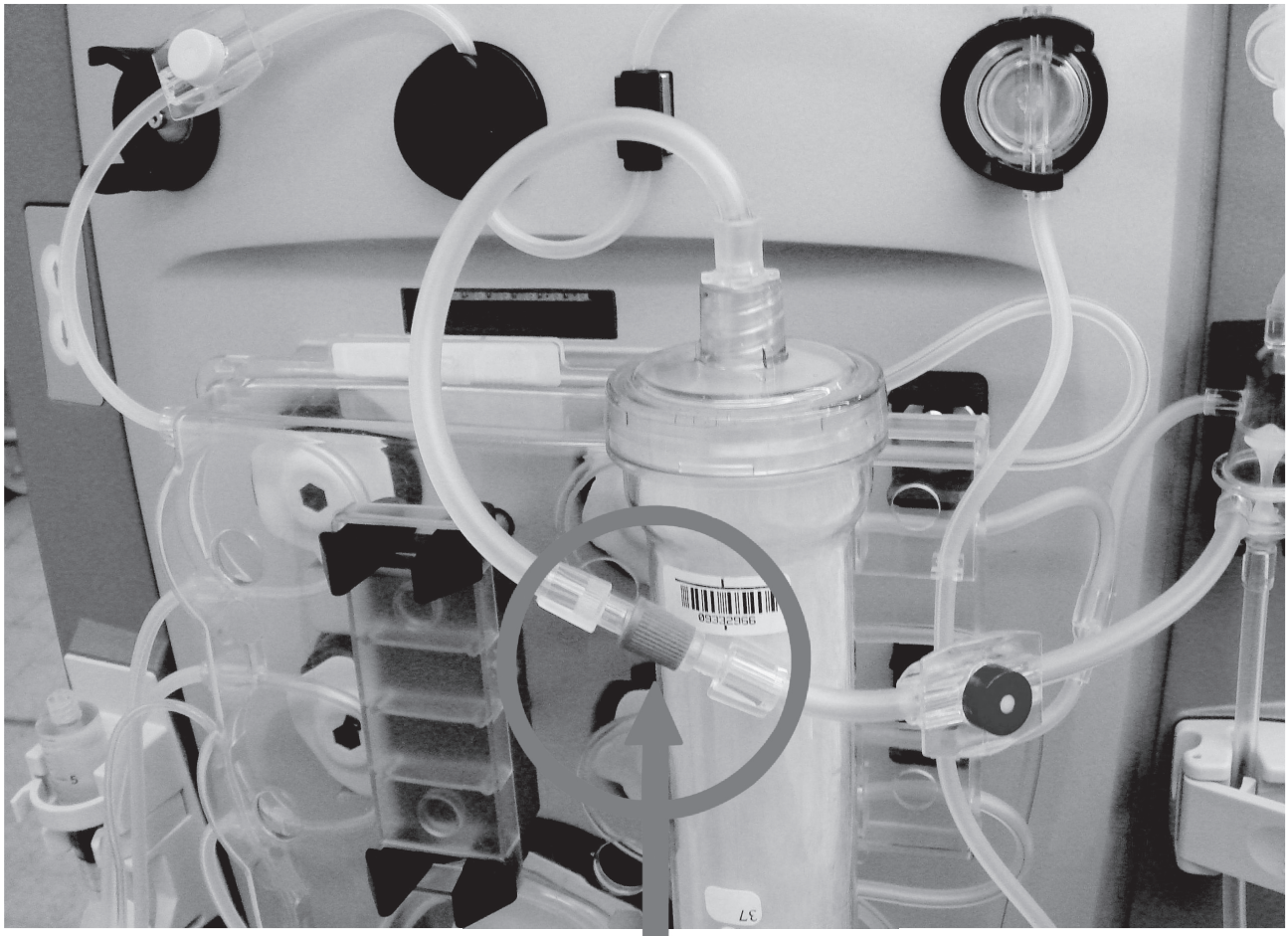
Made in France

CE 2797

Date of Revision: 2019-12-01

10000147955

Baxter



Blood warmer connection (blue)
Connexion réchauffeur sang (bleue)
Blutwärmeranschluss (blau)
Conexión del calentador de sangre (azul)
Collegamento del riscaldatore ematico (blu)
Anslutning för blodvärmare (blå)
Aansluiting bloedverwarmer (blauw)
Conexão para aquecedor de sangue (azul)
Blodvarmerkobling (blå)
Blodvarmertilslutning (blå)
Verenlämmittimen liitäntä (sininen)
Złącze podgrzewacza krwi (niebieskie)
Kan ısıtıcısı bağlantısı (mavi)
Соединение для нагревателя крови (синее)
Σύνδεση θερμαντήρα αίματος (μπλε)
Spojka ohřívače krve (modrá)
Konekcija grejača krvi (plava)
З'єднання нагрівача крові (синій колір)
Pripojenie ohrievača krvi (modré)
Priključek za grelnik krvi (moder)
Vérmelegítő csatlakozása (kék)
Priključak grijača za krv (plavo)
Veresoojendaja ühendus (sinine)
Asins sildītāja savienojums (zils)
Kraujo šildytuvo jungtis (mėlyna)
Връзка за нагревател на кръв (синя)
Conexiune încălzitor sânge (albastru)

