

## Use of Spectrum Medical M3 monitor in pediatric cardiac surgery: gaseous emboli monitoring in Capiiox RX05 and Capiiox FX05 oxygenators

*Spectrum Medical M3 monitörünün pediyatrik kalp cerrahisinde kullanımı: Capiiox RX05 ve Capiiox FX05 oksijenatörlerinde gaz embolisinin monitörizasyonu*

Yusuf Kenan Yalçınbaş,<sup>1</sup> Serdar Günaydın,<sup>2</sup> Murat Boz,<sup>1</sup> Zekeriya Telli,<sup>1</sup> Tayyar Sarıoğlu<sup>3</sup>

*Institution where the research was done:*

Department of Cardiovascular Surgery, Acıbadem Bakırköy Hospital, İstanbul, Turkey

*Author Affiliations:*

<sup>1</sup>Department of Cardiovascular Surgery, Acıbadem Bakırköy Hospital, İstanbul, Turkey

<sup>2</sup>Department of Cardiovascular Surgery, Medline Eskişehir Hospital, Eskişehir, Turkey

<sup>3</sup>Department of Cardiovascular Surgery, Medical Faculty of Acıbadem Hospital, İstanbul, Turkey

**Background:** The clinical use of Spectrum Medical M3 monitor, and the results of emboli monitoring for Terumo Capiiox RX05 oxygenator without arterial filter and Terumo Capiiox FX05 oxygenator with built in arterial filter were evaluated.

**Methods:** Spectrum Medical M3 monitor was used for 50 patients between December 2010 and June 2011. Capiiox RX05 oxygenator was used for 30 patients (group 1; 21 boys, 9 girls; mean age 26.3±12.4 months), and Capiiox FX05 oxygenator was used for 20 patients (group 2; 10 boys, 10 girls; mean age 22.4±12 months). Heparin dose was 400 units/kg. Activated clotting time was maintained at >500 seconds, hematocrit was maintained at 25-30%, and cardiopulmonary bypass flow was maintained at 125-150 mL/kg/minute. Moderate hypothermia (28-34 degrees), alpha stat blood gas management, and antegrade isothermic blood cardioplegia were used.

**Results:** No mortality was observed in group 1. In group 2, one patient died due to pulmonary hypertension. Two patients needed prolonged respiratory support for pneumonia in group 1 and group 2. In group 1, the mean number of arterial gaseous emboli was 32573 (23063-60051) (25-75% percentile), and mean volume of arterial gaseous emboli was 4.2 mL (2.1-7.5 mL) (25-75% percentile). In group 2, the mean number of arterial gaseous emboli was 25053 (9096.3-37352.3) (25-75% percentile), and mean volume of arterial gaseous emboli was 1.1 mL (0.5-3.2 mL) (25-75% percentile) (*p* value for the number of arterial emboli was 0.043, and *p* value for arterial emboli volume was 0.001).

**Conclusion:** Spectrum Medical M3 monitor is a useful device for monitoring gaseous emboli in pediatric cardiac surgery. Terumo Capiiox FX05 oxygenator with built in arterial filter may be more effective for the prevention of gaseous emboli than Terumo Capiiox RX05 oxygenator without arterial filter.

**Keywords:** Cardiopulmonary bypass; gaseous emboli; pediatric cardiac surgery.

**Amaç:** Spectrum Medical M3 monitörünün klinik kullanımıyla birlikte arteriyel filtresiz Terumo Capiiox RX05 ve entegre arteriyel filtreli Capiiox FX05 oksijenatörlerde emboli monitörizasyonunun sonuçları incelendi.

**Çalışma planı:** Spectrum Medical M3 monitörü Aralık 2010 ve Haziran 2011 tarihleri arasında 50 hastada kullanıldı. Otuz hastada (grup 1; 21 erkek, 9 kız; ort. yaş 26.3±12.4 ay) Capiiox RX05, 20 hastada (grup 2; 10 erkek, 10 kız; ort. yaş 22.4±12 ay) Capiiox FX05 oksijenatörü kullanıldı. Ortalama yaş grup 1'de 26.3±12.4 ay, grup 2'de 22.4±12 ay idi. Heparin dozu 400 ünite/kg idi. Etkinleştirilmiş pıhtılaşma zamanı >500 saniyede, hematokrit %25-30 arasında ve kardiyopulmoner baypas debisi 125-150 mL/kg/dakikada korundu. Orta dereceli hipotermi (28-34 derece), alfa stat kan gazı yönetimi ve antegrad izotermik kan kardiyoplejisi kullanıldı.

