

FloPump™ 32 Centrifugal Pump

The FloPump™ 32 is a non-occlusive extracorporeal centrifugal pump.

The FloPump™ 32 is a ruby suspension, magnetically-centered centrifugal pump intended to be used in conjunction with the Maquet® Rotaflow™ pump system. The FloPump™ 32 is for single-use, competitively priced, and equivalent to the Rotaflow.™

Low Hemolysis

This type of pump has an advanced parallel cone rotor connected by airfoil segments which gently pump the incoming blood to the outlet port. Hemolysis is very low, and in a recent study, the Rotaflow™ was found to be equivalent to hemolysis with the Centrimag™ pump¹. The FloPump™ 32 is equivalent to the Rotaflow.™

Those authors concluded;

“From our investigation, there is no difference between the CMAG (CentriMag™) and the RF (Rotaflow™) blood pumps with regards to the creation of hemolysis during ECMO. The difference in cost of the devices does not correlate with the performance and outcomes.”

Features and Benefits

Priming Volume: ~32ml

Flow Rate: 0 – 7 l/min

Maximum Outlet Pressure (mmHg): 750

Connector: 3/8”



Indications:

The FloPump™ 32 Centrifugal Pump is an extracorporeal circuit pump for procedures lasting less than 6 hours for the purpose of providing either:

- Full or partial cardiopulmonary bypass (i.e., circuit includes an oxygenator) during open surgical procedures on the heart or great vessels; or
- Temporary circulatory bypass for diversion of flow around a planned disruption of the circulatory pathway necessary for open surgical procedures on the aorta or vena cava.

Part Numbers:

Catalog Number	Description
6400S	FloPump™ 32, Sterile, Case of 12

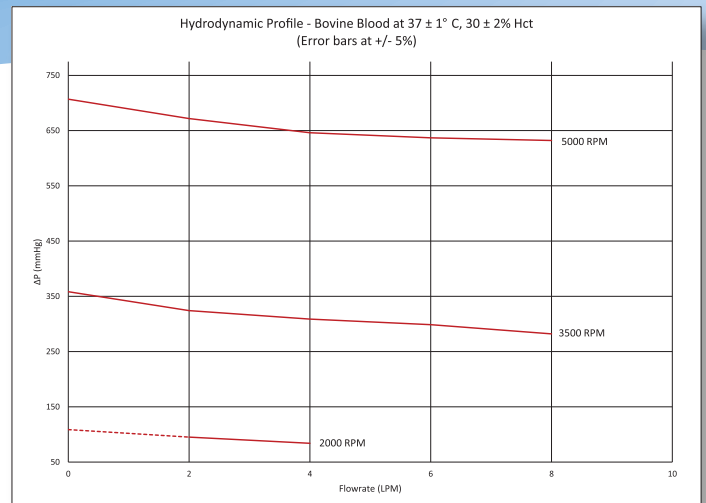
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¹Palanzo, D, et al, “Comparison of Hemolysis Between CentriMag and RotaFlow Rotary Blood Pumps During Extracorporeal Membrane Oxygenation” Artificial Organs, (2013) 37:9, pp E162-166

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Hydrodynamics:

The hydrodynamic performance was measured using bovine blood, 37°C, Hct 30. The drive console was set to various speeds and the outflow tubing occluded to produce varied output. Results from multiple samples from multiple lots were averaged and shown in the table.



Performance:

Hemolysis: Hemolysis testing was performed using bovine blood according to ASTM F1841 on multiple samples from multiple lots, using various back pressures and flow rates. The Modified Index of Hemolysis (MIH) showed that the FloPump™ 32 MIH was 8.2 mg/mg, identical to the predicate device. In a separate clinical study, Rotaflow™ hemolysis was found to equivalent to the CentriMag™ pump¹.

Flow Sensor Output:

The flow sensor output reading was compared to a calibrated flow meter. The accuracy at 2, 4, 6 and 8 LPM was within ± 7%, the accuracy specification given by the pump console.

Reliability:

Multiple samples from multiple lots were subjected to runs of 24 hours under worst-case conditions. After 24 hours, pumps were torn down and inspected, all critical criteria revealed that all pumps met or exceeded the specifications after rigorous testing.

Packaging:

The device is packaged sterile and pyrogen-free.

Storage:

The device must be stored in a cool, dark and dry place until use.

Additional test results are available, contact OriGen.

The FloPump™ 32 is FDA 510K cleared.

The FloPump™ 32 is manufactured in the USA by International Biophysics Corporation.

OriGen
BIOMEDICAL

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