DEFINITION OF SYMBOLS

		ENGLISH		FRANÇAIS		DEUTSCH	
SYMBOL GRAPHIC & REF NUM / SYMBOLES GRAPHIQUES ET N° RÉF. / SYMBOLGRAFIKUND REFERENZNUMMER	**TITLE AND NUMBER OF STANDARD / TITRE ET NUMÉRO DE LA NORME / TITEL UND NUMMER DER NORM**	**SYMBOL TITLE**	**SYMBOL DESCRIPTION (EXPLANATORY TEXT)**	**TITRE DU SYMBOLE**	**DESCRIPTION DU SYMBOLE (TEXTE EXPLICATIF)**	**SYMBOLNAME**	**SYMBOLBESCHREIBUNG (ERKLÄRENDER TEXT)**
5.1.1 	ISO 15223-1[1]	Manufacturer	Indicates the medical device manufacturer, i.e. the natural or legal person with responsibility for the design, manufacture, packaging and labelling of a device before it is placed on the market under his own name.	Fabricant	Indique le fabricant du dispositif médical, c'est-à-dire la personne physique ou morale responsable de la conception, de la fabrication, du conditionnement et de l'étiquetage d'un dispositif avant sa commercialisation sous son nom propre.	Hersteller	Gibt den Hersteller des Medizinprodukts an, d. h. die natürliche oder juristische Person, die für das Konzept, die Herstellung, die Verpackung und die Etikettierung eines Produkts verantwortlich ist, bevor es unter ihrem Namen auf den Markt kommt.
5.1.3 	ISO 15223-1[1]	Date of manufacture	Indicates the date when the medical device was manufactured. Format should be YYYY-MM-DD.	Date de fabrication	Indique la date de fabrication du dispositif médical. Elle doit respecter le format AAAA-MM-JJ.	Herstellungsdatum	Gibt das Datum an, an dem das Medizinprodukt hergestellt wurde. Das Format sollte JJJJ-MM-TT sein.
5.1.4 	ISO 15223-1[1]	Use-by date	Indicates the date after which the medical device is not to be used. Format should be YYYY-MM-DD	Date limite d'utilisation	Indique la date après laquelle le dispositif médical ne doit plus être utilisé. Elle doit respecter le format AAAA-MM-JJ.	Verfallsdatum	Gibt das Datum an, ab dem das Medizinprodukt nicht mehr verwendet werden soll. Das Format sollte JJJJ-MM-TT sein.
5.1.5 	ISO 15223-1[1]	Batch code	Indicates the manufacturer's batch code. Synonyms are "lot number" and "batch number"	Numéro de lot	Indique le code du lot du fabricant. Synonyme : « numéro du lot ».	Chargencode	Gibt den Batchcode des Herstellers an. Synonyme sind „Losnummer" und „Chargennummer".
5.1.6 	ISO 15223-1[1]	Catalogue number	Indicates the manufacturer's catalog number. Synonyms are "reference number" and "reorder number"	Référence catalogue	Indique le numéro de catalogue du fabricant. Synonymes : « numéro de référence » et « numéro de commande ».	Katalognummer	Gibt die Katalognummer des Herstellers an. Synonyme sind „Referenznummer" und „Nachbestellnummer".
5.2.3 	ISO 15223-1[1]	Sterile fluid path	Indicates the presence of a sterile fluid path within the medical device in cases where other parts of the medical device, including the exterior, might not be supplied sterile. The method of sterilization shall be indicated in the empty box, as appropriate.	Circuit de fluide stérile	Indique la présence d'un circuit de fluide stérile dans le dispositif médical dans le cas où d'autres parties du dispositif médical, y compris l'extérieur, ne seraient pas stériles. La méthode de stérilisation doit être indiquée dans la case vide, si nécessaire.	Sterile Flüssigkeitsbahn	Zeigt das Vorhandensein einer sterilen Flüssigkeitsbahn innerhalb eines Medizinproduktes an, in den Fällen wo andere Teile des Medizinproduktes, einschließlich der außen gelegenen Teile, nicht steril geliefert werden können. Sofern geeignet, muss das Sterilisationsverfahren in dem leeren Kästchen angegeben sein.
5.2.8 	ISO 15223-1[1]	Do not use if package is damaged	Indicates a medical device that should not be used if the package has been damaged or opened.	Ne pas utiliser si l'emballage est endommagé	Indique un dispositif médical qui ne doit pas être utilisé si l'emballage a été endommagé ou ouvert.	Bei beschädigter Verpackung nicht verwenden.	Zeigt ein Medizinprodukt an, das nicht verwendet werden sollte, falls die Verpackung beschädigt oder geöffnet sein sollte.
5.3.1 	ISO 15223-1[1]	Fragile, handle with care	Indicates a medical device that can be broken or damaged if not handled carefully.	Fragile, à manipuler avec précaution	Indique un dispositif médical pouvant être brisé ou endommagé s'il n'est pas manipulé avec précaution.	Vorsicht, zerbrechlich!	Gibt an, dass ein Medizinprodukt bei unvorsichtiger Handhabung beschädigt werden kann.
5.3.4 	ISO 15223-1[1]	Keep dry OR Keep away from rain	Indicates a medical device that needs to be protected from moisture. OR Indicates a medical device that needs to be kept away from rain.	Conserver au sec OU Ne pas exposer à la pluie	Indique un dispositif médical à protéger de l'humidité. OU Indique un dispositif médical à protéger de la pluie.	Vor Nässe schützen! ODER Vor Regen schützen!	Gibt an, dass ein Medizinprodukt vor Feuchtigkeit geschützt werden muss. ODER Gibt an, dass ein Medizinprodukt vor Regen geschützt werden muss.
5.3.7 	ISO 15223-1[1]	Temperature Limit	Indicates the temperature limits to which the medical device can be safely exposed.	Limite de température	Indique les limites de température auxquelles le dispositif médical peut être exposé en toute sécurité.	Temperaturgrenzwert	Gibt die Temperaturgrenzwerte an, denen das Medizinprodukt gefahrlos ausgesetzt werden kann.
5.4.2 	ISO 15223-1[1]	Do not re-use	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure. Synonyms for "Do no re-use" are "single use" and "use only once".	Ne pas réutiliser	Indique un dispositif médical conçu pour une utilisation unique ou une utilisation sur un seul patient pendant une seule procédure. Synonyme : « à usage unique ».	Nicht wiederverwenden	Gibt an, dass ein Medizinprodukt für einen Gebrauch oder für einen Gebrauch an einem einzigen Patienten während eines einzigen Verfahrens vorgesehen ist. Synonyme für „Nicht wiederverwenden" sind „Für den Einmalgebrauch" und „Nur einmal verwenden".
5.4.4 	ISO 15223-1[1]	Caution	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.	Attention	Indique qu'il est nécessaire que l'utilisateur consulte le mode d'emploi pour obtenir des informations importantes telles que des avertissements et mises en garde ne pouvant pas, pour des raisons diverses, être mentionnées sur le dispositif proprement dit.	Vorsicht	Gibt an, dass der Anwender die wichtigen Sicherheitsinformationen in der Gebrauchsanweisung, wie Warnhinweise und Vorsichtsmaßnahmen, beachten sollte, die aus unterschiedlichen Gründen nicht auf dem Medizinprodukt selbst angegeben werden können.
	NA, European countries only / NA, pays européens seulement / NA, nur europäische Länder	Green Dot Symbol	To indicate the manufacturer of the product contributes to the cost of recovery and recycling	Symbole du point vert	Indique que le fabricant du produit contribue aux frais de récupération et de recyclage	Der Grüne Punkt	Gibt an, dass sich der Hersteller des Produkts an den Kosten der Verwertung und Entsorgung beteiligt.
0623 	ISO 7000[2]	This way up	Indicates the correct, upright position of the package	Haut	Indique la position correcte, à la verticale du carton	Diese Seite nach oben	Gibt die korrekte aufrechte Position der Verpackung an.
5.4.3 	ISO 15223-1[1]	Consult instructions for use	Indicates the need for the user to consult the instructions for use. Synonym for "Consult instructions for use" is "Consult operating instructions".	Consulter le mode d'emploi	Indique que l'utilisateur a besoin de se reporter au mode d'emploi. « Consulter le mode d'emploi » a pour synonyme «Consulter la notice d'utilisation».	Gebrauchsanweisung beachten	Weist darauf hin, dass der Anwender die Gebrauchsanweisung beachten muss. „Gebrauchsanweisung beachten" ist gleichbedeutend mit „Bedienungsanweisungen beachten".