**Bulgular:** Grup 1'de mortalite gözlenmedi. Grup 2'de bir hasta pulmoner hipertansiyon nedeni ile öldü. Grup 1 ve grup 2'de iki hastada pnömoni nedeni ile uzun süreli solunum desteği gerekti. Grup 1'de arteriyel gaz embolisi sayısı ortalama 32573 (23063-60051) (%25-75 persentil), ortalama gaz embolisi volümü 4.2 mL (2.1-7.5 mL) (%25-75 persentil) idi. Grup 2'de arteriyel gaz embolisi sayısı ortalama 25053 (9096.3-37352.3) (%25-75 persentil), ortalama gaz embolisi volümü 1.1 mL (0.5-3.2 mL) (%25-75 persentil) (Arteriyel emboli sayısı için *p* değeri 0.043, arteriyel emboli volümü için *p* değeri 0.001) idi.

**Sonuç:** Spectrum Medical M3 monitörü pediyatrik kalp cerrahisinde gaz embolisi monitörizasyonu için faydalı bir cihazdır. Gaz embolisinden korunmada entegre arteriyel filtreli Terumo FX05 oksijenatör, arteriyel filtresi olmayan Capiiox RX05 oksijenatörden daha etkili olabilir.

**Anahtar sözcükler:** Kardiyopulmoner baypas; gaz embolisi; pediyatrik kalp cerrahisi.



Available online at  
www.tgkdc.dergisi.org  
doi: 10.5606/tgkdc.dergisi.2014.10444  
QR (Quick Response) Code

Received: May 31, 2014 Accepted: August 29, 2014

Correspondence: Yusuf Kenan Yalçınbaş, M.D. Acıbadem Bakırköy Hastanesi, Kalp ve Damar Cerrahisi Kliniği, 34140 Bakırköy, İstanbul, Turkey.

Tel: +90 212 - 414 44 08 e-mail: ykylcinbas@yahoo.com

Emboli detection and removal are crucial to safely perform pediatric cardiopulmonary bypass (CPB) surgery. Varying degrees of embolization can be seen in critical organs such as the brain, heart, and abdominal organs), and occasionally there are negative clinical outcomes.<sup>[1,2]</sup> In addition, gaseous emboli cause vascular endothelial injuries and leukocyte aggregation as well as complement and platelet activation along with fibrin deposition in the capillaries. During the course of pediatric CPB, a significant number of gaseous emboli can be detected via various devices and monitors, with transcranial Doppler also being used for this purpose. While it is not possible to totally eliminate air from passing through the CPB circuit, the size and volume of gaseous bubbles can be limited in order to reduce the effects of embolization. Hence, a variety of techniques and devices have been developed for gaseous bubble emboli detection and elimination. The Spectrum M3 Non-Invasive Diagnostic Monitoring System (Spectrum Medical, Fort Mill, SC, USA) has been on the market since 2007, and it is capable of detecting cardiopulmonary bypass flow, gaseous emboli, hematocrit and oxygen saturation noninvasively. This device uses near-infrared light sensor technology for arterial oxygen saturation and mixed venous oxygen saturation. Ultrasonic technology is used for flow rate and gaseous emboli detection. In this study, we evaluated the clinical use of the Spectrum Medical M3 monitoring system as well as the results of the Terumo Capiiox® RX05 Baby RX™ Oxygenator (Terumo Corporation, Tokyo, Japan) without an arterial filter and the Terumo Capiiox® FX05 Oxygenator with an integrated arterial filter, both of which were used to monitor emboli.

