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# A Device for Sampling Earlobe Arterialized Blood in Space and Other Austere Environments

*Thais Russomano*

## Abstract

The coming decades will see a large increase in the numbers of people who will have the opportunity to go into space, whether on traditional Earth-orbiting space stations, tourist spaceflights or proposed space hotels. In addition, humans are likely to be spending longer periods of time in the microgravity of space and the reduced gravity environments found on the moon and Mars, with plans for long-duration spaceflight to reach the red planet and habitation of a moon colony. The anatomy, physiology and psychology of humankind are shaped by the gravity we are subject to on Earth, and it is known that the removal or reduction of this force can have a detrimental effect on our health and wellbeing. Therefore, all steps must be taken to monitor these aspects. Currently, there is no safe and acceptable method to collect arterial blood in space, which can be used to obtain valuable blood gas and blood component variables. This chapter will outline the development of a method for safely collecting arterialized blood in space, the research and steps taken to ensure its suitability and applicability, in preparation for this growing presence of humans in space.

**Keywords:** space medicine, space physiology, medical emergencies, arterial blood, arterialized blood, blood collector, parabolic flight

## 1. Introduction

There is an increased need to accurately monitor and medically evaluate human beings in a variety of clinical and research situations in space, with plans for long-duration manned spaceflight, the proposed return to the moon and potential moon and Mars colonies in the future. In addition, greater flexibility in the selection process of astronauts and the advent of space tourism increases the need for adequate health and medical monitoring and evaluation in space, requiring improvements in currently available space medical monitoring systems.

The accurate measurement of arterial blood gas tensions, as opposed to venous, in medical practice and physiological studies on Earth and in space is of particular importance, as these can better reflect alterations in performance of the cardiopulmonary system and related diseases. However, there is currently no suitable method to access arterial blood in microgravity, and consequently, values for blood gas tensions are usually derived from measurements of respiratory gas partial pressures. Nonetheless, the measurements of oxygen saturation by oximetry are not considered comprehensive or accurate enough for detailed research or clinical practice.

The utility of finding a solution to this problem is not in doubt. Physiological findings could be confirmed with greater accuracy and more detailed studies conducted in the future. Clinical emergencies could also be managed with greater facility, resulting in increased safety for all crew involved in space missions. To this end, the arterialized earlobe blood collection technique for evaluating blood gas tensions has been considered for use in space, as analyses of the blood obtained could provide valuable information regarding the diagnosis of a number of medical conditions. This technique was first developed in 1944 and adopted under certain circumstances as an alternative to arterial puncture and arterial cannulation [1]. Nonetheless, the current earlobe arterialized blood collection technique is untested in microgravity, as is the risk of contamination of the environment with blood droplets. Therefore, a series of researches and tests have taken place to validate the suitability of the arterialized blood as an analogue of arterial blood and its suitability for use in microgravity, the creation of an easy-to-use and safe device for collecting arterialized blood from the earlobe, validating its use in ground-based studies on Earth and in microgravity, and determining the space preparedness of the device for surviving the stresses caused by a space rocket launch.

## **2. Validation of the arterialized blood technique**

### **2.1 Arterialized versus arterial blood**

Arterial gas analyses are essential for the clinical evaluation of astronauts, since they provide important physiologic information and can be an important tool for performing disease diagnoses during a space mission. However, currently available devices and methods, such as puncture and cannulation of an artery, are considered unsuitable for use in this scenario.

Arterial cannulation, the positioning of an intra-arterial catheter, is a technique which allows continuous and direct monitorization of blood pressure and frequent sample withdrawal for blood analyses. Arterial blood by means of puncture is usually collected from the wrist or from the inner part of the elbow or other arteries, through the insertion of a needle in a previously cleaned area. The blood then flows into a heparinized syringe, and the needle is removed as soon as enough blood is collected [2].

Both arterial cannulation and puncture are known to be difficult techniques to perform, requiring specialist training, causing pain to the patient and having the possibility of contamination of the environment with blood droplets. Moreover, although low, there is an increased risk of serious complications, such as haematoma, excessive bleeding and infection. Therefore, it is well accepted that the direct sampling of arterial blood is unsuitable for use in many austere environments, such as in space missions [2].

The earlobe arterialized blood technique makes use of the fact that the capillary blood taken from the arterialized earlobe originates from the arterioles and thus has the composition of arterial blood. The technique has been available as a substitute for arterial puncture for more than 60 years in clinical medicine and physiological research. The success of the technique depends upon careful preparation of the earlobe, which is arterialized by rendering it hyperaemic. This can be executed by heating the earlobe or massaging it with a rubefacient cream, thus ensuring free flow of blood from any incision made. The time of preparation varies from study to study, though conventionally it ranges from 3 to 10 minutes, with the standard being around 4 minutes. Ensuring adequate vasodilatation is of primary

importance; therefore, if the earlobe is not hyperaemic after 4 minutes of preparation, massage or heating should continue. Conventionally, the skin of the earlobe is cleaned with alcohol, and a puncture, 2–4 mm deep, is made with a sterile blade. The blood is collected in a heparinized capillary tube or cartridge, which is held in such a way that the blood enters anaerobically by capillary action. This blood can then be analyzed using a standard blood analyzer [1, 3–6].

**Table 1** summarizes the differences between the two techniques of blood collection via arterial puncture and blood collection from an arterialized earlobe.

**2.2 Earlobe arterialized blood technique in microgravity simulation studies**

A series of studies were conducted at King’s College London, as part of the PhD thesis entitled ‘The effect of 3h of 6-degree Head-Down Tilt (HDT) with and without hypoxia and light exercise on lung function’ [7], with the aim of evaluating the feasibility of performing this technique in space missions.

