Carbon dioxide analysers: accuracy, alarm limits and effects of interfering gases

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Six mainstream and twelve sidestream infrared carbon dioxide (CO_2) analysers were tested for accuracy of the CO_2-display value, alarm activation and the effects of nitrous oxide (N_2O), oxygen (O_2) and water vapour according to the ISO Draft International Standard (DIS) #9918. Mainstream analysers (M-type): Novametrix Capnogard 1265; Hewlett Packard HP M1166A (CO_2-module HP M1016A); Datascope Passport; Marquette Tramscope 12; Nellcor Ultra Cap N-6000; Hellige Vicom-sm SMU 611/612 ETC. Sidestream analysers: Brüel & Kjaer Type 1304; Datex Capnomac II; Marquette MGA-AS; Datascope Multinex; Ohmeda 4700 OxiCap (all type S1: respiratory cycles not demanded); Biochem BCI 9000; Bruker BCI 9100; Dräger Capnodig and PM 8020; Criticare Poet II; Hellige Vicom-sm SMU 611/612 A-GAS (all type S2: respiratory cycles demanded). The investigations were performed with premixed test gases (2.5, 5, 10 vol%, error $\le 1\%$ rel.). Humidification (37° C) of gases were generated by a Dräger Aquapor. Respiratory cycles were simulated by manually activated valves. All monitors complied with the tolerated accuracy bias in CO_2 reading ($\le 12\%$ or 4 mmHg of actual test gas value) for wet and dry test gases at all concentrations, except that the Marquette MGA-AS exceeded this accuracy limit with wet gases at 5 and 10 vol% CO_2. Water condensed in the metal airway adapter of the HP M1166A at 37° C gas temperature but not at 30° C. The Servomex 2500 (nonclinical reference monitor), Passport (M-type), Multinex (S1-type) and Poet II (S2-type) showed the least bias for dry and wet gases. Nitrous oxide and O_2 had practically no effect on the Capnodig and the errors in the others were max. 3.4 mmHg, still within the tolerated bias in the DIS (same as above). The difference between the display reading at alarm activation and the set point was in all monitors (except in the Capnodig: bias 1.75 mmHg at 5 vol% CO_2) below the tolerated limit of the DIS (difference ≤ 0.2 vol%). The authors conclude that the tested monitors are safe for clinical use (except those failing the DIS limits). The accuracy of the CO_2-reading (average of mean absolute bias) is better in the M-type than in the S1- or S2-type analysers although no statistical (nor clinical) significant differences could be detected. Most manufacturers work with stricter limits than those proposed by the DIS.

Key words
CARBON DIOXIDE: end-tidal, measurement, monitoring;
MEASUREMENT TECHNIQUES: capnometry;
MONITORING: carbon dioxide.

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Des analyseurs de gaz carbonique (CO_2) à infrarouge dont six à soutirage latéral et 12 de courant central sont évalués au regard de la précision, de l'activation des alarmes et des effets du protoxyde d'azote (N_2O), de l'oxygène (O_2) et de la vapeur d'eau conformément à la norme internationale ISO (DIS) 9918. Les analyseurs de courant central sont les suivants: (Type-M): Novametrix Capnogard 1265; Hewlett Packard HP M1166A (CO_2-module HP M1016A); Datascope Passport; Marquette Tramscope 12; Nellcor Ultra Cap N-6000; Hellige Vicom-sm SMU 611/612 ETC. Les analyseurs à soutirage latéral: Brüel & Kjaer Type 1304; Datex Capnomac II; Marquette MGA-AS; Datascope Multinex; Ohmeda 4700 OxiCap (tous de type S1: sans demande de cycle respiratoire); Biochem BCI 9000; Bruker BCI9100; Dräger Capnodig et PM 8020; Criticare Poet II; Hellige Vicom-sm SMU 611/612 A-Gas (tous de type S2: avec demande de cycle respiratoire). Les études sont réalisées avec des gaz étalons prémélangés (2,5, 5, 10 vol.%, erreur relative $\le 1\%$). Les gaz sont humidifiés (37% C) grâce à un Dräger Aquapor. Les cycles respiratoires sont simulés par des valves actionnées manuellement. Par rapport au biais de tolérance, tous les capnographes sont précis pour la lecture du CO_2 ($\le 12\%$ ou 4 mmHg de la valeur du gaz étalon) pour les gaz secs et humidifiés entre 5 et 10% en vol. de CO_2. L'eau se condense sur le raccord métallique du HP M1166A à 37° C mais non à 30° C. Le Servomex 2500 (moniteur de référence non clinique), Passport (Type M) Multinex (Type S1) et Poet II (Type

