

prismaflex

HF 20 SET

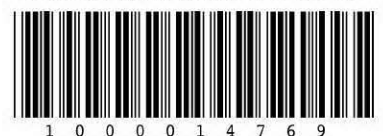
eng	Instructions for use	rus	Инструкция по применению
fre	Notice d'utilisation	hrv	Upute za uporabu
ger	Gebrauchsanweisung	lav	Lietošanas instrukcijas
spa	Folleto de utilización	cze	Návod k použití
ita	Istruzioni per l'uso	slv	Navodila za uporabo
swe	Handhavandeninstruktioner	srp	Uputstvo za upotrebu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

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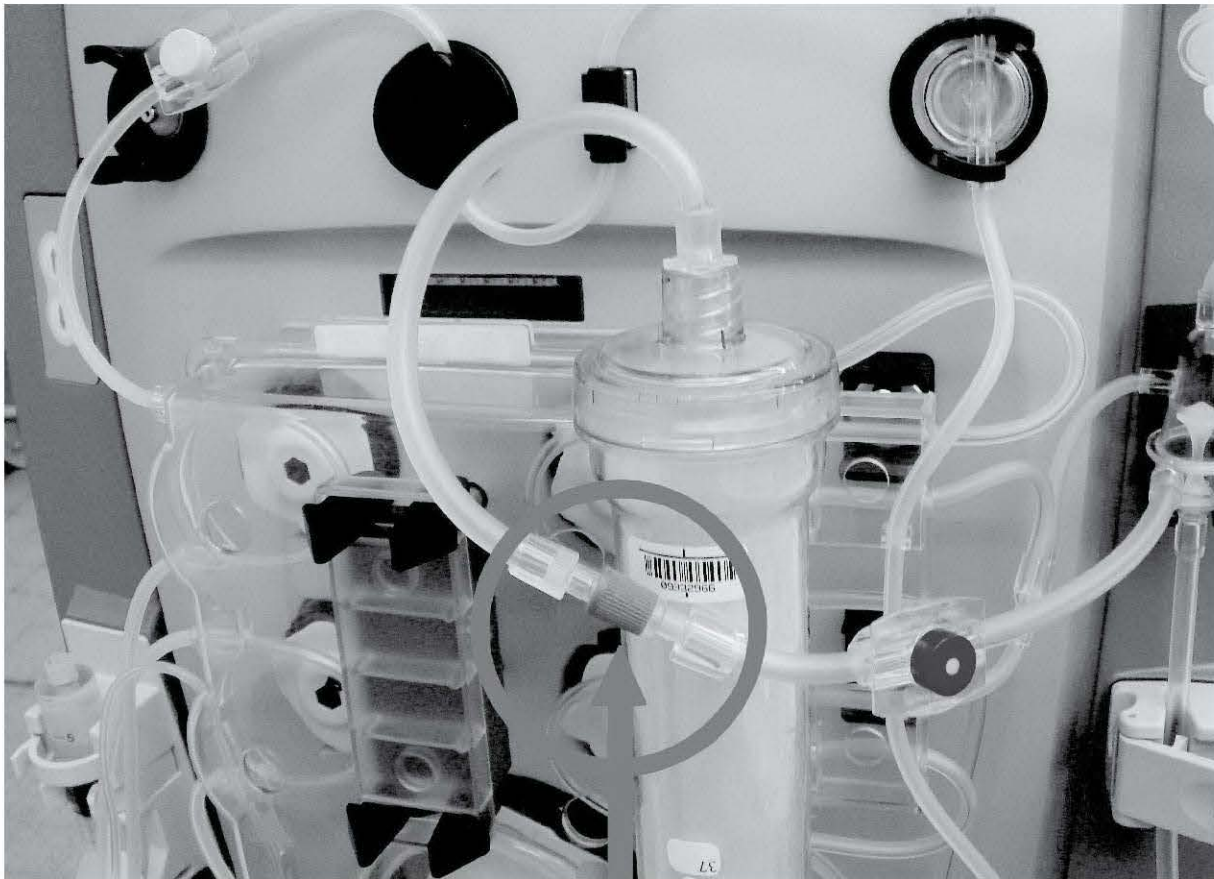
Made in France

CE 2797

Date of Revision: 2019-12-01


















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)
Σύνδεση θερμαντήρα αίματος (μπλε)
Соединение для нагревателя крови (синее)
Priključak grijača za krv (plavo)
Asins silditāja savienojums (zils)
Spojka ohřívače krve (modrá)
Priključek za grelnik krvi (moder)
Konekcija grejača krvi (plava)
Pripojenie ohrievača krvi (modré)
Vérmelegítő csatlakozása (kék)
Veresoojendaja ühendus (sinine)
Kraujo šildytuvo jungtis (mėlyna)
Връзка за нагревател на кръв (синя)
Conexiune încălzitor sânge (albastru)
Kết nối máu ấm hơn (màu xanh)
З'єднання нагрівача крові (синій колір)

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DEFINITION OF SYMBOLS

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	ENGLISH		FRANÇAIS		DEUTSCH	
		SYMBOL TITLE	SYMBOL DESCRIPTION (EXPLANATORY TEXT)	TITRE DU SYMBOLE	DESCRIPTION DU SYMBOLE (TEXTE EXPLICATIF)	SYMBOLNAME	SYMBOLBESCHREIBUNG (ERKLÄRENDE TEXT)
	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.
	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.
	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.
	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“.
	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“.
	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.
	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.
	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.
	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.	Conservé 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.
	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.
	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 not 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“.
	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.
	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.
	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 HF20 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 Venous-Hemofiltration.