There was first the need to establish whether the lower to upper body redistribution of blood that occurs during microgravity exposure, with the subsequent venous congestion of the face and neck of astronauts, could cause contamination of the arterial blood from venous blood, thereby affecting results. The arterialized capillary blood sample technique had not been used previously during ground-based microgravity simulations, parabolic flights or space missions, and therefore, a preliminary study was designed to evaluate the possible effect of the head congestion on the gas tensions of earlobe arterialized blood samples. In order to avoid the cardiopulmonary changes associated with tilting to the 6° head-down position, the ground-based microgravity simulation used, the increase in venous pressure in the earlobe associated with this position was reproduced by inflating a cuff around the neck, with the volunteer in the supine position.

The venous pressure at the earlobe was calculated as the change in the vertical height of the ear relative to the heart on transition from supine to 6° head-down. Assuming a 30 cm distance between the earlobe and the right atrium, the increase

| Characteristic          | Radial artery  | Arterialized earlobe   |
|-------------------------|--|--|
| Level of discomfort     | Potentially painful  | Virtually pain-free  |
| Potential complications | <ul style="list-style-type: none"><li>• Haematoma formation</li><li>• Hemorrhage</li><li>• Infection</li><li>• Potential for reduced wrist mobility</li><li>• Nerve damage</li></ul> | <ul style="list-style-type: none"><li>• Hemorrhage—from the earlobe, and therefore easily controlled with direct pressure</li><li>• Cutaneous infection at incision site (superficial)</li></ul>                                       |
| Ease of use             | Requires training: currently only physicians and specialist nurses are able to carry out this procedure  | Very easy technique to learn and carry out by non-medically qualified personnel  |
| Potential usages        | Currently used in hospital setting but only by trained personnel<br>Use in research circumstances is limited by the need for a physician to be available to carry out the technique  | Potential for many spheres of use:<br><b>Terrestrial:</b> hospitals, private clinics, rural health centres<br><b>Aeronautic:</b> patient transport<br><b>Space:</b> space station, extraterrestrial bases for research and medical use |

**Table 1.**  
*Comparison between the characteristics of radial artery puncture and blood collection from the arterialized earlobe.*

in hydrostatic pressure at the ear was 2.3 mmHg.<sup>1</sup> The increase in central venous pressure secondary to the headward shift of the blood during head-down tilt was of the order of 3 [8] to 5 mmHg [9], resulting in a total increase in venous pressure on moving from the horizontal to 6° HDT ranging from 5.3 to 8.3 mmHg. Therefore, a neck cuff pressure of 10 mmHg was adopted for the study, which would produce a slightly greater degree of venous congestion of the ear.

The research evaluated seven healthy volunteers, aged 21–36 years. Each volunteer laid supine on a couch and completed three phases of 10 min each, divided into baseline (neck cuff deflated, control), test (neck cuff inflated) and recovery (neck cuff deflated, recovery). During each phase, the respired gases at the lips were sampled continuously, using O<sub>2</sub> and CO<sub>2</sub> rapid response gas analysers, from which their outputs were recorded and used to calculate respiratory frequency, end-tidal PO<sub>2</sub> (partial pressure of O<sub>2</sub>) and PCO<sub>2</sub> (partial pressure of CO<sub>2</sub>). Two earlobe arterialized blood samples were collected during the last 2 min of each phase, and the PO<sub>2</sub> and PCO<sub>2</sub> were determined using the pH/blood gas analyser. During the performance of the earlobe blood collection, no participant showed apprehension or distress, and there were no reports of complication (skin infection or bleeding) after the completion of the experiment. The healing of the incision was well advanced 72 h following the procedures. These findings are in accordance with those of Spiro and Dowdeswell [10], who found the arterialized earlobe technique to have no morbidity and to be virtually pain-free.

The means ( $\pm$ standard deviation, SD) of the respiratory frequency, end-tidal PO<sub>2</sub> and PCO<sub>2</sub>, earlobe arterialized blood PO<sub>2</sub> and PCO<sub>2</sub> and the end-tidal minus earlobe arterialized blood PO<sub>2</sub> and PCO<sub>2</sub> differences before, during (test phase) and after inflation of the neck cuff are presented in **Table 2**.

The findings of this study showed no significant differences in the mean values of respiratory frequency, end-tidal PO<sub>2</sub> and PCO<sub>2</sub> and earlobe arterialized blood PO<sub>2</sub> and PCO<sub>2</sub> between the three phases. During the baseline, test and recovery phases, the end-tidal minus earlobe arterialized blood PO<sub>2</sub> and PCO<sub>2</sub> differences were 7.4 ( $\pm$ 2.8) and 1.0 ( $\pm$ 0.9), 7.7 ( $\pm$ 4.3) and  $-0.5$  ( $\pm$ 1.4) and 7.7 ( $\pm$ 3.3) and  $-0.6$  ( $\pm$ 1.0), respectively. The mean values of the differences found in this study are very similar to those reported in the literature for healthy volunteers breathing air at rest [11, 12].

The findings of this study were very important, as it demonstrated that congestion of the head did not affect the PO<sub>2</sub> and PCO<sub>2</sub> of the arterialized blood taken from the earlobe and the end-tidal arterialized blood differences. Therefore, it is possible to state that raising the venous pressure in the head by 10 mmHg, used to simulate the venous congestion encountered during microgravity exposure, did not cause any deleterious effect on the relationship between the PO<sub>2</sub> and PCO<sub>2</sub> of the arterialized blood sampled from the earlobe and the PO<sub>2</sub> and PCO<sub>2</sub> of the systemic arterial blood [7, 13, 14].

