

# Technical validation of the EMMA capnometer under hyperbaric conditions

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## Keywords

Carbon dioxide; Capnography; Hyperbaric oxygen treatment; Intensive care medicine; Patient monitoring

## Abstract

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**Introduction:** End-tidal carbon dioxide (ETCO<sub>2</sub>) monitoring is essential for monitoring intubated critical care patients, yet its use in hyperbaric environments can be problematic. We postulated that the EMMA mainstream capnometer may function accurately under hyperbaric conditions.

**Methods:** Stage 1. The EMMA mainstream capnometer was tested at 101 kPa against a reference side-stream capnometer, Philips IntelliVue M3015B microstream, using 10 customised reference gases of various carbon dioxide (CO<sub>2</sub>) concentrations (2.47%–8.09%, or 18.5–60.7 mmHg at 101 kPa) in either air or oxygen. Stage 2. The functionality and accuracy of the EMMA capnometer was tested under hyperbaric conditions, 121–281 kPa, using the same test gases.

**Results:** At 101 kPa, the EMMA capnometer measured CO<sub>2</sub> at levels lower than expected (mean of differences = -2.5 mmHg (95% CI -2.1 to -2.9,  $P < 0.001$ )). The Philips capnometer measured CO<sub>2</sub> more closely to expected CO<sub>2</sub> (mean of differences = -1.1 mmHg (95% CI -0.69 to -1.4,  $P < 0.001$ )). Both devices demonstrated a significant linear relationship with expected CO<sub>2</sub>. The EMMA capnometer functioned up to the maximum test pressure (281 kPa). The device over-read CO<sub>2</sub> measurements at pressures > 141 kPa. Although variance increased at pressures in the therapeutic range for hyperbaric treatments, a significant linear relationship between expected and EMMA measured CO<sub>2</sub> was demonstrated. The EMMA capnometer tolerated pressures to 281 kPa, but its display was limited to CO<sub>2</sub> < 99 mmHg.

**Conclusions:** This study validated EMMA capnometer function to 281 kPa in the hyperbaric environment. The device over-read CO<sub>2</sub> measurements at pressures >141 kPa, however there was a linear relationship between expected and measured CO<sub>2</sub>. The EMMA capnometer may be clinically useful for monitoring expired CO<sub>2</sub> in patients undergoing hyperbaric oxygen treatment.

## Introduction

Hyperbaric oxygen treatment (HBOT) has approved indications in Australia.<sup>1,2</sup> Some patients requiring hyperbaric oxygen are critically ill. They require the same standard of care and monitoring when pressurised as occurs at 101.3 kPa (1 atmosphere absolute [atm abs]).<sup>3–5</sup> For ventilated patients, pulse oximetry and end-tidal carbon dioxide (ETCO<sub>2</sub>) are essential for monitoring patients.<sup>6</sup> End-tidal CO<sub>2</sub> monitoring provides real-time evidence of ventilatory compromise such as hyper- or hypoventilation, and displacement or obstruction of the tracheal tube.<sup>7,8</sup> Central nervous system (CNS) oxygen toxicity during HBOT may be worsened by hypercapnia.<sup>9</sup> Preventing hypercapnia is an important reason for monitoring ETCO<sub>2</sub> in ventilated patients receiving HBOT.

Hyperbaric medical devices must meet strict safety guidelines.<sup>10</sup> Hyperbaric facilities with critical care capability must test equipment to ensure devices are safe and

can function in hyperbaric conditions.<sup>11</sup> Some devices may not physically withstand pressure, requiring modification. Modifications carry a risk of voiding the device warranty. Electrical equipment also produces heat which increases fire risk during HBOT.<sup>12</sup> This risk can even occur for battery-operated (or backed up) equipment, especially if powered by lithium batteries, or if sparks are generated by brushed motors.<sup>13</sup>

Options to minimise risk from electrical devices include not using the equipment or situating the devices outside the chamber and connecting the equipment to sensors (including sampling lines) or effectors inside the chamber via ‘penetrators’ which traverse the chamber hull.<sup>4,14</sup> In-chamber devices may also be placed in nitrogen-flushed housings to reduce fire risk. In such cases, this limits accessibility to the equipment which then must be operated remotely.

Mainstream ETCO<sub>2</sub> determination, in hyperbaric conditions, is subject to errors due to the ‘pressure broadening effect’

produced by the increased density of gas. As a result, falsely high values of the patient’s  $\text{ETCO}_2$  are usually reported, which need to be corrected using mathematical equations for each device.<sup>15,16</sup> One study demonstrated a good correlation between  $\text{ETCO}_2$ , using a mainstream capnometer, and  $\text{P}_a\text{CO}_2$  taken during hyperbaric conditions at 284 kPa.<sup>17</sup> In hyperbaric facilities, devices to monitor  $\text{ETCO}_2$  may increase fire risk because they produce heat via infrared transmitters, particularly with traditional mainstream devices, exacerbated by 100% oxygen under pressure.

To monitor patients’ ventilation, hyperbaric physicians have also used arterial blood gas (ABG)  $\text{P}_a\text{CO}_2$  analysis, transcutaneous carbon dioxide tension ( $\text{P}_{\text{TC}}\text{CO}_2$ ), or externally connected side-stream  $\text{ETCO}_2$  samplers. In some facilities, in-chamber  $\text{ETCO}_2$  monitoring is not even used due to the lack of a suitable and easily applicable device (Personal correspondence with Australian clinical leads 2019).