CVVHD: Continuous Venous-Hemodialysis.

CVVHDF: Continuous 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** HF20 set is a disposable, extracorporeal circuit for use with the **PrismaFlex** system or with the **PrisMax** system (in countries where **PrisMax** is cleared or registered).
- The **Prismaflex** HF20 set consists of a PAES hollow fiber hemofilter/dialyzer* and tubing lines; refer to the control unit operator manual drawings for details.
- The **Prismaflex** HF20 set is compatible with the sleeve blood warmers, which should be installed on the return line. Refer to the specific instructions for use.
- All line connectors are compatible with the ISO594-1 and ISO594-2 international standards concerning conical fittings.
- The fluid pathways of the **Prismaflex** set are guaranteed sterile and non pyrogenic.
- The **Prismaflex** HF20 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 with the **Prismaflex** 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.

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** HF20 set should be restricted to patients with a body weight greater than 8kg (18lb).
2. 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.
3. If citrated blood is used for the priming of the extracorporeal circuit before patient connection, it is recommended that the pH of this blood be verified and buffered at a value between 7.3 and 7.5. The ionized calcium should be adjusted at a value > or = 1.0.
4. If the patient is not immediately connected to the **Prismaflex** set after priming is complete, flush the set with at least 500 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.
5. 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.
6. 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. In the case of patients with a high risk of hemorrhage it is recommended not to add heparin to the priming solution.
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.
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 the end of the document.

SET MATERIALS

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

Hang bag of priming solution saline or alkaline solution (pH ≥ 7.3) with or without heparin added (5000IU heparin/liter) according to usual institutional practice, on priming hook. Connect access (red)/effluent (yellow) Y-line to priming solution bag.

Anticoagulation considerations

According to the literature* continuous heparinization at a rate of 10 to 20.IU/kg/h ensures proper operation of the extracorporeal circuit when performing treatment with patients having normal coagulation status.

Depending on the patient's condition, however, heparinization can be lowered to less than 5 IU/kg/h.

Heparinization can be controlled, for instance, by partial thromboplastin time (PTT) measurements: in this case, PTT could be maintained at 20 to 30 seconds over baseline.

* "Continuous renal replacement therapy in critically ill neonates"; G.ZOBEL & Al., *Kidney International, Vol.53, Suppl. 66 (1998)*.

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.

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.

MALAYSIA:

Authorized Representative: Baxter Healthcare (Malaysia) Sdn. Bhd.
B-21-3A, Level 21, The Ascent,
Paradigm, No. 1, Jalan SS7/26A,
Kelana Jaya, 47301 Petaling Jaya,
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Malaysia Registration number: GC25696881418

INDONESIA:

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

Imported and distributed by Baxter Healthcare Philippines, Inc.
Silangan Industrial Estate, Brgy. Canlubang, Calamba City, Laguna, Philippines
MDR-01243

