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prismaflex

M60 SET / M100 SET / M150 SET

AN69 HF
MEMBRANE

eng **Instructions for use**

chi **使用説明**

REF **115305**

REF **115306**

REF **115307**

Made in France

CE 2797

Baxter

Date of Revision: 2019/12/01

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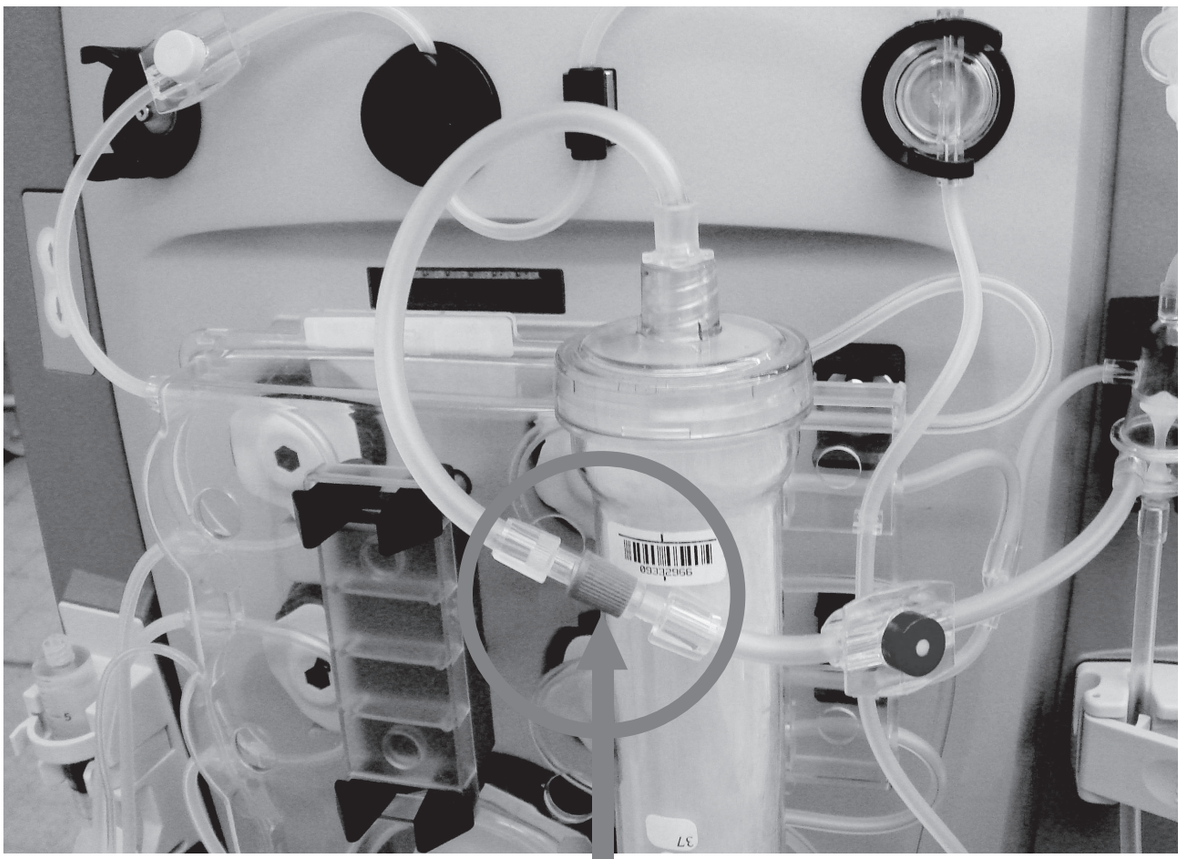

Blood warmer connection (blue)
血液加溫器連接（藍色）

DEFINITION OF SYMBOLS

		ENGLISH		繁體中文	
SYMBOL GRAPHIC & REF NUM / 符號圖形和參考編號	TITLE AND NUMBER OF STANDARD / 標準名稱和編號	SYMBOL TITLE	SYMBOL DESCRIPTION (EXPLANATORY TEXT)	符號名稱	符號描述（解釋性文字）
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.	製造廠	表示醫療器材製造廠， 即在以其名義將器材 上市前負責器材設計、 生產、包裝和標籤的自然 人或法人。
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.	製造日期	表示生產該醫療器材的日 期。格式應為年-月-日。
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	保存期限	表示在該日期後不應使用 該醫療器材。格式應為 年-月-日
5.1.5 	ISO 15223-1[1]	Batch code	Indicates the manufacturer's batch code. Synonyms are "lot number" and "batch number"	批次代碼	表示製造廠的批次代碼。 同義字為“批號”和“批次號”
5.1.6 	ISO 15223-1[1]	Catalogue number	Indicates the manufacturer's catalog number. Synonyms are "reference number" and "reorder number"	目錄編號	表示製造廠的目錄編號。 同義字為“參考編號” 和“再訂購編號”
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.	無菌液體通路	表示當該醫療器材其它部 分（包括外部）不能以無 菌形式供應情況下，該醫 療器材的內部為無菌液體 通路。應將滅菌方法標示 在外盒。
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.	如果包裝破損，請勿使用	表示如果包裝已破損或打 開，不應使用醫療器材
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.	易碎、小心輕放	表示如果不注意操作， 可能會打破或損壞醫療 器材。
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.	保持乾燥 或 遠離雨水	表示醫療器材需要防潮。 或 表示醫療器材需要遠離 雨水。
5.3.7 	ISO 15223-1[1]	Temperature Limit	Indicates the temperature limits to which the medical device can be safely exposed.	溫度限值	表示該醫療器材可安全地 暴露於該溫度限值內。
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".	請勿重複使用	表示醫療器材僅供單次使 用，或用於單一病人的單 次治療。 “請勿重複使 用”的同義字為“單次使 用”和“僅使用一次”。
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.	注意	表示使用者需要參閱使用 說明、了解重要警訊，如 因為各種原因不能標示在 醫療器材機體上的各種警 告和預防措施。
	NA, European countries only / NA, pays européens seulement / NA, sólo países europeos	Green Dot Symbol	To indicate the manufacturer of the product contributes to the cost of recovery and recycling	綠點符號	表示該產品製造廠落實回 收和重複利用
0623 	ISO 7000[2]	This way up	Indicates the correct, upright position of the package	此面朝上	表示包裝的正確、 朝上位置
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".	參閱使用說明	表示使用者需要參閱使用 說明。 “參閱使用說明” 的同義字為 “參閱操作 手冊” 。

[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 / 醫療器材 - 要提供與醫療器材標籤配合使用的符號、標記和資訊第 1 部分：基本要求

[2] ISO 7000 Graphical symbols for use on equipment - Registered symbols / 供設備上使用的圖形符號 - 已註冊符號

ENGLISH

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The PRISMAFLEX M60/M100/M150 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"** is used to alert the user/operator not to take a certain action which, if taken, can cause a potential hazard and result in a serious adverse reaction, injury or death.

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

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

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

PRODUCT DESCRIPTION

- The **PRISMAFLEX** M60/M100/M150 Set is a disposable, extracorporeal circuit for use with the **PRISMAFLEX** system.
- The **PRISMAFLEX** M60/M100/M150 Set consists of a AN69 HF hollow fiber hemofilter/dialyzer* and tubing lines.
- This filter is permanently connected to a blood access line (red-striped), a blood return line (blue-striped), a dialysate inlet line (green-striped) and an effluent outlet line (yellow-striped).
- The other lines of the set include:
  - a replacement solution line (purple-striped),
  - a pre blood pump line (white striped),
  - an anticoagulant line (syringe).
- The configuration of the **PRISMAFLEX** set allows the following uses depending on the configuration of the automated clamps on the machine:
  - purple circuit: replacement in pre or post dilution (CVVH and CVVHDF),
  - green circuit:
    * dialysate in CVVHD and CVVHDF,
    * replacement in post dilution in CVVH.
- The pre blood pump line allows the addition of infusion solution close to the end of the patient access line and before the blood pump. This can be used as an additional pre-dilution infusion to the replacement circuit.
- The **PRISMAFLEX** Set is provided with a specific small volume deaeration chamber in which blood does not appear to mix with the replacement liquid the majority of the time; this is a normal operation of the device.
- A 5-liter bag is provided to be connected to the end of the blood return line to initially collect priming solution, during priming. Then, during treatment, this bag is used to collect ultrafiltrate and/or used dialysate (connection at effluent line). Other sterile 5 and 9 liter bags and sterile, non pyrogenic spikes can be ordered separately.
- All line connectors are compatible with the ISO 594/1 & 2 international standards concerning conical fittings.
- The fluid pathways of the **PRISMAFLEX** Set are guaranteed sterile and non pyrogenic.
- The **PRISMAFLEX** Set is sterilized by ethylene oxide (EtO). Deaeration is such that EtO residuals comply with the ones described in ISO 10993-7.
- Expiration date: please refer to product label.

