



Prismaflex ST Set

Emergency Use Authorization for the United States

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

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

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

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

Intended Use for Patients with COVID-19

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

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

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

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

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

Additional Product Information for the United States

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

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

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

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

prismaflex

ST60 SET / ST100 SET / ST150 SET

AN69ST
MEMBRANE

eng Instructions for use
kor 사용 지침

REF 115308

REF 115309

REF 115310

Made in France

CE 2797

Date of Revision: 2019-12-01



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











Baxter



Blood warmer connection (blue)
혈액가온기 연결부(파란색)

| | | |
|-------|--------------------------|----|
| ◆ eng | English..... | 5 |
| ◆ kor | 한국어..... | 9 |
| | Installation guide | 16 |

DEFINITION OF SYMBOLS

| SYMBOL GRAPHIC & REF NUM / 기호 그래픽 및 참조 번호 | TITLE AND NUMBER OF STANDARD / 이름 및 표준 번호 | ENGLISH | | 한국어 | |
|---|---|---------------------------------------|--|--------------------------------|---|
| | | SYMBOL TITLE | SYMBOL DESCRIPTION (EXPLANATORY TEXT) | 기호 이름 | 기호 설명 (설명문) |
| 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. | 제조사 | 현재 이름으로 시중에 출시되기 전 장치의 설계, 제조, 포장, 라벨 표기 등에 책임이 있는 자연인 또는 법인을 가리키는 의료 장치 제조사를 나타냅니다. |
| 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. | 제조일자 | 의료 장치를 제조한 날짜입니다. YYYY-MM-DD의 형식입니다. |
| 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 | 사용기한 | 이 날짜 이후에 의료 장치를 사용해서는 안 됩니다. YYYY-MM-DD의 형식입니다. |
| 5.1.5  | ISO 15223-1 ¹ | Batch code | Indicates the manufacturer's batch code. Synonyms are "lot number" and "batch number" | 배치 코드 | 제조사의 배치 코드입니다. "로트 번호", "배치 번호"와 같은 말입니다. |
| 5.1.6  | ISO 15223-1 ¹ | Catalogue number | Indicates the manufacturer's catalog number. Synonyms are "reference number" and "reorder number" | 카탈로그 번호 | 제조사의 카탈로그 번호입니다. "참조 번호", "재주문 번호"와 같은 말입니다. |
| 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. | 무균 수액 경로 | 의료 장치의 외부를 비롯한 다른 부분은 무균 상태가 아닐 수도 있지만 장치 내에 무균 수액 경로가 존재한다는 의미입니다. 살균 방법을 빈 상자에 적절하게 명시해야 합니다. |
| 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. | 포장 손상 시 사용 금지 | 포장이 손상되거나 열려 있는 경우 사용하면 안 되는 의료 기기를 뜻합니다. |
| 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. | 깨지기 쉬우므로 주의 요함 | 주의해서 다루지 않으면 깨지거나 손상될 수 있는 의료 기기를 뜻합니다. |
| 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. | 건조한 곳에 보관 또는 비 맞지 않도록 주의 | 습기로부터 보호해야 하는 의료 장치라는 의미입니다. 또는 비를 맞지 않도록 주의해야 하는 의료 장치라는 의미입니다. |
| 5.3.7  | ISO 15223-1 ¹ | Temperature Limit | Indicates the temperature limits to which the medical device can be safely exposed. | 온도 제한 | 의료 장치를 노출해도 안전한 온도 제한입니다. |
| 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 not re-use" are "single use" and "use only once". | 재사용 금지 | 한 번만 사용해야 하거나 환자 한 명의 단일 처치에 사용해야 하는 의료 장치를 나타냅니다. "재사용 금지"는 "일회용" 및 "한 번만 사용"과 같은 말입니다. |
| 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. | 주의 | 다양한 이유로 의료 장치 자체에 명기되지 않은 경고 및 지침과 같은 중요한 주의 정보에 대하여 사용자가 사용 지침을 숙지해야 함을 나타냅니다. |
|  | 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 | 그린 도트 기호 | 해당 제품의 제조업체가 회수 및 재활용 비용을 부담함을 나타냅니다. |
| 0623  | ISO 7000 ² | This way up | Indicates the correct, upright position of the package | 이 쪽을 위로 | 포장을 올바르게 세우는 방향을 나타냅니다. |
| 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". | 사용 지침 참고 | 한다는 의미입니다. "사용 지침 참고"는 "조작 지침 참고"와 같은 말입니다. |