## MATERIALS AND METHODS

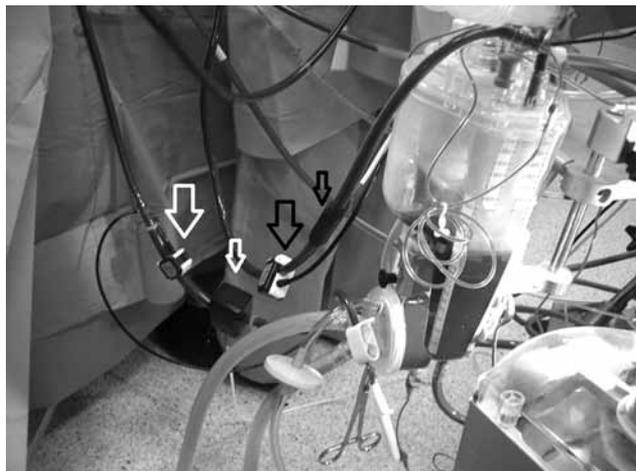
The Spectrum Medical M3 system is an integrated, non-invasive system that is used for monitoring continuous, real-time arterial and venous OS, flow, Hct levels, and arterial and venous gaseous emboli. It measures the reflected amplitude of light at 100 discrete wavelengths via a miniature scanning spectrometer and a near-infrared light source. The monitor uses a non-invasive sensor that contains an emitter and a photo diode receiver that works in the near-infrared region. The photo diode detects the received light level and converts the resultant light energy into electrical output. There are two independent flow channels, each with flow and emboli detection. Sensors are also clipped onto the outside of the blood tube to measure the blood flow, and the emboli are detected using ultrasonic sensing technology. This sensor system uses ultrasonic signal

phase variations to determine the flow rates and uses direction and changes in ultrasonic signal amplitude to detect the emboli.

The Capiiox® RX05 is a neonatal and infant hollow fiber oxygenator that provides a maximum blood flow rate of 1.5 L/min with a priming volume of 43 mL. It is coated with a biocompatible, hydrophilic polymer surface coating (X Coating) that reduces platelet adhesion and protein denaturation. The integrated hardshell venous reservoir has independent venous and cardiotomy filters with a very low minimal operating level of 15 mL. The Capiiox® FX05 has an integrated arterial line filter and a 32 micron filter mesh screen that surrounds the woven fiber layer of the oxygenator that allows for a reduction in the prime volume and surface area. This design also promotes fewer homologous blood transfusions and optimizes hemostasis.

In this study, we employed the Spectrum M3 monitoring system on 50 patients between December 2010 and June 2011 at Acıbadem Bakırköy Hospital, Department of Cardiovascular Surgery, Istanbul, Turkey, and the study was approved by the Scientific Committee of Kırıkkale University. The sensors were placed on the extracorporeal circuit tubing at the arterial outlet and venous inlet, and the recordings were then transferred to the monitor (Figures 1 and 2). Detection and sizing sensitivity were set at 20 microns, and the data was simultaneously stored throughout the entire extracorporeal circulation process (Figures 1 and 2). A radiometer blood gas analysis system was also used for routine blood gas analysis during CPB.

In 30 patients (group 1), we employed the Capiiox® RX05 oxygenator, and in 20 others (group 2), the Capiiox® FX05 oxygenator was used. The tubing system was non-coated in each system. Twenty-one of the patients in group 1 (70%) and 10 in group 2 (50%) were male. The mean age of group 1 was 26.3±12.4 months while it was 22.4±12 months for group 2. In addition, the two groups were comparable in terms of age, height, weight, and CPB variables (Tables 1 and 2). Midazolam, sevoflurane, fentanyl, and norcuronium were used as anesthetic agents, and heparin (400 units/kg) was given to all of the patients. We also maintained the activated clotting time at >500 seconds. Furthermore, the priming volume consisted of a balanced crystalloid solution, fresh frozen plasma (FFP), cefazoline, heparin, sodium bicarbonate, and packed red cells. Moreover, the Hct levels were maintained at 25-30%, and the CPB flow was kept at 125-150 mL/kg/min. We also utilized 28-32 °C



**Figure 1.** Photo showing the placement of the sensors on the arterial and venous lines. Big black arrow: Flow sensor on the venous line; Small black arrow: Bubble sensor on the venous line; Big white arrow: Flow sensor on the arterial line; Small white arrow: Bubble sensor on the arterial line.



**Figure 2.** Operative view of the Spectrum M3 monitoring system during the course of pediatric cardiopulmonary bypass.

hypothermia, alpha-stat blood gas management, and antegrade isothermic blood cardioplegia in this study. Arterial and venous blood gas readings were taken once the patients were stable on CPB and every 30 minutes thereafter. Additionally, the protamine reversal was adjusted to a 1.5 protamine / 1 heparin ratio. We also used the Terumo® Advanced Perfusion System 1 heart-lung machine with a roller pump head and the Terumo® Advanced Perfusion System heater-

cooler unit. The tubing line diameters were ¼ inches for both the arterial and venous tubing lines.