* 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 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 contraindications to continuous renal replacement therapies.

CAUTIONS AND WARNINGS

Note: additional warnings and cautions pertaining to the **PRISMAFLEX** system are included in the **PRISMAFLEX** control unit operator's manual.

⚠ Cautions

It is recommended that particular attention must be paid with respect to extra-corporal blood volume (see General Characteristics).

The pediatric use of the **PRISMAFLEX** M60 Set should be restricted to children with a body weight greater than 11 kg (24lb) with respect to extracorporeal blood volume. Refer to **PRISMAFLEX** operator's manual for any additional weight restrictions that might apply.

The **PRISMAFLEX** M100 Set and M150 Sets should be restricted to patients with a body weight greater than 30kg (66lb).

1. Carefully read these instructions for use and the **PRISMAFLEX** control unit operator's manual before using this product.

2. Store the **PRISMAFLEX** Set in a dry place, between 0° C (32° F) and 30° C (86° F).

3. Some solvents and other chemicals, if used in contact with the filter, could damage the set. No chemical of this type should be used without permission of the manufacturer. The following are especially forbidden:
a) halogenated aromatic and aliphatic solvents,
b) ketonic solvents.

4. To prevent contamination, this **PRISMAFLEX** Set must be used as soon as its packaging and sterilization caps are removed.

5. Do not use this set if the packaging is damaged, if the sterilization caps are missing or loose, or if any of the lines in the set are kinked.

6. Do not try to remove the filter from the cartridge plate.

7. Destroy this set after single use, using aseptic technique for potentially contaminated equipment. Do not resterilize. The **PRISMAFLEX** M is intended for single use only. Re-using the **PRISMAFLEX** M may cause serious damage to the product resulting in patient injury or death.

8. Use aseptic techniques when handling all blood and fluid lines in the set.

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

9b. In CVVHD and CVVHDF modes, it is recommended to use only sterile bagged dialysate.

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

10. Connect the **PRISMAFLEX** Set to a patient via venous blood access and return devices. A double-lumen venous catheter is the recommended blood access device; however, two single-lumen venous catheters can also be used. There are 3 possible accesses for **PRISMAFLEX** system therapies: subclavian, jugular or femoral vein.

11. During priming and operation, observe closely for leakage at joints and connections within the set, notably the bags. Leakage can cause blood loss or air embolism. If leakage cannot be stopped by tightening the connections, replace the set.

12. Before connecting the blood return line to the patient, check for absence of air between the segment of line inserted in the air detector and the patient-end of the return line.
    If air is present in this part of the return line, connect the access line to the patient and start the blood pump while leaving the return line connected to the collection bag. Purge the air present in the end-part of the return line, then stop the blood pump. Disconnect the return line from the collection bag, and connect it to the patient.
    If the amount of air in the blood circuit is too large, reprime the circuit completely before patient connection.
13. After priming is complete, do not remove the pressure pods from the pressure sensor housings. If pods are removed, the set must be changed or the Diaphragm Reposition procedure performed (refer to **PRISMAFLEX** control unit operator's manual).
14. If the patient is not immediately connected to the **PRISMAFLEX** Set after priming is complete, flush the set with at least 1000 mL priming solution [saline or alkaline solution (pH ≥ 7.3) with heparin added] prior to connecting the patient. This requires use of a new bag of priming solution.
15. Use a 21-gauge or smaller needle to obtain blood/fluid samples or remove trapped air from the **PRISMAFLEX** Set. Use of larger needles can cause holes in the sample sites, resulting in blood loss or air embolism.
16. The **PRISMAFLEX** control unit may not be able to detect disconnections of the set from the patient's catheter. Carefully observe the set and all operations while using the **PRISMAFLEX** system for a patient treatment.
17. Due to the nature of use of the **PRISMAFLEX** Set (low blood flow rates, extended treatment time, and other special factors), the possibility for coagulation within the blood flowpath is substantially enhanced. Give careful attention to the possible medical hazards associated with coagulation of the blood flowpath and comply with the minimum blood flow rates specifications of each filter (see the "Filter Operating Specifications" section).
18. In the case of patients who pose a high risk of hemorrhaging it is recommended not to add heparin to the priming solution.
19. Filter performance specifications require a minimum blood flow rate, specific to each filter, to avoid risk of hemoconcentration (see "Filter Operating Specifications" section).
20. During use, closely monitor the patient's clotting parameters, especially when increasing the amount of anticoagulant delivered or after changing the anticoagulant syringe.
21. To assure proper anticoagulant flow control, only use the syringes listed in the operator's manual. The use of non-recommended syringes can be a hazard for the patient. Particularly if there is no Luer-lock on the syringe, the seal between the syringe and the heparin line can no longer be guaranteed.
22. When not using the pre blood pump infusion circuit, it is recommended to clamp this circuit close to its connection to the access line; this will prevent the sedimentation of blood into the pre blood infusion line.
23. Always inspect the blood flowpath for signs of clotting before returning the blood in the set to the patient. If clotting is suspected, do not return the blood to the patient.
24. In case of re-circulation mode, the set must be replaced if the maximum re-circulation time is exceeded; refer to the **PRISMAFLEX** operator's manual for more information.
    In case of poor blood return, the set must be replaced.
    In all cases, it is essential to reprime the set with fresh saline immediately before patient connection.
25. The **PRISMAFLEX** set offers a specific design of the deaeration chamber which aims to trap air before blood is returned to the patient.
26. The **PRISMAFLEX** Set is not designed for a heater to be connected to the replacement solution line. A heater generates air bubbles which collect in the return deaeration chamber. Therefore, it is recommended not to use a heater on the replacement solution line.
27. The **PRISMAFLEX** set is not designed for a heater to be connected to the dialysate solution line. A heater generates air bubbles which collect in the filtrate/dialysate compartment of the filter and decrease diffusive performance of the device. Therefore it is recommended not to use a heater on the dialysate solution line.
    In general terms, introduction of air in the dialysate circuit should be minimised throughout the course of the treatment, especially when replacing dialysate solution bags.
28. Hypothermia must be monitored in all CRRT treatments, and special attention should be paid when increasing exchange volumes above 2 L/h ; it may be necessary to warm the patient because of hypothermia.
29. The deaeration chamber line (blue-striped) is equipped with a Luer-lock connection near the deaeration chamber.
    This connector is intended to join the extension line of a blood warmer. Refer to the specific Instructions for Use and strictly follow detailed instructions for set up of this line. Do not use this connection for any other purpose.
30. Do not attach/connect the extension line of a blood heater to the return line downstream of the air detector. The **PRISMAFLEX** system cannot detect air introduced in the line downstream of the air detector.

⚠ Warnings

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

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

The **PRISMAFLEX** Set is not made with rubber natural latex.

INSTRUCTIONS FOR USE

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

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

Perform the following procedures when the appropriate instructions appear on the display of the **PRISMAFLEX** control unit.

Load Set

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

Prepare and Connect Solutions

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

4. In CVVHD/CVVHDF hang dialysate on green scale hook. Connect dialysate line (green). In CVVH hang replacement solution on green scale hook (postdilution replacement). Connect green striped line to bag.

   Note: see Caution no. 10 a, b, c.
5. Connect anticoagulant line to filled anticoagulant syringe. Install syringe in pump (see Help).
6. Unclamp any clamped lines. **Verify all connections are secure.** Press PRIME to start automatic priming.

Prime Set

Note: see Cautions no. 12 through 15, cautions no. 27, 28 and 31, and Warning no. 4.

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

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

The **PRISMAFLEX** Set must be carefully deaerated.