A second experiment was then designed within the scope of the same PhD thesis [7] to further understand the effects of HDT on the earlobe arterialized blood method. Therefore, hypoxia was added to the ground-based microgravity simulation in order to create an extra stressor. The differences between the tensions of oxygen and carbon dioxide in the end-tidal gas and earlobe arterialized blood were examined under two experimental conditions: breathing air (normoxia) and breathing a mixture of 10.7% O<sub>2</sub> in N<sub>2</sub>, which is equivalent to breathing air at an altitude of 16,000 feet<sup>2</sup> (hypoxia).

<sup>1</sup> A pressure of 1 mmHg corresponds approximately to 1.33 mbar.

<sup>2</sup> Equivalent to 4876.8 m



|                               | Baseline mean (±SD) | Test mean (±SD) | Recovery mean (±SD) |
|-------------------------------|---------------------|-----------------|---------------------|
| RF (br/min)                   | 13.1 ± 2.1          | 13.0 ± 2.2      | 13.0 ± 2.2          |
| PETO <sub>2</sub> (mmHg)      | 103.6 ± 3.3         | 107.2 ± 8.7     | 101.6 ± 5.0         |
| PabO <sub>2</sub> (mmHg)      | 96.2 ± 2.5          | 99.7 ± 7.1      | 93.9 ± 3.7          |
| PETCO <sub>2</sub> (mmHg)     | 38.2 ± 4.0          | 37.8 ± 4.1      | 38.2 ± 4.1          |
| PabCO <sub>2</sub> (mmHg)     | 38.0 ± 4.0          | 38.5 ± 4.0      | 38.8 ± 3.7          |
| PET-ab O <sub>2</sub> (mmHg)  | 7.4 ± 2.8           | 7.7 ± 4.3       | 7.7 ± 3.3           |
| PET-ab CO <sub>2</sub> (mmHg) | 1.0 ± 0.9           | -0.5 ± 1.4      | -0.6 ± 1.0          |

**Table 2.**  
*The effect of inflation of a neck cuff (test) on respiratory frequency (RF, breath/minute), end-tidal PO<sub>2</sub> (PETO<sub>2</sub>) and PCO<sub>2</sub> (PETCO<sub>2</sub>), earlobe arterialized blood PO<sub>2</sub> (PabO<sub>2</sub>) and PCO<sub>2</sub> (PabCO<sub>2</sub>) and end-tidal minus earlobe arterialized blood PO<sub>2</sub> (PET-ab O<sub>2</sub>) and PCO<sub>2</sub> (PET-ab CO<sub>2</sub>) differences.*

A system was designed for this experiment permitting volunteers to breathe the inspired gas mixture through an oronasal mask. The normoxic gas (air) was supplied to the volunteer from a compressed air cylinder, and the hypoxic gas mixture was produced by mixing appropriate flows of air and nitrogen. The gases were mixed in a 100 L Douglas bag, before being delivered to the participant. The concentration of oxygen in the bag was monitored at 1 min intervals throughout the experiment. The following safety procedures were put in place: a source of 100% O<sub>2</sub> was connected to the gas supply, and the concentration of oxygen in the inspired gas was monitored with an oxygen rapid response gas analyser (alarm set to operate at 10.2% O<sub>2</sub>). Arterial oxygen saturation (alarm set to operate at 65%) by means of pulse oximeter and blood pressure and heart rate were continuously monitored with a Finapres device. The ability of the volunteer to respond to simple commands was assessed every 2 min in order to identify any deleterious effect of hypoxia on mental performance and cognition.

Six healthy volunteers, aged 21–26 years, participated in the experiment and were not informed as to whether they were breathing air or the hypoxic mixture until the study was complete. The experiment began with the tilt table placed horizontally, and the individual was asked to lie in the supine position for 30 min (rest period). They were then placed into the required position (either supine or 6° HDT), wearing an oronasal mask and breathing the gas supply (either 20.9% O<sub>2</sub> or 10.7% O<sub>2</sub>) for 20 min. For the final 10 min, the oronasal mask was replaced with a mouthpiece, a valve box and a nose clip, the earlobe was arterialized using massage and a vasodilating cream, and two earlobe blood samples were collected. The PO<sub>2</sub> and PCO<sub>2</sub> of the blood samples were immediately determined by means of the pH/ blood gas analyser. End-tidal PO<sub>2</sub> and PCO<sub>2</sub> were continuously analyzed via the gas analysers and recorded during the last 10 minutes.

All volunteers completed the study without any untoward effects. The means of the end-tidal PO<sub>2</sub> and PCO<sub>2</sub>, the earlobe arterialized blood PO<sub>2</sub> and PCO<sub>2</sub> and the end-tidal minus earlobe arterialized blood PO<sub>2</sub> and PCO<sub>2</sub> differences for each body position during normoxia and hypoxia are presented in **Table 3**.

End-tidal PO<sub>2</sub> and earlobe arterialized blood PO<sub>2</sub> decreased, as expected, from approximately 103 and 94 mmHg during normoxia to 40 and 36 mmHg during hypoxia, respectively, for both positions together ( $p < 0.05$ ). The PET-abO<sub>2</sub>, consequently, also decreased from a combined mean of 9.6 mmHg during normoxia to a mean of 3.4 mmHg during hypoxia ( $p < 0.05$ ). The mean end-tidal and earlobe arterialized capillary PCO<sub>2</sub> decreased ( $p < 0.05$ ) during hypoxia in comparison