[1] ISO 15223-1:2016 Medical Devices - Symbols to be used with medical device labels, labelling and information to be supplied Part 1: General Requirements / Dispositifs médicaux : Symboles à utiliser avec les étiquettes, l'étiquetage et les informations à fournir relatifs aux dispositifs médicaux - Partie 1 : Exigences générales / „Medizinprodukte – Bei Aufschriften von Medizinprodukten zu verwendende Symbole, Kennzeichnung und zu liefernde Informationen – Teil 1: Allgemeine Anforderungen"

[2] ISO 7000 Graphical symbols for use on equipment - Registered symbols / Symboles graphiques utilisables sur le matériel - Symboles enregistrés / „Grafische Symbole auf Einrichtungen – Index und Übersicht"

The Prismaflex ST60/ST100/ST150 set is manufactured by GAMBRO Industries, 7 avenue Lionel Terray, BP 126, 69883 MEYZIEU CEDEX, FRANCE.

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

DEFINITION OF EXPRESSIONS USED IN THIS MANUAL

In this document :

⚠ **"Warning"** indicates a hazardous situation which, if not avoided, could result in death or serious injury.

⚠ **"Caution"** indicates a hazardous situation which, if not avoided, could result in minor or moderate injury;

"Note" to give additional information.

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

"Control unit" refers to the **PrismaFlex** control unit, or to the **PrisMax** control unit (in countries where **PrisMax** is cleared or registered).

PRODUCT DESCRIPTION

- The **Prismaflex** ST60 / ST100 / ST150 set is a disposable, extracorporeal circuit for use with the **PrismaFlex** control unit or with the **PrisMax** control unit (in countries where **PrisMax** is cleared or registered).
- The **Prismaflex** ST60 / ST100 / ST150 set consists of a AN69 ST hollow fiber hemofilter/dialyzer* and tubing lines ; refer to the control unit operator manual drawing for details.
- The blood return line (blue-striped) is equipped with a Luer-lock connection near the deaeration chamber, dedicated to the connection of authorized devices and accessories described in the control unit operator's manual.
- All line connectors are compatible with the ISO 594-1 and ISO 594-2 international standards concerning conical fittings.
- The fluid pathways of the **Prismaflex** set are guaranteed sterile and non pyrogenic.
- The **Prismaflex** ST60 / ST100 / ST150 set is sterilized by ethylene oxide (EtO). Deaeration is such that EtO residuals comply with the standards in ISO 10993.
- Expiration date: please refer to product label.

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

INTENDED USE / INDICATIONS

The **Prismaflex** set is indicated for use only with the **PrismaFlex** control unit or with the **PrisMax** control unit (in countries where **PrisMax** is cleared or registered) in providing continuous fluid management and renal replacement therapies. The system is intended for patients who have acute renal failure, fluid overload, or both.

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

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

CONTRAINDICATIONS

There are no known absolute contraindications to continuous renal replacement therapies.

For the following conditions a careful assessment of the individual risk/benefit ratio has to be made by the treating physician (relative contraindications):

- inability to establish vascular access,
- severe hemodynamic instability,
- known hypersensitivity to any component of the **Prismaflex** set.

CAUTIONS AND WARNINGS

Note: refer to the control unit user interface and operator's manual for additional cautions and warnings.

⚠ Cautions

1. Particular attention must be paid to extra corporeal blood volume with respect to patient size. Consider the sum of the **Prismaflex** set blood volume (refer to "Specifications") plus the blood volume of any accessory or device if used. The **Prismaflex** ST60 set should be restricted to patients with a body weight greater than 11kg (24lb). The **Prismaflex** ST100 set and ST150 set should be restricted to patients with a body weight greater than 30kg (66lb).
2. If the patient is not immediately connected to the **Prismaflex** set after priming is complete, flush the set with at least 1 000 mL priming solution [saline or alkaline solution (pH ≥ 7.3), with or without heparin added according to usual institutional practice] prior to connecting the patient. This requires use of a new bag of priming solution.
3. When not using the pre blood pump infusion line, it is recommended to clamp this line close to its connection to the access blood tubing line; this will prevent the sedimentation of blood into the pre-blood pump infusion line.
4. Using the **Prismaflex** set with blood flow rates lower than the recommended minimum values (see "Operating Parameters" section) may impair filter performance due to hemoconcentration, or to increased risk of coagulation.
5. Since drugs can be removed by the membrane of the filter, the dosage of associated drug treatments may need to be adjusted for patients on continuous renal replacement therapy. Monitoring of blood drug levels of relevant compounds should be performed. The removal of other water-soluble compounds (e.g. vitamins, trace elements) during therapy also requires clinical consideration.