Anticoagulation Considerations

Note: see Cautions no. 18 through 22 and Warning no. 6.

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

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

Change Set Procedure

To remove this set, load a new set and continue with present treatment:
Press "STOP" from the Status screen, then press "CHANGE SET" and follow the on-line instructions.

Note: operator can return blood to the patient prior to disconnecting, if desired (see Caution no. 24).

Re-circulation procedure

To set-up the re-circulation of the circuit:
Press "STOP" on the status screen; then press "RECIRC" and follow the on-line instructions.

Note: the operator must return blood present in the set to the patient, then disconnect the patient and circulate a sterile saline solution in the blood circuit of the set. Once the treatment can be re-started, the set must be re-primed and re-rinsed with a sterile saline solution before reconnecting the patient (see cautions n° 24 and 25).

End Treatment Procedure

To end the present treatment and remove this set :
Press "STOP" from the Status screen, then press "END TREATMENT" and follow the on-line instructions.

Note: operator can return blood to the patient prior to disconnecting, if desired (see Caution no. 24).

MANUAL TERMINATION

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

Note: the following instructions are also found in "Troubleshooting" in the **PRISMAFLEX** control unit operator's manual.

A. With Blood Return

Note: see Caution no. 24.

Note: a sterile spike connector may be required.

1. Turn off the power. Clamp the access line (red-striped) and disconnect from the patient. Attach the access line to a 1-liter bag of sterile saline (use spike connector if needed). Unclamp the access line.
2. Press the return clamp button (left side of the return line clamp assembly) and hold in the "in" position. With the other hand, remove the return line (blue-striped) from the return line clamp.
3. Visually check the fluid level in the deaeration chamber. If the level is insufficient:
   - disconnect the deaeration chamber service line from the return pressure port on the **PRISMAFLEX** machine (the level will automatically rise in the deaeration chamber),
   - reconnect the line once the correct fluid level is reached.
4. Remove the pump crank from its holder on the rear panel. Insert crank into the rotor of the blood pump and turn clockwise until sufficient blood is returned to the patient.

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

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

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

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

B. Without Blood Return

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

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

SPECIAL PROCEDURES IN CASE OF COMPLICATION

Filter Membrane Blood Leaks

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

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

External Blood Leaks

Note: see Cautions no. 16, 17 and 22.

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

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

Hypersensitivity Reactions

Note: see Warning no. 3.

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

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

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

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

WARRANTY AND LIMITATION OF LIABILITY

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

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

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

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

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

INDIA

- **Name and address of importer:** Baxter India Pvt. Ltd., Gala No. 1 to 6, Building No. C15, Ground Floor, Shree Arihant complex, Kalher, Bhiwandi,

  Dist. Thane, Tal: Bhiwandi (Thane-Zone 5) 421302
- Name, address, telephone no., email address (in case of consumer complaint):

  Baxter India Pvt. Ltd.

  5th Floor, Block A, Building 9,

  DLF Phase III, Cyber City, Gurgaon- 122002.

  Consumer Care No.: 0124-4603200

  Consumer Care email ID: Customerservice_SHS_India@baxter.com
- Import License No.: MD-1591-2310

繁體中文

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普利司馬弗列克斯套組
規格: M60/M100/M150
衛署醫器輸字第013757號

PRISMAFLEX M60/M100/M150 套組是由 GAMBRO Industries 製造，廠址為 7 avenue Lionel Terray, BP 126, 69883 MEYZIEU CEDEX, FRANCE。

本手冊中之名詞定義

在本文件中：

⚠「**警告**」係用來提醒使用者/操作者不得採取特定動作，否則可能會導致某項潛在的危險發生，並引發嚴重的不良反應、傷害甚至死亡。

⚠「**注意**」係用來提醒使用者/操作者必須採取特定的動作，以防止某項潛在危險發生；如果未留意該項危險的話，可能會對病患或器材造成不良的影響。

「**備註**」係用來提醒使用者/操作者一般的治療行為，或是在特定情況下必須採取的適當行動。

SCUF: 緩慢連續性超過濾
CVVH: 連續性靜脈-靜脈血液過濾
CVVHD: 連續性靜脈-靜脈式血液透析
CVVHDF: 連續性靜脈-靜脈血液透析過濾
前稀釋：在過濾器之前的血流中注入置換溶液
後稀釋：在過濾器之後的血流中注入置換溶液

產品說明

- **PRISMAFLEX** M60/M100/M150 套組是搭配 **PRISMAFLEX** 系統使用的體外循環迴路耗材。
- **PRISMAFLEX** M60/M100/M150 套組包含一個 AN69 HF 空心纖維血液過濾器/透析器* 和數個管路。
- 這個過濾器是固定連接到血液輸入管路（紅條紋）、血液回輸管路（藍條紋）、透析液入口管路（綠條紋）以及廢液出口管路（黃條紋）。
- 套組中的其他管路包括：
  - 置換溶液管路（紫條紋），
  - 血液幫浦前管路（白條紋），
  - 抗凝劑管路（注射器）。
- 視機器上的自動管路夾配置而定，**PRISMAFLEX** 套組的配置可用做下列用途：
  - 紫色迴路：在前稀釋或後稀釋作為置換液管路 (CVVH 和 CVVHDF)；
  - 綠色迴路：
    * CVVHD 和 CVVHDF 中作為透析液管路；
    * 在 CVVH 時在後稀釋中進行置換。
- 血液幫浦前管路可用來在靠近病人輸入管的末端以及血液幫浦前注入輸注溶液，以便在置換迴路中進一步進行前稀釋輸注。
- **PRISMAFLEX** 套組隨附有小容量的特製排氣室，大部分的時間其中的血液看來不會與置換液混合；這是本裝置運作的正常狀況。
- 隨附的 5 公升液袋是連接到血液回輸管的末端，用來在預充期間的初期收集預充溶液。接著，在治療期間，則會用這個液袋收集超過濾液和/或用過的透析液（連接到廢液管路）。如需其他無菌的 5 和 9 公升液袋，以及無菌且無熱原的穿刺針，可另外訂購。
- 所有的管路連接器，都相容於 ISO 594/1 和 2 國際標準的錐形接頭。
- **PRISMAFLEX** 套組的液體通路均保證為無菌且無熱原。
- **PRISMAFLEX** 套組係以環氧乙烷 (EtO) 滅菌，並經過排氣，使其 EtO 殘留物符合 ISO 10993-7 的規定。
- 保存期限：請參閱產品標籤。

* 在本文件中，血液過濾器/透析器將統稱為「過濾器」。

用途/ 適應症

PRISMAFLEX 套組僅能搭配 **PRISMAFLEX** 控制單元，用來進行連續性液體管理以及腎功能替代治療。此系統是用來治療急性腎衰竭、體液過多或兩者兼具的病人。

此套組適用於下列靜脈-靜脈治療：SCUF, CVVH, CVVHD, CVVHDF。

所有透過 **PRISMAFLEX** 套組施予的治療，都必須要依醫師處方進行。每次治療前都必須由處方醫師審慎評估病人的體型、體重、尿毒狀態、心臟狀態以及一般生理情況。

禁忌症

連續性腎功能替代治療沒有已知的禁忌症。

注意及警告事項

備註：如需 **PRISMAFLEX** 系統其他警告和注意事項的詳細資訊，請參閱《**PRISMAFLEX** 控制單元操作手冊》。

⚠ 注意

建議應特別注意體外循環的血液容積。(請參閱「一般特性」)。

如要對兒童病患使用 **PRISMAFLEX** M60 套組，根據體外循環血液容積的要求，兒童的體重必須高於 11 公斤 (24 磅)。請參閱《**PRISMAFLEX** 操作手冊》，了解任何適用的其他體重限制。

PRISMAFLEX M100 和 M150 套組僅能使用於體重高於 30 公斤 (66 磅) 的病患。

1. 使用本產品前，請先仔細閱讀這些「使用說明」及《**PRISMAFLEX** 控制單元操作手冊》。

2. 請將 **PRISMAFLEX** 套組存放在溫度介於 0° C (32° F) 到 30° C (86° F) 之間的乾燥處。

3. 直接在過濾器上使用某些溶劑或化學藥品，可能會造成套組毀損。未經製造商同意，請勿使用這類化學藥品。嚴禁使用下列化學藥品：
a) 鹵化芳香及脂肪族溶劑；
b) 酮類溶劑。