**Statistical analysis**

We used the 2007 Number Cruncher Statistical System (NCSS) 2007 and 2008 Power Analysis and Sample Size (PASS) statistical software (NCSS LLC, Kaysville, Utah, USA) to analyze our data, and the results were given as mean, standard deviation (SD), median, and frequency. In addition, Student’s t-test was

**Table 1. Patient data**

	Group 1 (RX05) (n=30)			Group 2 (FX05) (n=20)			<i>p</i> <sup>‡</sup>
	n	%	Mean±SD	n	%	Mean±SD	
Gender							
Male	21	70		10	50		0.2*
Female	9	30		10	50		
Age (months)			26.3±12.4			22.4±12	0.3
Height (cm)			72±15			70.2±13.6	0.7
Weight (kg)			7.6±3.3			6.7±2.7	0.4
Body surface area (m <sup>2</sup> )			0.4±0.1			0.4±0.1	0.5

SD: Standard deviation; ‡: Student t-test; \*: Yates’ continuity correction test.

**Table 2. Cardiopulmonary bypass data**

	Group 1 (RX05) (n=30)	Group 2 (FX05) (n=20)	<i>p</i> <sup>‡</sup>
	Mean±SD	Mean±SD	
Cardiopulmonary bypass (minutes)	108.8±47.3	111±37.5	0.8
Aortic cross clamp (minutes)	80±33	79.9±35.7	1
Pump flow (mL/min)	910.4±298	843.8±266	0.4
Hypothermia (°C)	30.1±2.5	30.1±1.8	0.7

SD: Standard deviation; ‡: Student t-test.

**Table 3. Gaseous emboli data**

	Group 1 (RX05) (n=30)		Group 2 (FX05) (n=20)		<i>p</i>
	Median	(25-75 <sup>th</sup> percentile)	Median	(25-75 <sup>th</sup> percentile)	
Number of arterial emboli	32,573	(23,063-60051)	25,053	(9,096.3-37,352.3)	0.043*
Arterial emboli (volume-mL)	4.2	(2.1-7.5)	1.1	(0.5-3.2)	0.001**

Mann-Whitney U test; \*:  $p < 0.05$ ; \*\*:  $p < 0.01$ .

used to compare the normally distributed parameters, whereas the Mann-Whitney U test was used to compare the parameters without normal distribution. Furthermore, the descriptive data was compared using Yates' continuity correction test. Statistical significance was set at  $p < 0.05$ .

## RESULTS

The patients in both groups tolerated CPB without any significant problems. The perfusionists easily learned how to use the Spectrum M3 system, and the perfusion was carried out with no complications. Placement of sensors did not add any extra time to the operation. No mortality occurred in group 1; however, two patients needed prolonged respiratory support for pneumonia and one required the implantation of a permanent pacemaker. There was one mortality in group 2 due to pulmonary hypertension. Moreover, two patients in this group needed prolonged respiratory support for pneumonia and one had a permanent pacemaker implanted. The mean number of arterial gaseous emboli in group 1 was 32,573 (range 23,063-60,051; 25-75<sup>th</sup> percentile), and the mean number of particles and volume of arterial gaseous emboli in group 1 was 4.2 mL (range 2.1-7.5; 25 -75<sup>th</sup> percentile). The mean number of arterial gaseous emboli in group 2 was 25,053 (range 9,096.3-37,352.3; 25-75<sup>th</sup> percentile), and the mean number of particles and volume of arterial gaseous emboli was 1.1 mL (0.5-3.2; 25-75<sup>th</sup> percentile). The *p* value for the number of arterial emboli was 0.043 and *p* value for the volume of arterial emboli was 0.001 (Table 3).

## DISCUSSION

Perfusion technology and embolic protection in pediatric cardiac surgery is evolving. There are devices that eliminate the embolic material and some that monitor the amount of embolic material, for example the emboli detection and quantification (EDAC) monitor. This monitor has parts which should be integrated to the tubing system. In addition, when using the EDAC, careful attention should also be paid to the amount of air in the venous line, the air related to vacuum-assisted venous drainage, and any other factors