|           | PETO <sub>2</sub><br>mean<br>(±SD) | PabO <sub>2</sub><br>mean<br>(±SD) | PET-abO <sub>2</sub><br>mean<br>(±SD) | PETCO <sub>2</sub><br>mean<br>(±SD) | PabCO <sub>2</sub><br>mean<br>(±SD) | PET-abCO <sub>2</sub><br>mean (±SD) |
|-----------|------------------------------------|------------------------------------|---------------------------------------|-------------------------------------|-------------------------------------|-------------------------------------|
| Supine, N | 101.6 ± 8.8                        | 92.7 ± 8.9                         | 8.9 ± 2.9                             | 43.6 ± 2.9                          | 42.8 ± 3.2                          | 0.77 ± 2.4                          |
| 6° HDT, N | 105.6 ± 4.0                        | 95.4 ± 4.5                         | 10.3 ± 4.0                            | 42.1 ± 2.5                          | 41.9 ± 3.7                          | 0.13 ± 2.4                          |
| Supine, H | 40.9 ± 4.5 <sup>*</sup>            | 36.5 ± 3.3 <sup>*</sup>            | 4.7 ± 1.8 <sup>*</sup>                | 37.7 ± 3.3 <sup>*</sup>             | 35.7 ± 3.0 <sup>*</sup>             | 2.1 ± 3.4 <sup>*</sup>              |
| 6° HDT, H | 40.8 ± 3.8 <sup>*</sup>            | 36.9 ± 4.6 <sup>*</sup>            | 2.1 ± 3.4 <sup>*</sup>                | 35.8 ± 3.8 <sup>*</sup>             | 34.3 ± 5.2 <sup>*</sup>             | 1.4 ± 3.0 <sup>*</sup>              |

<sup>\*</sup>Different from normoxia; *p* < 0.05. All pressures in mmHg.

**Table 3.**  
Mean end-tidal PO<sub>2</sub> and PCO<sub>2</sub> (PET), earlobe arterialized blood PO<sub>2</sub> and PCO<sub>2</sub> (Pab) and end-tidal minus earlobe arterialized blood PO<sub>2</sub> and PCO<sub>2</sub> differences (PET-ab) during normoxia (N) and hypoxia (H) for 6° HDT and supine positions.

with normoxia in both positions, due to hyperventilation secondary to the low arterial PO<sub>2</sub>. There were no significant differences between the values of end-tidal, arterialized blood and end-tidal minus earlobe arterialized blood differences for PO<sub>2</sub> and PCO<sub>2</sub> when the two positions were compared during either normoxia or hypoxia.

These findings led to the conclusion that the 6° HDT position did not alter the end-tidal minus earlobe arterialized blood PO<sub>2</sub> and PCO<sub>2</sub> differences from those obtained in the supine position during either normoxia or hypoxia, which reinforces the belief that this technique is suitable for use in either ground-based microgravity studies or in space missions.

**3. Development and validation of an earlobe arterialized blood collector (EABC) device**

The previously presented two studies were pioneering, as they were the first to be conducted during HDT using the earlobe arterialized blood collection technique. It was demonstrated that this technique is feasible for application in space missions or for physiological studies during microgravity simulation on Earth; however, the technique has the possibility of causing contamination of the environment to take place. This could be of major concern, especially in a spacecraft or space station, as blood droplets in microgravity would float with the potential to contaminate fellow astronauts or equipment. Taking this into consideration, a self-contained device was developed that would permit a standardized sampling of earlobe arterialized blood to be safely collected in a microgravity environment by non-medical personnel and without discomfort to the volunteer. The device was developed by the Microgravity Centre in collaboration with IDEIA Institute, both from the Pontifical Catholic University of Rio Grande do Sul, Brazil.

**3.1 Evolution of the earlobe arterialized blood collector**

The vision for the design of the earlobe arterialized blood collector was to develop a device with the following properties:

- Able to produce a suitable incision in the earlobe, such that sufficient flow of blood ensues to allow rapid and easy blood collection.

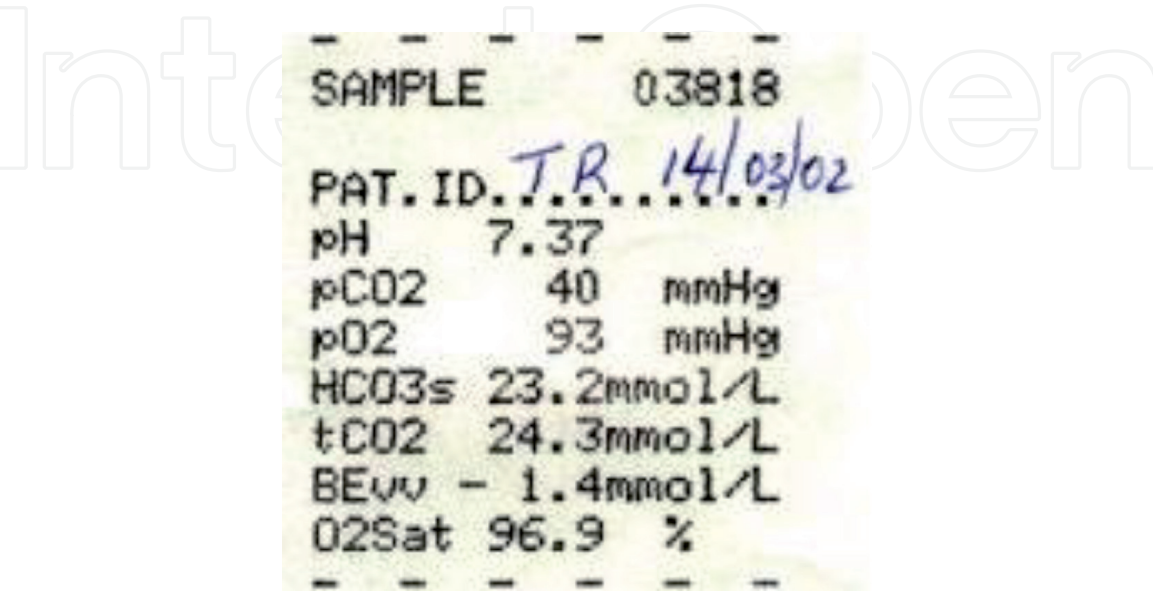
- The incision should be relatively pain-free and as accurate in depth and position as possible (in as far as these two variables should be predictable and easily adjustable).
- Capillary tubes or cartridges should provide anaerobic blood collection, through being positioned easily, quickly and precisely over the incision made and reducing the potential for contamination of the environment or any other part of the device.
- The device itself should be easy to use in terrestrial, aviation and extraterrestrial environments, with minimal training (user-friendly).
- The device must be easy to apply and remove from the earlobe, allowing quick application of gauze or a similar material to the incision to promote rapid hemostasis.
- The device must be small, lightweight, disposable and low-cost.