4. 為了避免污染，本 **PRISMAFLEX** 套組的包裝與滅菌蓋一經拆封後便應立即使用。

5. 發生下列狀況時請勿使用本套組：包裝已破損、滅菌蓋遺失或脫落，或套組中有任何管路有異狀。

6. 請勿將過濾器從卡匣底盤拆下。

7. 本套組應於使用完後銷毀，如果設備可能有污染，請採無菌技術銷毀。請勿重複滅菌。**PRISMAFLEX** M 僅供單次使用。重複使用 **PRISMAFLEX** M 可能會嚴重損壞產品，導致病人受傷或死亡。

8. 操作套組中所有的血液和液體管路時，請採用無菌操作技術。

9a. **PRISMAFLEX** 系統上僅能使用醫師處方的透析溶液和置換溶液。這些溶液的密度必須與生理食鹽水相近（接近 1），以避免液體交換所使用的體積出錯。

9b. 在 CVVHD 和 CVVHDF 模式中，建議僅使用無菌的透析液袋。

9c. 在 CVVH 模式和 CVVHDF 中，如要使用市售的置換溶液，其標籤必須標明為專供靜脈注射使用。

10. 請透過靜脈血液輸入及回輸裝置將 **PRISMAFLEX** 套組連接到病人身上。建議使用雙腔靜脈導管的血液通路裝置；不過也可使用兩個單腔的靜脈導管。**PRISMAFLEX** 系統治療共有 3 種可能的通路：鎖骨下靜脈、頸靜脈或股靜脈。

11. 在預充和操作期間，請仔細觀察套組內的接頭與連接處是否有滲漏，尤其是液袋，因為滲漏可能會造成失血或空氣栓塞。如果轉緊連接處仍無法停止滲漏，請更換套組。

12. 將血液回輸管路連接到病人之前，請先檢查由插入氣泡偵測器那端到回輸管路靠近病人那端之間的管路，確定沒有任何空氣存在。
如果回輸管路的這個部分有空氣存在，請將輸入管路連接到病人，維持回輸管路連接到收集袋，然後啟動血液幫浦。等管路中的氣泡被趕到回輸管的末端時，停止血液幫浦，從收集袋上卸下回輸管，然後再將回輸管連接到病人身上。
如果血液迴路內的空氣量太多，請重新充分地預充迴路後再與病人連接。

13. 完成預充後，請不要從壓力感應器外罩取下壓力室。如果壓力室被取下，就必須更換套組，或進行「壓力室隔膜復位」(Diaphragm Reposition) 程序（請參閱《**PRISMAFLEX** 控制單元操作手冊》）。

14. 如果 **PRISMAFLEX** 套組完成預充後未能立即連接到病人，請先以至少 1 000 mL 的預充溶液 [加入含肝素的生理食鹽水或鹼性溶液 (pH ≥ 7.3)] 沖洗套組後，再接到病人身上。這時請使用新的預充溶液袋。

15. 採集血液/液體樣本或排除 **PRISMAFLEX** 套組中的空氣時，請使用 21 號或更小內徑的針頭。針頭口徑過大，可能會在採樣點造成孔洞，進而導致失血及空氣栓塞。

16. **PRISMAFLEX** 控制單元可能無法偵測到套組與病人導管分離。使用 **PRISMAFLEX** 系統進行病人治療時，要仔細檢查套組和所有操作。

17. 基於 **PRISMAFLEX** 套組的使用本質（低血液流速、較長的治療時間以及其他特殊因素），血流途徑內發生凝血的可能性會大幅增高。請特別小心注意與血流途徑內發生凝血相關的醫療危險，並依照各個過濾器的最低血液流速規格操作(請參閱「過濾器操作規格」一節)。

18. 如果病人是出血的高風險群，建議不要在預充溶液中加入肝素。

19. 為了避免發生血濃縮，過濾器效能規格對各個過濾器都有最低的血液流速要求。請參閱「過濾器操作規格」一節。

20. 在使用期間，請密切監控病人的凝血參數，特別是在提高注射的抗凝劑量時，或是更換抗凝劑注射器後。

21. 為了確保能適當控制抗凝劑溶液的流動，請僅使用《操作手冊》中所列的注射器。使用未經建議的注射器可能會對病人造成危險，尤其是注射器上如果沒有魯爾鎖，便無法保證注射器與肝素管路間可完全密封。

22. 未使用血液幫浦前輸注迴路時，建議將此迴路與輸入管連接的地方夾緊，這樣可以避免血液前輸注管路內發生血液沈降。

23. 將套組中的血液回輸到病人之前，一定要先檢查血流途徑，觀察是否有任何凝血的跡象。如果懷疑有凝血，請不要回血給病人。

24. 處於再循環模式時，如果已超過最大的再循環時間，就必須更換套組；進一步資訊請參閱《**PRISMAFLEX** 操作手冊》。
血液回輸不良時，必須更換套組。

不管是什麼情況，請務必要先以新鮮的生理食鹽水預充套組，然後再立即連接到病人。

25. **PRISMAFLEX** 套組隨附有特殊設計的排氣室，可以先蓄積並排除血液中的空氣，再回血給病人。
26. **PRISMAFLEX** 套組的設計並不包括連接加熱器到置換溶液管路，因為加熱器產生的氣泡會堆積在回輸管排氣室，所以建議不要在置換溶液管路上使用加熱器。
27. **PRISMAFLEX** 套組的設計並不包括連接加熱器到透析溶液管路，因為加熱器產生的氣泡會堆積在過濾器的過濾液/透析液腔室，降低裝置的擴散效能，所以建議不要在透析溶液管路上使用加熱器。
    一般而言，在治療過程中，應盡量避免空氣滲入透析液迴路內，尤其是在更換透析液袋時。
28. 所有的 CRRT 治療都必須監控病人是否體溫過低，將交換容積提高到 2 L/h 時尤其更要特別注意；當病人體溫過低時，便需要為病人加溫。
29. 血液回輸管 (藍條紋) 在靠近排氣室的地方設有魯爾鎖。
    這個連接器可用來連接血液加溫器的延長管。請參閱所屬的「使用說明」，並完全遵照使用說明來裝配此管路。請不要將此連接使用於任何其他用途。
30. 血液加溫器的延長管不能安裝/連接到氣泡偵測器下游的回輸管，這是因為 **PRISMAFLEX** 系統無法偵測氣泡偵測器下游管路內是否有空氣。

⚠ 警告

1. 使用與製造商說明不符的操作程序，或是使用製造商未建議使用的輔助裝置，均可能會導致病人受傷或死亡。
2. **PRISMAFLEX** 控制單元上僅能使用 **PRISMAFLEX** 套組，使用非 **PRISMAFLEX** 的套組可能導致病人受傷或死亡。
3. 萬一病人在接受治療時發生急性過敏反應 (初次使用症候群)，請立即停止治療並施以適當的醫療措施。對於接受 ACE 抑制劑治療和/或已經出現類似反應的病人，應特別小心注意。(請參閱「過敏反應」一節)。
4. 一旦開始進行預充後，請注意絕對不要讓空氣跑進過濾器的血液腔室中。如果跑進大量空氣，就必須更換套組。
5. 由於藥物能穿透過濾器的過濾膜，因此應該要針對接受連續性腎功能替代治療的病人，調整相關藥物治療的劑量。
6. 為了確保過濾器有一定的效能表現，建議每使用 24 小時更換一次套組。然而，使用超過 3 天 (72 小時) 和/或最大處理血液容積 (780L) (視何者為先) 後，就一定要更換套組。
   在達到這些限值 (72 小時或 780L) 後仍繼續使用，可能會造成幫浦管破裂，甚至導致病人受傷或死亡。
7. 僅使用與規格部分所列塑膠材質相容的藥品。有些塑膠材質當與 pH > 10 的溶液接觸時，可能與藥品不相容。

規格

請參閱文件末尾的表格。

套組材質

AN69 HF 空心纖維	:	丙烯腈 (Acrylonitrile) 和甲基丙烯磺酸鈉 (Sodium Methallyl Sulfonate)共聚合物
外殼及蓋子	:	聚碳酸酯 (Polycarbonate)
填充化合物	:	聚氨酯 (Polyurethane)
管路材質	:	聚氯乙烯 (PVC)
卡匣	:	PETG

