

# Best Practice Model Determination: Oxygenator Selection for Cardiopulmonary Bypass.

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## **Abstract**

In recognizing the uniqueness of perfusion practice, building a best practice model can be a daunting task. As a start, establishing a baseline assessment of patient care is required prior to examining the impact of any change in the cardiopulmonary bypass circuit. A department must be able to have a measure of the care currently provided before determining if a proposed change will have a positive impact on the current care model. This manuscript outlines the steps taken to evaluate the current care model then, through evaluation of numerous membranes oxygenators, the creation of a scoring mechanism to assess performance of a number of variables including clinical measures and the non-tangible evaluation of staff impressions. Outlined is a comprehensive scoring mechanism to build a best practice model for membrane oxygenator evaluation and change.

Key Words: best practice, membrane oxygenator, cardiopulmonary bypass, cardiac surgery, perfusion

## **Introduction**

The inability of a manufacturer to supply product required the department to promptly replace a membrane oxygenator in a busy cardiac surgery program. This, along with the realization that the product was approaching the end of its production cycle, motivated the group to subsequently conduct a quality assessment of *current* practice. It was decided that with a caseload of over 1000 adult procedures requiring cardiopulmonary bypass (CPB), it would be advantageous to take a critical examination of current practice in order to establish a baseline and then determine if a change in membrane oxygenator, being a major component of the CPB circuit, would have a significant impact on patient care. After the identification of critical parameters in membrane oxygenator function, the current oxygenator and five new devices were evaluated.

It is critical to base decisions of clinical equipment on *actual* clinical data and not on pre-conceived notions of the equipment. This manuscript outlines steps we utilized in creating a best practice model determination for our clinical perfusion group. The data presented within the current manuscript are derived from work published elsewhere<sup>1,2</sup>.

## **Methods and Results**

As a first step in the development of the quality assessment tool, medical ethics department was consulted. With their guidance, investigators were permitted, through a '*quality assurance*' initiative, to collect the data required to establish our baseline of practice. An evaluation sheet

was developed (Figure 1A) in conjunction with input from members of our department and Laboratory Services.

The membranes used included: Sorin Synthesis (current model), Sorin Inspire 8F, Sorin Inspire 6F, Terumo Capiox FX25, Medtronic Fusion and Maquet Quadrox-i. The results are blinded as to the identification of the manufacturer and in no particular order.

#### Quantitative Data (derived from Stanzel and Henderson, 2016<sup>1,2</sup>)

To evaluate the function of the devices, the following clinical parameters were measured:

Prime volume – Both static and dynamic, as well as a quantitative value for total crystalloid volume removed (including retrograde autologous priming (RAP)).

Gas Transfers – A quantitative value was placed on the ability to transfer both oxygen and carbon dioxide across the membrane. The values were normalized to fractional inspired oxygen concentration (FiO<sub>2</sub>) and sweep gas, respectively. This allowed for easily applied ratios for the clinician to use in comparisons.

Pressure Gradients- Since there is the possibility that high pressure gradients may contribute to shear stress-induced blood cell damage, these data were deemed important to capture. Also, the results of our audit demonstrated a strong trend towards a negative relationship between increased trans-membrane pressure and inflammatory cell activation<sup>1</sup>. Pressure gradient was normalized to blood flow (mmHg/Liters per minute blood flow).

Hematology- A quantitative analysis of the effect of the membranes on patients' blood was utilized. At two different time intervals data were retrieved from laboratory data and compared (pre-bypass and 10 minutes post-aortic cross clamp removal). The objective was to evaluate the extent to which different membranes affected patient hematology, once again striving to provide for the best quality in our practice. Parameters measured were hemoglobin, platelet, white blood cells and neutrophil counts at the two time periods, normalizing the post cross clamp value to the pre-bypass baseline (expressed as percent change from baseline).