⚠ Warnings

1. Carefully read these instructions for use and the control unit operator's manual before using this product.
2. The use of operating procedures other than those published by the manufacturer or the use of accessory devices not recommended by the manufacturer can result in patient injury or death.
3. Store the **Prismaflex** set in a dry place, between 0° C (32° F) and 30° C (86° F).
4. Do not use this set if the packaging is damaged, if the sterilization caps are missing or loose, or if any of the lines in the set are kinked.
5. To prevent contamination, this **Prismaflex** set must be used as soon as its packaging and sterilization caps are removed.
6. Do not try to remove the filter from the cartridge plate.
7. Use aseptic techniques when handling all blood and fluid lines in the set.
8. **Prismaflex** sets are compatible with the usual disinfection agents used for aseptic setup; however solvents and other chemicals, if used in contact with the product, could damage the set.
9. During priming and operation, observe closely for leakage at joints within the set, and connections to other approved accessories and bags. Leakage can cause blood loss, fluid imbalance or air embolism. If a leakage is detected at a Luer connection and cannot be stopped by tightening the connections, or if leakage occurs at any other location, replace the set.
10. Tightening Luer connections with an excessive force can damage the connectors.
11. Once priming is complete the set's blood circuit will still contain heparinised saline solution. Depending on the level of the patient's bleeding risk the physician must decide if an additional priming using 500 mL non heparinised saline solution is necessary.
12. Do not allow air to enter the blood compartment of the filter after priming is started. If a large amount of air enters, the set must be replaced.
13. Should acute allergic reactions (first-use syndrome) occur in patients receiving treatment, **immediately stop the treatment** and administer appropriate intervention. Pay special attention to patients receiving ACE inhibitors and/or having already shown similar allergic reactions (see "Hypersensitivity Reactions" section).
14. Use a 21-gauge or smaller needle to obtain blood/fluid samples or remove trapped air from the **Prismaflex** set. Use of larger needles can cause holes in the sample sites, resulting in external leak or air intake.
15. External blood leakage may not be immediately identified by monitoring equipment and could result in significant blood loss. Check the filter and all connections of the disposable tubings during treatment to minimize the risk of leakage.

16. To assure adequate filter performance, it is recommended that the set be changed every 24 hours of use. However, the set must be changed after 3 days (72 hours). Continued use beyond this limit could result in rupture of the pump segments, with risk of patient injury or death.
17. Destroy this set after single use, using aseptic technique for potentially contaminated equipment and following local regulation for disposal. Do not re-sterilize. The Prismaflex set is intended for single use only. Re-using the Prismaflex set may cause serious damage to the product resulting in patient injury or death.
18. Use only drugs compatible with plastics listed in the specifications section. Some plastics can be incompatible with drugs when in contact with solutions with pH > 10.

SPECIFICATIONS

See Tables at end of document.

SET MATERIALS

AN69 ST hollow fiber	:	Acrylonitrile and sodium methallyl sulfonate copolymer + Polyethylene Imine (surface treatment agent)
Housing and headers	:	Polycarbonate
Potting compound	:	Polyurethane
Tubing material	:	Plasticized polyvinyl chloride (PVC)
Cartridge	:	Polyethyleneterephtalate Glycol

Note : the following information is available from the manufacturer upon request :
- information about test methods used to obtain performance characteristics,
- the number and range of particles in the effluent from the dialyzer prepared as recommended for clinical use,
- the types and amounts of residue from the sterilization process.

Note: the **Prismaflex** set is not made with rubber natural latex.

Note: all fluid pathways in direct or indirect blood contact are DEHP-free.

INSTRUCTIONS FOR USE

Note: use the set by following the detailed on-line instructions provided by the control unit. Additional information is available in the control unit operator's manual.

Load Set

Install the set onto the control unit using the photographs on the inside cover as a guide - the same procedure applies for both **Prismaflex** and **PrisMax** control units (in countries where **PrisMax** is cleared or registered).

Prepare and Connect Solutions

In order to gain full benefit from the AN69ST in terms of improvement of hemocompatibility, it is recommended to add 5000IU of unfractionated heparin per liter of priming/rinsing solution. This procedure allows the adsorption of active heparin onto the AN69ST before the start of extracorporeal circulation.

Consequently, the systemic anticoagulation strategy during treatment will be adapted with respect to patient specificity. In the cases where priming/rinsing without addition of unfractionated heparin, we recommend infusing the loading dose of heparin to the patient 2 to 5 minutes before connection to the filter.

Hang bag of priming solution [saline or alkaline solution (pH ≥ 7.3) with added 5000IU unfractionated heparin/liter according to usual institutional practice, correctly homogenised] on priming hook. Connect access (red)/effluent (yellow) Y-line to priming solution bag.

SPECIAL PROCEDURES IN CASE OF COMPLICATION

External Blood Leaks

Note: see Warning no. 15.

If an external blood leakage is observed, immediately stop the blood pump. Initiate corrective action by securing connections or replacing the Prismaflex set.

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

Hypersensitivity Reactions

Note: see Warning no. 13.

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

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

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

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

The following factors are considered essential to minimize the risk of hypersensitivity reaction and other side effects:
- Strict adherence to the set-up, priming and rinsing procedures detailed in the manufacturer's instructions for use.
- Setting up and monitoring the treatment operating parameters according to the manufacturer's recommendations specified for each type of **Prismaflex** set and to the patient's needs and tolerance.
- Strict adherence to all WARNINGS and CAUTIONS given by the manufacturer in the instructions for use.

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

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

Therefore, the prescribing physician must pay special attention to patients receiving ACE inhibitors and/or having already shown similar reactions.

WARRANTY AND LIMITATION OF LIABILITY

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

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

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

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

d) The manufacturer is GAMBRO Industries, 7 avenue Lionel Terray, BP 126, 69883 MEYZIEU CEDEX, FRANCE.