備註：如需下列資訊，請向製造商索取；
- 取得效能特性之測試方法的相關資訊,
- 依照臨床使用建議準備的透析器，其廢液中的顆粒數目與範圍,
- 滅菌程序的殘留物類型和數量。

PRISMAFLEX 並非用天然橡膠乳膠製造 。

使用說明

備註：請按照 **PRISMAFLEX** 控制單元提供的詳細線上使用指導使用套組。進一步詳細資訊，請參閱《**PRISMAFLEX** 控制單元操作手冊》。

備註：TMP > 40 kPa (300 mmHg) 時，便無法再提高超過濾速率。

當 **PRISMAFLEX** 控制單元螢幕顯示相關指導時，請按照下列程序進行。

安裝設定

1. 從包裝支撐物上取下套組，垂直拿著過濾器 (標籤朝上)，小心地將套組卡匣卡入卡匣支架 (前面板中央)。
2. 將 3 個壓力室分別安裝到所屬的壓力感應器外殼。將廢液管路按入血液滲漏偵測器；將放電環卡入其導引座。
3. 暫時將輸入/廢液 Y 型管路懸掛在預充液袋鉤上。
4. 將排氣室放到其支架上；把排氣室監控管連接到回輸壓連接埠。
5. 將回輸管插入氣泡偵測器和回輸夾中。
6. 將回輸管連接到廢液袋。
7. 打開廢液秤；掛上收集袋/廢液袋； 關閉磅秤。

準備並連接溶液

1. 將預充溶液 [肝素濃度為 5000IU/L 的生理食鹽水或鹼性溶液 (pH ≥ 7.3)] 掛到預充液袋鉤上 (前面板上方最左邊的掛鉤)。將輸入 (紅色)/廢液 (黃色) Y 型管路連接到預充液袋。
2. 如有需要，將 PBP 管路 (白色) 連接到血液幫浦前 (PBP) 液袋；將液袋吊到所屬的磅秤上。
3. 將置換溶液 (CVVH, CVVHDF) 吊到紫色的磅秤鉤上，再將置換溶液管路 (紫色) 連接到置換液袋。
4. 如為 CVVHD/CVVHDF 治療，請將透析液吊到綠色的磅秤鉤上，再連接透析液管路(綠色)。如為CVVH治療，請將置換溶液吊到綠色的磅秤鉤上(後稀釋置換)，再將綠條紋的管路連接到液袋。
   備註：請參閱注意事項 10 a,b,c。
5. 將抗凝劑管路連接到注滿的抗凝劑注射器；再將注射器安裝到幫浦上(請參閱「輔助說明」)。
6. 鬆開任何被夾住的管路，檢查所有的連接是否穩固。按「預充」(PRIME) 開始自動預充。

預充套組

備註：請參閱注意事項 12 到 15、注意事項 27、28 和 31，以及警告事項 4。

預充包括多項自我測試，大約需時 10 分鐘。在週期結束後：

1. 請仔細檢查套組，確認所有連接都很穩固，所有管路均暢通無阻，同時管路沒有滲漏。
2. 在準備好連接病人前，請讓預充溶液和預充收集袋維持連接狀態。
3. 按照 **PRISMAFLEX** 控制單元螢幕顯示的指示，繼續進行所選的治療。

必須小心地為 **PRISMAFLEX** 套組進行排氣。

抗凝法考量

備註：請參閱注意事項 18 到 22，以及警告事項 6。

請根據醫師處方，開始對血流途徑進行抗凝。在使用期間，請監控病人的凝血參數；請根據醫師處方，調整 **PRISMAFLEX** 控制單元上的抗凝設定。如處方需要，請記得在連接病人後立即輸注抗凝劑起始劑量。

抗凝可以減緩阻塞或凝血的形成，對延長過濾器的使用壽命至關重要。

更換套組程序

如要卸下此套組、安裝新套組，再繼續進行目前的治療：

按下「狀態」畫面中的「停止」(STOP)，然後按「更換套組」(CHANGE SET)，再依照線上使用指導進行。

備註：如有需要，操作者可以在分離病人前先回血給病人 (請參閱注意事項 24)。

再循環程序

如要設定迴路的再循環：

按下「狀態」畫面中的「停止」(STOP)，然後按「再循環」(RECIRC)，再依照線上使用指導進行。

備註：操作者必須將套組中的血液回輸給病人，然後再分離病人，接著以無菌生理食鹽水在套組中的血液迴路中循環流動。一旦可以重新開始治療時，套組必須先以無菌生理食鹽水重新預充及沖洗，然後再重新連接病人。(請參閱注意事項 24 和 25)。

結束治療程序

如要結束目前治療並卸下此套組：

按下「狀態」畫面中的「停止」(STOP)，然後按「結束治療」(END TREATMENT)，再依照線上使用指導進行。

備註：如有需要，操作者可以在分離病人前先回血給病人。(請參閱注意事項 24)。

手動終止

當 **PRISMAFLEX** 控制單元斷電或發出警報，便可能需要手動終止。警報畫面會告訴操作者是否需要手動終止。

備註：您也可以在《**PRISMAFLEX** 控制單元操作手冊》的「疑難排解」中找到下列指導。

A. 要回血時

備註：請參閱注意事項 24。

備註：可能需使用無菌的穿刺針連接器。

1. 關閉電源。夾住輸入管（紅條紋）並將其從病人身上取下； 將輸入管連接到 1 公升裝的無菌生理食鹽水液袋。(如有需要請使用穿刺針連接器)。鬆開輸入管上的管路夾。
2. 按下回輸管夾按鈕 (回輸管夾組件的左側) 並保持在「內」(In) 位置。接著用另一隻手，從回輸管夾取下回輸管 (藍條紋)。
3. 目視檢查排氣室的液體等級，如果等級高度不足：
   - 從 **PRISMAFLEX** 機器的回輸壓連接埠拆下排氣室維修管路（排氣室內的等級高度會自動上升),
   - 等液體等級回到正確高度時，再重新連接管路 。
4. 從後面板的支架上取出幫浦曲軸，將曲軸插入血液幫浦的轉子，然後順時針轉動曲軸，直到將足夠的血液送回病人體內為止。

⚠ **警告：**警報系統會停用。在完成病人分離之前，請目視檢查血液回輸管中的空氣。

5. 夾住回輸管 (藍條紋) 並將其從病人身上取下。夾住所有液袋的管路。
6. 按下卡匣支架的兩個夾鉗，鬆開卡匣。先從蠕動幫浦開始，將幫浦曲軸插入轉子，再依逆時針方向轉動各個幫浦。
7. 等到可順利拿出幫浦管時，請抓住卡匣並將其拉出，以便分離管路與管路夾閥。從控制單元取出套組，並按照正常步驟丟棄。

備註：如有需要，可將剩餘的溶液使用於新套組上。

⚠ **警告：**請確定病人與套組已經完全分離，再接著從控制單元取出套組。

B. 不回血時

備註：在進行手動終止治療但不回血的步驟時，病人會流失殘留在血流途徑中的血液。

1. 關閉電源。夾住輸入管 (紅條紋) 與回輸管 (藍條紋)，並將它們從病人身上取下。
2. 夾住所有液袋的管路。
3. 按下卡匣支架的兩個夾鉗，鬆開卡匣。先從血液幫浦開始，將幫浦曲軸插入轉子，再依逆時針方向轉動各個幫浦。
4. 等到可順利拿出幫浦管時，請抓住卡匣並將其拉出，以便分離管路與管路夾閥。從控制單元取出套組，並按照正常步驟丟棄。

發生併發症時的特殊程序

過濾膜血液滲漏

PRISMAFLEX 控制單元的警報系統會自動偵測過濾膜是否有血液滲漏，一旦偵測到便會發出警告警報，並立即停止所有幫浦以減少失血量。

如要回血給病人，請按下「警報」畫面中的「停止」(STOP)，然後按「停止」畫面的「更換套組」(CHANGE SET)，再依照線上使用指導進行。

外部血液滲漏

備註：請參閱注意事項 16、17 和 22。

由於監控設備可能無法立即發現外部血液滲漏，病人可能會因此大量失血。在治療期間，請檢查過濾器以及管路耗材的所有連接，盡量降低滲漏的風險。如果發現外部有血液滲漏現象，請立即停止血液幫浦，並採取加強連接密合度或更換 **PRISMAFLEX** 套組等矯正措施。