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S2) sont ceux qui offrent le moins de biais pour les gaz secs et humides. Le protoxyde d'azote et l'O_2 n'ont pratiquement pas d'influence sur le Capnodig et les erreurs pour les autres capnographes sont au maximum de 3,4 mmHg, ce qui est toujours en deçà du biais toléré par le DIS. La différence entre l'affichage et l'activation de l'alarme pour un niveau donné est la même pour tous les moniteurs (à l'exception du Capnodig: biais 1,75 mmHg pour un vol. CO_2 5%) sous la limite tolérée du DIS (différence $\leq$0,2 vol%). Les auteurs concluent que les moniteurs mis à l'épreuve sont satisfaisants pour l'usage clinique (excepté ceux qui sont en deçà des limites déterminées par le DIS). La précision de la lecture du CO_2 (la moyenne du biais absolu) est supérieure pour les appareils de type M aux analyseurs de type S1 et S2 bien qu'aucune différence statistique (ou clinique) n'ait été décelée. La plupart des manufacturiers utilisent des limites plus strictes que celle que recommande le DIS.

Capnography has gained great popularity over the last ten years.[1] The measurement of carbon dioxide (CO_2) in the respiratory gases has become a standard for basic monitoring in the operating room and intensive care units throughout the world.[2-5] The American Society of Anesthesiologists (ASA) revised the standards for basic intraoperative monitoring in October 1993. The new standard recommends that operating rooms should be equipped with oxygen (O_2) analyser (with a low O_2-concentration limit alarm), pulse oximetry and encourages CO_2 monitoring (strongly recommended after tracheal intubation).[6] The Canadian Anaesthetists' Society guidelines call for the use of capnographs as a required monitor. More than 20 different types of infrared CO_2 analysers are now available world-wide. All new models are able to display the CO_2 waveform continuouly using varying display formats.[7,8] The multigas analysers and the majority of capnometers are sidestream analysers,[9] where a portion of respired gases is diverted with a suction pump from the sampling site through a sampling tube to the sensor. The mainstream technique (the heated sensor is placed directly in the breathing line) has, however, regained great interest. The light and small airway sensors now offer several advantages, especially a fast response time that is suitable for paediatric monitoring.[10,11] The topic of capnometry has been reviewed in depth.[12-15] Raemer *et al.* have explored technical causes of errors in end-tidal CO_2 (PETCO$_2$) measurement and compared different commercially available infrared analysers including one Raman spectrometer and one stand-alone quadrupole mass spectrometer.[16]

The Draft International Standard (DIS) 9918 of the International Standard Organisation (ISO): "Capnometers for use with humans; requirements",[17] which will lead to the European Norm 864, proposes a series of test methods and limits which a commercially available carbon dioxide analyser should meet.

The aim of this study was to investigate the feasibility of DIS #9918 and to investigate 18 currently available CO_2 analysers (six are recently developed mainstream analysers) for:

- Accuracy of PETCO$_2$ reading with dry and wet gases; effect of the interfering gases nitrous oxide (N_2O) and oxygen (O_2).

DIS: CO_2 reading shall be ±12% of the actual gas value or ±4 mmHg, whichever is greater, over the full range.

- Accuracy of alarm limits.

DIS: The difference between the alarm set point and the CO_2 reading when the alarm is activated shall not exceed 0.2 vol%.

Methods

The monitors were divided into three groups. Type M: mainstream monitors, type S1: sidestream monitors with continuous PETCO$_2$ measurement (respiratory cycles not demanded) and type S2: sidestream monitors with non-continuous PETCO$_2$ measurement (respiratory cycles demanded). The Servomex 2500 precision infrared analyser served as a nonclinical reference device. All monitors were commercially available (in Europe) and factory new. Technical data of the monitors are shown in the Appendix (Appendix, Table IV to VI).