Indonesia - Distributor : PT. Tawada Healthcare, Rukan Permata Senayan Blok A No. 18-19, Jl. Tentara Pelajar No. 5, Grogol Utara, Jakarta Selatan - Indonesia

KEMENKES RI AKL 20805713569

TRANSLATIONS

ENGLISH	FRANCAIS	DEUTSCH	ESPAÑOL
PHYSICAL CHARACTERISTICS **Nominal values - given for indication**	**CARACTÉRISTIQUES PHYSIQUES** **Valeurs nominales fournies à titre indicatif**	**ÄUSSERE MERKMALE** **Nominalwerte – geringe Abweichungen möglich**	**CARACTERÍSTICAS FÍSICAS** **Valores nominales, indicativos**
Membrane effective surface area Fiber internal diameter (wet) Fiber wall thickness	Surface efficace de la membrane Diamètre interne des fibres (mouillées) Épaisseur de la paroi des fibres	Effektive Membranoberfläche Faser-Innendurchmesser (nass) Faser-Wandstärke	Superficie útil de la membrana Diámetro interno de la fibra (húmeda) Grosor de pared de la fibra
Blood volume in set	Volume de sang dans le set	Blutvolumen im Set	Volumen de sangre en el set
Overall dimensions • Length • Width • Height	Dimensions • Longueur • Largeur • Hauteur	Abmessungen • Länge • Breite • Höhe	Dimensiones generales • Longitud • Anchura • Altura
Weight	Poids	Gewicht	Peso
OPERATING PARAMETERS	**PARAMÈTRES OPÉRATIONNELS**	**BETRIEBSPARAMETER**	**PARÁMETROS DE FUNCIONAMIENTO**
Maximum TMP	PTM maximum	Maximaler TMP	PTM máxima
Maximum blood pressure	Pression artérielle maximale	Maximaler Blutdruck	Presión sanguínea máxima
Minimum blood flow rate Maximum blood flow rate	Débit sanguin minimum Débit sanguin maximum	Minimale Blutflussrate Maximale Blutflussrate	Velocidad de flujo sanguíneo mínima Velocidad de flujo sanguíneo máxima
PERFORMANCES SPECIFICATIONS **Typical mean values obtained from laboratory testing of post-sterilization, sample lots. Results may vary depending on patient and clinical conditions.**	**SPÉCIFICATIONS DES PERFORMANCES** **Valeurs moyennes types obtenues par tests en laboratoire sur lots d'échantillons, après stérilisation.** **Les résultats peuvent varier en fonction du patient et des conditions cliniques.**	**LEISTUNGSSPEZIFIKATIONEN** **Typische Mittelwerte, die an sterilen Probechargen im Labor ermittelt wurden.** **Die Ergebnisse können abhängig vom Patienten und den klinischen Bedingungen schwanken.**	**ESPECIFICACIONES DE RENDIMIENTO** **Valores medios típicos obtenidos en ensayos de laboratorio realizados en lotes elegidos al azar después de la esterilización. Los resultados pueden variar en función del paciente y las condiciones clínicas.**
Maximum ultrafiltration rate (bovine blood)	Débit d'ultrafiltration maximum (sang de bovin)	Maximale Ultrafiltrationsrate (Rinderblut)	Tasa de ultrafiltración máxima (sangre bovina)
Sieving cœfficient (bovine plasma) • Urea • Creatinine • Vitamin B12 • Inulin	Coefficient de tamisage (plasma de bovin) • Urée • Créatinine • Vitamine B12 • Inuline	Siebkoeffizient(Rinderplasma) • Harnstoff • Kreatinin • Vitamin B12 • Inulin	Coeficiente de cribado (plasma bovino) • Urea • Creatinina • Vitamina B12 • Inulina
Sieving cœfficient (human plasma) • Myoglobin • Albumin	Coefficient de tamisage (plasma humain) • Myoglobine • Albumine	Siebkoeffizient(menschliches Plasma) • Myoglobin • Albumin	Coeficiente de cribado (plasma humano) • Mioglobina • Albúmina
Clearance (saline solution) Parameters	Clairance (solution saline) Paramètres	Clearance (Kochsalzlösung) Parameter	Aclaramiento (solución salina) Parámetros
ACRONYMS	**ACRONYMES**	**AKRONYME**	**ACRÓNIMOS**
TMP: transmembrane pressure	PTM : pression transmembranaire	TMP: Transmembrandruck	PTM: presión transmembrana
QB/QS: arterial blood flow rate	QB/QS : débit sanguin artériel	QB/QS: arterieller Blutfluss	QB/QS: velocidad de flujo de sangre arterial
QUF: Ultrafiltration flow rate (fluid removal + replacement flow rate + pre blood pump flow rate).	QUF : débit d'ultrafiltration (élimination des liquides + débit de réinjection + débit pré-pompe sang).	QUF: Ultrafiltrationsflussrate (Flüssigkeitsentzugsrate + Substituatflussrate + und Substituatflussrate Prä-Blutpumpen-Flussrate)	QUF: velocidad de flujo de ultrafiltración (extracción de líquido + velocidad de flujo de sustitución + velocidad de flujo de bomba previa de sangre)
QD: dialysate flow rate	QS : débit du dialysat	QD: Dialysatflussrate	QD: velocidad de flujo de dializante
Hct: hematocrit	Hct : hématocrite	Hkt: Hämatokrit	Hct: hematocrito
Cp: protein concentration	Cp : concentration de protéines	Pk: Proteinkonzentration	Cp: concentración de proteína
(1) Nominal values - given for indication	(1) Valeurs nominales fournies à titre indicatif	(1) Nominalwerte – geringe Abweichungen möglich	(1) Valores nominales, indicativos
(2) Typical mean values obtained from laboratory testing of post-sterilization sample lots. Results may vary depending on patient and clinical conditions.	(2) Valeurs moyennes types obtenues par tests en laboratoire sur lots d'échantillons, après stérilisation. Les résultats peuvent varier en fonction du patient et des conditions cliniques.	(2) Typische Mittelwerte, die an sterilen Probechargen im Labor ermittelt wurden.Die Ergebnisse können abhängig vom Patienten und den klinischen Bedingungen schwanken.	(2) Valores medios típicos obtenidos en ensayos de laboratorio realizados en lotes elegidos al azar después de la esterilización. Los resultados pueden variar en función del paciente y las condiciones clínicas.
(3) Ultrafiltration is controlled by the control unit and is independent of the ultrafiltration cœfficient (KUF). Note : a TMP > 40 kPa (300 mmHg) does not allow a higher ultrafiltration.	(3) L'ultrafiltration est gérée par le moniteur et est indépendante du coefficient d'ultrafiltration (KUF). Remarque : une PTM > 40 kPa (300 mmHg) ne permet pas d'atteindre un débit d'ultrafiltration supérieur.	(3) Die Ultrafiltration wird von der Steuereinheit kontrolliert und ist unabhängig vom Ultrafiltrationskoeffizienten (KUF). Hinweis: Ein TMP > 40 kPa (300 mmHg) ermöglicht keine gesteigerte Ultrafiltration.	(3) La ultrafiltración es controlada por la unidad de control y es independiente del coeficiente de ultrafiltración (KUF). Nota: un TMP> 40 kPa (300 mmHg) no permite una ultrafiltración más alta.