related to arterial embolization.<sup>[3]</sup> The portable, non-invasive Spectrum M3 monitoring system combines emboli detection and blood gas monitoring, and it also provides quick access to the data with real-time system updates, zero-drift data readings, and extended communication features. Bailey et al.<sup>[4]</sup> evaluated the in vitro performance of the the Spectrum M3 for OS and found that it was reliable when compared with other blood gas analyzers. The Terumo CDI® Blood Parameter Monitoring System 500 (Terumo Cardiovascular Systems Corporation, Ann Arbor, MI, USA) is an alternative device that can be used to measure continuous blood gases during CPB, but this system has parts which need to be integrated with the tubing system. The newer Spectrum M4 monitoring system has extended monitoring capabilities and can measure the cardiac index, partial pressure of oxygen (PO<sub>2</sub>), partial pressure of carbon dioxide (PCO<sub>2</sub>), hemoglobin, fraction of inspired oxygen (FiO<sub>2</sub>), fraction of inspired carbon dioxide (FiCO<sub>2</sub>), CO<sub>2</sub> exhaust levels, and sweep gas flow. These expanded features may promote the routine use of combined continuous blood gas and emboli monitoring in pediatric cardiac operations.

Further studies may also improve our understanding of the creation and distribution of bubbles. According to Yee et al.,<sup>[5]</sup> centrifugal pumps may function better than roller pumps with respect to the occurrence of gaseous bubbles, but Wang et al.<sup>[6]</sup> determined that pulsatile perfusion with either a centrifugal or rotary pump may introduce more microemboli than non-pulsatile perfusion.

The Capiox® FX05 and Capiox® RX05 oxygenators were similar in terms of gas exchange, pressure drops, and heat exchange coefficients, and Dogal et al.<sup>[7]</sup> showed that the Capiox® RX05 was effective for reducing the number of microemboli in neonates. Integrated arterial line filters, like those on the Capiox® FX05, are easier to prime and de-air than external arterial line filters, which can be found on the Capriox® RX05. Moreover, the lack of an external arterial filter allows for the oxygenator to be brought closer to the patient and manipulated more easily, and the priming

volume is reduced as well. However, Nuskowskil et al.<sup>[8]</sup> determined that there were no differences between the two Terumo oxygenators in terms of inflammation markers. Additionally, as pointed out by Deptula et al.,<sup>[9]</sup> the Capiox® RX05 oxygenator was effective for 17.5 hours of extended support for a baby who underwent the stage I Norwood procedure after developing shunt thrombosis following general surgery.

In another evaluation of these two monitoring systems, Horton et al.<sup>[12]</sup> showed that the Capiox® FX05 was as effective at removing emboli as the Capiox® RX05. Furthermore, it has other advantages, including prime volume reduction and circuit simplification.<sup>[12]</sup> Reducing the prime volume and foreign surface area might be useful for decreasing inflammation and could also result in the potential elimination or reduction of blood product exposure. Furthermore, the FX series of oxygenators also offer good gas exchange capabilities and low pressure drop along with the safety of an integrated arterial line filter.<sup>[13-15]</sup> These types of filters are commonly used in neonatal and infant cardiac operations in the United States, but they are not widely used in Europe and other countries. However, newer features on oxygenators, such as integrated arterial filters, may promote and increase their usage. The Maquet Quadrox-I (MAQUET Cardiovascular LLC, Wayne, NJ, USA) neonatal oxygenator, which was released to the market after the Capiox® FX05, also has an integrated arterial filter, and studies related to this device are currently being conducted to determine its merits.<sup>[10,11]</sup> If all goes well, it could provide another viable option along with the two Terumo oxygenators.

In our study, there was one mortality in group 2 caused by pulmonary hypertension, and two patients needed prolonged respiratory support for pneumonia. We found it difficult to comment on the clinical outcomes and correlate our findings because of the number and volume of arterial emboli in our patients. Thus, multicenter studies that feature a large number of patients and standardized monitoring protocols are needed to elucidate the clinical significance of emboli detection during CPB. Future studies could also target high-risk patients with longer CPB duration who are more likely to be exposed to a larger embolic load. However, until there is more research on this topic, we think it is reasonable to minimize the amount of air in extracorporeal circuits via the use of advanced CPB circuit components.

### Conclusion

The Spectrum Medical M3 Non-Invasive Diagnostic Monitoring System is a useful device for the real-

time, continuous monitoring of gaseous emboli in pediatric cardiac surgery. In addition, our findings show that the Terumo Capiox® FX05 oxygenator with an integrated arterial filter might offer better gaseous emboli handling capability than the Terumo Capiox® RX05 oxygenator without this type of filter.

### Declaration of conflicting interests

The authors declared no conflicts of interest with respect to the authorship and/or publication of this article.

### Funding

The authors received no financial support for the research and/or authorship of this article.

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