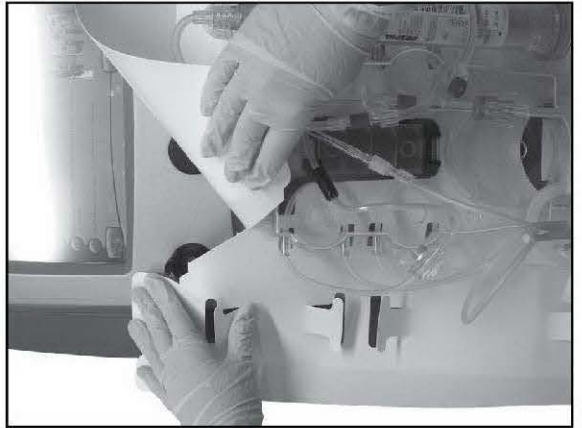
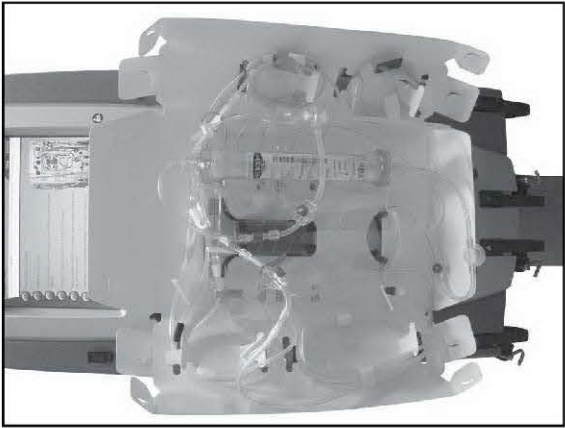
Prismaflex HF20 SET	
PHYSICAL CHARACTERISTICS ⁽¹⁾	
Membrane effective surface area	0.2 m ²
Fiber internal diameter (wet)	215 µm
Fiber wall thickness	50 µm
Blood volume in set	58 mL
Overall dimensions	
• Length	27 cm
• Width	22 cm
• Height	9 cm
Weight	677 g
OPERATING PARAMETERS	
Maximum TMP	500 mm Hg 66.6 kPa
Maximum blood pressure	500 mm Hg 66.6 kPa
Minimum blood flow rate	20 mL/min
Maximum blood flow rate	100 mL/min
PERFORMANCE SPECIFICATIONS ⁽²⁾	
Maximum ultrafiltration rate (mL/min) ⁽³⁾ (bovine blood, Hct 32%, Cp 60 g/L, 37°C)	
QB (mL/min)	20 50 100
Max.QUF (± 20%)	9 17 24
Sieving coefficient (bovine plasma, Cp 60 g/L, 37°C) QB = 50 mL/min, QUF = 10 mL/min	
• Urea	1.00
• Vitamin B12	1.00
• Inulin	0.92
• Albumin	<0.01
Clearance (mL/min) (saline solution; 37°C) Parameters: QB/QS QUF QD (L/h) QD (mL/min)	
	20 mL/min 0 mL/min
	50 mL/min 0 mL/min
	100 mL/min 0 mL/min
	0.5 1 1.5 2 2.5 0.5 1 1.5 2 2.5 0.5 1 1.5 2 2.5 8 17 25 33 42 8 17 25 33 42 8 17 25 33 42
Urea (± 10%)	8 12.5 14.5 15.7 16.5 8.3 15.5 20.9 25.1 28.7 8.3 16.4 23.6 30.1 36.3
Creatinin (± 10%)	7.8 11.7 13.6 14.7 15.6 8.3 15.0 19.7 23.1 26.0 8.3 16.2 22.9 28.5 33.5
Vitamin B12 (± 20%)	6.5 8.6 9.5 10.0 10.3 7.6 11.7 13.9 15.4 16.5 8.1 13.9 17.6 20.3 22.5
Inulin (± 20%)	5.6 7.0 7.5 7.8 7.9 6.9 9.8 11.2 12.1 12.7 7.9 12.6 15.2 16.9 18.1

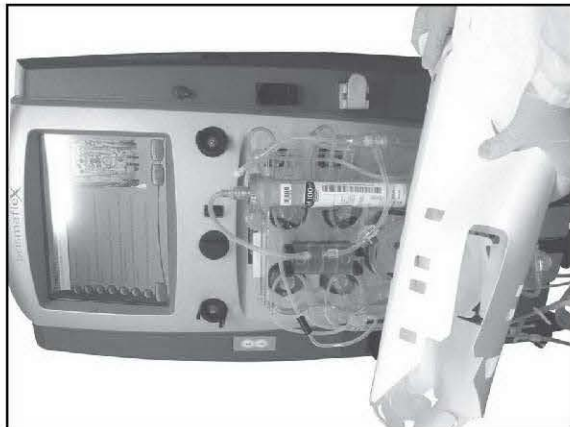
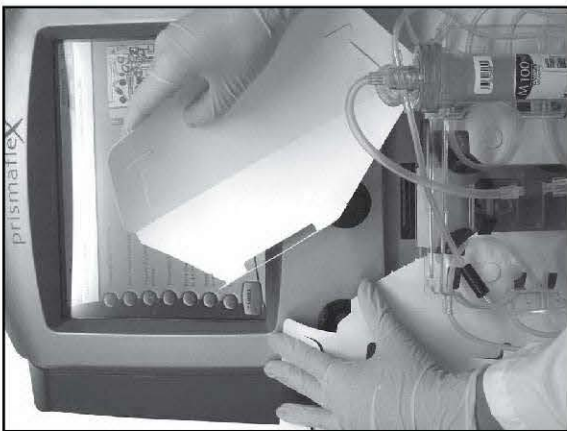
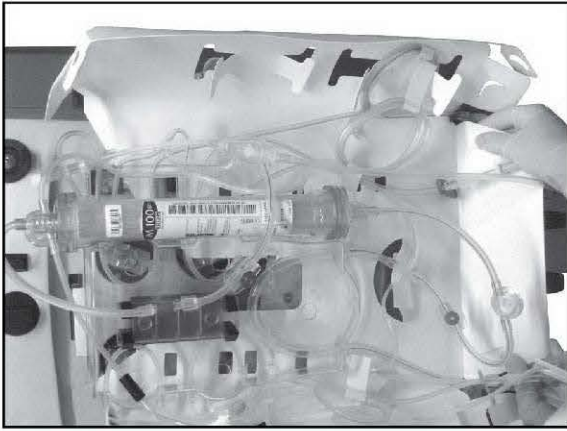
⁽¹⁾ Nominal values - given for indication

⁽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 coefficient (KUF).

INSTALL SET DIRECTLY ONTO THE CONTROL UNIT





Patented ready to use PrismaFlex set packaging.