Side-stream capnometers aspirate gas from the breathing circuit. Even at sea level pressures, the measurements may be affected by water removal, different conditions at the sampling site and sample cell (temperature and humidity), mixing of the sample gas when drawn through the cell and variable pressure drop across the tubing. Some of these effects can be compensated, but not all.<sup>18</sup> Side-stream capnometers have been used successfully during hyperbaric treatments, with the mains-powered analyser remaining outside of the chamber, and sampling gas lines exiting through a penetrator. Practical limitations to these devices include: the requirement for additional penetrators and potential delays in displaying and calculating corrected  $\text{ETCO}_2$  which delays clinical interventions. Mass spectrometry has been successfully used with side-stream analysis of decompressed gas samples, but this is clinically impractical.<sup>19</sup>

The EMMA mainstream capnometer (Masimo, Daneryd, Sweden) is a small, in-line device that contains a  $\text{CO}_2$  sensor and display in the same unit. It can be rapidly deployed and displays an averaged  $\text{ETCO}_2$  and respiratory rate.<sup>20</sup>

Given its compact, small size and low voltage (two AAA alkaline batteries), our study planned to technically evaluate the EMMA capnometer under hyperbaric conditions. We assessed whether it would accurately monitor  $\text{ETCO}_2$  under a range of hyperbaric pressures (121–283 kPa) using test gases of known  $\text{CO}_2$  concentrations.

**Methods**

Low-risk ethics approval was sought from the Human Research Ethics Committee (HREC) Network (Tasmania) but waived following direct communication from the Chair, due to being an equipment validation study without test subjects (personal communication from Chair of HREC, March 2019).

In stage 1, we tested the reliability of the EMMA mainstream capnometer at 101 kPa against a reference microstream (side-stream) capnometer, Philips IntelliVue M3015B using a range of  $\text{CO}_2$ -containing test gases 2.47%–8.09% (18.5–60.7 mmHg at 101.3 kPa [1 atm abs]).<sup>22</sup>

In stage 2, the functionality and accuracy of the EMMA capnometer was tested under hyperbaric conditions, 121–281 kPa, using the same calibrated test gases as Stage 1.

A third stage was intended to compare the EMMA capnometer against the same reference microstream capnometer in Stage 1 (Philips IntelliVue M3015B), however, the latter failed to function beyond 110 kPa, the cause of which could not be identified or remediated. This stage was abandoned.

**EQUIPMENT**

*Capnometers*

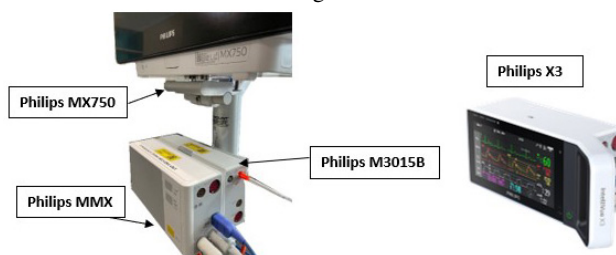
The EMMA mainstream capnometer is a small, alkaline battery-powered, in-line device that contains an infrared  $\text{CO}_2$  sensor and display in the same unit (Figure 1). It displays the average maximum measured  $\text{CO}_2$  of the last 4 breaths when  $\text{ETCO}_2$  changes by < 25%, or the last breath when  $\text{ETCO}_2$

**Figure 1**  
EMMA capnometer



**Figure 2**

Philips IntelliVue MX750, Philips Microstream capnometer (M3015B), Philips IntelliVue MMX and X3 multi-measurement monitoring modules



changes by > 25%.<sup>20</sup> It also displays a respiratory rate. The EMMA capnometer displays an average of maximum expired CO<sub>2</sub>, which in a strict sense, is not the ET-CO<sub>2</sub>. In addition, measurements in this study were conducted on test gases, so we have adopted a convention of describing data values in this study as concentration or partial pressure of CO<sub>2</sub>, not ET-CO<sub>2</sub>.

The Philips IntelliVue MX750 (Figure 2) is an integrated critical care monitor. The M3015B (Figure 2) extension module can be attached to either the IntelliVue X3 (Figure 2) or MMX (Figure 2) multi-measurement monitoring modules that integrate with the MX750 monitor. Gas is sampled from a sidestream (microstream M3015B device) which is placed in line with the airway tubing. The infrared CO<sub>2</sub> sensor is located inside the extension module instead of utilising an external sensor.

The MX750 itself was assessed as not suitable for pressurisation, owing to heat production and battery type (lithium ion). Like the MX750, the IntelliVue X3 has an LED touch screen which could be affected with changes in ambient pressure. The screenless MMX monitoring pod and microstream device also contained electronics and motorised pumps. It was assessed by local biomedical technicians as suitable for hyperbaric conditions provided continuous purging with nitrogen occurred.<sup>12</sup> The MX750 power source and output leads traversed the chamber wall via a penetrator. A hyperbaric compatible slave screen inside a nitrogen purged housing allowed viewing of observations within the chamber. Prior to use, both devices were calibrated according to the manufacturer's instructions.<sup>20,21</sup>

### Test gases

Ten customised reference gases of various concentrations of CO<sub>2</sub> in either air or oxygen were used. 'Air' and 'oxygen' test gases were chosen to represent a physiological range of expired gas from ventilated patients completing HBOT. This attempted to ensure that the EMMA was validated for the entirety of HBOT, including air breaks. For test cylinders containing 'air', the nitrogen percentage was kept constant, and the oxygen percentage was reduced in substitution of the additional CO<sub>2</sub> (Table 1). 'Oxygen' test cylinders contained a specific CO<sub>2</sub> percentage with the balance of the volumetric composition to 100% made up with oxygen. These were supplied with a certified standard analysis accuracy of ± 2% of the test gas concentration (BOC, Hobart, Australia). Final test gas mixes are summarised in Table 1.

### Conversion calculations

Test gases were presented as a percentage of CO<sub>2</sub>. Because the capnometers display measured CO<sub>2</sub> in mmHg, all test gas percentages were used to calculate an expected CO<sub>2</sub> (mmHg) measurement for each gas (Table 1). Conversion of test gas percent to mmHg was derived as follows:

Expected PCO<sub>2</sub> (mmHg) = (test gas CO<sub>2</sub>%/100) x 760 mmHg  
For example, PCO<sub>2</sub> for test gas A1 = (2.58/100) x 760 = 19.6 mmHg

The study was conducted in the Royal Hobart Hospital Department of Diving and Hyperbaric Medicine multi-place hyperbaric chamber (Fink Engineering Triple Lock Chamber S/N:229AH93, 10/2017 - Warana, Queensland, Australia).

