FloPump 32 by International Biophysics Corporation

Executive Summary Testing Report

This report is confidential and available only by specific request

BACKGROUND

The purpose of this executive summary is to describe the testing performed to validate the International Biophysics Corporation (IBC) FloPump™ 32 for use with Maquet ROTAFLOW™ Pump Console. The IBC FloPump 32 is indicated for use and compatible with the Maquet ROTAFLOW pump console, no adapter is needed.

The IBC FloPump 32 is manufactured in an FDA-registered and ISO 13485 certified facility located in Austin, TX. The FloPump 32 is CE-marked and FDA cleared (K170029).

TEST RESULTS

Extensive internal and third-party validation testing has been performed on the IBC FloPump 32 to validate the performance of the product compared to the Maquet Rotaflow centrifugal pump.

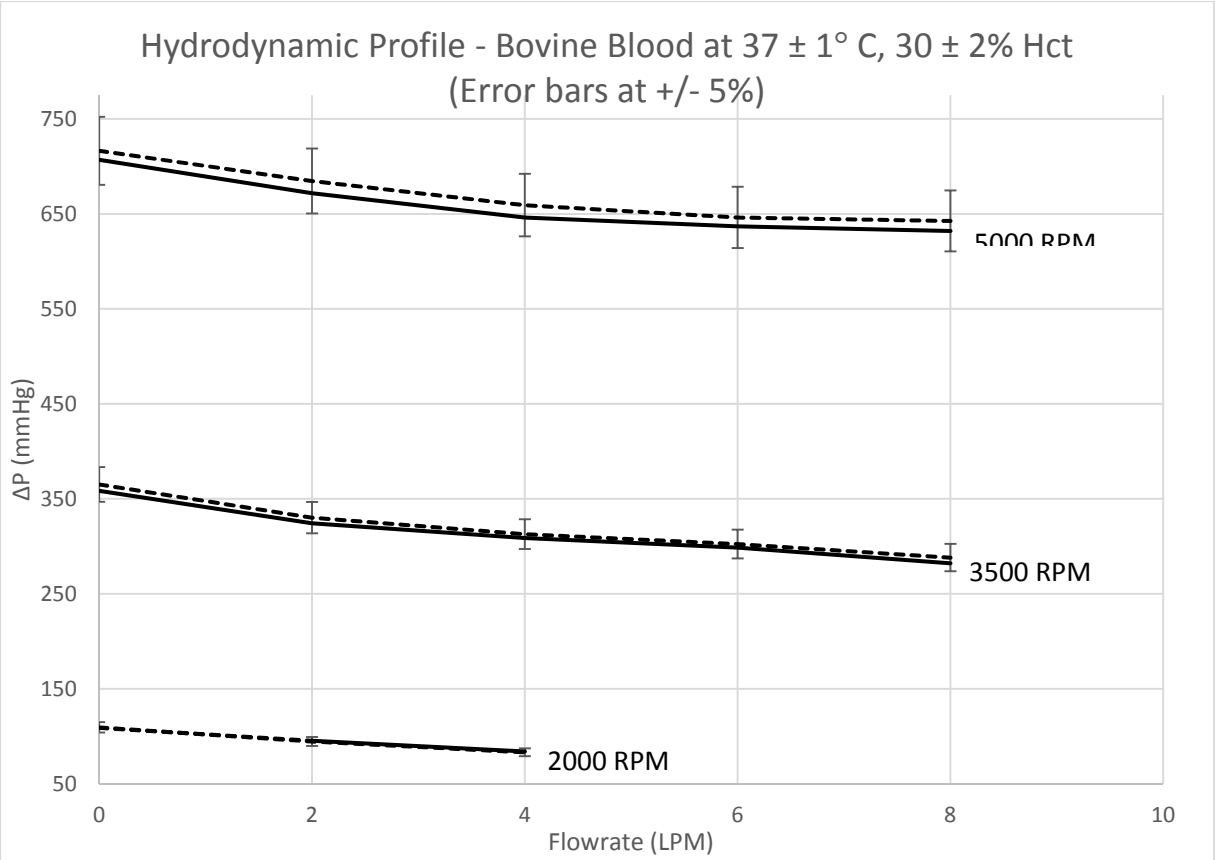
A summary of the testing performed and results are included below

Prime Volume

Prime volume of the IBC FloPump 32 and the Maquet Rotaflow centrifugal pump are both approximately 32 ml. Testing was performed on multiple samples and lots of each product using a calibrated high-precision gram scale in a laboratory setting. Variation was negligible.