Gaseous Micro Emboli (GME) – GME handling is an important aspect of the performance of the membrane and venous reservoir system that is not easily quantified in a clinical setting. Therefore, with the cooperation of one of the manufacturers, we were able to subject our own clinical units to a controlled scenario to evaluate how the devices handled a micro air challenge, one that would mimic a normal clinical scenario using the EDAC system<sup>2</sup>. The performance of the venous reservoir, membrane bundle separately and then the whole circuit combination was evaluated and compared.

### Subjective Evaluation

To evaluate the subjective aspects of the membrane oxygenators, the author focused on how the perfusionist perceived the ease of setup and use of the devices. Also, after presentation of the audit results, the perfusionists, as a group, was given the opportunity to discuss the devices used (with sample units available) with their peers and share experiences that may have been

unique and to investigate those issues that were not so unique. Equipped with the final results of this evaluation, individuals were given the opportunity to amend initial perceptions to provide what they *felt* was an accurate opinion of their experiences with each product (Figure 1B).

### Scoring Methods

Each membrane was scored by how it ranked in each category of the quantitative analysis (functional prime volume, oxygen transfer, carbon dioxide transfer, pressure gradient, hemoglobin and platelet retention, white blood cell and neutrophil activation, GME (total load), whole system performance). A simple scoring system of 1-6 points for ranking was applied for each of the six products, with the top-performing product in each category receiving 6 points. An example of this is presented in Figure 2, 'oxygen transfer'. In this example, Membrane 'C' was the top performer and received 6 points for oxygen transfer, while the lowest performing oxygenator, Membrane 'A', received 1 point. This scoring mechanism was utilized for all the categories including GME. GME scoring was done in a similar manner utilizing a score for total embolic load (after a constant volume injected in the venous line) exiting the membrane; this measured the efficacy of the entire system (membrane and venous reservoir).

The combined quantitative and qualitative scores are presented in Figure 3 and give a comprehensive score for the oxygenators by taking clinical data and staff input into

consideration. From highest to lowest scores, the oxygenators rank B, E, D, F, C, A. These data demonstrate a variation between oxygenators with the highest rated oxygenator B receiving a total score of 45 and the lowest rated oxygenator receiving 27. The second highest scoring oxygenator received a score of 40, while the remaining oxygenators had little variation in scores (34 to 31). Based on these data, it would appear that oxygenator B would be the optimal product to go forward with in the future. It is, however, possible that discrepancies exist between the subjective and quantitative scores that were used to produce this outcome. To further examine this possibility, these qualitative and quantitative scores were examined individually.

The qualitative data were examined first. These data were derived from the subjective evaluation sheet (Figure 1B) that captured how the staff felt the oxygenators performed. For this, these data were tabulated resulting in an overall subjective rating of all oxygenators. For this, the oxygenators were ranked 1-6, with the oxygenator having the highest score being assigned the value of '1' and the lowest scoring oxygenator being assigned a value of '6' (Figure 4). The order of oxygenators, were A, B, C, D, E, F in descending order. This demonstrated a marked discrepancy from the combined data in Figure 3. For example, in the subjective ratings, Oxygenator 'A' has the highest scoring, while in the combined score it has the lowest scoring. Comparing these data, only oxygenators 'B' and 'D' remained in a similar rank as they were only shifted a single rank, all others were shifted at least two ranks. This discrepancy must then be explained by variation in the qualitative and quantitative scores.

Scores from just the quantitative data are presented in Figure 5. The order of oxygenators in descending order was B, E, F, D, C, A. These data demonstrate variation between oxygenators with the highest scoring oxygenator, oxygenator B, receiving a score of 41 and the lowest, oxygenator A, receiving a score of 21. The remaining oxygenators also had a degree of variation with scores ranging from 27 to 38. Similar to the combined data in Figure 3, these data are in contrast to the subjective rankings.

## **Discussion**

The primary goal of the current membrane audit was to build a best practice model for our department and help us provide the best care for our patients. It was decided that we needed to take a critical look at our perfusion practice to establish a baseline of care and then attempt to improve on that level of care. The information we discovered during the comparison has allowed us to evaluate the new products on the market and our perceptions on what is desirable in product function. The clinicians gained a greater appreciation for design strategies that go beyond the marketing information supplied to us by some of the well-tuned marketing professionals.