**Table 1**  
Test gas mixtures, including calculated expected CO<sub>2</sub> at 101 kPa

Test gas	CO <sub>2</sub> (%)	Expected CO <sub>2</sub> (mmHg @ 101 kPa)	O <sub>2</sub> (%)	N <sub>2</sub> (%)
<b>'Oxygen' test gases</b>				
A1	2.58	19.6	97.4	0
B1	4.06	30.9	95.9	0
C1	5.04	38.3	95.0	0
D1	6.56	49.9	93.4	0
E1	8.09	61.5	91.9	0
<b>'Air' test gases</b>				
A2	2.47	18.8	18.3	79.2
B2	4.05	30.8	17.1	78.8
C2	4.92	37.4	15.7	79.4
D2	6.45	49.0	14.6	78.9
E2	8.00	60.8	12.9	79.1

Chamber pressure was measured in kPa using a Trafag digital transducer gauge (accuracy ± 0.25%, model 8253.77.2417, Trafag, Bubikon, Switzerland). The department is located on the third floor, approximately 10 m above sea level. Local barometric pressure can range from 99 to 104 kPa. During the study period, the pressure ranged between 100 and 101 kPa. For calculations a pressure of 101 kPa (760 mmHg) was assumed. It was accepted that a 0.9% error would occur in the expected CO<sub>2</sub> calculation for test gas mixes. EMMA and Philips capnometer measurements were in whole numbers of mmHg, hence, for a CO<sub>2</sub> measurement in the physiological range, this could lead to greater errors, up to 2.5% (1 mmHg/40 mmHg).

The expected CO<sub>2</sub> for each test gas was calculated at each hyperbaric test pressure (Table 2).  
 For example, PCO<sub>2</sub> for test gas A1 @ 121 kPa = (2.58/100) x (121/101) x 760 = 23.5 mmHg

*Gas delivery and ‘airway’ apparatus*

An oxygen clean flow meter was attached to the test gas cylinder. The test gas was delivered through a test circuit (Figure 3) using standard tubing and connectors. One-way valves were incorporated to prevent backflow.

Both capnometers were placed in series in the circuit. Initial testing demonstrated no difference in output readings if the devices were placed singularly or in a series configuration with either device in the primary position. The exhaust gas was released at least 1.5 m away from the test devices. During chamber testing, flushing occurred at regular intervals to keep the chamber atmosphere at acceptable standards in accordance with AS/NZS4774.2(2019).<sup>22</sup>

Chamber temperature and humidity were also kept within the operating ranges of each test device.

Initial testing was performed at 101 kPa to determine the best flow rate and time to reach steady readings for each test device. The Philips device would not show an ET<sub>CO</sub><sub>2</sub> reading until respiratory effort had been initiated (by detecting changes in flow). To remedy this, a disposable, paediatric resuscitator bag (Laerdal Medical Corporation, Norway), with a ventilation bag volume of 500ml, simulated a respiratory rate of 12·min<sup>-1</sup>. The paediatric resuscitator bag was used to create variability in the gas flow to simulate ventilation to trigger the Philips capnometer and to allow flushing of the circuit. It achieved both the latter and former with as low volumes as possible so as not to exhaust the test gas supply.

The ventilation bag was compressed by hand to achieve 50–100% of volume delivery. Measured CO<sub>2</sub> readings at 101 kPa were consistent, using this technique. A final flow rate of 3 L·min<sup>-1</sup> was chosen which produced steady readings for both devices in < 30 seconds.

*Repetitions*

During stage 1, EMMA and Philips capnometer readings were compared at 101 kPa. Ten readings were completed for each test gas at 101 kPa.

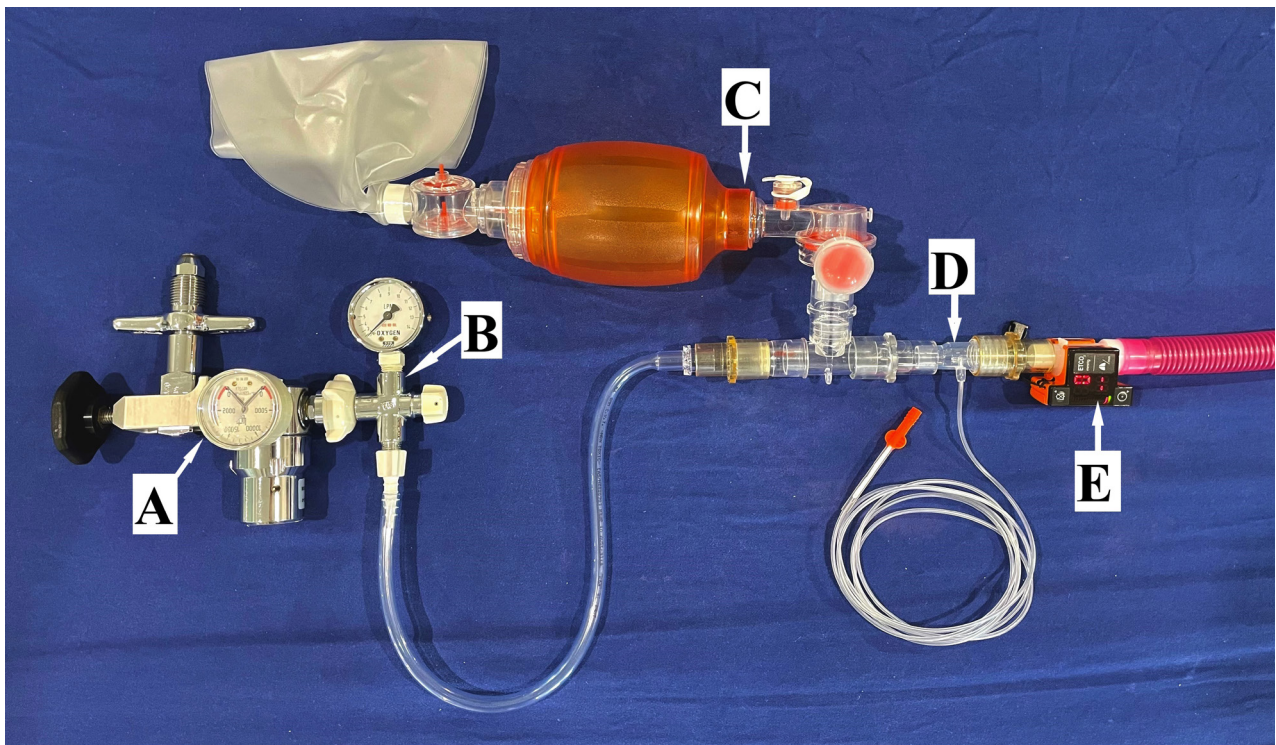
In stage 2, measurements of test gases in an ascending pressure profile (20 kPa increments 121–281 kPa) were conducted using the EMMA capnometer. Chamber pressure profiles were within DCIEM dive table no-decompression limits; supervised by trained hyperbaric technicians and