¹ISO 15223-1:2016 Medical Devices - Symbols to be used with medical device labels, labelling and information to be supplied Part 1: General Requirements / 의료 장치 - 의료 장치 라벨, 라벨링 및 정보에 사용하는 기호는 파트 1:

²ISO 7000 Graphical symbols for use on equipment - Registered symbols / 장비에 사용되는 그래픽 기호 - 등록 기호

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

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

DEFINITION OF EXPRESSIONS USED IN THIS MANUAL

In this document :

⚠ **“Warning”** 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 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.

PRODUCT DESCRIPTION

- The **PRISMAFLEX ST60 / ST100 / ST150 Set** is a disposable, extracorporeal circuit for use with the **PRISMAFLEX System**.
- The **PRISMAFLEX ST60 / ST100 / ST150 Set** consists of a AN69 ST 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 ST60 / ST100 / ST150 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 extracorporeal blood volume (see General Characteristics).

The **PRISMAFLEX ST60 Set** should be restricted to patients with a body weight greater than 11kg (24lb). Refer to **PRISMAFLEX operator’s manual** for any additional weight restrictions that might apply.

The **PRISMAFLEX ST100 Set** and **ST150 Set** 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 re-sterilize. The **PRISMAFLEX ST** is intended for single use only. Re-using the **PRISMAFLEX ST** 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 1 000 mL priming solution [saline or alkaline solution (pH \geq 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. Once priming is complete the Set's blood circuit will still contain heparinised saline solution. Depending on the level of the patient's bleeding risk the physician must decide if an additional priming using 500 mL **non heparinised** saline solution is necessary.
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. 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 via the **PRISMAFLEX** ST60 / ST100 / ST150 Set, **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.

SPECIFICATIONS

See Tables at end of document.

SET MATERIALS

| | |
|----------------------|---|
| AN69 ST hollow fiber | : Acrylonitrile and sodium methallyl sulfonate copolymer + Polyethylene Imine (surface treatment agent) |
| Housing and headers | : Polycarbonate |
| Potting compound | : Polyurethane |
| Tubing material | : Plasticized polyvinyl chloride (PVC) |
| Cartridge | : 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 \geq 7.3) with added 5000IU Unfractionated heparin/liter] (**correctly homogenised**) 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.

Note : in order to gain full benefit from the AN69ST in terms of improvement of hemocompatibility, it is recommended to add 5000IU of **unfractionated heparin** per liter of priming/rinsing solution. This procedure allows the adsorption of active heparin onto the AN69ST before the start of extracorporeal circulation. Consequently, the systemic anticoagulation strategy during treatment will be adapted with respect to patient specificity. In the cases where priming/rinsing **without** addition of unfractionated heparin, we recommend infusing the loading dose of heparin to the patient 2 to 5 minutes before connection to the filter.

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. Notably it is possible 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.

GENERAL DATA / 일반 데이터

| | PRISMAFLEX | | |
|---------------------------------------|------------|-----------|-----------|
| | ST60 SET | ST100 SET | ST150 SET |
| Weight / 무게 | 795 g | 830 g | 905 g |
| Overall dimensions / 전체 크기 | | | |
| length / 길이 | 27 cm | 27 cm | 27 cm |
| width / 너비 | 22 cm | 22 cm | 22 cm |
| height / 높이 | 9 cm | 9 cm | 9 cm |
| Blood volume in set / 세트의 혈액량 (± 10%) | 93 mL | 152 mL | 189 mL |

FILTER OPERATING SPECIFICATIONS

필터 작동 사양

| | PRISMAFLEX | | |
|----------------------------------|----------------------|------------|------------|
| | ST60 SET | ST100 SET | ST150 SET |
| Maximum TMP* / 최대 TMP* | 450 mmHg 60 kPa | | |
| Maximum blood pressure / 최대 혈압 | 500 mmHg 66,6 kPa | | |
| Minimum blood flow rate / 최소 혈류량 | 50 mL/min | 75 mL/min | 100 mL/min |
| Maximum blood flow rate / 최대 혈압 | 180 mL/min | 400 mL/min | 450 mL/min |