The first prototype was constructed in 1999, being 583 g in weight, 102 mm in length and 40 mm in diameter. This first prototype was mainly used to test the concept, and some earlobe arterialized blood collections were performed to evaluate the ability of the EABC to perform the cut and collect blood anaerobically, providing expected arterial gases results from a healthy volunteer (**Figure 1**).

The proof-of-concept success of this first EABC design led to its continued development, with a series of seven devices evolving over a 10-year period, leading to changes and improvements in shape, size, weight and used procedures (**Table 4**).

**Figure 2** illustrates the first four generations in the developmental process of the EABC and the final EABC device.

The technique of blood collection is demonstrated in the sequence of six pictures in **Figure 3**, which shows the earlobe arterIALIZATION procedure with massage and a vasodilating cream, cleaning of the earlobe skin, placement of the EABC with a cartridge, blood collection and analysis in an i-STAT blood analyser device (Abbott Point of Care Inc., Brazil).

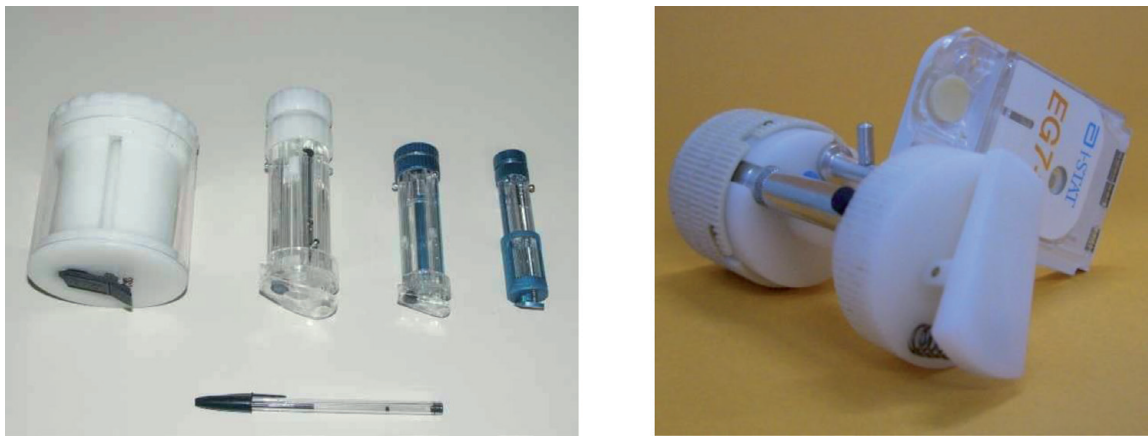


**Figure 1.**  
*First earlobe arterIALIZED blood result using the first version EABC.*



| Version | Dimensions L × Ø (mm)            | Weight (g) | Blade model      | Blood recipient   |
|---------|----------------------------------|------------|------------------|-------------------|
| 1       | 102 × 94                         | 583        | No 11            | Capillary tube    |
| 2       | 138 × 40                         | 228        | No 11            | Capillary tube    |
| 3       | 107 × 27                         | 85         | Adapted No 11    | Capillary tube    |
| 4       | 104 × 26                         | 42         | Adapted No 15°   | Capillary tube    |
| 5       | 90 × 23                          | 18         | Ophthalmic blade | Without cartridge |
| 6       | 57 × 26 (55 including cartridge) | 29.5       | Ophthalmic blade | I-STAT cartridge  |
| 7       | 73 × 26 (55 including cartridge) | 28.2       | Ophthalmic blade | I-STAT cartridge  |

**Table 4.**  
*Main characteristics of the seven versions of the EABC.*



**Figure 2.**  
*Evolution of the EABC—First four generations on the left and the seventh EABC device on the right.*

### 3.2 Preliminary EABC validation study

An initial EABC validation research was conducted involving six healthy volunteer students from King’s College London, using the second EABC prototype (**Figure 4**) [15, 16].

An 8° HDT was used as a microgravity simulator in combination with hypoxia, equivalent to breathing air at 12,000 ft.<sup>3</sup> Blood samples were collected from the radial artery of volunteers and simultaneously from their arterialized earlobe, after being in the HDT position and breathing a 12.8% O<sub>2</sub> in N<sub>2</sub> mix for 15 min (**Figures 5 and 6**).

The arterialization procedure involved first rendering the earlobe hyperaemic by the application of a rubefacient cream, massaged into the earlobe for a period of 5 minutes. The skin was then cleaned using an alcohol swab and dried with sterile gauze and the second version of the EABC attached to the earlobe. An incision was made in the earlobe and samples of blood collected in the two capillary tubes of the second version of the EABC, simultaneously with the drawing of a 2 mL sample of blood from the radial artery into a syringe lubricated with heparin solution (5000 IU/mL<sup>4</sup>).