General

Each instrument was switched on at least one hour before use and was calibrated according to the manufacturer's advice. All S1- and S2-type monitors (except Poet II) have to be calibrated with a gas mixture (containing CO_2, N_2O, O_2, volatile anaesthetic or freon). M-type monitors are calibrated with reference cells (except Tramscope 12, Ultra Cap, Vicom ETC) where, together with Poet II and Servomex, CO_2 mixtures with balance nitrogen are used. Laboratory and gas temperatures as well as the barometric pressure (P_b) were recorded continuously during each calibration and measuring procedure (Therm 3480-6 electronic precision thermocouple thermometer (Ahlborn, Holzkirchen/D); precision aneroid barometer (Barigo/D)). Test gases proposed by the ISO draft standard were used: 0.0, 2.5, 5.0 and 10.0 vol% CO_2 balance nitrogen (N_2) or air. The gas mixtures were gravimetrically produced (Carbagas, Bern, Switzerland) according to the ISO Norm 6142[18] with an error of $\leq$0.03 vol%. The pressure of the compressed gases was reduced from 15 MPa to 300 kPa using reduction valves and dosed via rotameters. The gases then passed to a sample dis-

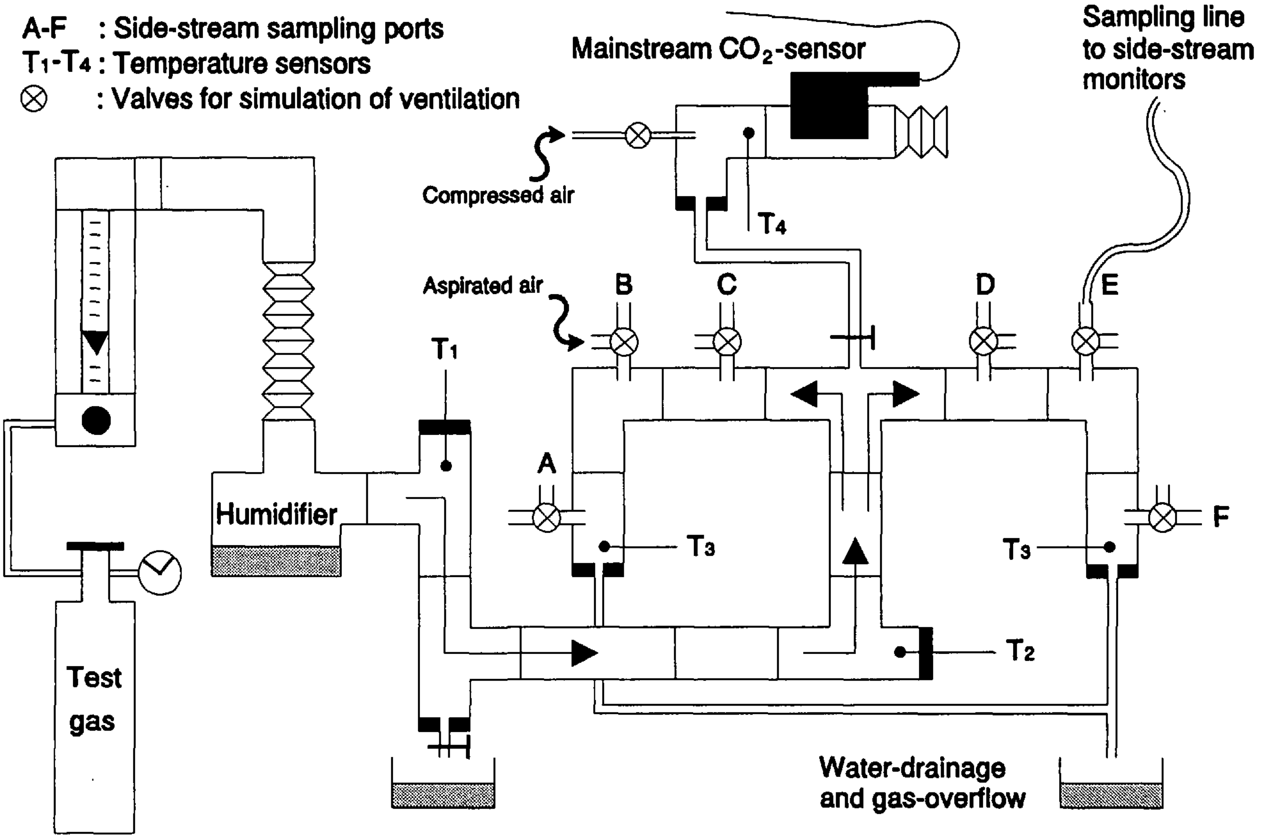


FIGURE 1 Schematic diagram of the test gas humidifying and distributing system. Mainstream and sidestream monitors (six simultaneously) were checked separately. Three-way taps (A-F) were used to simulate respiratory cycling. T_1 to T_4 are temperature measuring ports. The whole tubing system is thermically insulated.