| | | PRISMAFLEX ST60 SET | | | PRISMAFLEX ST100 SET | | | | PRISMAFLEX ST150 SET | | | |
|-------------------|----------|---|-----|----|----------------------|---|----|-----|----------------------|---|----|-----|
| | | QB/QS** = 100 mL/min QUF*** = 0 mL/min | | | | QB/QS** = 150 mL/min QUF*** = 0 mL/min | | | | 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 / 요소 | (± 10%) | 17 | 40 | 56 | 17 | 41 | 63 | 97 | 17 | 42 | 66 | 117 |
| Vit B12 / 비타민 B12 | (± 20%) | 15 | 26 | 30 | 16 | 32 | 41 | 50 | 17 | 38 | 51 | 68 |
| Inulin / 이눌린 | (± 20%) | 13 | 19 | 22 | 15 | 26 | 30 | 35 | 16 | 33 | 40 | 49 |

CVVHD CLEARANCES

(Continuous veno-venous hemodialysis) Clearances versus inlet dialysate flow rate (37°C)

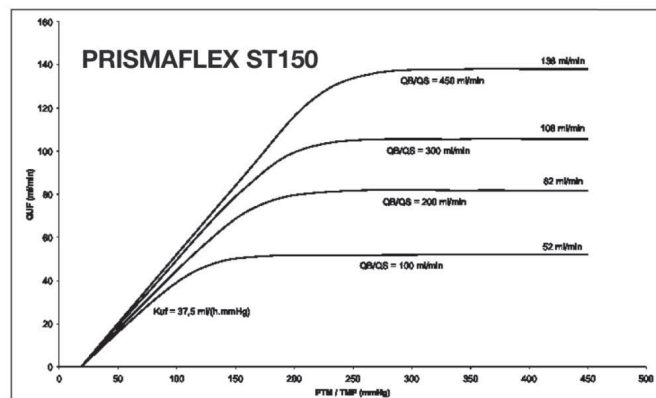
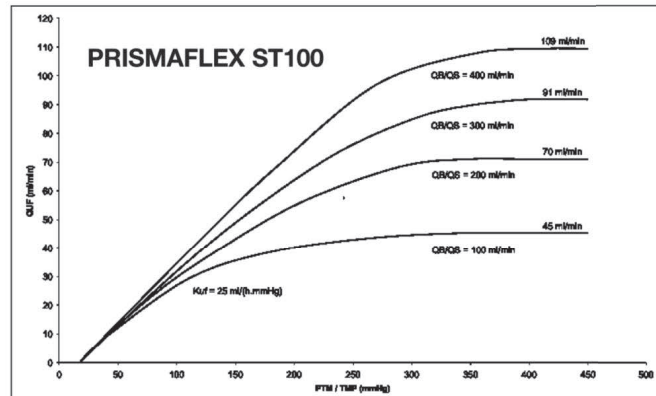
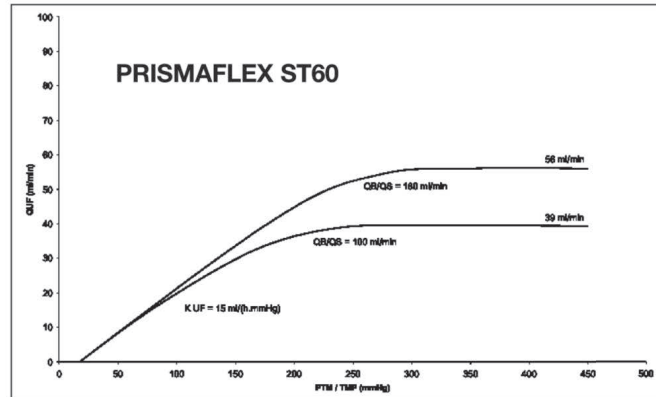
CVVHD 제거율