Since this comparison was relatively small in size, we were unable to capture differences in patient outcomes between the products. Outcomes after cardiac surgery are multifactorial in nature and proving benefit to outcomes by manipulating one component requires a larger

number of subjects, this was beyond the scope of the current evaluation. However, this is a desirable long-term project that can be achieved with a comprehensive database. We are currently in the process of initiating such a project at our center. For the purposes of building a best practice model with a limited number of subjects we felt that evaluating our short-term contribution to the patients' physiology would give us some useful information and allow us to achieve a measure of our quality of care.

One fact that became obvious in this project was the awareness of the difficulty and resistance to change in our profession. Despite being equipped with in-depth information (Figure 5) regarding our practice and the different products, the subjective rating performed by the staff members (Figure 4) is in stark contrast to the evidence-based rating. Even though oxygenator 'A', for example, was given the lowest score by the evidence-based clinical evaluation, many of the staff felt comfortable with the device and chose to award it with a very high rating. Conversely, oxygenator 'E' received second place in the quantitative score, but the staff relegated it to 5th in the subjective rating. The only consistency between the evidence based rating and the more subjective rating of the score-card was oxygenator 'B', rated second by the staff and first by all evidence-based methods.

As decisions to purchase a new product proceed, oxygenator 'B' may be the logical choice as it meets many common criteria in patient care rating and staff approval. Clinicians' perceptions

appear to be in contrast to some of the research data derived from our own practice. When choosing a product to add to a best practice model, decision makers must take this reluctance to change into account as comfort level and the need for reproducible results cannot be discounted. However, as noted in the paper by Bronson<sup>2</sup>, changing clinical practice by perfusionists and cardiac surgery care givers can eventually occur as comfort level increases. But to ignore change because of a reluctance to change may not be in the best interest for the advancement of medicine in any scenario.

Today, hospital purchasing processes are increasingly complex and take into consideration what is best for the patient and the staff's comfort level, yet the financial aspects are often just as or even more important. Providing a comprehensive evaluation system that takes into consideration *all* clinical components gives the clinician a greater voice in choosing what is best for their practice, not just what is financially the most appealing. Building a template such as described for best practice model determination will allow perfusion team members to regularly examine practice and to evaluate if a change is actually in the best interest of patient care.

In this evaluation, two products were close in clinical performance, one being ranked considerably higher by the perfusionists than the other. Given the potential for supply disruption issues, it could be reasonable to have more than one brand of important

components, such as membrane oxygenators, available. Expansion of this model is planned so that we may examine longer term outcomes on our patients by the evolving practice of perfusion techniques and acquire a more in-depth perspective of the contribution cardiopulmonary bypass has on our patients.

To determine best practice, it is essential to put in place a mechanism to regularly audit the contributions to the care of the cardiac surgical patients or continuous quality improvement (CQI). A critical examination of current practice is first required before any changes or manipulations can be considered. The nature of complex procedures makes this a formidable task. However, with the creation of a simple database and regular audits, quality of care can be measured and therefore a strategy to improve can be created.

Further to the departmental quality analysis is the comparison of practice with other centers. Currently, much of this described process is being conducted at other centers; the analysis of these data will not only provide each department with their own baseline of care but will allow a comparison of techniques so that improvements in quality can be undertaken in a controlled and scientific manner. The next step to this would be the creation of a perfusion registry. In many countries, regional and national registries are in place to do just this. Good medical practice stems from investigation, comparisons and improvements and perfusion practice is no exception.

