Attachment A: Baxter Dialysis Machines – Operator's Manual Excerpts

Product Family	Operator's Manual Excerpts
AK 95 S	When connecting the blood access to the extracorporeal circuit, the operator must ensure that the air detector is activated and the connections between the blood access and blood lines are tightly secured. Also make sure there is no leakage. **WARNING** Blood loss or air embolism may be caused if the connection between the extracorporeal circuit and the patient access (e.g. needles or catheters) is not tightly secured. **CAUTION** 1. The AK 95 S has been tested and validated for use with the concentrates, accessories, and disposables specified above. 2. Gambro does not accept any responsibility or liability for use of concentrates, accessories or disposables other than those specified above. Depending on the circumstances, use of concentrates, accessories or disposables other than those specified above may also reduce Gambro's warranties for the AK 95 S.
AK 200 S and AK 200 ULTRA S	To avoid blood loss to the environment it is essential to ensure that all connections in the extracorporeal blood circuit are tight and secured, that the fistula needle is correctly positioned and secured and that the low alarm limit is set as close as possible to the working venous pressure. A visual monitoring by the user/operator is recommended. **CAUTION** The AK 200 ULTRA S dialysis machine has been tested and validated for use with the concentrates, accessories and disposables specified above. Gambro does not accept responsibility or liability for use of concentrates, accessories or disposables other than those specified above. Depending on the circumstances, use of concentrates, accessories or disposables other than those specified above may also reduce Gambro's warranties for the AK 200 ULTRA S.
AK 96	**Connect the Patient** When connecting the blood access to the extracorporeal circuit, the operator must ensure that the air detector is activated and the connections between the blood access and blood lines are tightly secured. Also make sure there is no leakage. **WARNING** Blood loss or air embolism may be caused if the connection between the extracorporeal circuit and the patient access (e.g. needles or catheters) is not tightly secured. **CAUTION** The AK 96 dialysis machine has been tested and validated for use with the concentrates, chemical disinfectants, accessories, and disposables specified as follows. Gambro does not accept responsibility or liability for use of concentrates, chemical disinfectants, accessories, or disposables other than those specified as follows. Depending on the circumstances, use of concentrates, chemical disinfectants, accessories, or disposables other than those specified may also reduce Gambro's warranties for the AK 96 dialysis machine. Observe the manufacturer's instructions for use regarding single use of blood lines and dialyzers.

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AK 98	**4.2.12 Connect the patient** **Before you begin** **WARNING!** Check that the blood lines and the patient accesses (needles or catheters) are tightly connected. If not, the patient could suffer from blood loss or air embolism. **1.2.2 Responsibility and disclaimer** The manufacturer accepts responsibility for the safety, reliability, and performance of this equipment only if the following conditions are fulfilled: • Installation, operational procedures, maintenance, calibrations and repairs are carried out by appropriately trained and suitable qualified people. • All equipment modifications are authorised in writing by the manufacturer and carried out by appropriately trained and suitable qualified people. • The electrical installation of the relevant room complies with all applicable local electrical codes and, if applicable, IEC requirements. • The equipment is used in accordance with the published operator's manual. Baxter does not accept any responsibility or liability for use of accessories or disposables other than those specified in this manual or if any specified accessory or disposable is not used in accordance with this manual, online instructions and the instructions for use accompanying those accessories and disposables. The patient's physician is responsible for counselling, home care follow-up and medical maintenance that comes with the treatment. Baxter has no responsibility for any of these activities. **WARNING!** Hazard for blood loss to the environment may remain when the machine has issued alarms regarding venous needle dislodgement, arterial needle dislodgement or blood pump stop time expired. Check the position of the venous needle and arterial needle. Check blood lines and restart the blood pump when it can be done safely. **WARNING!** Under certain circumstances the patient may suffer from blood loss, without the venous pressure passing any alarm limit. To avoid this, make sure that the blood circuit and the needle are correctly connected, tight and secure and that the low alarm limit is set as close as possible to the actual venous pressure.
Phoenix/ Innova	**Intended Use** **WARNING** This manual contains a number of references to accessories and disposables for use with the Phoenix machine. The Phoenix machine has been tested and validated for use with the accessories and disposables listed in this manual. The Manufacturer has not validated the use of accessories or disposables other than those specified in this manual. The Manufacturer does not assume responsibility or liability for use of accessories or disposable other than those specified in this manual. It is the responsibility of the user to validate that other accessories or disposables provide safe and effective performance.