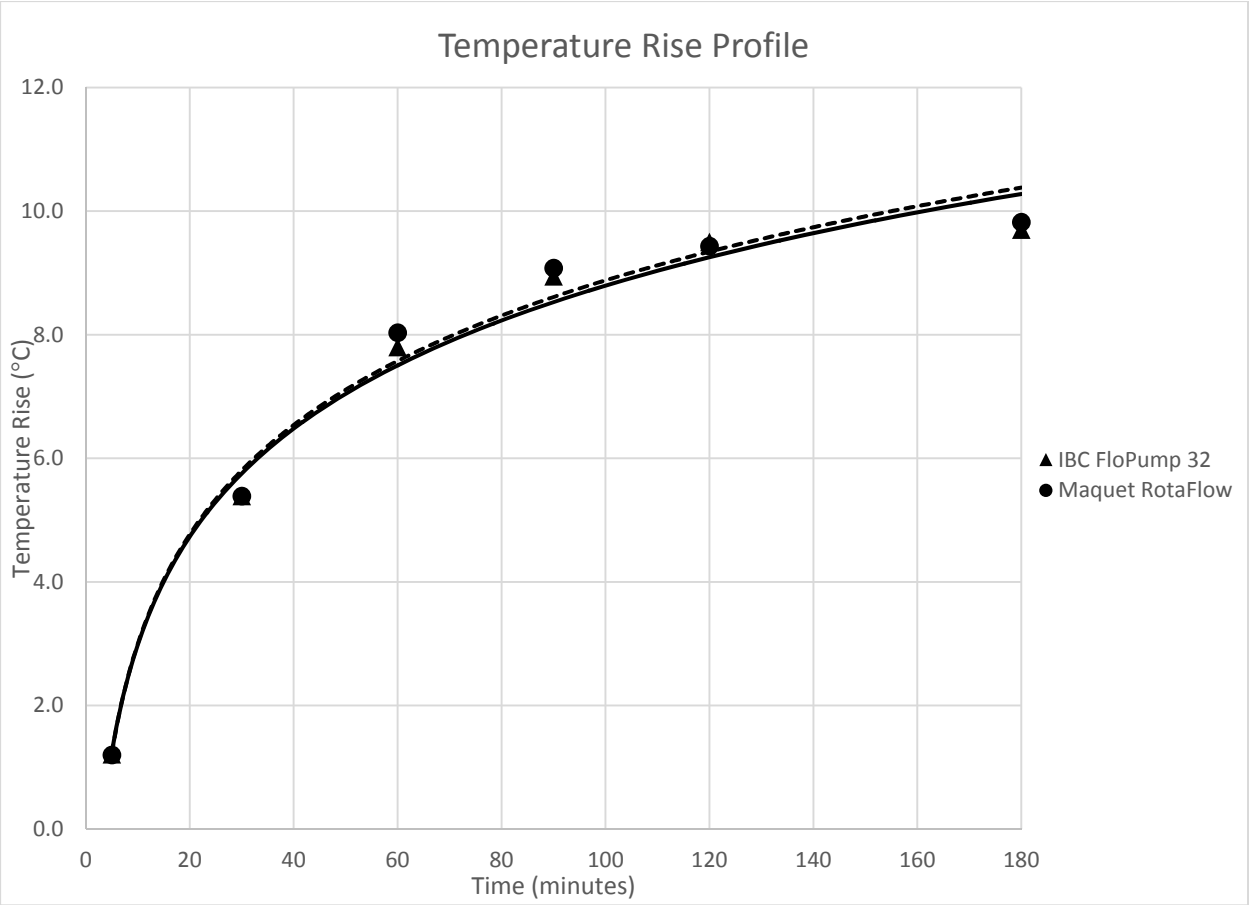
2101 E St Elmo Rd Bldg 2 #275 Austin, TX 78744
P: 512-326-3244 E: info@biophysicscorp.com
www.biophysicscorp.com

Flow Hydrodynamics



The hydrodynamic profiles of the FloPump 32 and Maquet Rotaflow centrifugal pump were compared using bovine blood in a laboratory setting. The console was set to various speeds and the resulting flow rate vs pressure curves were generated. The FloPump 32 hydrodynamic profile was within the same performance specification as the Maquet Rotaflow at 2000, 3500 and 5000 RPM's. Testing was performed on multiple samples from multiple lots for each product.

