

## LIPOSORBER<sup>®</sup> LA-15 System Facts

The Liposorber LA-15 System is used for performing low-density lipoprotein cholesterol (LDL-C) apheresis to acutely remove LDL-C from patient plasma. It is comprised of a tubing set, a hollow fiber plasma separator (Sulflux KP-05) and two dextran sulfate LDL-adsorption columns, all of which are disposable and intended for single use only. The MA-03 is the computer-controlled machine that controls the entire LDL-Apheresis procedure.

### Indications of Use

The Liposorber LA-15 System is approved by FDA and is indicated for use in to acutely remove LDL-C from the plasma of the following high-risk patient populations for whom diet has been ineffective and maximum drug therapy has either been ineffective or not tolerated:

Patients with LDL-C  $\geq$  300 mg/dl or

Patients with LDL-C  $\geq$  200 mg/dl with documented coronary heart disease (CHD).

The LDL-C levels for the indicated patient populations are baseline LDL-C levels obtained after the patient has had, at a minimum, a six-month trial of an American Heart Association (AHA) Step II diet (or equivalent) and maximum tolerated combination drug therapy designed to reduce LDL-C.

### Recommendations

#### Treatment Frequency:

Patients with LDL-C between 200 mg/dL and 300 mg/dL: Every other week.

Patients with LDL-C greater than 300 mg/dL: Weekly.

#### Treatment Volume:

The Liposorber LA-15 System Operator's Manual provides a calculation for determining the treatment volume, using the patient's sex, height, weight and hematocrit. Approximately 1.5 plasma volumes are treated.

#### Anticoagulation:

Heparin is the only anticoagulant recommended for use with the Liposorber System. The system is primed with heparinized Lactated Ringer's Injection, USP (3,000 USP units). At the beginning of the treatment the patient is given a "loading dose" of heparin and the MA-03 is then set to give a continuous infusion of heparin throughout the treatment. The requesting physician determines these dosages (usually 30–60 USP units of heparin per kilogram of body weight).

## Operational Overview

The patient's blood is withdrawn via a venous access and enters the plasma separator. As blood is pumped through the hollow fibers in the plasma separator, plasma is separated and exits from the plasma outlet. The remaining blood, including red and white blood cells and platelets, exits from the blood outlet. The cell-free plasma is pumped into one of the two LDL adsorption columns. As the plasma passes through the column, the apolipoprotein B-containing lipoproteins — LDL, VLDL, and Lp(a) — are selectively adsorbed in the column. There is minimal effect on high-density lipoprotein cholesterol (HDL-C), IgG, albumin or other plasma components. The LDL-depleted plasma exits the column, passes through a membrane filter and is recombined with the blood cells originally exiting the plasma separator. This recombined blood and plasma flows through a built-in blood warmer and is returned to the patient via a second venous access.

When the first column has completed adsorbing LDL, the computer-regulated machine automatically switches the plasma flow to the second column to continue LDL adsorption. Simultaneously, the plasma remaining in the first column is returned to the patient. The first column is regenerated using 5% Sodium Chloride Injection USP, eluting the LDL, VLDL and Lp(a). When elution is completed and flushed through the waste lines to a waste bag, the column is reprimed completely and ready for the next cycle of adsorption, allowing continuous LDL apheresis. No additional fluids are given to the patient during these column switch overs and only the treated plasma is returned. A typical procedure takes about three hours.

## The LIPOSORBER® LA-15 System

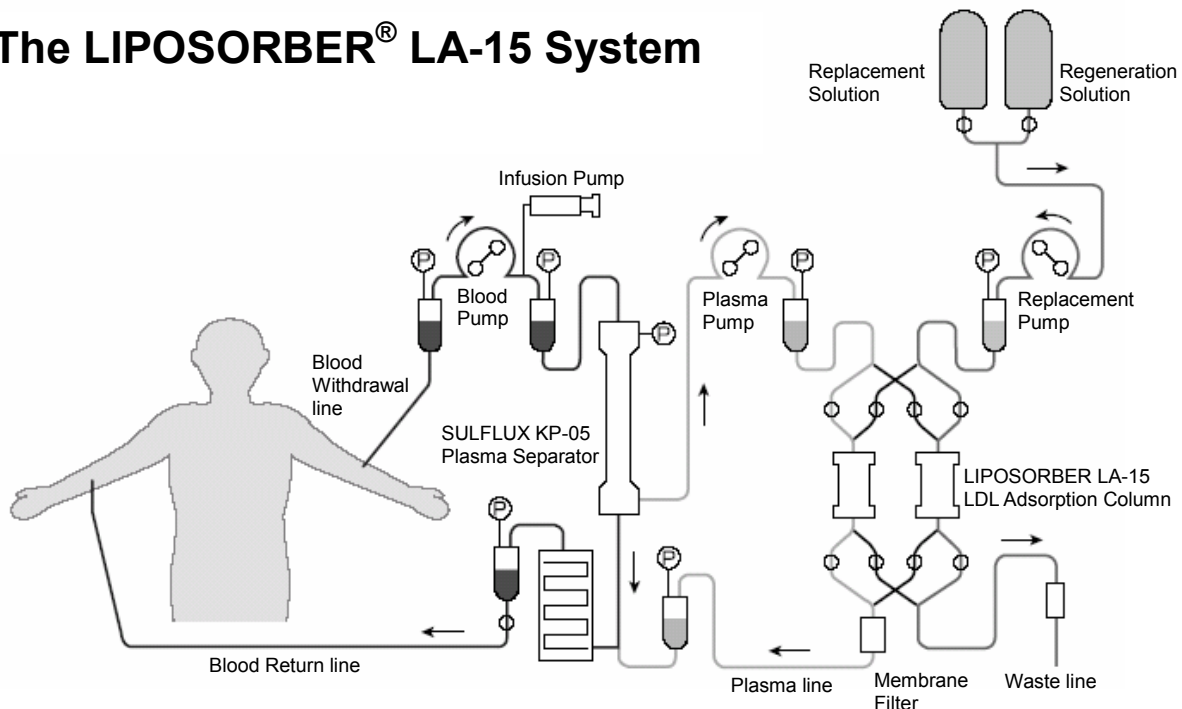


Figure A. LIPOSORBER® LA-15 System overview.

## Specifications

Extracorporeal volume = approx. 400 ml (170 ml blood, 230 ml plasma)  
Plasma volume treated = approx. 1.5 plasma volumes  
Treatment time = 2 - 4 hours  
LDL-C acute reduction = 73 - 83%

## Machine settings (MA-03)

Possible treated volume = 0 ~ 20,000 mL plasma  
Whole blood flow rate = 7 ~ 200 mL/min  
Plasma flow rate = 5 ~ 70 mL/min  
Plasma/whole blood ratio = 0 ~ 40%  
Heparin infusion rate = 0 ~ 10.0 mL/hr  
Blood warmer temp = 35° - 39° C

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