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	5.2.2 Load the Cartridge Blood Set **WARNING** Improper connections of the extracorporeal circuit may cause potential patient safety hazards, that might not be detected by the machine: for instance, hemolysis caused by kinks, twists, loops, sharp bends, clamps or other restrictions on the blood line, blood loss to the environment/air into the blood circuit due to leakage in the extracorporeal circuit. **1.7 Monitoring of Venous Pressure and Venous Needle Dislodgment** **WARNING** Monitoring of the Venous Pressure could not always detect the disconnection of a venous needle from its access site, which may result in extracorporeal blood loss to the environment. When a venous needle disconnects from its access, pressure at the venous monitoring side may only decrease by the pressure maintained within the patient's access site. This pressure drop may be less than the width of the machine's venous pressure alarm window: in this particular case the disconnection of a venous needle from its access site is not detectable by the machine, even if pressure alarms and alarm windows are properly set. To reduce the risk of needles disconnection: • ensure that venous needle and line are firmly secured to the access site area according to your clinic's protocol; • ensure that the patient's access is visible at all times during the dialysis treatment; • inspect frequently the patient's access; • adjust properly the venous pressure alarm window: the venous pressure alarm lower limit should be set as closely as practical to the actual patient's venous pressure value without generating excessive nuisance alarms.
Integra	**Introduction** **Note** This manual contains a number of references to concentrates, disposables, accessories and spare parts for use with INTEGRA. INTEGRA has been tested and validated for use with concentrates, disposables, accessories and spare parts listed in this manual. The Manufacturer does not accept responsibility or liability for use of concentrates, disposables or accessories other than those specified in this manual, for use of not genuine spare parts and for use/mounting of those components not in accordance with the official Gambro/Hospal Instruction for Use accompanying those components. Depending on the circumstances, use of concentrates, disposables or accessories other than those specified in this manual, use of not genuine spare parts and use/mounting of those components not in accordance with the above mentioned Instruction for Use may reduce the Manufacturer's warranties for the INTEGRA Hemodialysis System. **Treatment** **WARNING** The user is responsible for the correct mounting, connection and use of the proper disposables. **WARNING** Check that the blood circuits are correctly mounted. Carefully check the blood lines in order to guarantee that no kinks, clamps or other restrictions are present. Check, moreover, that the connections are carried out properly.

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	WARNING Monitoring of the Venous Pressure could not always detect the disconnection of a venous needle from its access site, which may result in extracorporeal blood loss to the environment. When a venous needle disconnects from its access, pressure at the venous monitoring side may only decrease by the pressure maintained within the patient's access site. This pressure drop may be less than the width of the machine's venous pressure alarm window: in this particular case the disconnection of a venous needle from its access site is not detectable by the machine, even if pressure alarms and alarm windows are properly set. To reduce the risk of needles disconnection, ensure that needles are firmly secured to the access site area.
Artis/ Evosys/ Artis Physio Plus	**Chapter: Introduction** **Concentrate, Accessories and Disposables accessories** **WARNING** The Artis Dialysis System has been tested and validated for use with the concentrates, accessories and disposable listed above. Gambro does not accept any responsibility or liability for use of concentrates, accessories and disposables other than those specified above. The use of different kinds of concentrates, accessories and disposables may reduce Gambro's warranties for the Artis Dialysis System. **Chapter 2.5 Extracorporeal circuit preparation** **WARNING** Improper connections of the extracorporeal circuit may cause potential safety hazards, that might not be detected by the machine: for instance, hemolysis caused by kinks, clamps, too thin cannulas or other restrictions on the lines, blood loss to the environment/air into the blood circuit due to a leakage in the extracorporeal circuit. **Chapter 3.3 Start Treatment** **Note** In all dialysis systems air can enter the circuit during the treatment. In order to minimize the risk of this occurring there are good practices that can be followed, they include: • Making sure all connections are made securely; • Ensuring all clamps that should be closed, are closed; • Ensuring all caps are tightened; • Ensuring the correct amount of priming fluid is available; • Ensuring the correct priming volume for the dialyzer used is set; • Ensuring that the dialyzer is not turned during the priming process; • Avoiding the use of solutions in glass bottles; • Check that the pressure transducers are properly greased. **Chapter 1: General description** **WARNING** Monitoring of the Venous Pressure could not always detect the disconnection of a venous needle from its access site, which may result in extracorporeal blood loss to the environment. When a venous needle disconnects from its access, pressure at the venous monitoring side may only decrease by the pressure maintained within the patient's vascular access. This pressure drop may be less than the width of the machine's venous pressure alarm window: in this particular case the disconnection of a venous needle from its access site is not detectable by the machine, even if pressure alarms and alarm windows are properly set. To reduce the risk of needles disconnection:

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	• ensure that venous needle and line are firmly secured to the access site area according to your clinic's protocol; • ensure that the patient's access is visible at all times during the dialysis treatment; • inspect frequently the patient's access; • adjust properly the venous pressure alarm window: the venous pressure alarm lower limit should be set as closely as practical to the actual patient's venous pressure value without generating excessive nuisance alarms. **Chapter 3, 4, 5: General description** **WARNING** During patient connection/disconnection, follow your facility's policies and procedures for managing patient's vascular access and Venous and Arterial Patient lines used for hemodialysis. The use of central venous catheters with atrial location leads to additional hazardous situations with respect to the other types of vascular access, due to their proximity to the heart. In particular, if the patient's catheter disconnects from the patient lines or the integrity of the catheter is compromised in any other way, follow your facility's policy for preventing air embolism and infection, including clamping the patient's lines immediately.