# Medical Device/Equipment **ALERT**

**Ref. MDEA(NI)2007/12**

**Issued: 7 February 2007**

**For:**

| | |
|---|---|
| IMMEDIATE ACTION | |
| **ACTION** | ✓ |
| UPDATE | |
| INFORMATION REQUEST | ✓ |

HEALTH ESTATES
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| | Section |
|---|---|
| **Medical Device/Equipment:**<br>Intensive care continuous renal replacement system: Gambro Prismaflex Model Number 6023014700. All serial numbers. | ► ① |
| **Problem:**<br>There have been reports of discrepancies between the flow rate set by the user (as displayed on the 'Enter Flow Rate' screen) and the resulting flow rate (as displayed in the 'Status' screen).<br>A software upgrade was issued to correct this flow rate problem, however **there is still a risk of flow rate discrepancies occurring after the software is upgraded.** | ► ② |
| **Action by:**<br>Intensive care staff, renal physicians, maintenance and engineering staff. | ► ③ |
| **Action:**<br>**Ensure systems are in place for users to:**<br>• be aware that the Prismaflex system may be affected by flow discrepancies, requiring vigilance whilst using this equipment<br>• check that the displayed flow rate value is the set flow rate. If a problem is found, follow the manufacturer's instructions, as described in the Appendix. | ► ④ |
| **Distributed by NIAIC to:**<br>Chief Executive of each HSS Board<br>Chief Executive of each HSS Trust<br>Chief Executive of each Agency<br>NIAIC Liaison Officers | ► ⑤ |
| **Contacts**<br>Details of manufacturer contacts and MHRA contacts for technical aspects. | ► ⑥ |
| **Feedback Requirements to NIAIC**<br>Report problems, such as discrepancies in flow rate, whilst using the Prismaflex system to the NI Adverse Incident Centre (NIAIC). | ► ⑦ |

**This Alert is on our web site: http://www.dhsspsni.gov.uk/niaic**

# 1. DEVICE/EQUIPMENT:

Intensive care continuous renal replacement system: Gambro Prismaflex Model Number 6023014700. All serial numbers.

# 2. PROBLEM:

There have been reports of discrepancies between the flow rate set by the user (as displayed on the 'Enter Flow Rate' screen) and the resulting flow rate (as displayed in the 'Status' screen). A software upgrade was issued to correct this flow rate problem, however there is still a risk of flow rate discrepancies occurring after the software is upgraded.

Gambro is also aware of a number of other problems that can affect the operation of this equipment and are implementing a number of hardware and software corrective actions.

The MHRA has been made aware of a number of problems which may affect the operation of the Prismaflex machine. Gambro has issued Advisory Notices 014, 015, 016B and 017 concerning these problems between June and December 2006:

- Misreading of scale (Notice 014, issued June 2006)
- Risk of air/fluid infusion via blood access lines (Notice 014, issued June 2006)
- Scale calibration (Notice 015, issued Aug 2006)
- Discrepancies in flow rate (Notice 017, issued Dec 2006)
- Occurrence of 'frozen screen' displays (Notice 017, issued Dec 2006)
- Improved protection against rough handling/redesigned scale handle (Notice 016B, issued Dec 2006)
- Potential lifetime limitation of blood pump rotor (Notice 016B, issued Dec 2006)
- Replacement of air bubble detectors (Notice 016B, issued Dec 2006)
- Risk of uncontrolled emptying of heparin syringe (Notice 016B, issued Dec 2006)

Gambro has implemented the following corrective actions:

a) Software upgrade (version 3.00) which should significantly decrease the likelihood of flow discrepancy and frozen screen occurrence affecting the operation of this device.

b) Hardware modifications which include: introduction of a side wings kit, replacement of scales, replacement of blood pump rotor, replacement of air bubble detector and updating the current version of syringe holder to incorporate a new plunger holder.

**There is still a risk of flow rate discrepancies even after the software is upgraded.** A further software upgrade is planned to rectify the problem.

# 3. ACTION BY:

Intensive care staff, renal physicians, maintenance and engineering staff.

# 4. ACTION:

**Ensure systems are in place for users to:**

- be aware that the Prismaflex system may be affected by flow discrepancies, requiring vigilance whilst using this equipment
- check that the displayed flow rate value is the set flow rate. If a problem is found, follow the manufacturer's instructions, as described in the Appendix.
- report problems, such as discrepancies in flow rate, whilst using the Prismaflex system to the NIAIC Adverse Incident Centre.

**Maintenance and engineering staff should:**

- check that the corrective actions in Gambro Advisory Notices 14, 15, 16B and 17 have been implemented by Gambro on the affected devices.
- contact Gambro to arrange for corrective actions to be carried out.

## 5. ONWARD DISTRIBUTION TO:

Please bring this notice to the attention of all who need to know or be aware of it. This will include distribution to:

- Adult intensive care units
- Anaesthetists
- Biomedical engineering staff
- Clinical governance leads
- EBME departments
- Haematologists
- Haemodialysis nurses
- Haemodialysis units
- Health and safety managers
- Independent Health and Social Care Providers – Private Clinics & Hospitals through RQIA
- Intensive care medical staff/paediatrics
- Intensive care nursing staff (adult)
- Intensive care nursing staff (paediatric)
- Intensive care units
- Intensive care, directors of
- Maintenance staff
- Medical directors
- Nurse managers (dialysis units)
- Nurse managers (ITUs)
- Nursing directors
- Paediatric dialysis units
- Paediatric intensive care units
- Purchasing managers
- Renal medicine departments
- Renal medicine, directors of
- Renal technicians
- Renal units
- Risk managers

## 6. CONTACTS:

Enquires to manufacturer should be addressed to:

Jenny Shaw
Intensive Care Business Manager
Gambro Hospal Ltd
Ermine Business Park
Huntingdon
PE29 6XX

Tel: 07970 217 974
E-mail: jenny.shaw@gambro.com

Enquires to NIAIC should quote reference number MDEA(NI)2007/12 and be addressed to:
Northern Ireland Adverse Incident Centre (NIAIC)
Health Estates
Estate Policy Directorate
Stoney Road
Dundonald
Belfast BT16 1US

Tel: 028 9052 3868
Fax: 028 9052 3900
Email: NIAIC@dhsspsni.gov.uk

## 7. FEEDBACK:

Report problems, such as discrepancies in flow rate, whilst using the Prismaflex system to the NI Adverse Incident Centre (NIAIC).