BAXTER CONFIDENTIAL - INTERNAL USE ONLY

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prismaflex

◆ **EXTRA CORPOREAL CIRCUIT WITH FILTER** / Blood access line (red-striped) / Blood return line (blue-striped) / Dialysate line (green-striped) / Effluent line (yellow-striped) / Replacement solution line (purple-striped) / Pre-blood pump line (white-striped) / 5-liter effluent collection bag. Sterile and non-pyrogenic fluid pathways. **Caution:** Do not use if protective caps are not in place or if packaging is damaged. **Caution:** Federal law (USA) restricts this device to sale by or on the order of a physician.

Indonesia - Distributor: PT. Tawada Healthcare, Rukan Permata Senayan Blok A No. 18-19, Jl. Tentara Pelajar No. 5 Grogol Utara, Jakarta Selatan - Indonesia. KE-MENKES RI AKL 20805711114 (Prismaflex M sets) / 20805714919 (Prismaflex HF1000/ HF1400 sets) / 20805714921 (Prismaflex HF20 set) / 20805713569 (Prismaflex ST sets).
Philippines - Imported and distributed by Baxter Healthcare Philippines, Inc. Silangan Industrial Estate, Brgy. Canlubang, Calamba City, Laguna, Philippines. MDR-01243 (Prismaflex HF20 set) / MDR-07338 (Prismaflex M sets).
Malaysia - Authorised Representative Baxter Healthcare (Malaysia) Sdn. Bhd. B-21-3A, Level 21, The Ascent, Paradigm, No. 1, Jalan SS7/26A, Kelana Jaya, 47301 Petaling Jaya, Selangor Darul Ehsan, Malaysia. Registration number: GC99624912318 (Prismaflex M sets) / GC2566881418 (Prismaflex HF20 set).

◆ **CIRCUITO EXTRACORPOREAL AVEC FILTRE** / Ligne d'entrée sang (liseré rouge) / Ligne retour sang (liseré bleu) / Ligne dialysat (liseré vert) / Ligne de liquide effluent (liseré jaune) / Ligne de solution de réinjection (liseré violet) / Ligne pré-pompe sang (liseré blanc) / Poche de recueil effluent 5 litres. Compartiments sang et dialysat stériles et apyrogènes. **Attention:** ne pas utiliser si les protecteurs de stérilité ne sont pas en place ou si l'emballage est endommagé.

◆ **EXTRAKORPORALE ENWEG-SET MIT FILTER** / Zugangslleitung (rot gestreift) / Rückfuhrleitung (blau gestreift) / Dialysatleitung (grün gestreift) / Abaufleitung (gelb gestreift) / Substitutionslösungsleitung (violett gestreift) / Substitutionsleitung prä-Blutpumpe (weiß gestreift) / 5 Liter Auffangbeutel. Flüssigkeitskreisläufe sind steril und pyrogenfrei. **Achtung:** nicht verwenden, wenn die Sterilschutzkappen nicht an ihrem Platz sind oder die Packung beschädigt ist.

◆ **CIRCUITO EXTRACORPOREAL CON FILTRO** / Línea de entrada de sangre (banda de color rojo) / Línea de retorno de sangre (banda de color azul) / Línea de entrada del dializado (banda de color verde) / Línea de salida de efluente (banda de color amarillo) / Línea para la solución de reinyección (banda de color violeta) / Línea de la pre-bomba de sangre (banda de color blanco) / Bolsa colector de efluente de 5 litros. Compartimentos sanguíneos y baños estériles y apirógenos. **Atención:** No utilizar si se han quitado los protectores de esterilidad o si el empaque no está íntegro. No se garantiza la esterilidad del producto en caso de que el empaque primario tenga señales de haber sufrido ruptura previa.

Argentina - Importado y Distribuido en Argentina por Baxter Argentina S.A. Av. Olivos 4140, (B1667AUT) Tortuguitas, Prov. de Buenos Aires, Argentina. VENTA EXCLUSIVA A PROFESIONALES E INSTITUCIONES SANITARIAS. Dirección Técnica: Farmacéutica Carla Di Verniero, M.P. 18.970. Autorizado por la ANMAT PM 770-51 (Prismaflex HF20 set).

Colombia - Importado y distribuido por: Laboratorios Baxter S.A., Calle 36 N°2C-22, Cali-Colombia. Registros Sanitarios: INVIMA 2010DM-0006415 / INVIMA 2010DM-0006469 (Prismaflex M/HF/ST sets) / INVIMA 2017DM-0017272 (Prismaflex HF20 set).

Guatemala - PMQ-12214 (Prismaflex HF20 set) / PMQ-12111 (Prismaflex ST sets). Mexico - Importado y Distribuido en Mexico por: Baxter, S.A. de CV, Av. de los 50 Metros No. 2, Colonia CVAC, C.P. 62578, Jiutepec, Morelos, Mexico. y/o Distribuido por: Baxter, S.A. de CV, Boulevard Benito Juárez No. 10 Nave F, Ejido de San Mateo Cuautepec, Tuxtla, C.P. 54948, Estado de Mexico, Mexico. Reg. No. 2634C2011 (Prismaflex ST sets) / 1607E2008 S5A (Prismaflex HF sets).

