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- 12) Angina/chest pain: The procedure should be stopped and medical therapy instituted at the discretion of the physician. If the angina persists, the procedure should be terminated.
- 13) Fainting/lightheadedness: See hypotension.
- 14) Anemia: May be minimized by the appropriate use of iron supplements.
- 15) Prolonged bleeding (at cannulation site after removing venous cannulae): Direct manual pressure should be applied until the bleeding stops. If prolonged bleeding occurs (in excess of 20 minutes), adjustment of the heparin dosing may be necessary. It is recommended that, during the subsequent procedure, the heparin dose be reduced and monitored by Activated Clotting Time (ACT). Repetitive LDL apheresis treatment may affect the patient's clotting time. Therefore, a periodic check, of other relevant coagulation parameters is recommended, including the number of thrombocytes and the fibrinogen concentration, in order to ensure that these parameters are sufficient to maintain adequate coagulation.
- 16) Hemolysis: as evidenced by discoloration of plasma or hemolysis as Indicated by activation of the blood leak detector alarm of the MA-03. If either indicator of hemolysis occurs, the procedure should be terminated and the patient's hematocrit, urine output and kidney function monitored.
- 17) Device malfunction: The system contains various components, including LDL adsorption columns (2), plasma separator, tubing system, and an electronic control unit. System malfunction may occur due to any of these components. If system malfunction occurs, the patient's vital signs and clinical status should be monitored immediately and repeatedly. It may be necessary to suspend treatment if the patient develops symptoms or if the problem cannot be readily solved.
- 18) Vertigo
- 19) Diaphoresis
- 20) Urticaria: Mild discomfort may occur requiring supportive care. Vital signs and physical examination of the patient are required in order to assess if urticaria is a component of a more severe, generalized reaction to the therapy. Specific associated symptoms, including, but not limited to, difficulty breathing, chest pain, and dizziness should be addressed by the physician.
- 21) Shivering
- 22) Headaches