The PO<sub>2</sub>, PCO<sub>2</sub> and pH of the blood samples were determined immediately using a blood gas analyser (Ciba Corning 238 pH/blood gas analyser, Ciba Corning

<sup>3</sup> Equivalent to 3657.6 m

<sup>4</sup> Heparin is a medication used as an anticoagulant (blood thinner). One unit of heparin is an amount approximately equivalent to 0.002 mg of pure heparin, which is the quantity required to keep 1 ml of cat’s blood fluid for 24 hours at 0°C.



**Figure 3.**  
*Sequence of six pictures showing the earlobe arterialized blood collection and subsequent analysis, placing the EG7 cartridge in the i-STAT device.*

Diagnostics Ltd., Halstead, Essex). The mean differences ( $\pm$ SD) in  $\text{PO}_2$  between earlobe arterialized and radial artery blood samples were  $0.25 \pm 1.25$  mmHg for  $\text{PO}_2$  and  $1.0 \pm 0.75$  mmHg for  $\text{CO}_2$ ; neither difference was significant. There was no difference between the pH values obtained by the two techniques. **Table 5** summarizes the results of the blood analyses.

### 3.3 Clinical evaluation of the EABC in haemodialysis patients

All EABC clinical studies were funded by the European Space Agency via the Medical Projects and Technology Unit from the Crew Medical Support Office, European Astronaut Centre, Cologne, Germany.

The physiological studies performed during microgravity simulation suggested that the arterialized blood sampled from the earlobe using the EABC may provide sufficiently accurate measurements of the  $\text{PO}_2$ ,  $\text{PCO}_2$  and pH of the arterial blood



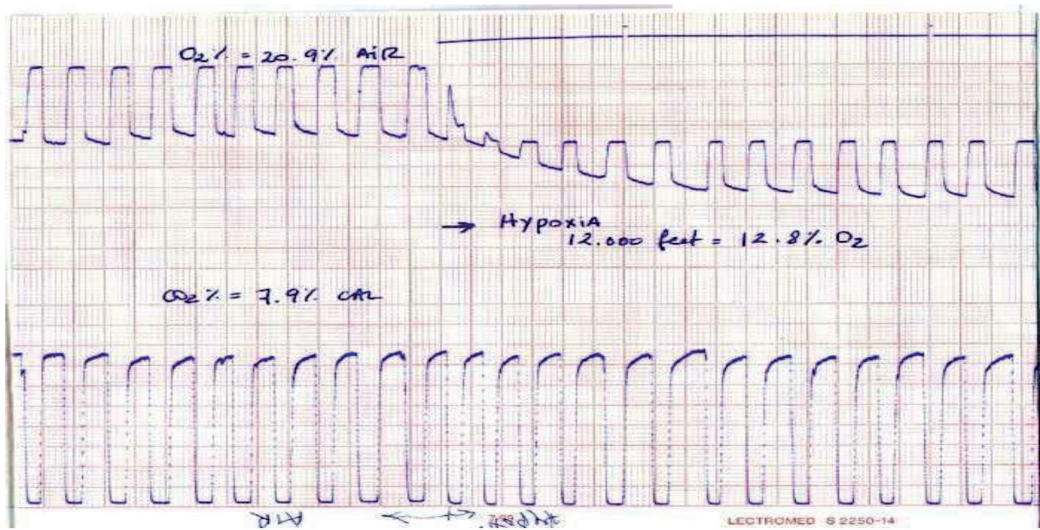


Length = 138 mm  
Diameter = 40 mm  
Weight = 228 g  
Blade number 11  
Materials: Acrylic, Polyacetal and  
Inox  
Structure: 4 Stages (Cut, 2 Collect,  
Gauze)  
Cut Size: Length: 3mm – Depth:  
1.7mm – Curvature radius 12mm

**Figure 4.**  
*Characteristics of the second EABC version.*



**Figure 5.**  
*Volunteer in HDT whilst breathing the hypoxic mixture.*



**Figure 6.**  
*Example of data being recorded during the beginning of hypoxic exposure (12.8% O<sub>2</sub> in N<sub>2</sub>, equivalent to breathing air at 12,000 ft<sup>3</sup>).*

|                         | Radial artery<br>Mean ± SD (range) | Arterialized earlobe<br>Mean ± SD (range) |
|-------------------------|------------------------------------|---|
| pH                      | 7.43 ± 0.02 (7.4–7.46)             | 7.43 ± 0.02 (7.4–7.46)                    |
| PO <sub>2</sub> (mmHg)  | 42.1 ± 3.66 (38–47)                | 42.9 ± 3.88 (37–50)                       |
| PCO <sub>2</sub> (mmHg) | 34.1 ± 1.88 (31–37)                | 33.12 ± 2.38 (29–37)                      |
| SaO <sub>2</sub> (%)    | 79 ± 3.85 (75–84.5)                | 79.9 ± 3.29 (74–85.6)                     |

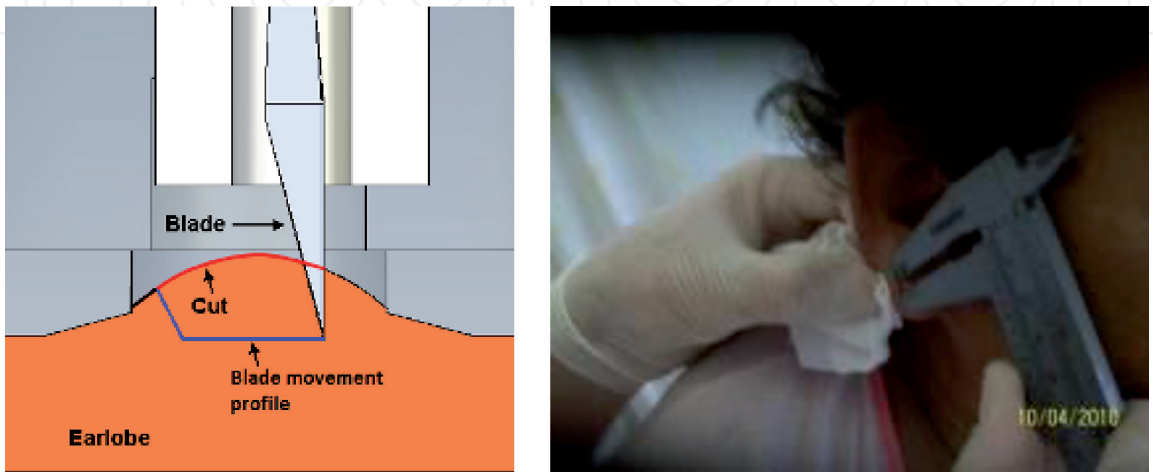
**Table 5.**  
*Blood gas data for simultaneous radial artery and earlobe arterialized blood samples collected using the EABC.*