tribution line consisting of a series of six standard sample connectors for the sidestream devices, or were conducted directly to the measuring cuvette in M-type monitors (see Figure 1). The selected measurement unit was mmHg unless otherwise stated. The actual partial pressure (PCO_2) of the dry test gases was simultaneously computed ($PCO_2 = P_b[\text{mmHg}] \cdot$ test gas concentration [vol %]/100). Sidestream and mainstream monitors were tested on separate occasions. Since the S2- and M-type monitors will display $P_{ET}CO_2$ only when one or more respiratory cycles are detected, changes of CO_2 concentration (cycles) were generated as follows. Sidestream devices: modified three-way taps were installed at the beginning of the sampling line and manually switched to either air or test gas sampling. Mainstream devices: The airway adapter was flushed periodically with air obtained from an oil-free compressed air supply (Jun Air 2000, Norresundby, Denmark), using a Herion-5/2-switchvalve (Vektor AG, Volketswil, Switzerland) installed before the sensor (Figure 1). Normal capnograms, with a baseline (during air phase) showing a CO_2 concentration of zero and a horizontal plateau (during test gas phase) with steady state $P_{ET}CO_2$ values, were obtained after three cycles and a sampling time ratio between air and test gas of 1:10 at a frequency of 6–10 cycles · min^{-1}. In the S1-type monitors displayed $P_{ET}CO_2$ values remained stable, whether respiratory cycles occurred or not.

Each measurement was repeated four times, both in ascending and descending order of CO_2 test gas concentration (taking into account a possible hysteresis effect), using both air and nitrogen as balance gas: 100% N_2 or air was used as zero gas concentration. The bias (display value – test gas concentration) and its standard deviation (mmHg) were computed. A small bias means high accuracy. In each monitor group (M, S1, S2) the mean absolute bias (MAB, all four concentrations) and the average (all monitors) of MAB was computed and compard with a t test ($P \leq 0.05$) to reveal a possible difference. The Servomex analyser was left switched on during the measuring period, continuously checking the test gas concentration at the sampling sites of the distributing line.

Accuracy with dry test gases

In sidestream devices the gas flow rate was adjusted about 300 ml · min^{-1} above the total sum of the sampling flows of the investigated monitors (150–250 ml · min^{-1} each) and the resulting overflow was conducted to the atmosphere via a short tube. The overflow was verified by briefly submerging the end of the tube into a receptacle of water watching for bubbles. For the M-type monitors the gas flow rate was kept at a constant 2 L · min^{-1}.

Interference by water vapour

To test the effect of water vapour the same test gas mixtures, fully saturated with water vapour in a heated cascade humidifier (Aquapor, Dräger, Lübeck, Germany) resulting in an end temperature of 37 ± 2°C (T_3, T_4 in Figure 1), were used. In order to keep the temperature of the saturated gases within narrow limits, the T-shaped sampling unit was thermically isolated with cotton wool and tinfoil and provided with four temperature measuring ports (T_1 to T_4 in Figure 1). Temperatures, T_1 and T_2 were measured by mercury thermometers; T_3 and T_4 represent the measurement points at the sampling inlet of the sidestream devices and at the mainstream sensor site. Temperature and humidity of $T_3 + T_4$ were measured by a calibrated capacitive hygrometer combined with a thermocouple temperature probe (Rotronic, Zürich, Switzerland; series 100, range 1–100°C and 1-100% relative humidity), which had previously been calibrated according to the manufacturer's instruction. Voltages at the analogue output of the probes were measured by precision digital voltmeters (Metex M-4630), which had previously been calibrated in the range of 0 to 10 volts with a calibrator (PJN 5210, AOIP, Evry Cedex, France). The gas flow rate through the humidifier (setting at position 2 of a scale 1–12) was kept at 1.5 L · min^{-1} which resulted in constant temperature readings after 30 min.