◆ **CIRCUITO EXTRACORPOREAL CON FILTRO** / Línea de acceso emático (con bordo rosso) / Línea di rientro ematico (con bordo blu) / Línea dializzato (con bordo verde) / Línea di scarico (con bordo giallo) / Línea per l'iniezione di soluzione (con bordo porpora) / Línea per l'infusione per pompa sangue (con bordo bianco) / Sacca di raccolta dell'effluente da 5 litri. Compartimenti sangue e dializzato sterili e apirogeni. **Avvertimento:** non utilizzare se i mezzi di protezione della sterilità sono stati rimossi o se l'imballaggio è danneggiato.

◆ **EXTRAKORPORAL KRETS MED FILTER** / Blod accesslang (rödrandig) / Blod returflödeslang (blårandig) / Dialysatslang (grönrandig) / Avflödeslang (gulrandig) / Ersättningslösningsslang (lilårandig) / Pre-blodpumpslang (vitrandig) / Uppsamlingspåse 5 liter. Sterilt och pyrogenfritt blod. **Varning:** Använd ej om skyddskapslar inte är på plats eller om förpackningen är skadad.

◆ **UITWENDIG CIRCUIT MET FILTER** / Bloed aanvoerlijn (rood gestreepd) / Bloed terugflödelijn (blauw gestreepd) / Dialysaallijn (groen gestreepd) / Effluentlijn (geel gestreepd) / Lijn voor de substitutievoestof (paars gestreepd) / Pre-bloedpomplijn (wit gestreepd) / 5 liter effluent opvangzak. Steriele en niet-pyrogene vloeistoflijnen. **Waarschuwing:** niet gebruiken als de beschermingskapjes niet op de juiste plaats zitten of als de verpakking is beschadigd.

◆ **CIRCUITO EXTRACORPOREAL COM FILTRO** / Linha de entrada de sangue (faixa vermelha) / Linha de retorno de sangue (faixa azul) / Linha para dialise (faixa verde) / Linha de liquido efluente (faixa amarela) / Linha de reposição (faixa rosa) / Línea de sangue anterior a bomba (faixa branca) / Bolsa de coleta de efluente de 5 litros. Compartimentos de passagem do fluido estériles e apirógenos. **Atenção:** Não utilizar se os protectores de esterilidade tenham sido retirados ou se a embalagem estiver danificada.

◆ **EXTRAKORPORAL SIKKULUS KOS FILTRIG** / Blodaksess slange (røde stiper) / Blodreturslange (blå stiper) / Dialysatslange (grønne stiper) / Avfalls (effluent) slange (gule stiper) / Slange for erstatningsløsning (colette stiper) / Slange for pre-blodpumpe (hvite stiper) / 5 liters avfalls (effluent) pose. Sterile og ikke-pyrogene væskebæner. **OBES:** Må ikke bruges hvis beskyttelsestæpper er fjernet eller hvis emballagen er skadet.

◆ **EXTRAKORPORAL KREDSLOV MED FILTER** / Blodindløbslange (røde stiber) / Blodreturløbslange (blå stiber) / Dialysatslange (grønne stiber) / Væskeudløbslange (gule stiber) / Erstatnings væskeflange (lilla stiber) / Pre-blodpumpeflange (hvide stiber) / 5 liter udløbs opsamlingspose. Sterile og ikke-pyrogene væskebæner. **Forsigtig!** Må ikke anvendes, hvis beskyttelsestæpper er fjernet, eller hvis emballagen er beskadiget.

◆ **KENON ULKOPORALINEN VERILETKUSTO JA SUODATIN** / Veren ottoletku (punaarainen) / Veren paluuletku (siniraitainen) / Ulkonesteleku (violetiraitainen) / Veripumppu edeltävä letku (valkoinen) / Voidon litran pöytäjosten keräyspöytä. Steriili ja pyrogeeniton nesteletku. **Vaaroitus:** Älä käytä, jos suojakorkit eivät ole paikallaan tai jos pakkaus on vioittunut.

◆ **ЭКСТРАКОРПОРАЛЬНЫЙ КОНТУР С ФИЛЬТРОМ** / Кровопроводящая магистраль доступа (с красной полосой) / Магистраль возврата (с синей полосой) / Магистраль диализата (с зеленой полосой) / Магистраль эффлюента (с желтой полосой) / Магистраль заместительного раствора (с пурпурной полосой) / Магистраль насоса перед насосом крови (с белой полосой) / Мешок для сбора эффлюента, 5 литров. Стерильно и Апиrogenно / Повторно не стерилизовать. **Предостережение:** Не использовать устройства, если стерильные колпачки отсутствуют на своих местах или его упаковка повреждена. Организация, уполномоченная на принятие претензий на территории РФ – АО Компания «Бакстер», 125171, Москва, Ленинградское шоссе, д. 16А, стр. 1, +7(495)647-68-07 электронная почта: Russia@baxter.com Per. удостоверение № P3H 2016/4169

◆ **EXTRAKORPORALNI KRUG S FILTROM** / Linija za pristup krvi (s crvenom prugom) / Linija za povrat krvi (s plavom prugom) / Linija za dijalizatu (sa zelenom prugom) / Linija za otpadnu tekućinu (sa žutom prugom) / Linija za nadomjesnu tekućinu (s ljubičastom prugom) / Linija prijne krvne pumpe (s bijelom prugom) / 5-litarska vrećica za prikupljanje otpadne tekućine. Sterilni i nepirogeni prostori za tekućine. **Opze:** Nemojte koristiti ako zaštitne kapice nisu na svojim mjestima ili ako je pakiranje oštećeno.