(지속적 정정맥 혈액 투석) 유입 투석액 유속(37°C)에 대한 제거율

- * Transmembrane pressure / 막투과압
- ** Arterial blood flow rate / 동맥 혈류량
- *** Ultrafiltration flow rate (on PRISMAFLEX system, the ultrafiltration flow rate = fluid removal flow rate + replacement flow rate + pre blood pump flow rate) / 초여과 유속(PRISMAFLEX 시스템에서 초여과 유속 = 수분 제거율 + 대체용액 유속)
- **** Hematocrit / 헤마토크릿
- ***** Protein concentration / 단백질 농도
- ***** Dialysate flow rate / 투석액 유속

| FILTER DATA | 필터 데이터 | PRISMAFLEX ST60 SET | PRISMAFLEX ST100 SET | PRISMAFLEX ST150 SET |
|--|--|------------------------------|---|--|
| NOMINAL PHYSICAL CHARACTERISTICS Effective surface area Fiber internal diameter (wet) Fiber wall thickness | 공칭 물리적 특성 유효 표면적 섬유 내부 직경 섬유 벽 두께 | 0.6 m ² | 1 m ² | 1.5 m ² |
| IN VITRO PERFORMANCES ≠ Blood priming volume | 시험관 내 성능 ≠ 혈액 프라이밍 용량 | 44 mL ± 10 % | 69 mL ± 10 % | 105 mL ± 10 % |
| Blood pressure drop (post dilution) (bovine blood, Htc****32%, Cp***** 60 g/L, 37°C) QB** = 100 mL/min, QUF*** = 1 L/h QB** = 180 mL/min, QUF*** = 2 L/h QB** = 300 mL/min, QUF*** = 2 L/h QB** = 400 mL/min, QUF*** = 2 L/h | 혈압 강하 (후희석) (소 혈액, Htc****32%, Cp***** 60g/L, 37°C) QB** = 100 mL/min, QUF*** = 1 L/h QB** = 180 mL/min, QUF*** = 2 L/h QB** = 300 mL/min, QUF*** = 2 L/h QB** = 400 mL/min, QUF*** = 2 L/h | ± 20 % 46 mmHg 84 mmHg | ± 20 % 31 mmHg 55 mmHg 79 mmHg 100 mmHg | ± 20 % 20 mmHg - 51 mmHg 64 mmHg |
| Sieving coefficient (bovine plasma, Cp 60 g/L, 37°C) QB/QS** = 100 mL/min, QUF*** = 20 mL/min - Urea - Vitamin B12 - Inulin - Myoglobin - Albumin | Sieving 계수 (소 혈장, Cp 60 g/L, 37°C) QB/QS** = 100 mL/min, QUF*** = 20 mL/min - 요소 - 비타민 B12 - 이눌린 - 미오글로빈 - 알부민 | | 1 1 0.96 0.58 < 0.01 | |

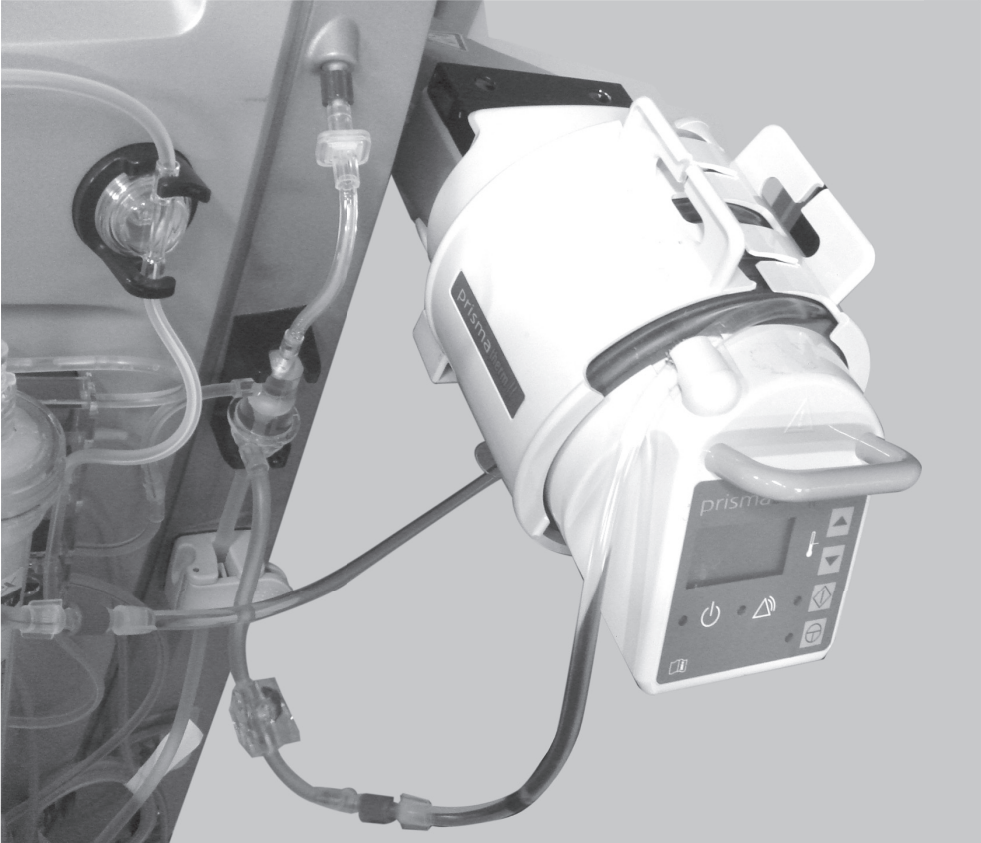
≠ Typical mean values obtained from laboratory testing of post-sterilization sample lots. Results may vary depending on patient and clinical conditions. /
 평균 이후의 샘플 로트에 대한 실험실 테스트를 통해 확인한 일반적인 평균값입니다. 결과는 환자 및 임상적 조건에 따라 달라질 수 있습니다.