**Table 2**  
 Calculated expected CO<sub>2</sub> at various test pressures

Test gas	CO <sub>2</sub> (%)	Expected CO <sub>2</sub> (mmHg)								
		101 kPa	121 kPa	141 kPa	161 kPa	181 kPa	201 kPa	221 kPa	241 kPa	281 kPa
<b>‘Oxygen’ test gases</b>										
A1	2.58	19.6	23.5	27.4	31.3	35.1	39.0	42.9	46.8	54.9
B1	4.06	30.9	37.0	43.1	49.2	55.3	61.4	67.5	73.6	86.5
C1	5.04	38.3	45.9	53.5	61.1	68.6	76.2	83.8	91.4	107.3
D1	6.56	49.4	59.2	69.0	78.7	88.5	99.2	109.1	119.0	138.7
E1	8.09	61.5	73.7	85.8	98.0	110.2	122.4	134.5	146.7	171.1
<b>‘Air’ test gases</b>										
A2	2.47	18.8	22.5	26.2	29.9	33.6	37.4	41.1	44.8	52.6
B2	4.05	30.8	36.9	43.0	49.1	55.2	61.3	67.4	73.5	86.2
C2	4.92	37.4	44.8	52.2	59.6	67.0	74.4	81.8	89.2	104.8
D2	6.45	49.0	58.7	68.4	78.1	87.8	97.6	107.3	117.0	136.4
E2	8.00	60.8	72.8	84.9	96.9	109.0	121.1	133.0	145.1	169.2

**Figure 3**

Test circuit connected to the EMMA and Philips capnometers; A – regulator; B – oxygen clean flow meter; C – paediatric Laerdal bag; D – Philips capnometer; E – EMMA capnometer



clinicians. Ten measurements of CO<sub>2</sub> were made for each test gas at each test pressure.

### STATISTICS

Expected CO<sub>2</sub> was paired with the EMMA capnometer and Philips capnometer measured CO<sub>2</sub> at 101 kPa for correlation. Sampling under hyperbaric pressures compared expected CO<sub>2</sub> to the measured CO<sub>2</sub> samples from the EMMA capnometer at each pressure. Data were entered into Excel Spreadsheets (Microsoft® Corporation, Redmond Washington USA) and analysed using GraphPad Prism version 9.1.0.03 for Windows (GraphPad Software, San Diego, California, USA, 2021). Simple descriptive statistics were used to report reproducibility data.

Basic analyses included means, means of differences, standard deviations, and linear regression. Measurement data were subjected to simple linear regression and correlation analysis comparing EMMA Capnometer CO<sub>2</sub> measurements with expected CO<sub>2</sub> for test gases.

Bland-Altman plots were generated to assess agreement between the EMMA measured CO<sub>2</sub> and the expected CO<sub>2</sub> across the range of CO<sub>2</sub> concentrations and hyperbaric pressures. Graphs were produced comparing the EMMA CO<sub>2</sub> measurements at various chamber pressures, compared to expected CO<sub>2</sub> values from the test gas to determine if a predictable relationship would allow a correction equation

to be calculated. Statistical significance was accepted when  $P < 0.05$ .

### Results

Data were collected from June 2020 to July 2021.

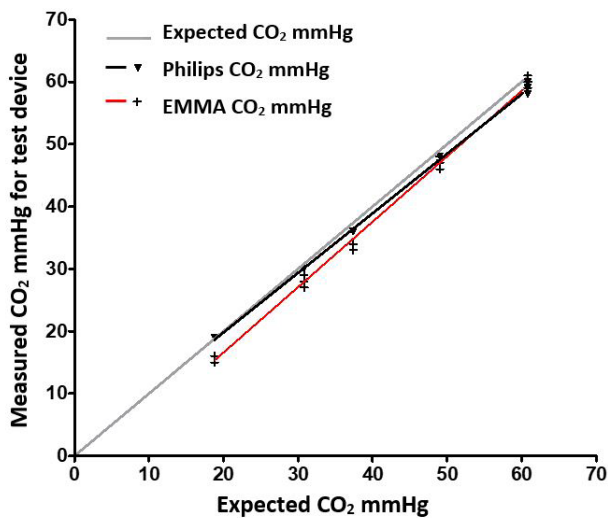
#### STAGE 1: DEVICE AGREEMENT AT 101.3 kPa

Measurements across the test gas concentrations using the Philips capnometer at 101 kPa were highly reproducible with standard deviations ranging from 0.0 to 0.7 mmHg (0–1% of the means). Measurements using the EMMA capnometer at 101.3 kPa were also highly reproducible with standard deviations ranging from 0.4 to 0.7 mmHg (0–2% of the means).