◆ **EXTRAKORPORALA KÈDE AR FILTRUM** / asins pievades linija (ar sarkanām svītrām) / asins atdošanas linija (ar zilām svītrām) / dializēšanas linija (ar zaļām svītrām) / izplūdes linija (ar dzeltenām svītrām) / aizvietošanas šķidruma linija (ar violetām svītrām) / pakaltnio tirpalo linija (pažymēta violetā jostelē) / linija priekš kraujo pumpa (pažymēta balta jostelē) / 5 litru talpos nuotekų sūrinimo maisas. Sterilus ir nepirogenius šķisčių tekimo trajektorijos. **Įspėjimas:** nenaudokite, jei nėra apsauginių dangtelių arba jei sugadinta pakuočių.

◆ **EXTRAKORPORALNÉ GRANDINÉ SU FILTRU** / kraujo pažymėta linija (pažymėta raudona juostele) / kraujo grąžinimo linija (pažymėta mėlyna juostele) / dializato linija (pažymėta žalia juostele) / nuotekų linija (pažymėta geltona juostele) / pakaitinio tirpalo linija (pažymėta violetine juostele) / linija prieš kraujo pumpą (pažymėta balta juostele) / 5 litrų talpos nuotekų sūrinimo maišas. Sterilus ir nepirogeninio skysčio tekimo trajektorijos. **Įspėjimas:** nenaudokite, jei nėra apsauginių dangtelių arba jei sugadinta pakuočių.

◆ **MIMOTĚLNĚ OKRUH S FILTREM** / Krevní přístupové vedení (s červeným pruhem) / Krevní návratové vedení (s modrým pruhem) / Vedení pro dialýzát (se zeleným pruhem) / Odpadní vedení (se žlutým pruhem) / Vedení pro náhradní roztok (s fialovým pruhem) / Vedení před krevní pumpou (s bílým pruhem) / Odpadní sběrný vak o objemu 5 litrů. Sterilní a apyrogenní dílčové části. **Upozornění:** Nepoužívejte, pokud ochranná krytka není na místě nebo pokud je obal poškozený.

◆ **KEHAVÄLINE RINGLUS KOOS FILTRIGA** / Vere juurdevoolulin (punasetribuline) / Vere tagasvoolulin (sinisestribuline) / Dialüüsiväline lin (rohkestribuline) / Väljavoolulin (kollasetribuline) / Asendussüüsiue lin (lillaestribuline) / Verepumbaeseline lin (valgestribuline) / 5-litriine väljavoolu kogumiskott. Sterilised ja pirogeenivabad vedelikud. **Etevaatust!** Ärge kasutage, kui kaitsesektor ei ole kohal võlli kui pakend on kahjustatud.

◆ **ZUNAJTELESNI OBTOK S FILTROM** / cevka za dovod krvi (z rdećmi ćrtami) / cevka za odvod krvi (z modrimi ćrtami) / cevka za dijalizat (z zelenimi ćrtami) / odvajalna cevka (z rumenimi ćrtami) / cevka za nadomestno raztopino (z vijolićnimi ćrtami) / dovodna cevka ćrpakle za kri (z belimi ćrtami) / zbina vrećica za odvajanje (5 l). Sterilni in apirogeni obojni tekoćini. **Opzorenje:** Izdelka ne uporabljajte, če varnostni pokrovec ni pravilno namešten ali če je embalaža poškodovana.

◆ **MIMOTELOVÝ OBĚH S FILTROM** / Linka prívodu krvi (s červeným páiskom) / Linka pre návrat krvi (s modrým páiskom) / Linka pre dialýzát (so zeleným páiskom) / Odtoková linka (so žltým páiskom) / Linka pre náhradný roztok (s fialovým páiskom) / Linka predkrvnoho ćerpadla (s bielym páiskom) / 5-litrový odtokový zberný vak. Sterilné a nepyrogeenne časty na vedenie tekućiny. **Upozornenie:** Ak ochranný uzáver nie je na svojom mieste alebo ak je balenie poškodené, zariadenie nepoužívajte.

◆ **OBWÓD KRĄŻENIA POZAUSTROJOWEGO Z FILTREM** / Linia dostępu krwi (pasek czerwony) / Linia zwrotu krwi (pasek niebieski) / Linia dializatu (pasek zielony) / Linia odpływu (pasek żółty) / Linia wymiany roztworu (pasek fioletowy) / Linia do podłączenia przed pompą krwi (pasek biały) / 5-litrowy worek zbierający na płyn odpływowy. Sterylne i niepyrogenne części przepływowe. **Prezostro:** Nie używać, jeśli opakowanie jest uszkodzone lub jeśli nasadka ochronna nie znajduje się na swoim miejscu.