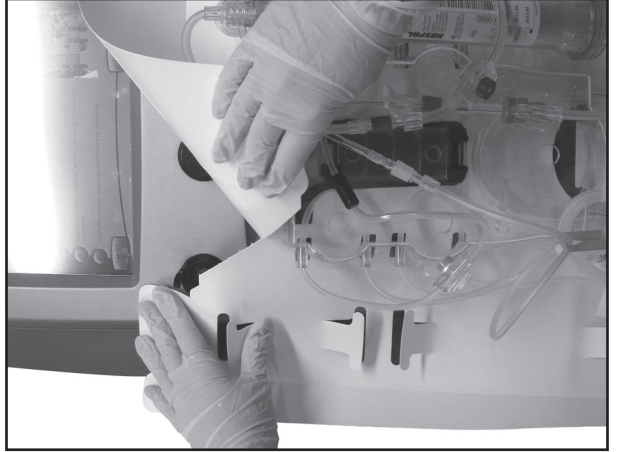
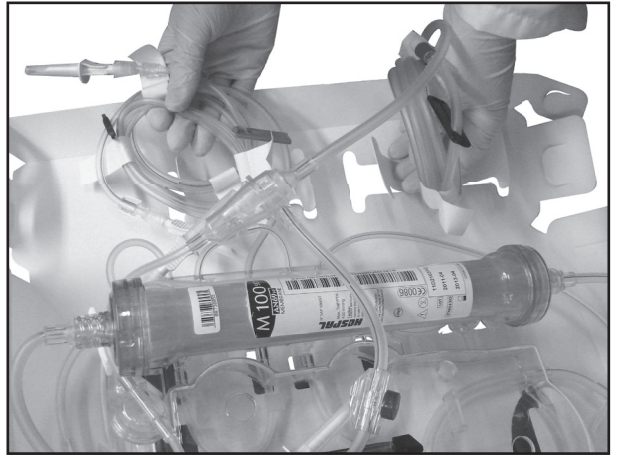
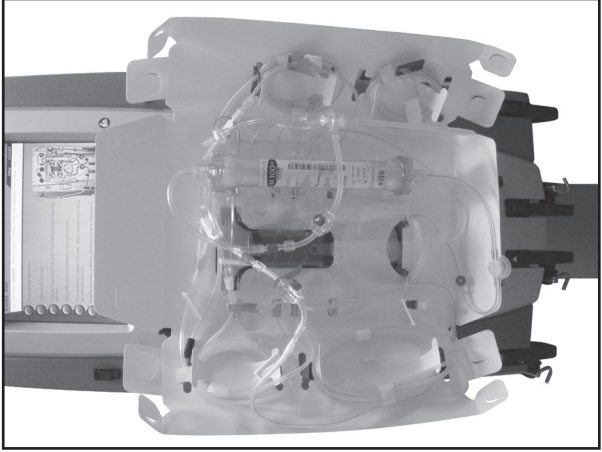
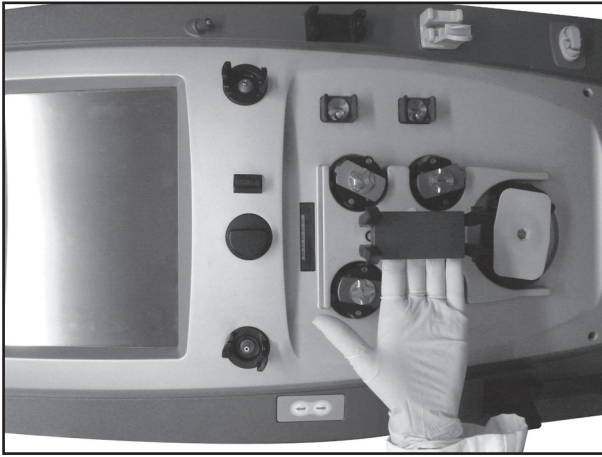
"In vitro" ultrafiltration with blood (values \pm 20 %).
 (Bovine blood at 37°C, Hct 32 %, Protein concentration 60 g/L).
 Ultrafiltration is controlled by the PRISMAFLEX System and is independent of the ultrafiltration coefficient (KUF).
 "시험관 내" 혈액 초여과 (값 20%).
 (소 혈액, 37°C, Hct 32%, 단백질 농도 60g/L).
 초여과는 PRISMAFLEX 시스템에서 제어되며 초여과 계수(KUF)의 영향을 받지 않습니다.