for clinical or research use in extreme environments, such as space. However, another important step would be to also evaluate the use of the EABC in a clinical setting on Earth, as technology transfer from space to terrestrial application was one of the aims for the use of this pioneering technology.

With this in mind, a first clinical study was conducted involving 12 patients from a hemodialysis clinic, meaning these individuals already had a medically determined need for measurement of arterial blood parameters, including arterial blood gas tensions and acid–base variables, and access to arterial blood was easily provided by an already existing fistula. The main goal was to compare arterial blood variables taken from the arterial side of the arterial–venous fistula with those obtained from the earlobe arterialized blood collected using the seventh version of the EABC. Blood collection was achieved simultaneously from the fistula and the arterialized earlobe in an i-STAT EC8+ cartridge, and the two samples were analyzed using a portable i-STAT blood analyser device (Abbott Point-of-care Inc., Brazil) [17].

In addition to blood parameters, earlobe incision length and subject pain perception were also evaluated. Incision length (mm) was measured with a caliper immediately after blood collection, and the patient pain perception was assessed, using a scale from 0 (no pain) to 10 (maximum perceived pain). **Figure 7** shows a schematic view of the earlobe cut and its measurement during the experiment.

The mean of the differences obtained from the earlobe arterialized and arterial samples ranged from 0.006 (for pH) to 2.8 mg/dL (for glucose). The R<sup>2</sup> was equal or above 0.93 in 10 of the 13 blood variables measured, and the lowest R<sup>2</sup> was for PCO<sub>2</sub> (0.68). Of the 13 blood measurements, 9 presented no significant difference, whilst the 4 that were significantly different (BUN, Cl<sup>−</sup>, K<sup>+</sup>, anion gap) had their values within normality, presented no clinical implication and did not affect



**Figure 7.**  
*Schematic view of the difference between cut length and blade movement profile (left) and cut measurement being performed with a caliper.*



treatment or diagnosis. The mean ( $\pm$ SD) of the earlobe cut length was 4.4 ( $\pm$ 1.3) mm, and the patient perceived pain was classified as minor with a mean of 2.7 points out of 10 points.

These findings were very motivating, as they indicated for the first time that the EABC works in a clinical setting and therefore could be considered a method for safe and easy access to arterialized blood sampling for medical diagnoses, not only in space missions but also on Earth. It led to two further studies, which assessed the use of the EABC in more gravely ill hospitalized patients.

### **3.4 Clinical evaluation of the EABC in critically ill patients**

Two studies were conducted involving critically ill adult patients in intensive care units, aiming to assess the diagnostic and operational capability of the EABC.

A pilot study was first conducted, evaluating the use of the EABC on a cohort of mechanically ventilated adult critically ill patients admitted to an intensive care unit [18]. A comparison was made between the collected arterial blood and earlobe arterialized blood parameters, and the EABC was evaluated for its ability to diagnose acute respiratory distress syndrome (ARDS) in a total of 55 patients.

The results showed a high precision of earlobe arterialized blood samples. The measures of  $PO_2$  demonstrated insufficient agreement levels; however, better agreement was seen for  $PCO_2$  and pH measurements. The findings of this experiment showed a sensitivity of 100% and specificity of 92.3% for diagnosing ARDS using earlobe arterialized blood gasometric measures.

Sampling with the EABC proved to be unsuccessful in 43.6% of cases, due to insufficient blood flow, although this is not a surprising result given the circumstances of the patients and some important factors must be taken into account. The haemodynamic conditions of critically ill individuals and the use of medications that can cause vasoconstriction can negatively impact on the production of adequate peripheral blood flow. Therefore, the earlobe arterialized blood technique, with or without the use of the EABC, would not seem to be the best alternative for the management of patients in an intensive care unit, though it may prove useful in several clinical conditions and other critical care scenarios, such as emergency rooms, advanced medical transportation and pre-hospital care.

A second study was conceived to perform an operational evaluation of the EABC in critically ill patients [19], looking at aspects such as the number of cuts and cartridges required, ratio of sampling failure and success, bleeding complications and storage requirements. Fifty-five ventilated patients hospitalized in an intensive care unit participated in the study. The findings revealed that researchers took 26 min to obtain blood analysis, broken down into 15 min of patient preparation and 11 min for earlobe arterialized blood sampling and analysis. An average of 1.3 cartridges was required to achieve a successful cut of the earlobe. The results also demonstrated that researchers faced difficulties in performing blood collection in 59% of cases, but only 10% of these problems were reported to be linked to the EABC itself, such as superficial cut, blood leak, collector misalignment and vision obstruction. After the cut was performed, homeostasis appeared to occur quickly, and no major complications were reported. The study results suggest that the EABC is quick and safe to use and user-friendly.