	Prismaflex									
	ST60 SET			**ST100 SET**				**ST150 SET**			
PHYSICAL CHARACTERISTICS [1]											
Membrane effective surface area	0.6 m^2			1 m^2				1.5 m^2			
Fiber internal diameter (wet)	240 µm										
Fiber wall thickness	50 µm										
Blood volume in set	97 mL			155 mL				193 mL			
Overall dimensions • Length • Width • Height	27 cm 22 cm 9 cm										
Weight	772 g			828 g				894 g			
OPERATING PARAMETERS											
Maximum TMP	450 mmHg 60 kPa										
Maximum blood pressure	500 mmHg 66.6 kPa										
Minimum blood flow rate	50 mL/min			75 mL/min				100 mL/min			
Maximum blood flow rate	180 mL/min			400 mL/min				450 mL/min			
PERFORMANCE SPECIFICATIONS [2]											
Maximum ultrafiltration rate (mL/min) [3] (bovine blood, Hct 32%, Cp 60 g/L, 37°C)											
QB (mL/min)	100	180		100	200	300	400	100	200	300	450
Max.QUF (± 20%)	39	56		45	70	91	109	52	82	106	136
Sieving cœfficient (bovine plasma, Cp 60 g/L, 37°C) QB = 100 mL/min, QUF = 20 mL/min											
• Urea	1										
• Vitamin B12	1										
• Inulin	0.96										
Sieving cœfficient (human plasma, Cp 60 g/L, 37°C) QB = 100 mL/min, QUF = 20 mL/min											
• Myoglobin	0.70										
• Albumin	< 0.0045										
Clearance (mL/min) (saline solution ; 37°C)											
Parameters:											
QB/QS	100 mL/min			150 mL/min				200 mL/min			
QUF	0 mL/min			0 mL/min				0 mL/min			
QD (L/h)	1	2.5	4	1	2.5	4	8	1	2.5	4	8
QD (mL/min)	17	42	67	17	42	67	133	17	42	67	133
Urea (± 10%)	17	40	56	17	41	63	97	17	42	66	117
Vitamin B12 (± 20%)	15	26	30	16	32	41	50	17	38	51	68
Inulin (± 20%)	13	19	22	15	26	30	35	16	33	40	49

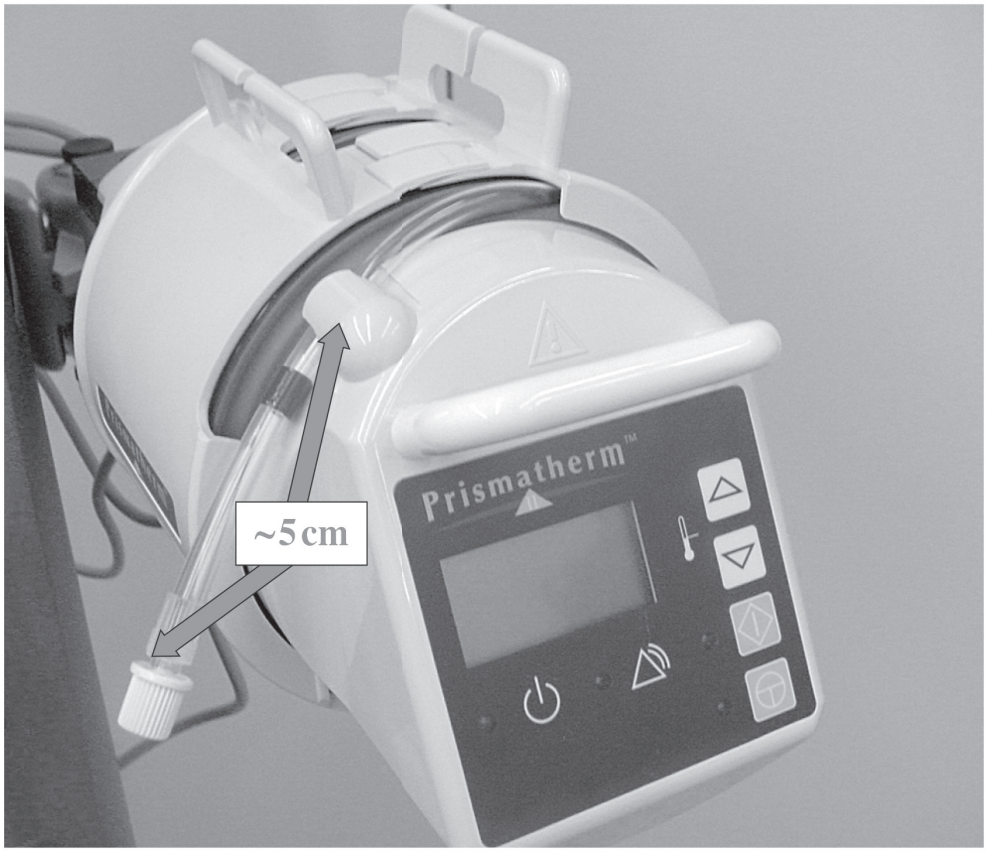
[1] Nominal values - given for indication