Figure 4 shows a graph of the expected CO<sub>2</sub> versus measured EMMA and Philips CO<sub>2</sub> readings at 101 kPa. The grey line indicates the line of exact agreement between the devices and expected CO<sub>2</sub>. The EMMA capnometer consistently measured CO<sub>2</sub> at lower levels than expected (mean of differences -2.5 mmHg (95% CI -2.1 to -2.9,  $P < 0.001$ ). The Philips capnometer measured CO<sub>2</sub> more closely to the expected CO<sub>2</sub> (mean of differences -1.1 mmHg (95% CI -0.69 to -1.4,  $P < 0.001$ ). There was a narrow variance in measured CO<sub>2</sub> for both devices. These results were consistent with the manufacturers' stated sensitivities for both devices.<sup>20,21</sup>

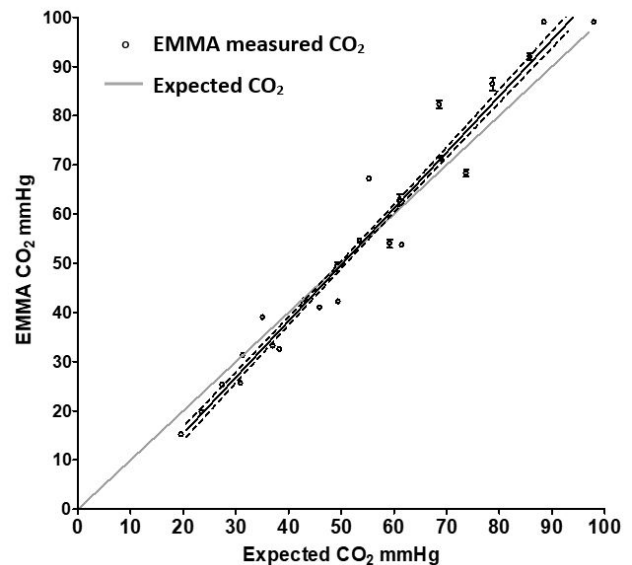
**Figure 4**

Expected CO<sub>2</sub> vs measured CO<sub>2</sub> with EMMA and Philips capnometers at 101 kPa



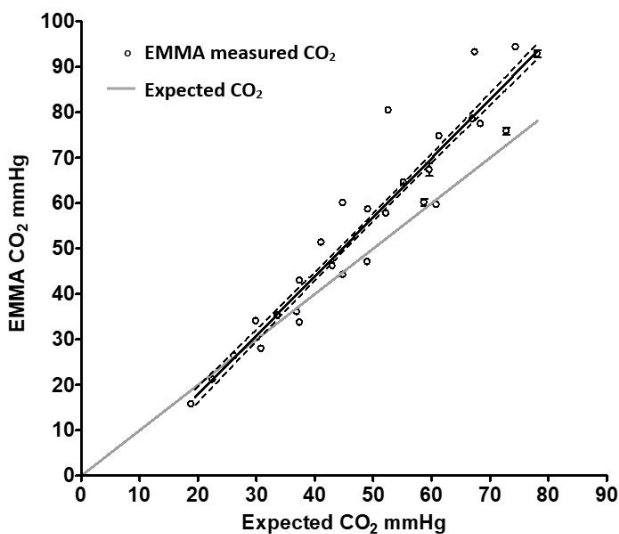
**Figure 5**

Measured EMMA CO<sub>2</sub> compared to expected CO<sub>2</sub> for oxygen/CO<sub>2</sub> test gases in hyperbaric conditions



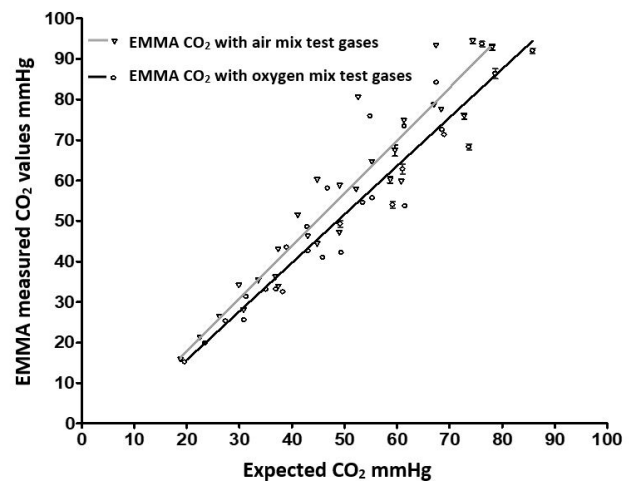
**Figure 6**

Measured EMMA CO<sub>2</sub> compared to expected CO<sub>2</sub> for air/CO<sub>2</sub> test gases in hyperbaric conditions



**Figure 7**

Linear regression graph showing EMMA CO<sub>2</sub> measurements comparing readings during exposure to oxygen and air test gases in hyperbaric conditions



At 101 kPa, both devices demonstrated a linear correlation with expected CO<sub>2</sub> and regression equations could be calculated for each device.

EMMA: Expected CO<sub>2</sub> = EMMA measured CO<sub>2</sub>/1.05 + 4.4 (R<sup>2</sup> = 1.0, P < 0.0001).

Philips: Expected CO<sub>2</sub> = Philips measured CO<sub>2</sub>/0.96 - 0.7 (R<sup>2</sup> = 1.0, P < 0.0001).

Between devices, the EMMA capnometer under-read compared to the Philips capnometer by a mean of -1.4 mmHg (95% CI -1.8 to -1.0, P < 0.001).

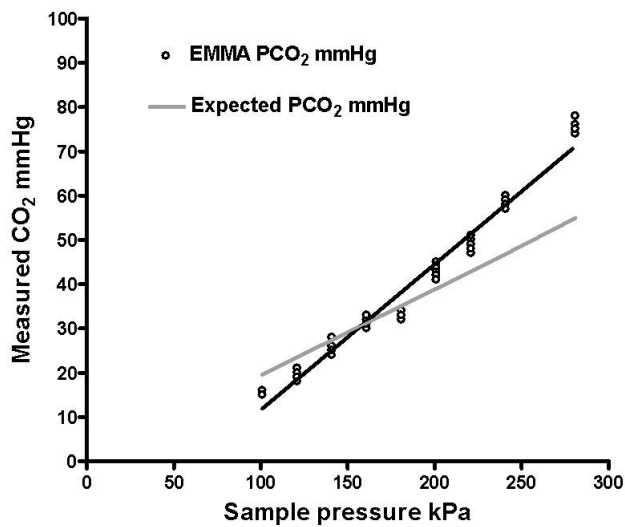
**STAGE 2: EMMA CAPNOMETER CO<sub>2</sub> MEASUREMENT UNDER HYPERBARIC CONDITIONS**

Figures 5 and 6 show measured EMMA CO<sub>2</sub> versus expected CO<sub>2</sub> for the oxygen/CO<sub>2</sub> and air/CO<sub>2</sub> test gases respectively.