如有必要，請為病人注射適當的置換溶液，做為失血的補償。

過敏反應

備註：請參閱警告事項 3。

如果在開始治療數分鐘內發生急性過敏反應 (初次使用症候群)，請務必立即中斷治療，並另外採取適當的治療措施。

接受血管收縮素轉換酶 (ACE) 抑制劑藥物治療的病患，可能會在開始治療的數分鐘內，出現類似急性過敏反應的症狀，亦即支氣管痙攣、呼吸道或喉嚨水腫、呼吸困難、血管水腫、蕁麻疹、噁心、嘔吐、腹瀉、停止呼吸、腹部痙攣、低血壓、低血容量性休克和死亡。

但是，對這些病人施以抗組織胺，通常無法減輕其症狀。在這種情況下，當症狀出現後，必須立即停止治療，並馬上更積極地施予過敏性紫斑反應的一線治療。

因此，對於接受 ACE 抑制劑治療和/或已經出現類似反應的病人，應特別小心注意。

保固及責任限制

a) 製造廠商保證 **PRISMAFLEX** 套組係依據其規格而製造，並符合優良製造規範、其他適用的業界標準及法規要求。

如果客戶提供瑕疵產品的批號/序號，製造廠商將以替換或退款方式，賠償 **PRISMAFLEX** 套組在保存期限之前出現的明顯製造瑕疵。

b) 前述 a) 段之保固足以取代並排除任何其他保固 (無論其他保固係採書面或口頭、明示或暗示、法定或其他形式)，且製造廠商並未提供超過 a) 段保固範圍的商品性能或其他保固。上述與製造瑕疵有關的賠償係任何人在 **PRISMAFLEX** 套組出現瑕疵時所能享有的唯一賠償，且製造廠商不應為因直接或間接使用 **PRISMAFLEX** 套組而造成的任何衍生性或附隨性損失、損害、傷害或費用負責。

c) 製造廠商不應為下列情況負責：任何誤用或不當處理；未遵守警告與說明；因製造廠商交付 **PRISMAFLEX** 套組後發生的事件而造成的損害；使用 **PRISMAFLEX** 套組前未經檢查以確保其狀況良好，或獨立配銷商或經銷商所允諾的任何保固。

d) 製造廠商為 GAMBRO Industries，製造廠址為 7 avenue Lionel Terray, BP 126, 69883 MEYZIEU CEDEX, FRANCE。

藥商名稱: 百特醫療產品股份有限公司

藥商地址: 台北市大安區敦化南路二段95號28樓

FILTER DATA	過濾器資料	PRISMAFLEX M60 SET	PRISMAFLEX M100 SET	PRISMAFLEX M150 SET
NOMINAL PHYSICAL CHARACTERISTICS	**標稱物理特性**			
Effective surface area	有效表面面積	0.60 m^2	0.90 m^2	1.50 m^2
Fiber internal diameter (wet)	纖維內徑 (潮濕)	240 µm		
Fiber wall thickness	纖維壁厚	50 µm		
IN VITRO PERFORMANCES ≠	**體外效能 ≠**			
Blood priming volume	**血液預充量**	42 mL ± 10%	66 mL ± 10%	105 mL ± 10%
Blood pressure drop (post dilution)	**血壓壓力降 (後稀釋)**			
(bovine blood, Htc****32%, Cp***** 60 g/L, 37°C)	(牛血, Htc****32%, Cp***** 60 g/L, 37°C)	± 20 %	± 20 %	± 20 %
QB** = 100 mL/min, QUF*** = 1 L/h	QB** = 100 mL/min, QUF*** = 1 L/h	47 mmHg	31 mmHg	20 mmHg
QB** = 180 mL/min, QUF*** = 2 L/h	QB** = 200 mL/min, QUF*** = 2 L/h	91 mmHg	60 mmHg	--
QB** = 250 mL/min, QUF*** = 2 L/h	QB** = 300 mL/min, QUF*** = 2 L/h		73 mmHg	51 mmHg
QB** = 400 mL/min, QUF*** = 2 L/h	QB** = 400 mL/min, QUF*** = 2 L/h		105 mmHg	64 mmHg
QB** = 450 mL/min, QUF*** = 2L/h	QB** = 450 mL/min, QUF*** = 2 L/h			70 mmHg
Sieving coefficient	**篩濾係數**			
(bovine plasma, Cp 60 g/l, 37°C)	(牛血漿, Cp 60 g/L, 溫度 37° C)			
QB** = 100 mL/min, QUF*** = 20 mL/min	QB** = 100 mL/min, QUF*** = 20 ml/min			
- Urea	- 尿素	1		
- Creatinine	- 肌酸酐	1		
- Vitamin B12	- 維生素 B12	1		
- Inulin	- 菊糖	0.95		
- Myoglobin	- 肌紅蛋白	0.55		
- Albumin	- 白蛋白	<0.01		

≠ Typical mean values obtained from laboratory testing of post-sterilization sample lots. Results may vary depending on patient and clinical conditions.
由實驗室測試滅菌後樣品所得之平均值。 視病人及臨床狀況而定，結果可能不同。

GENERAL DATA / 一般資料

	PRISMAFLEX M60 SET	PRISMAFLEX M100 SET	PRISMAFLEX M150 SET
Weight / 重量	780 g	800 g	860 g
Overall dimensions / 整體尺寸			
lenght / 長度	27 cm	27 cm	27 cm
width / 寬度	22 cm	22 cm	22 cm
height / 高度	9 cm	9 cm	9 cm
Blood volume in set / 套組中的血液容積	93 mL	152 mL	189 mL

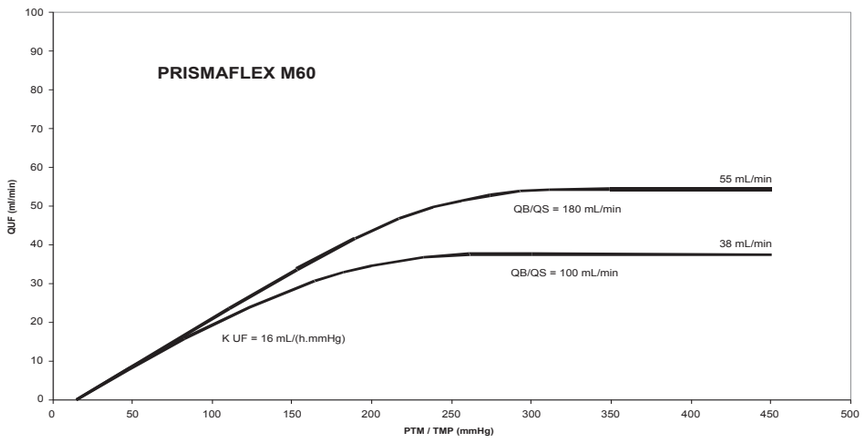
FILTER OPERATING SPECIFICATIONS
過濾器操作規格

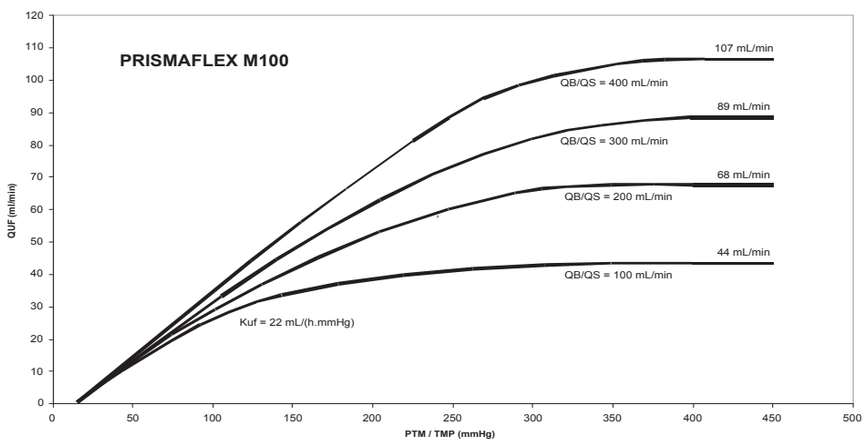
	PRISMAFLEX M60 SET	PRISMAFLEX M100 SET	PRISMAFLEX M150 SET
Maximum TMP* / 最高	450 mmHg 60 kPa		
Maximum blood pressure / 最高血壓	500 mmHg 66,6 kPa		
Minimum blood flow rate / 最低血液流速	50 mL/min	75 mL/min	100 mL/min