Robert Sergeant
NIAIC Operational Manager

**HOW TO REPORT ADVERSE INCIDENTS**

Adverse Incidents relating to medical devices, non-medical equipment, plant and buildings should be reported to NIAIC as soon as possible. Advice on how to report is given in MDEA(NI)2006/01. If you are in doubt about how to report incidents, please speak to your liaison officer or contact NIAIC using the telephone number provided. Adverse Incident reporting forms and an on-line reporting facility are available on the NIAIC website at www.dhsspsni.gov.uk/niaic

***Heath Estates is an Executive Agency of the Department of Health, Social Services and Public Safety***

GAMBRO

URGENT

**Voluntary Medical Device Advisory Notice**
**Concerning the Gambro Prismaflex™ Continuous Renal Replacement System – All Serial Numbers**

Dear Valued Customer

Gambro wishes to advise users of the Gambro Prismaflex Continuous Renal Replacement System – all models, of an important issue in relation to its use. This action is intended to ensure that all users of the equipment will receive this important information.

**Flow Rate Discrepancies**
The issuing of Software (SW) version 3.00 has rectified all then-known causes of flow rate discrepancies. Gambro is now aware of a specific circumstance when it is still possible to experience a flow rate discrepancy. However, the user, through a series of actions described in the below "Procedure to Remove a Flow Rate Discrepancy" can quickly and safely clear these discrepancies without interrupting patient treatment.

**Instructions**
Gambro has initiated corrective action to provide longer term an update of the SW to rectify this situation. Whilst this SW is in development and validation, the below "Procedure to Remove a Flow Rate Discrepancy" which is intended to aid users in addressing any flow rate discrepancy that may be observed, must be amended to the Operator's Manual for Prismaflex. Additionally, please continue to advise Gambro whenever a flow rate discrepancy is seen.

Please place the attached labels on the cover of the Prismaflex Operator's Manual and the "Procedure to Remove a Flow Rate Discrepancy" inside of the cover.

MHRA is aware of the publication of this Advisory Notice.

Gambro apologizes for any inconvenience this may cause and request you share this notice with all Prismaflex users at your facility. If you have any questions, please call your local Gambro representative.

Lund 2007-02-01

Sincerely,

Nils-Åke Lindberg
Quality & Regulatory Manager
Gambro Lundia AB

Doc.ID: AN019

GAMBRO

## Procedure to Remove a Flow Rate Discrepancy

The following label containing this information must be placed at the bottom of the front cover of the Prismaflex Operator's Manual.

**Procedure to Remove a Flow Rate Discrepancy**

A definition of flow rate discrepancy and information on how to remove a flow rate discrepancy has been attached to the inside of the cover of this manual.

Spare Part Order Number: G5025401

The following label containing this information must be placed on the inside of the cover of the Prismaflex Operator's Manual.

### Procedure to Remove a Flow Rate Discrepancy

#### Definition of a Flow Rate Discrepancy

A flow rate discrepancy is when any flow rate displayed on the Status Screen differs from that displayed on the Enter Flow Rate Screen.

#### Alarms Generated by Larger Flow Rate Discrepancies

Flow rate discrepancies beyond certain limits will be detected by the Prismaflex machine such that alarms will be generated:

- For Blood Pump Rate discrepancies Malfunction: Blood Pump Rate alarms will occur
- For Syringe Pump Rate discrepancies Malfunction: Syringe Pump Rate alarms will occur
- For discrepancies on the four fluid pumps: Caution: Weight Change alarms may occur

Therefore should any of these alarms occur;

- Malfunction: Blood Pump Rate
- Malfunction: Syringe Pump rate
- Caution: PBP, Replacement, Dialysate, or Effluent Weight

Initially use the on screen instructions to troubleshoot the alarm, however if this does not create a resolution, check for a flow rate discrepancy by comparing the Status screen and the Enter Flow Rates screen.

#### How to Remove a Flow Rate Discrepancy

1. On the Status screen, press the Flow Rates button to enter the Enter Flow Rates screen.
2. On the Enter Flow Rates screen, select the flow rate that contains misleading information.
3. For a discrepancy on the syringe flow rate, press the Syringe Pump button and select the type of delivery being used.
4. Press the Down Arrow to reduce the affected flow to a minimum.
5. After reaching the minimum flow, press the Down Arrow another five or more times.*
6. Press the Enter button to return to the Status screen.
7. Verify that the flow rate displayed on the Status screen matches the flow rate displayed on the Enter Flow Rates screen at the minimum value.
8. If the flow rate is not yet aligned, repeat steps 1 to 7.
9. As soon as Status and Enter Flow Rate Screens are aligned, reset the flow to its original value, as prescribed by a physician, and check that the displayed flows are aligned.

* Larger discrepancies may require more than five presses on the down arrow to align the Status and Enter Flow Rate screens. Entering too many down arrows is not a concern.

Spare Part Order Number: G5025401

Doc.ID: AN019