EMMA Device for oxygen/CO<sub>2</sub> Test Gases (Figure 5): Expected CO<sub>2</sub> = EMMA Measured CO<sub>2</sub>/1.2 + 6.9 (R<sup>2</sup> = 0.89, P < 0.0001).

**Figure 8**

Measured EMMA CO<sub>2</sub> versus expected CO<sub>2</sub> for test gas 2.58% CO<sub>2</sub> in 97.42% oxygen at nine different pressures



EMMA Device for air/CO<sub>2</sub> Test Gases (Figure 6):  
 Expected CO<sub>2</sub> = EMMA Measured CO<sub>2</sub>/1.25 + 6.2  
 (R<sup>2</sup> = 0.90, P < 0.0001).

The EMMA device demonstrated a statistically significant linear relationship between measured CO<sub>2</sub> and expected CO<sub>2</sub> for both the oxygen/CO<sub>2</sub> test gas mixes and the air/CO<sub>2</sub> test gas mixes in the hyperbaric environment. The linear regression line gradients were significantly different for oxygen versus air CO<sub>2</sub> measurements (P = 0.004) (Figure 7).

The EMMA device consistently under-read the test gas CO<sub>2</sub> pressure for the lower values of expected CO<sub>2</sub>. Conversely, as the expected CO<sub>2</sub> increased, the EMMA device consistently over-read the CO<sub>2</sub> values (Figures 5 and 6). This effect was observed for all gas mixes, as pressure increased. An example is shown in Figure 8.

There was a statistically significant greater variance in EMMA CO<sub>2</sub> measurement at higher pressures (> 141 kPa) (Tables 3 and 4).

Bland Altman plots were generated for all samples to assess agreement between the EMMA CO<sub>2</sub> measurements with the expected CO<sub>2</sub> values (Figures 9 and 10). Figure 9 shows the bias of the EMMA capnometer Ratio = 1.01 (SD 0.15) (red line) using ‘oxygen’ test gases. The 95% limits of agreement for the data = 0.72 to 1.3, represented by the grey lines. Figure 10 shows the bias of the EMMA capnometer Ratio = 1.11 (SD 0.16) (red line), using ‘air’ test gases. The 95% limits of agreement for the data = 0.80 to 1.42, represented by the grey lines. Both demonstrated a more positive trend of differences with increasing CO<sub>2</sub>. This was greater for the ‘air’ gas samples, for which the bias was also higher. However, the differences were

**Table 3**

Mean of differences and variance between the EMMA CO<sub>2</sub> readings versus expected for test gases containing air mix; P-value for all differences < 0.0001; CI – confidence interval

Pressure (kPa)	Mean of differences (mmHg)	95% CI (mmHg)
101	-2.5	-2.8 to -2.2 (0.6)
121	0.4	-0.26 to 1.1 (1.36)
141	5.2	3.9 to 6.5 (2.6)
161	9.1	7.6 to 11.0 (3.4)
181	17.0	15.0 to 19.0 (4)
201	13.0	10.7 to 15.3 (4.6)
221	18.1	14.3 to 21.9 (7.6)
241	15.3	14.5 to 16.1 (1.6)
281	27.9	27.0 to 28.8 (1.8)

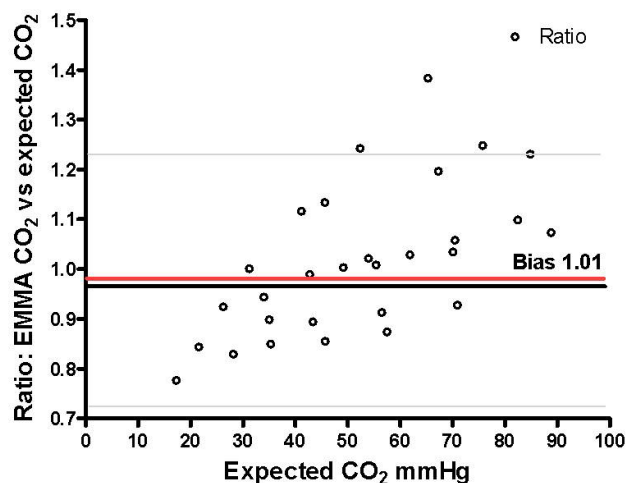
**Table 4**

Mean of differences and variance between the EMMA CO<sub>2</sub> readings versus expected for test gases containing oxygen mix; P-value for differences < 0.0001 except 141 kPa (P < 0.003) and 161 kPa (P < 0.001); CI – confidence interval

Pressure (kPa)	Mean of differences (mmHg)	95% CI (mmHg)
101	-6.1	-6.5 to -5.7 (0.8)
121	-4.6	-5.1 to -4.1 (1.00)
141	1.4	0.5 to 2.3 (1.8)
161	2.3	0.98 to 3.6 (2.62)
181	9.9	8.3 to 11.0 (2.7)
201	11.33	9.2 to 13.5 (4.3)
221	11.2	8.5 to 13.9 (5.4)
241	11.3	10.6 to 12.0 (1.4)
281	21.0	19.9 to 22.1 (2.2)