Measuring procedure

After six hours of continuous sampling of fully saturated air at 37°C by the sidestream devices (according to the DIS proposal), accuracy tests for wet gases were performed and the results computed in the same way as for dry gases, making the corresponding correction for the effect of gas dilution by the water vapour[19] ((P_b[mmHg]-47) · test gas concentration [vol%]/100). With mainstream devices a flushing period of more than one hour before the measurement with saturated air appeared to be sufficient as no difference in reading or water drop accumulation occurred in the measuring cuvette. Respiratory cycles were simulated for the sidestream devices as described above. The mainstream devices were cycled by flushing with warmed and fully saturated air at 35 ± 2°C (measured at T_4 in Figure 1) supplied by an extra humidifier (Puritan-Bennett Ltd, Overland Park/USA), thus avoiding temperature and humidity drops during cycling. At the end of the measurements with wet gases, humidity and temperature were measured at the exhaust outlet of the sidestream devices.

Temperature and moisture measurements of the breathing and sampling system in clinical conditions

To obtain temperature and moisture data found in the airways during clinical situations, temperature and humidity were measured in 15 ASA I and II patients scheduled for operations of two or more hours under general anaesthesia. Measurements were made at the patient side of the humidity and moisture exchanger (artificial nose), at the sampling site of the Y-piece and at the end of the sampling tube (entering the water trap of the monitors). The probe of the instrument was built into a modified non-metallic Y-piece creating a dead space of <10 ml. The probe was removed every 15 min for the measurement of the two variables in the operating room.

Accuracy of alarm activation

The accuracy of alarm activation was investigated by selecting two frequently used alarm set points, 50 and 25 mmHg. The alarms were activated by varying the CO_2 concentrations delivered to the sensors using dry test gases diluted with N_2. The resulting CO_2 readings were compared with the alarm set points and the display readings of the Servomex which was used as a reference device. Each monitor was prepared for the alarm test by setting the high and the low alarm limit at 50 and 25 mmHg respectively. The generated CO_2 concentrations were first roughly adjusted resulting in a reading of 10% above the low and 10% below the high alarm limit. The CO_2 concentrations were then increased or decreased stepwise (about 0.5 mmHg) until the alarms were activated. The measurements of the alarm limits were performed four times alternating high and low levels.

Effect of nitrous oxide and oxygen

The influence of the carrier gases, N_2O and O_2, was tested with test gases premixed according to the DIS: 5 vol% CO_2, 80 vol% N_2O, balance N_2 and 5 vol% CO_2, balance O_2, both with an absolute error of ≤0.5 vol%. The monitors which required a manual setting of the corresponding interfering gas correction were prepared accordingly each time before exposure to the test gases. In the devices where the $P_{ET}CO_2$ values are corrected automatically (based on the inspiratory O_2 and N_2O values) proper correction was achieved after an apnoea time (>20 sec) allowing the analysers to shift to the expiratory values. According to the DIS, the tested monitors should be exposed to the interfering test gases for two hours before

TABLE I Monitors not fulfilling the DIS accuracy test of the CO_2 display (DIS) or the manufacturers' information (MI) about accuracy for dry (d) and wet (w) gases

	2.5 vol% CO_2	*5.0 vol% CO_2*	*10.0 vol% CO_2*
Mainstream monitors			
Capnogard		MI: d	MI: d
S1-type monitors			
(respiratory cycles not demanded)			
Brüel & Kjaer 1304	MI: d	MI: d	MI: d,w
Capnomac II			MI: d, w
MGA-AS	MI: d, w	MI: d, w : DIS: w	MI: d, w : DIS: w
S2-type monitors			
(respiratory cycles demanded)			
BCI 9000	MI: w	MI: w	
BCI 9100	MI: w	MI: w	
PM 80-20		MI: w	MI: w
Poet II			MI: d, w

the measurements. In order to determine whether this long exposure had any influence on the results, we randomly chose five of the whole group of monitors and tested them strictly according to the proposal. The results of this subgroup and those given by full testing were then compared (mean of differences).