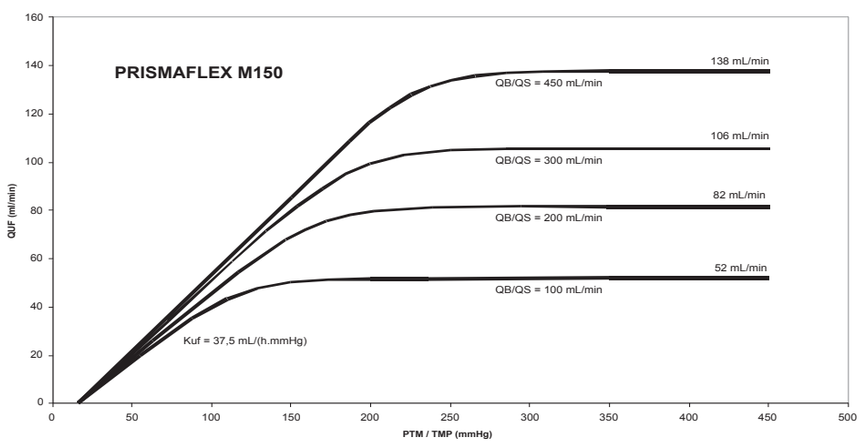
		PRISMAFLEX M60 SET QB/QS** = 100 mL/min QUF*** = 0 mL/min			PRISMAFLEX M100 SET QB/QS**= 150 mL/min QUF*** = 0 mL/min				PRISMAFLEX M150 SET QB/QS**= 200 mL/min QUF*** = 0 mL/min			
QD******	(L/h)	1	2,5	4	1	2,5	4	8	1	2,5	4	8
	(mL/min)	17	42	67	17	42	67	133	17	42	67	133
Urea / 尿素	(±10%)	17	39	54	17	41	63	95	17	42	66	117
Vit B12 / 維生素 B12	(±20%)	14	23	28	16	30	37	45	17	37	49	64
Inulin / 菊糖	(±20%)	12	17	19	14	23	26	30	16	31	37	45

CVVHD CLEARANCES
CVVHD 廓清率
(Continuous veno-venous hemodialysis) Clearances versus inlet dialysate flow rate (37°C)
(連續性靜脈-靜脈血液透析) 廓清率比入口透析液流速 (37°C)

* Transmembrane pressure / 跨膜壓
** Arterial blood flow rate / **動脈血液流速**
*** Ultrafiltration flow rate (on PRISMA system, the ultrafiltration flow rate = fluid removal flow rate + replacement flow rate) / 超過濾流速 (在 PRISMA 系統上，超過濾流速 = 液體清除流速 + 置換液流速) /
**** Hematocrit / 血容積比
***** Protein concentration / 蛋白浓度
****** Dialysate flow rate / 透析液流率





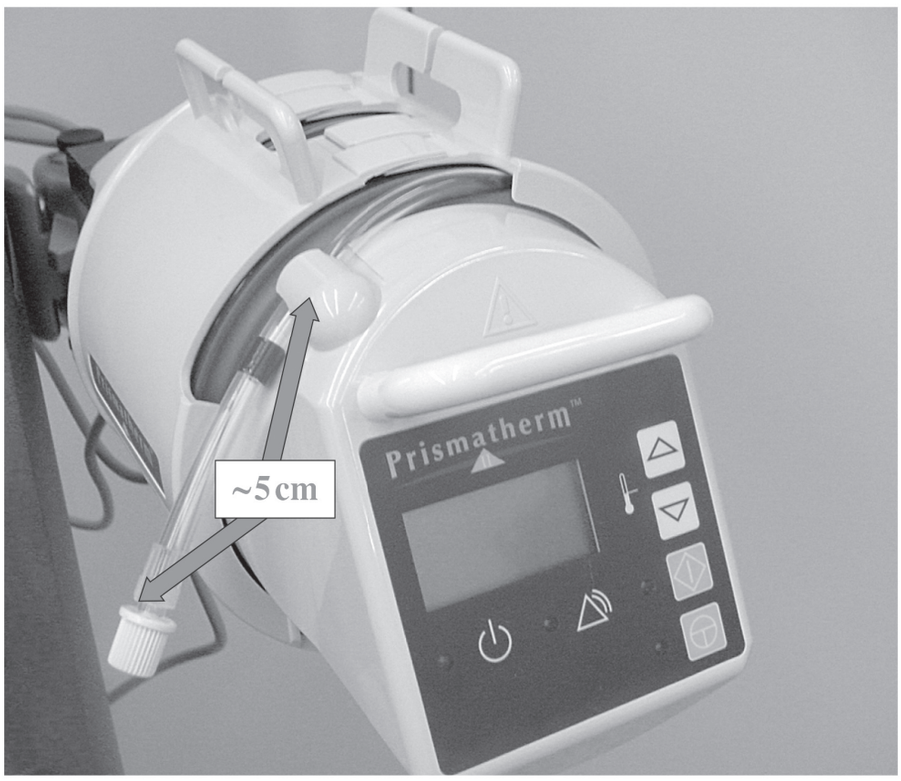


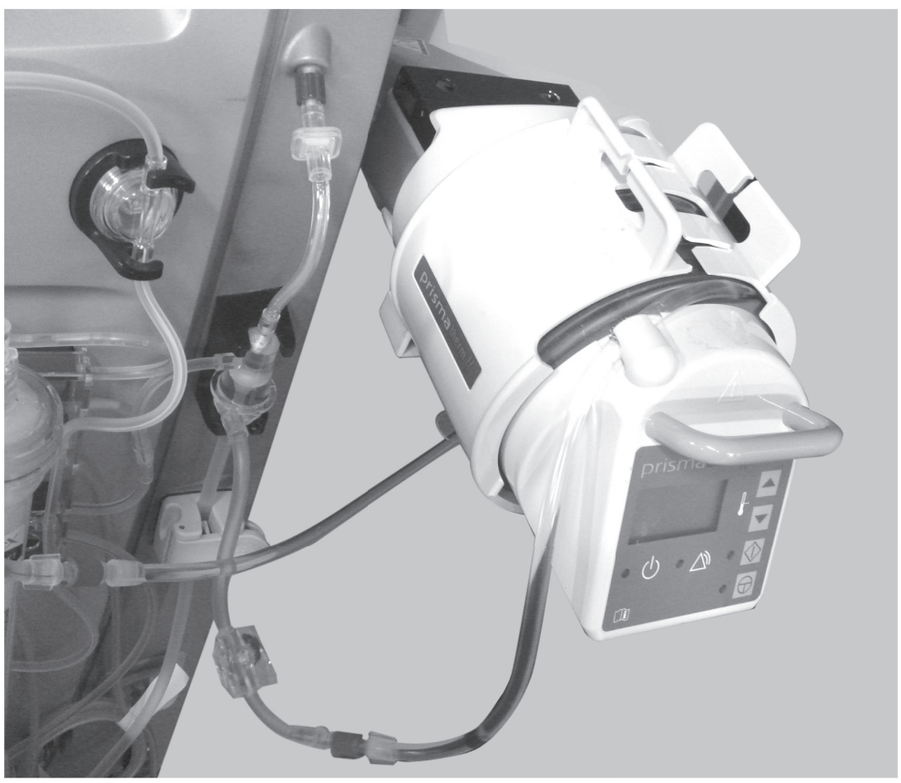
"In vitro" ultrafiltration with blood (values ± 15%).
(Bovine blood at 37°C, Hct 32 %, Protein concentration 60 g/L).
Ultrafiltration is controlled by the PRISMAFLEX System and is independent of the ultrafiltration coefficicent (KUF).