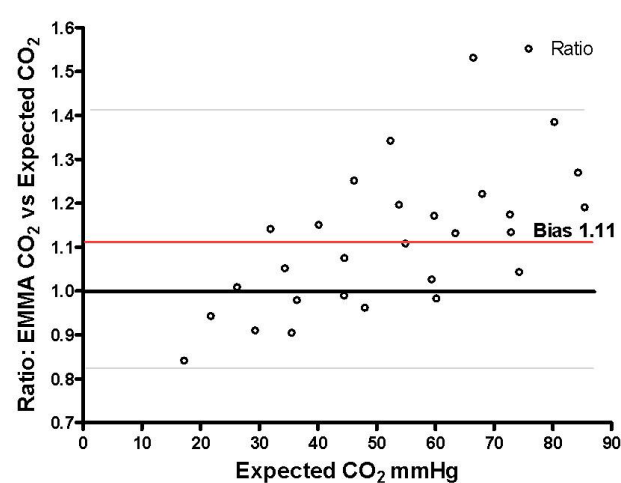
**Figure 9**

Bland Altman plot of EMMA CO<sub>2</sub> vs expected CO<sub>2</sub> ratio using oxygen test gases



**Figure 10**

Bland Altman plot of EMMA CO<sub>2</sub> vs expected CO<sub>2</sub> ratio using air test gases



more constant for values within the physiological range of CO<sub>2</sub> (30–60 mmHg) for both types of test gases.

Of note, data collection was limited by the EMMA device having a maximum displayed value of 99 mmHg CO<sub>2</sub>. The maximum reading of 99 mmHg was surpassed for a number of the test gases with increased chamber pressures. As a result, measurable data could only be obtained to 141 kPa or 161 kPa for some test gases. Only test gases A1 and A2 were able to be tested to our maximum test pressure of 281 kPa.

**Discussion**

Our study was designed to technically validate the function of the EMMA capnometer under hyperbaric conditions.

**BETWEEN DEVICE AGREEMENT AT 101.3 kPa**

At 101 kPa, both the EMMA and Philips capnometers had a linear relationship with the expected CO<sub>2</sub>. The EMMA capnometer consistently under-read, by a mean of 2.5 mmHg, compared to the expected CO<sub>2</sub>. Similarly, the Philips IntelliVue microstream capnometer also under-read by a mean of 1.1 mmHg.

The two test devices were limited to whole number displays of CO<sub>2</sub>, which could produce an error of ± 0.5 mmHg (1.25% at physiological ETCO<sub>2</sub> of 40 mmHg). The consistent CO<sub>2</sub> measurements demonstrated that both devices are sufficiently accurate for their intended clinical purpose of monitoring expired CO<sub>2</sub> at 101 kPa. Correction equations for expired CO<sub>2</sub> could be used, but the significant linear correlation means both devices reflect accurate trends in expired CO<sub>2</sub> without the need to apply correction calculations during clinical practice. These results were

consistent with the manufacturers’ stated sensitivities for both devices.<sup>20,21</sup>

The EMMA capnometer under-read compared to the Philips capnometer by a mean of -1.4 mmHg (95% CI -1.8 to -1.0, *P* < 0.001). Two previous studies have evaluated the EMMA capnometer against integrated ETCO<sub>2</sub> monitors under normobaric conditions. In patients undergoing a planned general anaesthetic, one study demonstrated a consistent between-device bias of -2.2 mmHg (limits of agreement -6.0 to +1.6) compared with a reference side-stream capnometer.<sup>23</sup> Another group compared nine EMMA capnometers with an integrated anaesthetic machine side-stream capnograph, using one participant. This study showed good agreement between the devices (median bias -0.3 mmHg), despite study limitations.<sup>24</sup> Both of the above studies assumed that the anaesthesia ETCO<sub>2</sub> equipment was the gold standard. Our study showed similar results using test gases. The EMMA capnometer would be an acceptable alternative to the Philips capnometer to monitor trends in CO<sub>2</sub> under normobaric conditions, especially in circumstances where mains power was not available.

**VALIDATION OF THE EMMA CAPNOMETER UNDER HYPERBARIC CONDITIONS**

Our literature search identified no published studies evaluating the functionality of the EMMA capnometer under increased ambient pressures. Given its size, portability and battery power, the device has potential for monitoring critical care patients in hyperbaric facilities.

Our study demonstrated a linear increase of the EMMA CO<sub>2</sub> measurements with increasing pressures. However, the EMMA capnometer measurements were lower than expected at low pressures and conversely higher than



expected at higher pressures (> 141 kPa). The slope of the EMMA CO<sub>2</sub> line was greater than the expected CO<sub>2</sub> slope. Additionally, there was greater variance in the measured CO<sub>2</sub> data collected where expected CO<sub>2</sub> was above the physiological range for ET<sub>CO</sub><sub>2</sub> (Figures 5–10). This may be due to both pressure and collision broadening. Despite this, the EMMA device demonstrated a statistically significant linear relationship between measured CO<sub>2</sub> and expected CO<sub>2</sub> for the oxygen/CO<sub>2</sub> test gas mixes and the air/CO<sub>2</sub> test gas mixes in the hyperbaric environment. The EMMA device potentially could be used to monitor trends in the hyperbaric environment.

We chose to use test gases, as opposed to test subjects, to remove the additional variables of inter-person variability in CO<sub>2</sub> production and elimination, and the challenges created by sample dilution and gas bypass in non-intubated patients. Our study cannot be considered an accurate representation of what would occur in a human subject.

The test gases were supplied as a specific concentration of CO<sub>2</sub>, so it is expected with increased pressure, the percentage of CO<sub>2</sub> would stay the same, but the measured CO<sub>2</sub> partial pressure would increase (Dalton's Law). The use of test gases is not the same as for a human subject exhaling CO<sub>2</sub>. A stable patient should produce CO<sub>2</sub> at a constant rate, and a consistent partial pressure of ET<sub>CO</sub><sub>2</sub> at 101 kPa. At higher chamber pressures, metabolic CO<sub>2</sub> would be diluted in the alveoli by the extra molecules of oxygen (+/- nitrogen). Theoretically, this would reduce alveolar CO<sub>2</sub> but maintain a measured ET<sub>CO</sub><sub>2</sub> within physiological ranges. Additionally, the test gases used during the study were dry. In humans, exhaled gas is normally saturated in water vapour, at body temperature. Its presence would likely further reduce measured ET<sub>CO</sub><sub>2</sub> when used clinically.<sup>18</sup> Therefore, ET<sub>CO</sub><sub>2</sub> at all pressures should remain in a range that could be measured by the EMMA capnometer (< 99 mmHg). EMMA measurements in the physiological range had less deviation from expected CO<sub>2</sub>, so the EMMA device may be useful clinically, particularly to monitor trends.