◆ **FILTRELİ EKSTRAKORPORAL DEVRE** / Kan giriř hattı (kırmızı çizgili) / Kan dönüş hattı (mavi çizgili) / Diyalizat hattı (yeşil çizgili) / Atık hattı (sarı çizgili) / Replasman solüsyonu hattı (mor çizgili) / Ön kan pompası hattı (beyaz çizgili) / 5 litrelik atık toplama torbası. Steril ve apirojen sıvı açığı yolları. **Dikkat:** Konuyuucu kapak yerinde değılirse veya ambalaj hasar görmüşse kullanmayın. İTİHALATÇI FIRMA: BAXTER Turkey, Renal Hizmetler A.Ş., Sanyer, İstanbul / TÜRK- YE. Telefon: +90 212 365 53 00. E-posta: tr_bilgi@baxter.com

◆ **ΕΞΩΣΩΜΑΤΙΚΟ ΚΥΚΛΩΜΑ ΜΕ ΦΙΛΤΡΟ** / Γραμμή προσέλευσης αίματος (κόκκινες ρίγιες) / Γραμμή επιστροφής αίματος (μπλε ρίγιες) / Γραμμή διαλύματος σποκιοκάρου (πράσινες ρίγιες) / Γραμμή υγρού εξαγωγής (κίτρινες ρίγιες) / Γραμμή διαλύματος υποκατάστασης (μωβ ρίγιες) / Γραμμή ανάλυσης προ αίματος (λευκές ρίγιες) / Σάκος συλλογής υγρού εξαγωγής 5 λίτρων. Αποστειρωμένα και μη πυρογόνα διαμερίσματα υπρών. **Προσοχή:** Μη χρησιμοποιείτε το προϊόν αν τα προστατευτικά μιάματα δεν βρίσκονται στη θέση τους ή αν η συσκευασία φέρει ίχνη φθοράς.

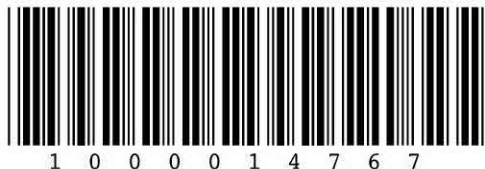
◆ **VANTELESNA CIRCULACIJA SA FILTEROM** / Linija za krvni pristup (označena crvenom prugom) / Linija za vraćanje krvi (označena plavom prugom) / Linija za dijalizat (označena zelenom prugom) / Linija za efluent (označena žutom prugom) / Linija za supstitucijsni rastvor (označena ljubičastom prugom) / Linija pred-krvne pumpe (označena belom prugom) / kes za prikupljanje efluenta zapremine 5 litara. Sterilne i apirogene putanje tečnosti. **Opze:** Nemojte koristiti ako je zaštitna kapica uklonjena ili je pakovanje oštećeno.

◆ **EXTRAKORPORALNÉ KAPKOVÉ SZÜRŐVÉ** / artériás szűr (vörös csíkos)/vénszűr (kék csíkos)/dialízis folyadék csöve (zöld csíkos)/kifolyósó (sárga csíkos)/pótlóoldat-beviteli cső (lilla csíkos)/vérgyűjtő tároló (fehér csíkos)/5 literes kifolyógyűjtőszék. Steril és nem pirogén folyadékáraklármási útvonalk. **Figyelem:** Ne használja fel a terméket, ha a védőkapokotq nincsenek a helyükön, illetve ha a csomagolásuk sérült.

◆ **ЭКСТРАКОРПОРАЛНА ВЕРИГА С ФИЛТЪР** / ФИЛТЪР/Линия за достъп за кръв (с червена ивица)/Връщаща линия за кръв (с синя ивица)/Линия за диализат (с зелено ивица)/Линия за ефлуент (с жълта ивица)/Линия за заместяващ разтвор (с лилав ивица) / Линия на предвръщащата помпа за кръв (с бяла ивица)/5-литрова торба за събиране на ефлуент. Стерилни и апиrogenни пътища на течността. **Внимание:** не използвайте, ако защитните капачки не са на местата си или ако опаковката е повредена.

◆ **CIRCUIT EXTRACORPOREAL CU FILTRU** / Linie de acces sanguin (cu dungi roșii) / Linie de retur sânge (cu dungi albastre) / Linie de dializat (cu dungi verzi) / Linie de efluent (cu dungi galbene) / Linie de soluție de substituție (cu dungi violete) / Linie pentru pre-sânge (cu dungi albe) / Pungă de colectare efluent de 5 litri. Trasee sterile și nepirogenice pentru lichide. **Precauție:** Nu utilizați în cazul în care capacele de protecție nu sunt în locul lor sau dacă ambalajul este deteriorat.