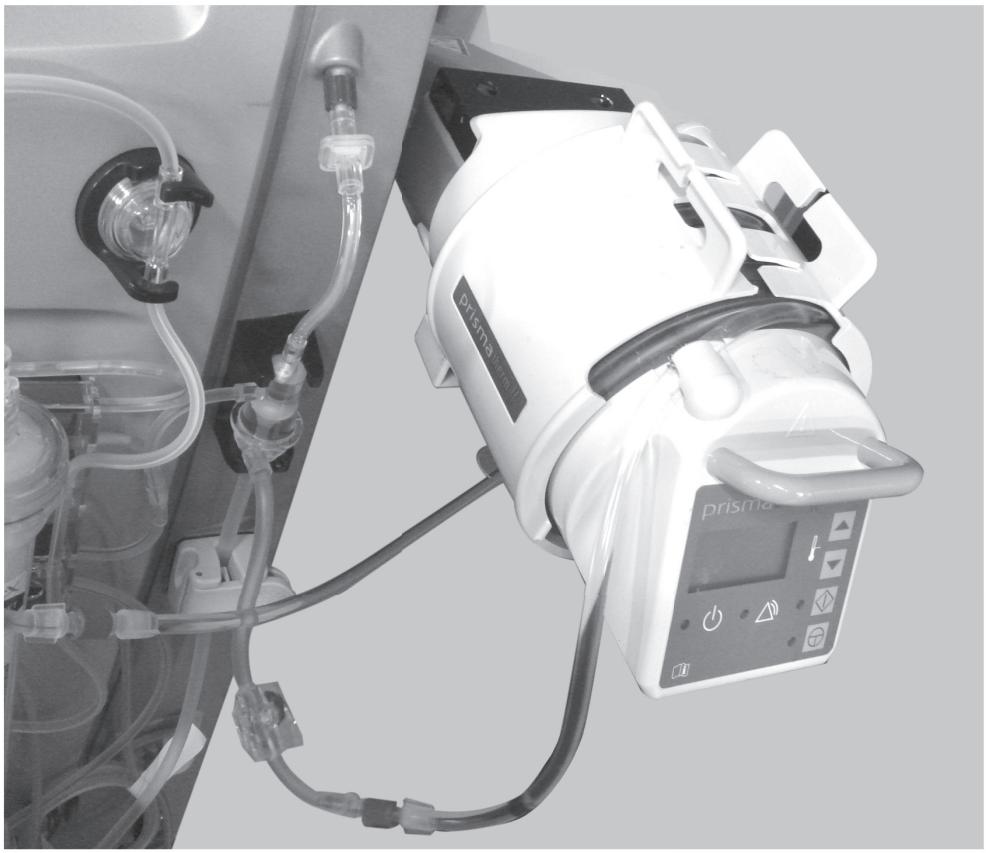
[2] Typical mean values obtained from laboratory testing of post-sterilization sample lots.
Results may vary depending on patient and clinical conditions.

[3] Ultrafiltration is controlled by the control unit and is independent of the ultrafiltration cœfficient (KUF).
Note : a TMP > 40 kPa (300 mmHg) does not allow a higher ultrafiltration.