## **4. Validation of the EABC for space use**

It is critically important that any device to potentially be launched into space must be able to withstand the launch process and spaceflight, remaining

undamaged. To be considered for use on the International Space Station (ISS) as part of a space mission, the EABC must demonstrate that it can meet the specifications of spaceflight conditions through being submitted to a series of electromechanical tests. The purpose of testing is to expose the EABC to the same circumstances as those encountered during launch onboard a Soyuz rocket and the microgravity environment on the ISS.

The required tests are shock and vibration tests, measurements and mass proprieties, low and high pressure and temperature tests, humidity test and off-gassing evaluation [20]. To confirm its suitability for space use, the following tests were applied:

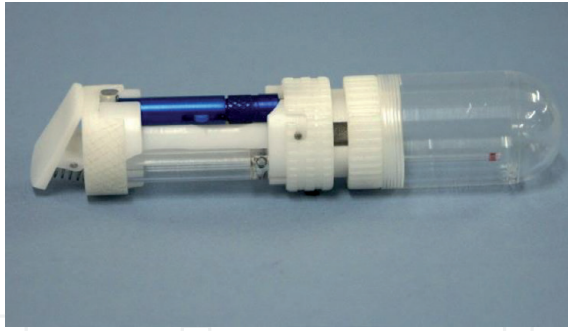
- Shock and vibration tests were conducted to check the functionality of the EABC after being launched to the ISS onboard the Soyuz. Two EABCs were placed inside a padded container and attached to a shaker and then submitted to different shock and vibration protocols.
- Measurements and mass proprieties must be known to determine precisely the mass and centre of gravity of the EABC.
- Low- and high-pressure and low- and high-temperature tests were performed to verify the physical and chemical stability of the EABC during variations of such conditions.
- Humidity test was applied to check the EABC functionality after the changes in relative humidity.
- Off-gassing levels were determined as different materials can contaminate the spacecraft ambient air and affect air filters, operation of other equipment and even astronaut health.

These tests were conducted at the National Institute for Space Research (INPE), in São José dos Campos, São Paulo, Brazil, with a successful evaluation of the variables tested. The final conclusion of the INPE experts was that the EABC was ready to fly in a space mission, as it is space-proof.

## **5. Validation of the earlobe arterialized blood collector for use in microgravity**

Having validated the EABC through studies performed in simulated microgravity, it was important to further validate the earlobe arterialized blood collection technique and device in an actual microgravity scenario. A study was conceived using the fifth EABC prototype (**Figure 8**, this was the prototype available when the proposal was submitted to ESA) to determine if it could effectively be used in the microgravity environment achieved during the free-fall phase of a parabolic flight (42nd ESA Parabolic Flight Campaign in 2006) [21], without contaminating the aircraft environment with blood products.

A total of eight healthy participants took part in the ESA parabolic flight campaign, acting as both volunteers and researchers. The blood collections took place inside a hood, especially designed by the Microgravity Centre/PUCRS, Brazil, in order to prevent any possible escape of blood to the aircraft environment. The hood had two openings on three sides for the insertion of two gloved hands each side and a larger opening in the front plastic wall for the volunteer to place their face and



Length = 90 mm  
Diameter = 23 mm  
Weight = 18 g  
Blade 15°  
Material: Tecaform AH, Acrylic,  
Aluminium  
Cut Size: Length: 4mm – Depth: 3mm –  
Curvature radius<sup>1</sup>: 8mm

**Figure 8.**  
*Fifth version of the EABC.*

be able to breathe, see and talk well. After blood collection, the capillary tube and blood were placed in a hard, human tissue disposal container placed inside the hood at the back (**Figure 9**).

An EABC device was assigned to each of the volunteers, and one or two samples were taken from their earlobes during the 20 s period of microgravity provided by the parabolas. This provided a final study sample of 25 successful earlobe arterialized blood collections in the capillary tubes with a volume of 75 mL (**Figure 10**). Each collection of blood was timed.

The mean ( $\pm$ SD) time for the collection of the arterialized blood from the earlobe during the microgravity phase of the parabolas was  $18.9 \pm 7.23$  s, which was very similar to the time required for the same group of researchers to collect on the ground (mean of 15 s). Researchers reported no difficulties in their ability to handle the EABC under microgravity conditions. It was also observed that no blood products emanated from the EABC, suggesting that the device seals were secure against blood leakage.

The data from this parabolic flight experiment strongly suggests that the arterialized blood from the earlobe can be as effectively sampled using the EABC in microgravity, in much the same way as the blood collections successfully occurred on the ground. Although this first study demonstrated the ability of the EABC to adequately acquire blood in microgravity, the next step required will be to assess the physiological blood variables in the weightlessness phase of a parabolic flight or during the sustained microgravity offered during space missions to ascertain whether this environment will affect such results [22].



**Figure 9.**  
*Hood system designed to avoid any possible blood contamination of the A300 cabin during the experiment.*





**Figure 10.**  
*Arterialized blood being collected during parabolic flight.*

## 6. Conclusion

The earlobe arterialized blood collection was considered for use in space and extreme environments by the author, due to the advantages of the technique, and researches were conducted to evaluate this possibility, with results suggesting it could be applied but at the same time highlighting the chance of blood contamination of the environment. Consequently, a device was developed to prevent this possibility, the earlobe arterialized blood collector, which subsequently underwent a series of tests in simulated microgravity on healthy volunteers and then in clinical practice to also evaluate its potential terrestrial use. Further evaluation was conducted in the microgravity provided by an ESA parabolic flight campaign, and the 'space readiness' of the EABC was assessed through a series of electromechanical tests. In summary, research results suggest the EABC device to be space-proof, easy-to-use and low-cost, enabling the collection of arterialized blood as an alternative possibility to arterial puncture/cannulation in the austere environment of space.

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