A

PERFUSION SERVICES  
MEMBRANE OXYGENATOR AUDIT

MEMBRANE:	
PERFUSIONIST:	
SURGEON/ANES:	
PUMP TIME:	
XC TIME	
PROCEDURE:	

Patient Sticker

TRANSFUSED BLOOD	(mls/UNITS)
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TIME	SAMPLE:	RBC	WBC	Neut	PLT	HGB	HCT	CRP	Ht	Wt
	PRE CPB:									BSA
	XC REMOVAL:									GENDER
	CVICU:									AGE

ON CPB	ART TEMP	Arterial O2 Content			Venous O2 Content			CO2 Transfer			Pressure		
		HgB	SaO2	PaO2	SvO2	HgB	PvO2	BLOOD FLOW	PaCO2	GAS FLOW	FiO2	PRE	POST
SAMPLE 1													
SAMPLE 2													
SAMPLE 3													
SAMPLE 4													
SAMPLE 5													
SAMPLE 6													
SAMPLE 7													
SAMPLE 8													

B

QUALITATIVE ANALYSIS  
SCORING 0-UNACCEPTABLE , 1-ACCEPTABLE, 2- ABOVE AVERAGE, 3- EXCEPTIONAL  
MEMBRANE \_\_\_\_\_  
PERFUSIONIST \_\_\_\_\_  
TOTAL \_\_\_\_\_  
Comments ( use back side as well ) \_\_\_\_\_

OBSERVATION	SCORE
HOLDER POSITIONING	
EASE OF PRIME	
INTEGRATION TO CIRCUIT	
PORT ALIGNMENT	
RESERVOIR PERFORMANCE	
GENERAL ERGONOMICS	
PRESSURE DROP	
HEAT EXCHANGE PERFORMANCE	
GAS EXCHANGE PERFORMANCE	
PERFORMANCE CONSISTENCY (FROM ONE UNIT TO NEXT)	

Figure 1: Data Collection Forms. Clinical data collection form for the quantitative evaluation of oxygenators (A). Qualitative data collection form for subjective impressions of perfusionists (B).