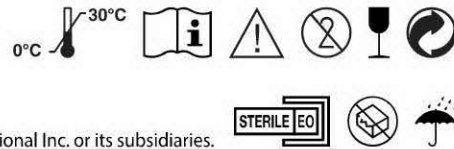
◆ **Комплект Prismaflex - Дані для ідентифікації виробу див. на етикетці, де: Prismaflex ST60/ST100/ST150 Set ma Prismaflex HF1000/HF1400/HF20 set відповідають назвам виробів українською мовою: Комплект Prismaflex ST60/ST100/ST150 та Комплект для зєнокфільтрації Prismaflex HF1000/HF1400/HF20 відповідно - Экстракорпоральный контур с фильтром / магистраль надхождения крови (в череной смужко)/магистраль повернення крови (в синьою смужко)/магистраль диализату (в зеленою смужко)/магистраль еффлюента (в жовтою смужко)/магистраль заместного розчину (в фіолетовою смужко)/пердвращаюча напіва магистраль (в білою смужко)/5-літровою пакет для збору еффлюента. Стерильні та апиrogenні канали проходження рідин. **Попередження:** Не використовувати, якщо захисні колпачки не на місці, або якщо упакування пошкоджено. **Виробник:** Гамбро Індустріс, 7 Авеню Ліонел Террай, BP 126, 69883 Мейтзеу Цедекс, Франція**



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7, avenue Lionel Terray, BP126,
69883 MEYZIEU CEDEX, FRANCE

CE 2797

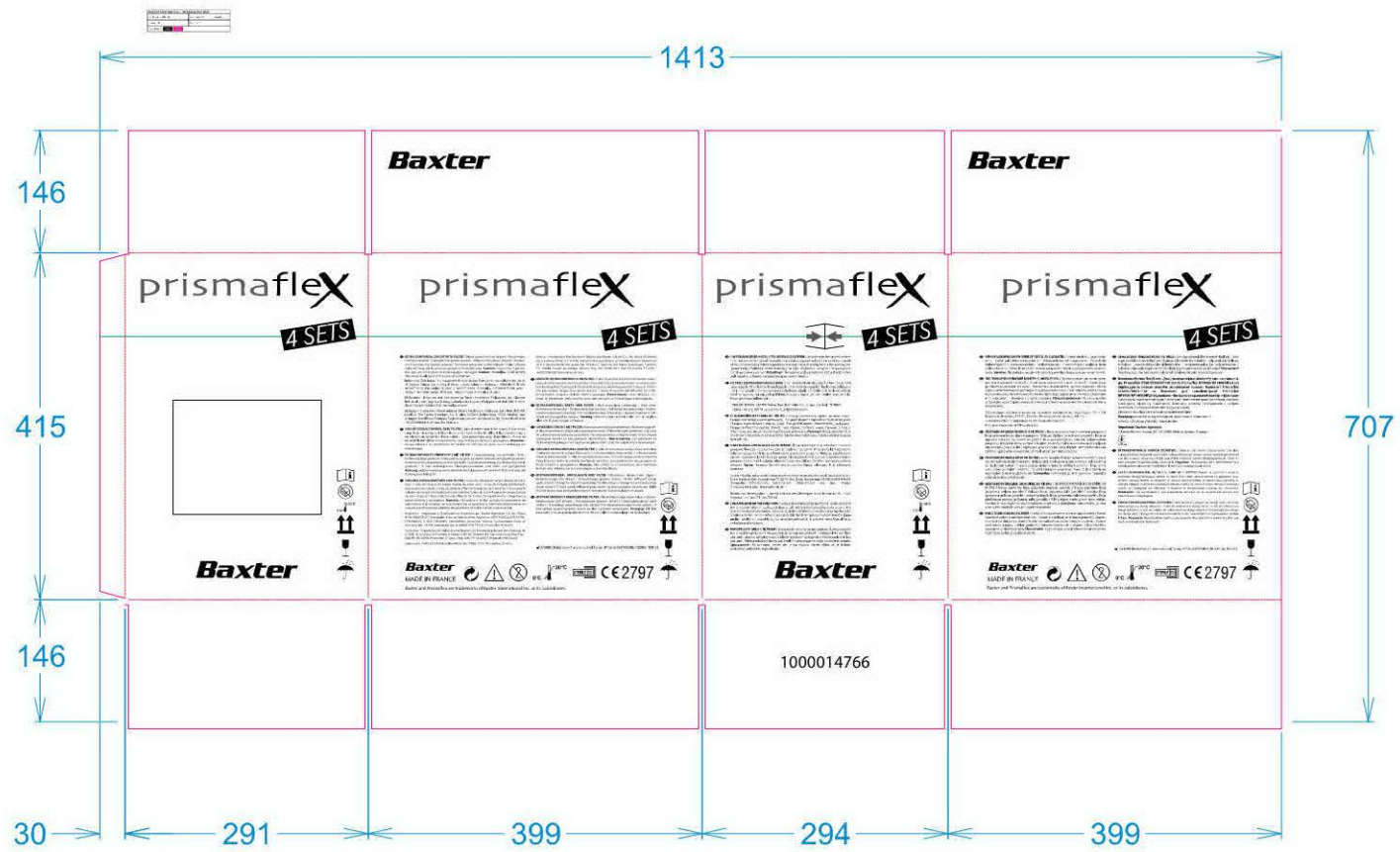
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ITALY 118



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Part Number: 1000014778

Date: 04-DEC-2019

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Designer: CDS

Page: 1 of 1

Colour Reference:

PMS 432

PMS 032

PMS 195

DIELINE

VARNISH

90 mm

60 mm

prismaflex

HF20 Set

REF 109841
REF 115313

Max. TMP/PTM: 500 mmHg

LOT



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

GAMBRO Industries
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BP 126,
69683 MEYZIEU CEDEX,
FRANCE



Baxter CE 2797



1000014778