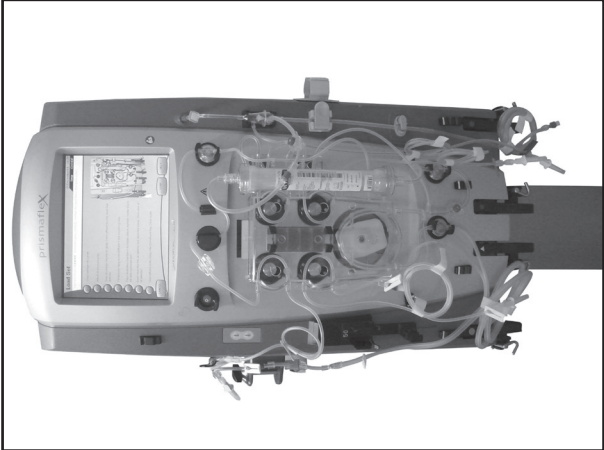
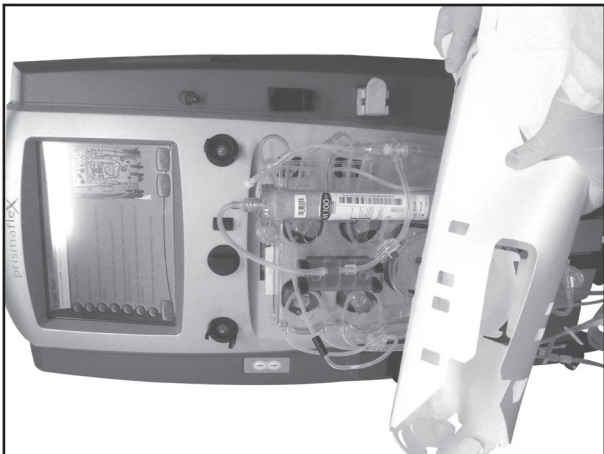
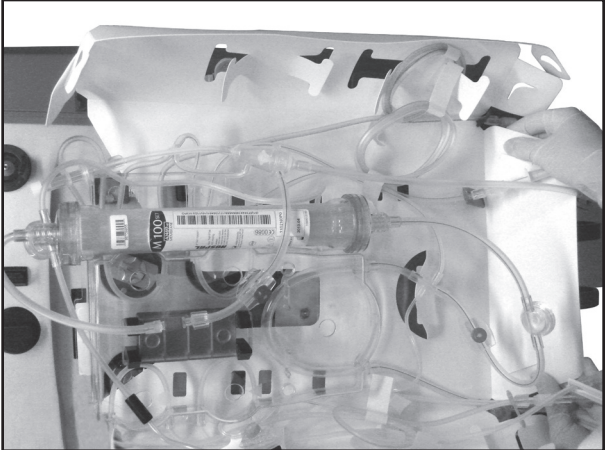
Prismatherm

SP420 line connexion



INSTALL SET DIRECTLY ONTO **Prismaflex** **MONITOR**





Patented ready to use PrismaFlex set packaging.