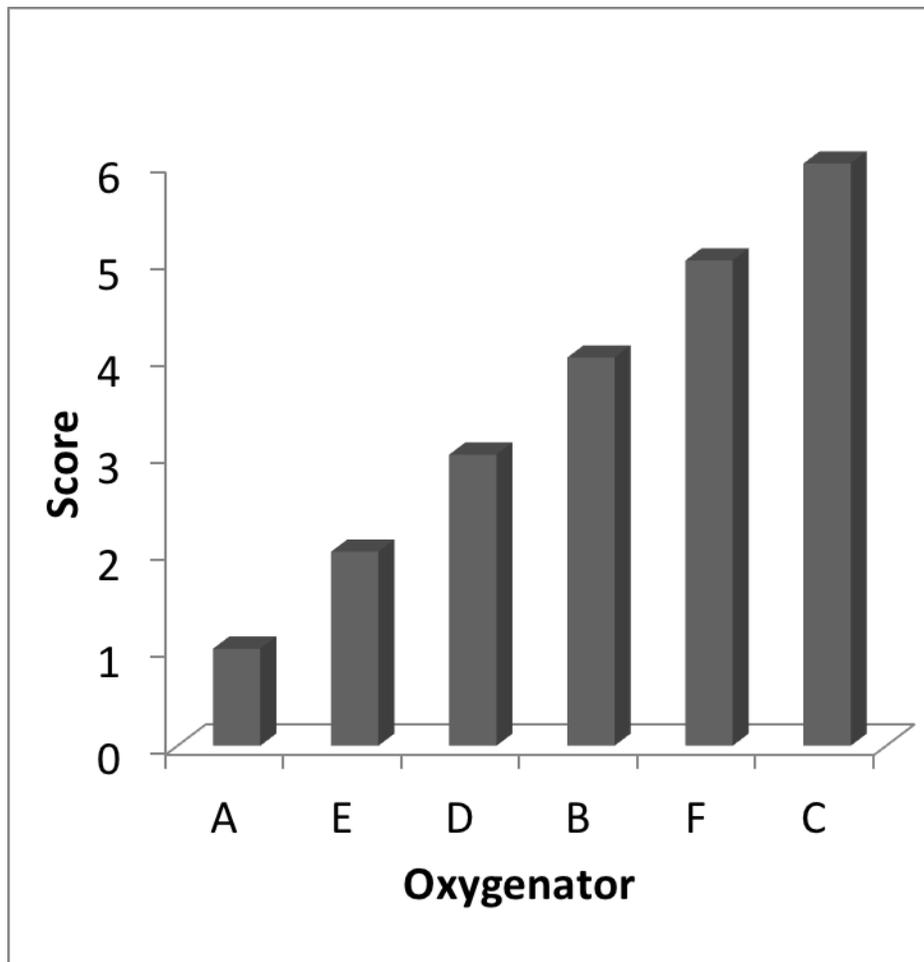


Figure 2: Oxygen Transfer Ranking of Oxygenators. An example of quantitative scoring of a clinical oxygenator parameter in which the top performing oxygenator is assigned a score of '6', while the lowest performing oxygenator is assigned a score of '1'. In descending order, oxygenators ranked C, F, B, D, E, and A for this specific parameter.

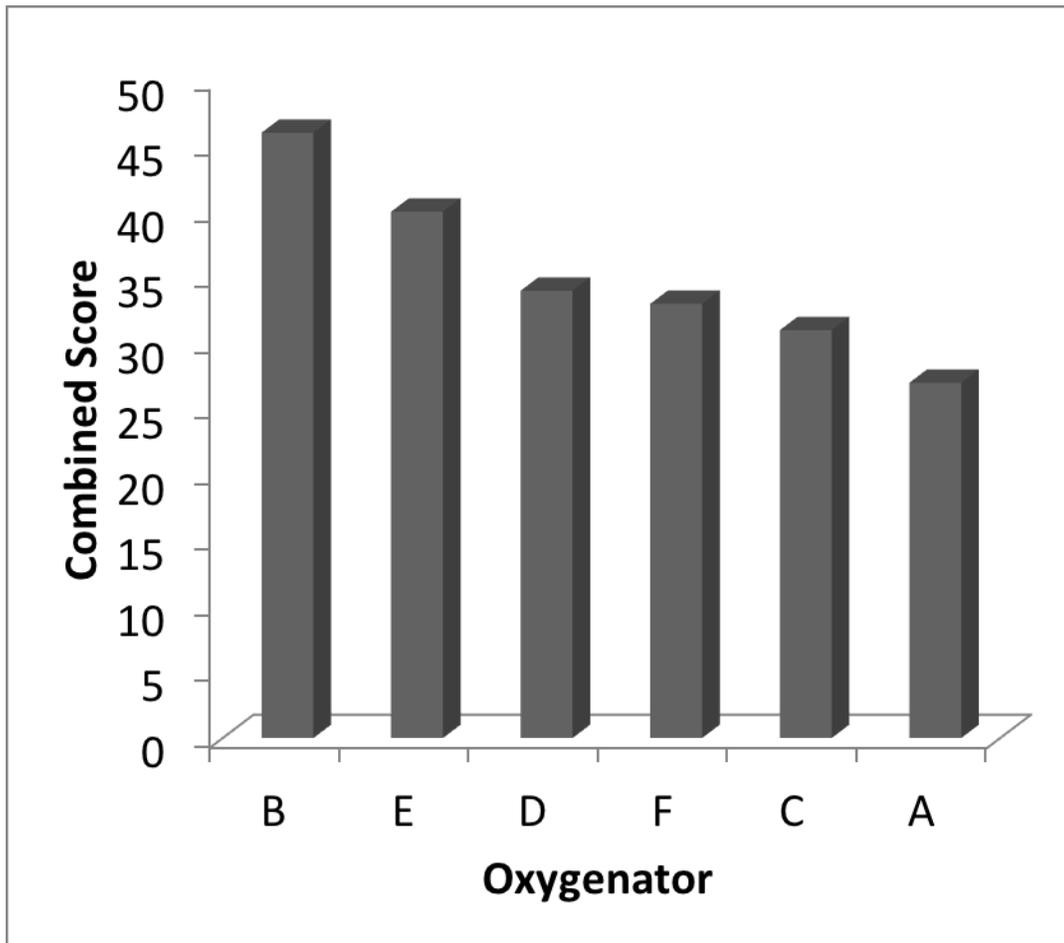


Figure 3: Combined Qualitative and Quantitative Oxygenator Scores. All data collected including clinical and subjective scores are pooled to generate a comprehensive score of all oxygenators evaluated. Oxygenators are ranked B, E, D, F, C and A in descending scores.