「體外」血液超過濾 (數值 ±15 %).
(37°C 牛血，Hct 32 %，蛋白質濃度 60 g/L).
超過濾係由 PRISMAFLEX 系統控制，與超過濾係數 (KUF) 無關

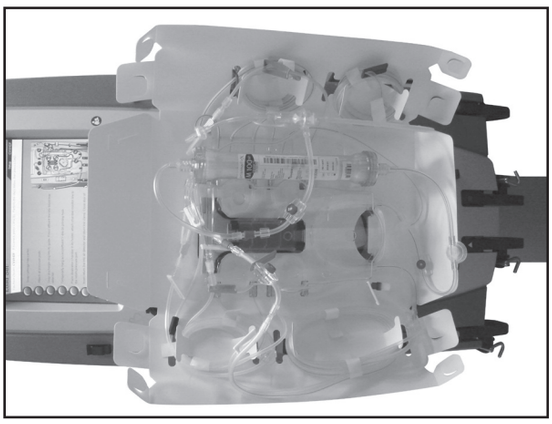
Prismatherm

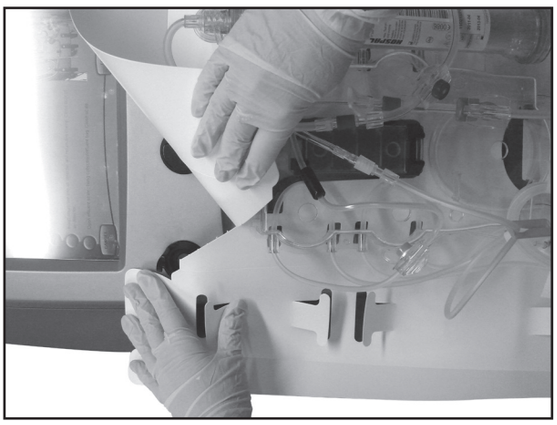
SP420 line connexion

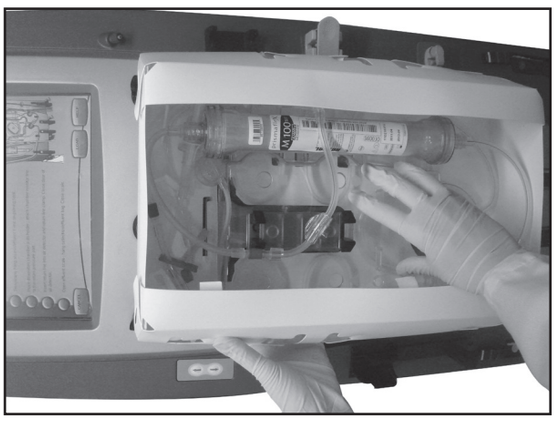


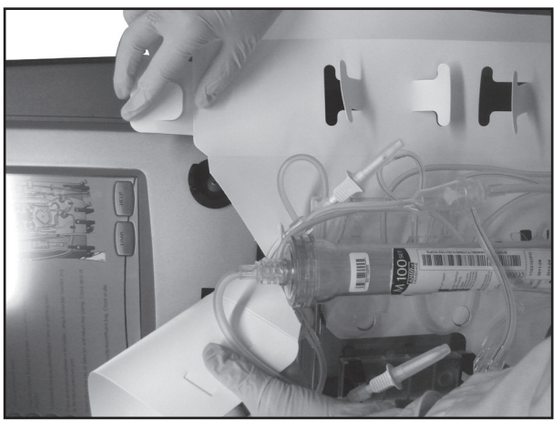


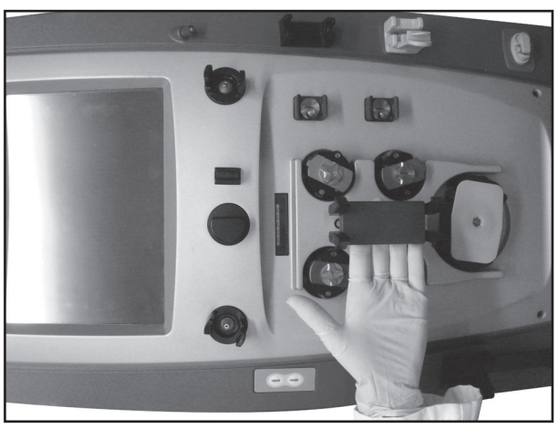
INSTALL SET DIRECTLY ONTO prismaflex MONITOR

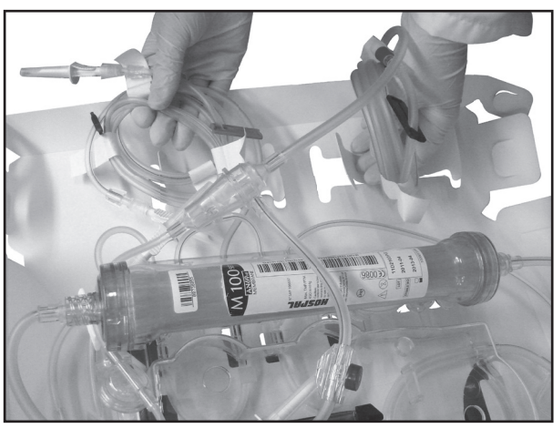


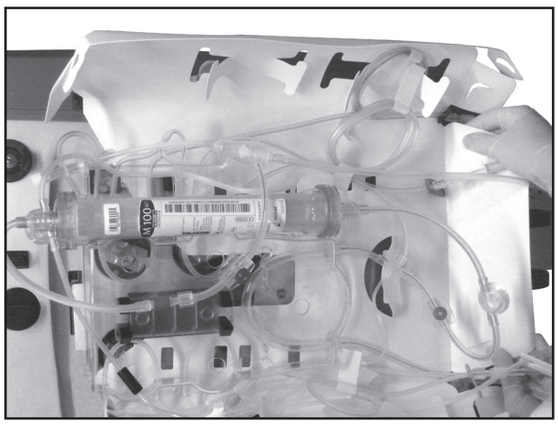


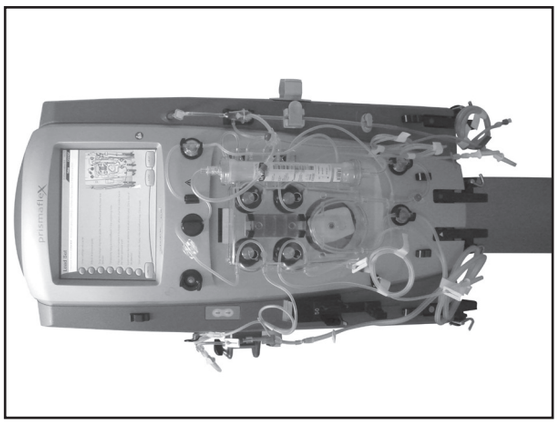


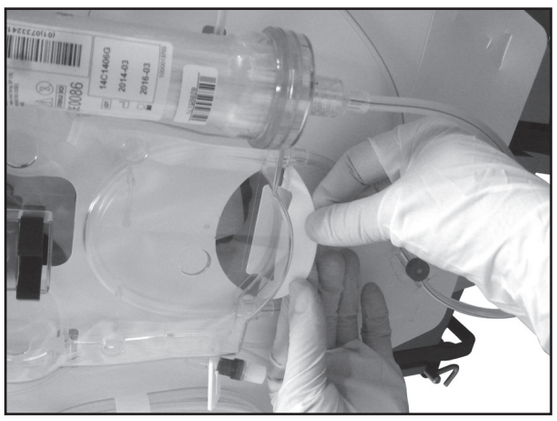


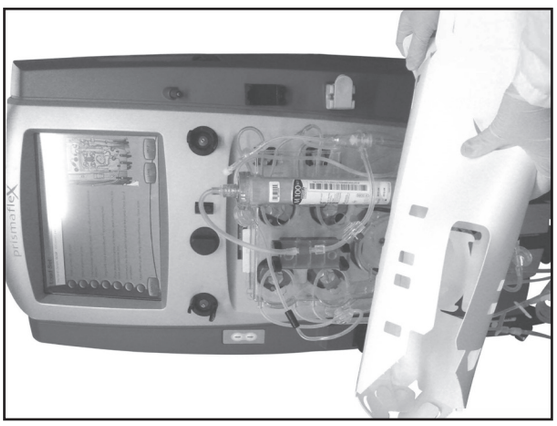












Patented ready to use PrismaFlex set packaging.