One group tested the SpaceLabs Medical 90369G mainstream capnometer using a range of test gases with known CO<sub>2</sub> concentrations (in oxygen only) under hyperbaric conditions.<sup>25</sup> This study tested the device at only one experimental pressure of 243 kPa (2.4 atm abs), a typical hyperbaric oxygen treatment pressure. Five test gas concentrations were selected to reflect an expected range of PCO<sub>2</sub> from 20.1–78.3 mmHg at this experimental pressure. Our findings with the EMMA capnometer, were similar to theirs. Their device also read erroneously high under hyperbaric conditions, which they presumed related to calibration issues, pressure broadening and collision broadening from oxygen. They identified a correction equation applicable to their device, but only under specific conditions of oxygen and pressure.

We used test gases of known CO<sub>2</sub> concentration in either an 'air' or 'oxygen' mix. Patients undergoing HBOT are treated with 100% oxygen periods with intermittent air breaks, to reduce the risk of oxygen toxicity.<sup>26</sup> Our test gases were chosen to represent typical ET<sub>CO</sub><sub>2</sub> in HBOT patients throughout their treatment period. We chose a range of CO<sub>2</sub> percentages to represent a range of ET<sub>CO</sub><sub>2</sub> of 20–60 mmHg at 101 kPa. These values represent normal physiological ET<sub>CO</sub><sub>2</sub> extended to include levels expected with possible hyper- or hypoventilation. Our study was limited by the inability to assess all test gases to our maximum experimental pressure of 281 kPa as some test gas expected CO<sub>2</sub> pressures were higher than the display capability (99 mmHg) of the EMMA device.

It is possible that a collision broadening effect may influence capnometer-measured CO<sub>2</sub> readings. This phenomenon affects the sensitivity of infrared analysers which leads to erroneous CO<sub>2</sub> readings.<sup>27</sup> It results in the broadening of spectral absorption peaks of a gas (e.g., CO<sub>2</sub>) due to the collision or proximity of molecules of another gas, e.g., N<sub>2</sub>O, oxygen. Typically, the addition of molecules such as He, N<sub>2</sub>O and H<sub>2</sub>O to a gas tends to cause erroneously higher CO<sub>2</sub> readings because the energy absorbed by a carbon dioxide molecule is transferred to the larger (additional) molecule when the two collide, permitting the carbon dioxide molecule to absorb more infrared energy, resulting in less infrared reaching the capnometer detector and a higher CO<sub>2</sub> reading.<sup>28</sup> This effect is less pronounced with homonuclear diatomic gases such as oxygen and nitrogen.<sup>28</sup> Capnometers are usually calibrated with known concentrations of CO<sub>2</sub> in nitrogen and oxygen at 101 kPa.<sup>28</sup> The practical consequences of collision broadening influencing the EMMA CO<sub>2</sub> readings for either our 'air' or 'oxygen' test mixes should be low, but data are limited from devices used at higher ambient pressures. In our study, both air and oxygen test gas mixes demonstrated a linear relationship between measured and expected CO<sub>2</sub> under normobaric and hyperbaric conditions with conversion equations able to be derived for both. However, there was a statistically significant difference between the air versus the oxygen test gas mixes under hyperbaric conditions, with more consistent readings (compared with expected) and a shallower slope with the oxygen test gases (Figures 7, 9–10). This could be due to the collision broadening effect of oxygen versus nitrogen. Even though this is statistically significant, the difference is so small, it would be unlikely to be clinically significant, and for practical purposes, the EMMA device can be used to monitor trends both during oxygen treatment periods and air breaks.

One group demonstrated that ET<sub>CO</sub><sub>2</sub> readings were erroneously high in hyperbaric conditions, which was attributed to the pressure broadening effect of increased gas density.<sup>15,16</sup> This is a similar concept to collision broadening described above, however, it is the density of the molecules that increases collisions and ergo energy absorption and

alters the infrared detection causing erroneously high measured CO<sub>2</sub> at higher pressures. Pressure broadening could be the main influence from nitrogen and oxygen on ETCO<sub>2</sub> measurements when measured at pressures > 101 kPa. Again, despite this phenomenon, a linear relationship could be derived for both groups of test gases.

Data collection was limited by the EMMA device having a maximum displayed value of 99 mmHg CO<sub>2</sub>. With increased pressures, there was an expected increase in CO<sub>2</sub> of the test gases. As per Table 2, we predicted that the expected CO<sub>2</sub> would surpass 99 mmHg for test gases C1 and C2 at 281 kPa, D1 and D2 by 201 kPa and for E1 and E2 by 181kPa. However, during our study, we observed that as the pressure increased, the EMMA device consistently overread at pressures higher than 141 kPa as well as having greater variance (Tables 3 and 4). The maximum reading of 99 mmHg was surpassed earlier than expected. As a result, measurable data could only be obtained to 141 kPa or 161 kPa for some test gases. Only test gases A1 and A2 were able to be tested to our maximum test pressure of 281 kPa. A possible solution for the maximum display value would be increasing the display capabilities of the EMMA device from two to three digits. However, as per previous reasoning, the EMMA capnometer display range should be adequate for clinical monitoring in the hyperbaric environment.

## Conclusion

This study validated the function of the EMMA capnometer in the hyperbaric environment. The device over-read CO<sub>2</sub> measurements at test pressures > 141 kPa, however there was a linear relationship between expected and measured CO<sub>2</sub>. These data suggests that the EMMA capnometer may be clinically useful for monitoring ETCO<sub>2</sub> trends in patients undergoing hyperbaric oxygen treatment.

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