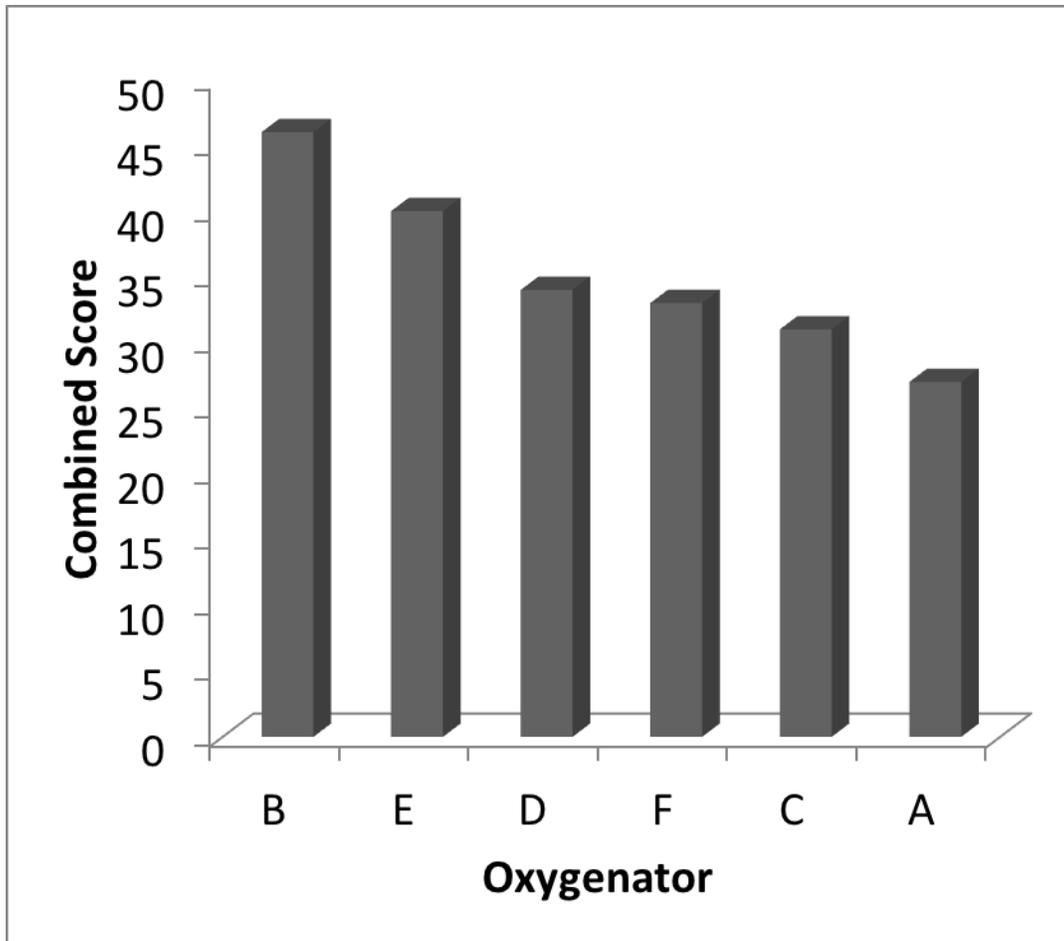


Figure 4: Subjective Oxygenator Evaluation Rankings. Data collected from the forms presented in Figure 1B were tabulated generating a score for each oxygenator. The subsequent rank of the oxygenators based on staff impressions is A, B, C, D, E and F in descending order.