Heat Generation



Temperature rise between the FloPump 32 and Maquet Rotaflow centrifugal pump were compared using phosphate-buffered saline in a laboratory setting. The temperature rise from ambient was monitored until the temperature stabilized. After 180 minutes, the temperature rise compared to ambient for the FloPump 32 was 9.70 C compared to 9.82 C for the Maquet Rotaflow centrifugal pump. Testing was performed on multiple samples from multiple lots for each product.

Flow Sensor Output

The accuracy of the integrated flow sensor was validated by comparing the console flowrate reading to a calibrated flow meter.

At various flow rates (2.00, 4.00, 6.00, 8.00 LPM) the calibrated flow sensor was compared to the console reading. The results indicated that the average output of the flow sensor was within ± 7%, the accuracy specification of the console.

Reliability

Multiple FloPump 32 samples from multiple lots were subjected to extended testing (24 hours continuous running) under worst-case conditions. After twenty-four (24) hours, the FloPump 32 products were thoroughly inspected and tested to ensure that they still met all performance specifications after the extended testing.

Hemolysis

Hemolysis testing using bovine blood according to ASTM F1841 was performed on multiple samples of multiple lots for both products.

Testing was performed at various backpressures to simulate varying clinical conditions. The Modified Index of Hemolysis (MIH) was calculated to compare the two products, with the following results:

IBC FloPump 32 MIH: 8.27 mg/mg

Maquet Rotaflow MIH: 8.64 mg/mg

Additional hemolysis trials were also performed at worst-case conditions (500mmHg, 7.00 LPM) with the following results:

IBC FloPump 32 MIH: 20.21 mg/mg

Maquet Rotaflow MIH: 18.17 mg/mg

There was no statistically significant difference between the IBC FloPump 32 and Maquet Rotaflow ($p=0.946$).

Air-Handling Capability

The IBC FloPump 32 and Maquet Rotaflow were subjected to several tests to analyze the air-handling capability of both pumps. Two simulations were performed and the results analyzed:

- Slow venous line leak
- Large bolus in venous line

For the slow leak in the venous line, there was a 1.3% difference in bubble detection counts between the IBC FloPump 32 and Maquet Rotaflow.

For the large bolus in the venous line, there was a 1.4% difference in the air volume required to deprime the IBC FloPump 32 and Maquet Rotaflow.

There were no significant differences in air-handling capability of the IBC FloPump 32 and Maquet Rotaflow.

Biocompatibility

The IBC FloPump 32 complies with ISO 10993 with respect to biocompatibility. All blood-contacting plastics are USP Class VI to ensure biocompatibility.

Sterility

The FloPump 32 is sterilized via ethylene oxide in a validated sterilization cycle. The validation has been conducted in accordance with ISO 11135.

In addition to validation of the sterilization cycle, EO residuals have also been tested and validated per ISO 10993-7.

After aeration, the EO residuals were:

- 0.374 mg EO/device
- < 0.0167 mg ECH /device

Both these results are well within the acceptable limits for EO residuals for this type of product per ISO 10993-7.

In addition, endotoxin testing was performed on multiple lots of validation samples of FloPump 32 with all products meeting the requirements for < 20.0 EU / device. Endotoxin testing is also performed routinely during production of the FloPump 32 product.

Packaging

The FloPump 32 packaging was validated according to the requirements of ISO 11607, including the following testing:

- Package strength and integrity, including visual inspection, bubble emission testing, dye penetrant testing and peel strength testing
- Three (3) year shelf-life validation, via accelerated aging per ASTM F1980
- Simulated distribution testing, per ASTM D4169, schedule DC-13

Usability

Usability testing was performed by several perfusionists using different lots of product. After using the product in a simulated perfusion circuit and with an emergency hand-crank, the perfusionists completed a survey questionnaire. The questionnaire included questions regarding:

- Sterile packaging
- Labeling
- Tubing connection
- Priming
- Performance in test circuit
- Performance using hand crank
- Overall equivalence to Maquet Rotaflow

The responses of the perfusionists indicated at least a neutral to positive view of all these survey items. Therefore, with respect to usability the FloPump 32 was deemed equivalent to the Maquet Rotaflow centrifugal pump based on the response of actual perfusionists.

CONCLUSION

Extensive testing performed by the manufacturer and third-party test laboratories have verified and validated the performance of the FloPump 32 for its approved intended use with the Maquet RotaFlow Pump Console.