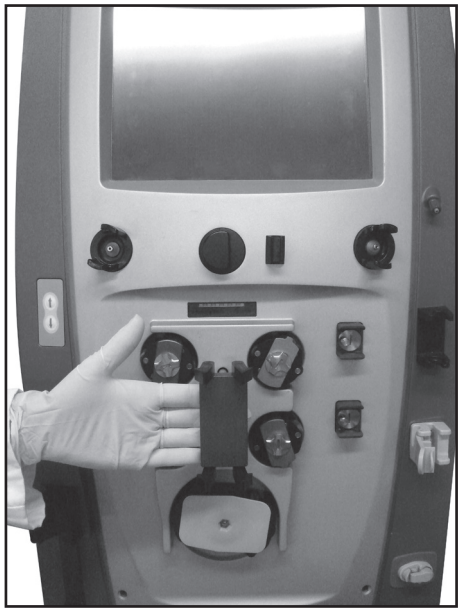
Prismatherm

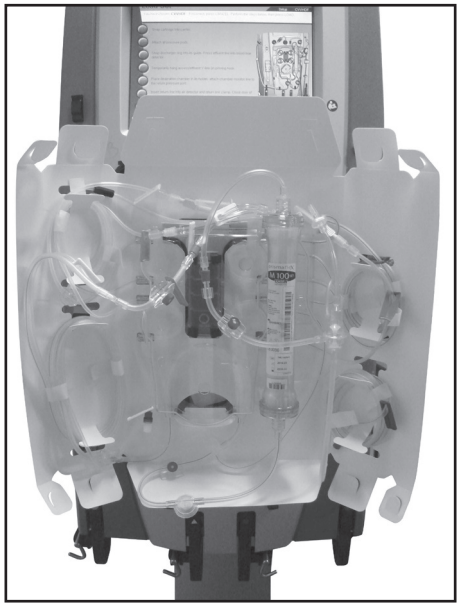
SP420 line connexion

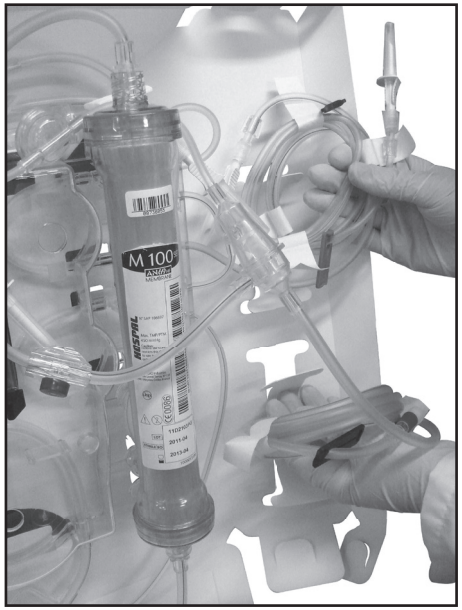


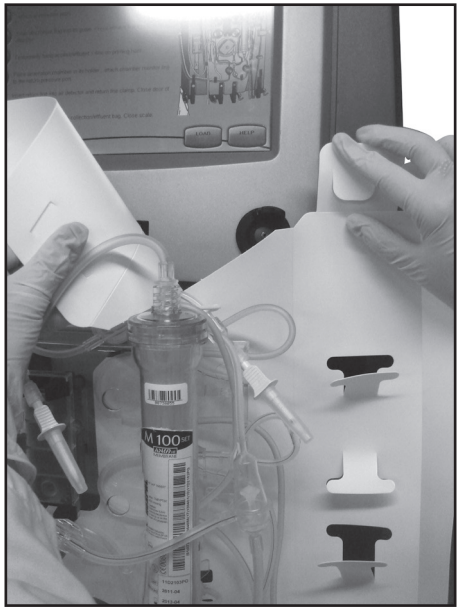


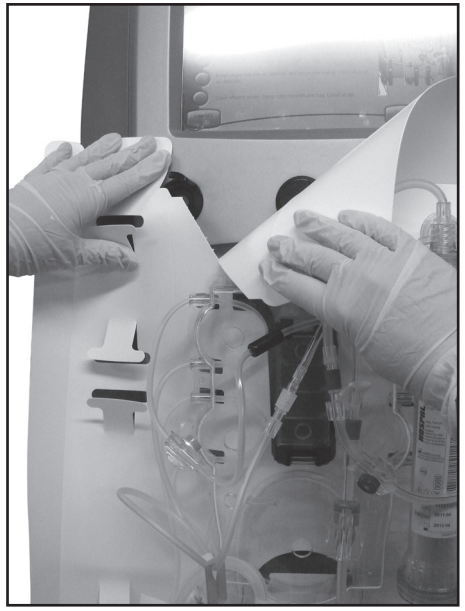
INSTALL SET DIRECTLY ONTO THE CONTROL UNIT

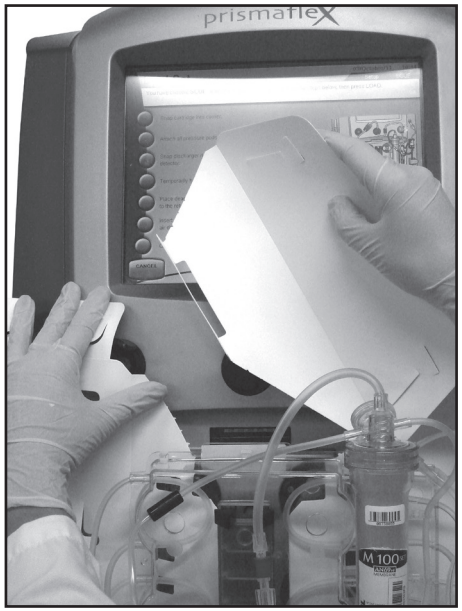


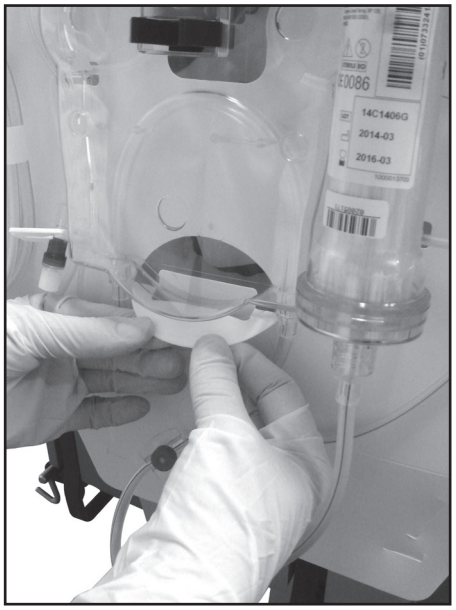


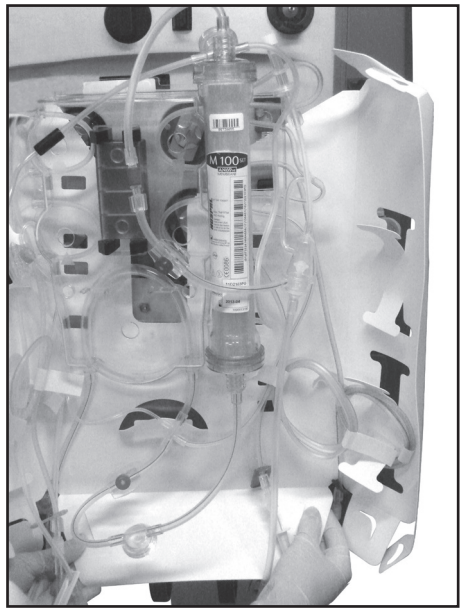


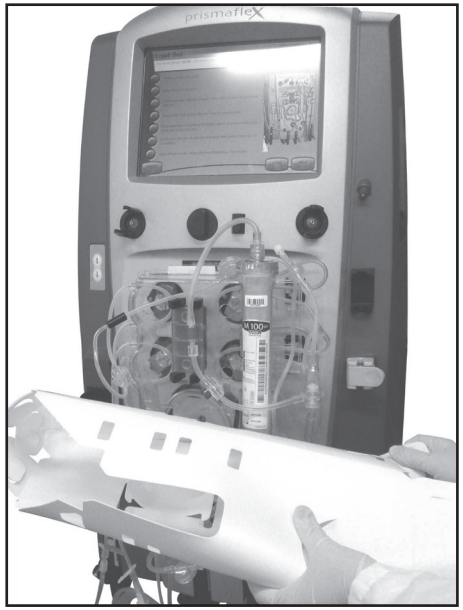


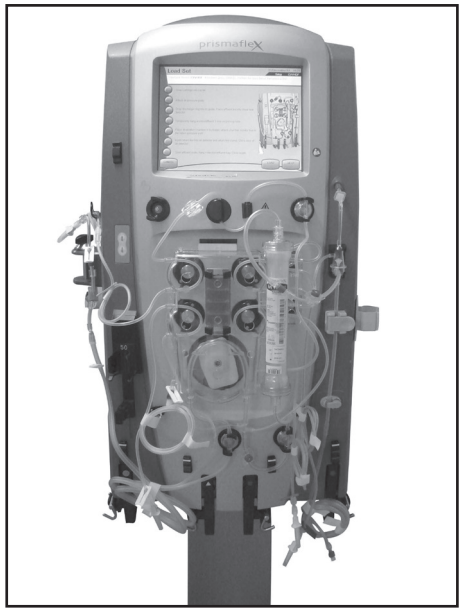












Patented ready to use PrismaFlex set packaging.