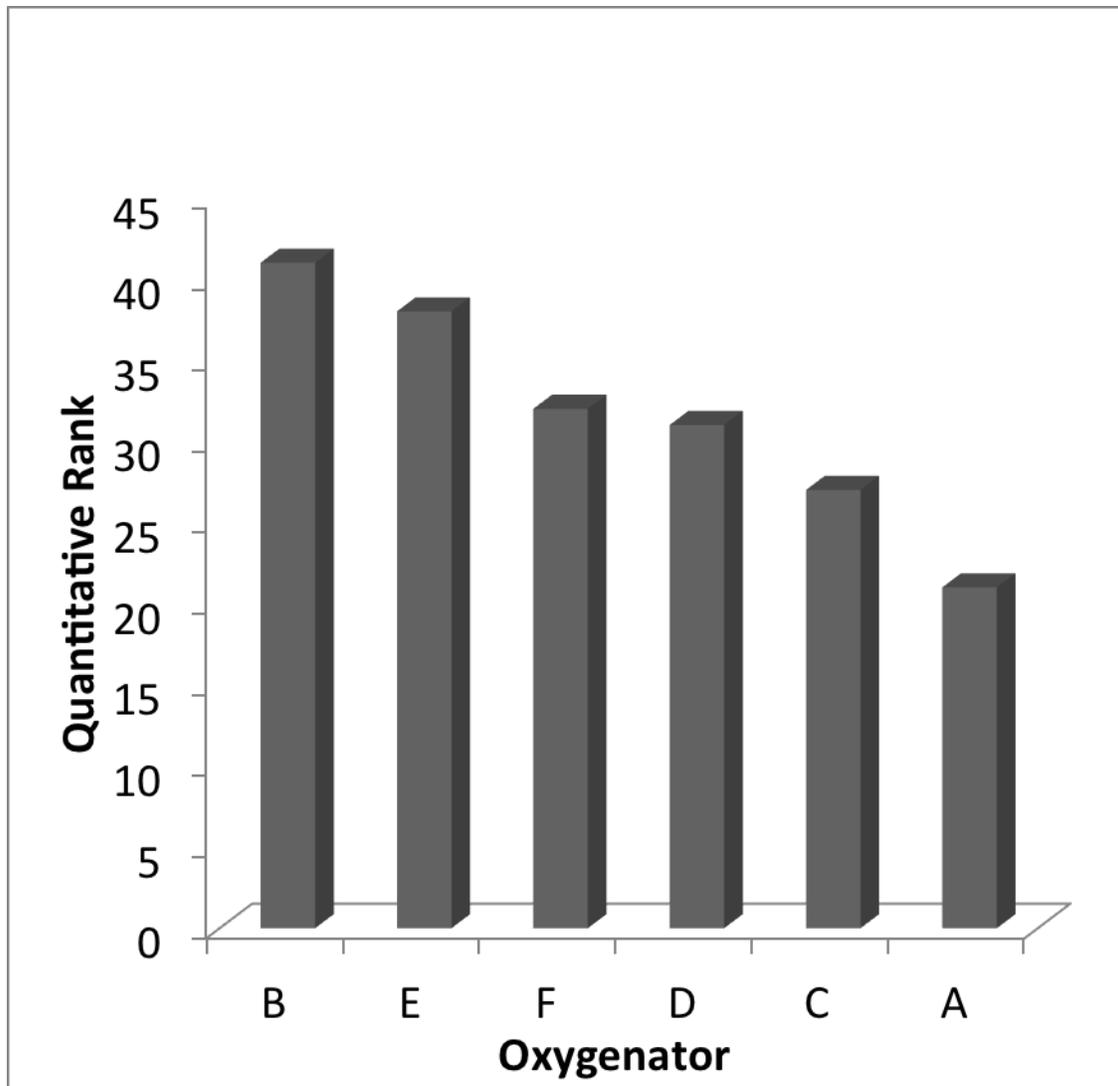


Figure 5: Quantitative Clinical Oxygenator Rankings. Data collected from the forms presented in Figure 1A were tabulated generating a score for each oxygenator. The subsequent rank of the oxygenators based on clinical parameters is B, E, F, D, C and A in descending order.

## References

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