Results

During all measurements the gas and ambient temperature remained at 22 ± 1.0°C; ambient pressure was in the range of 717.75 ± 5.63 mmHg. The reference monitor Servomex 2500 showed differences of ≤0.85% rel with all test gases.

Accuracy with dry test gases

All tested analysers complied with the accuracy required in the DIS for dry gases, balance N_2 and air, over the full scale, but not all monitors fulfilled the manufacturers' information concerning accuracy (Table I).

All monitors showed the greatest absolute bias with 10 vol% CO_2. The difference (N_2-air) of mean absolute bias (MAB) showed that all analysers were slightly (≤1 mmHg) more accurate with test gases containing air than N_2, except Poet II, MGA-AS and Passport. Best accuracy (MAB) was achieved in Hellige ETC (M-type 0.28 mmHg ± 0.27), Multinex (S1-type 0.25 mmHg ± 0.26) and Poet II (S2-type 0.86 mmHg ± 1.21). The average of MAB (balance air and N_2) revealed that M-type monitors are slightly more accurate (0.7 mmHg) than the S1- or S2-type analysers (1.4 mmHg); there is, however, no statistical significance (see Figures 2a to 4a).

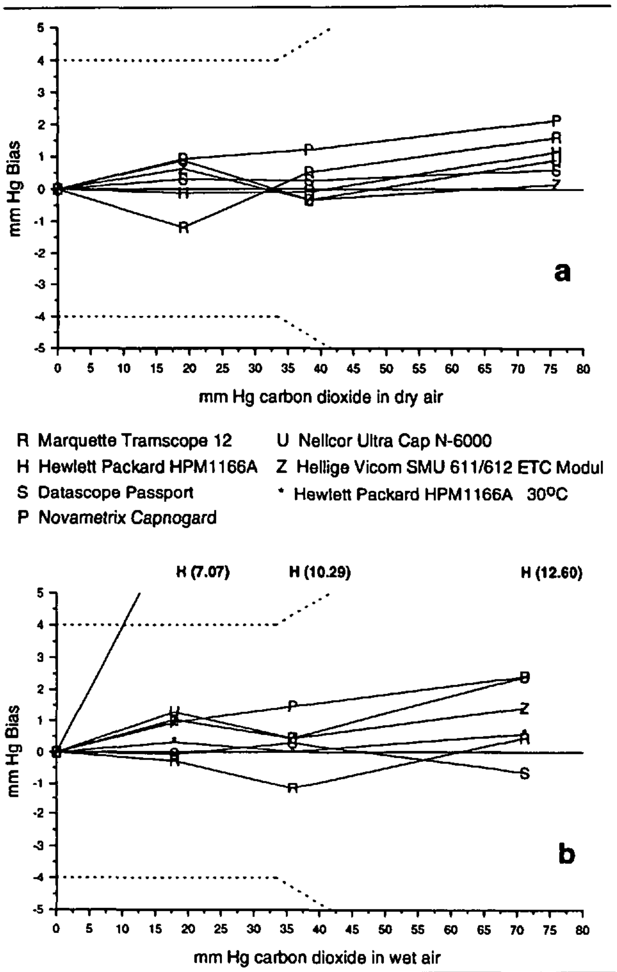


FIGURE 2 Bias (mean of four measurements) of the monitors display values to the (a) dry and (b) wet test gas values, balance air, in mainstream CO_2 analysers. The dotted lines denote the DIS limits. Standard deviations for (a) ≤±0.61 mmHg, (b) ≤±0.62 mmHg, except H: ≤±1.43 mmHg.

Interference by water vapour

The temperatures in the sampling unit remained stable during the testing period (T_1 = 45.7 ± 0.52°C; T_2 = 42.5 ± 0.55; T_3, T_4 = 37.2 ± 0.27).

Liquid water interference

Water condensation in the sample lines was considerable, almost completely filling the liquid trap after 10–12 hr of use under wet conditions. If no pooled water was aspirated, occlusion of the lines did not occur in any of the sidestream monitors. Water vapour condensed in the adult airway adapter (HP 14365A) of the HP M1166A resulting in a falsely high CO_2 reading and complete failure. However, repeating the wet gas testing by heating the saturated test gases to 30 ± 2°C only (comparable conditions at end of tube) changed the results of the CO_2 readings for this particular monitor dramatically (Figure 2b).

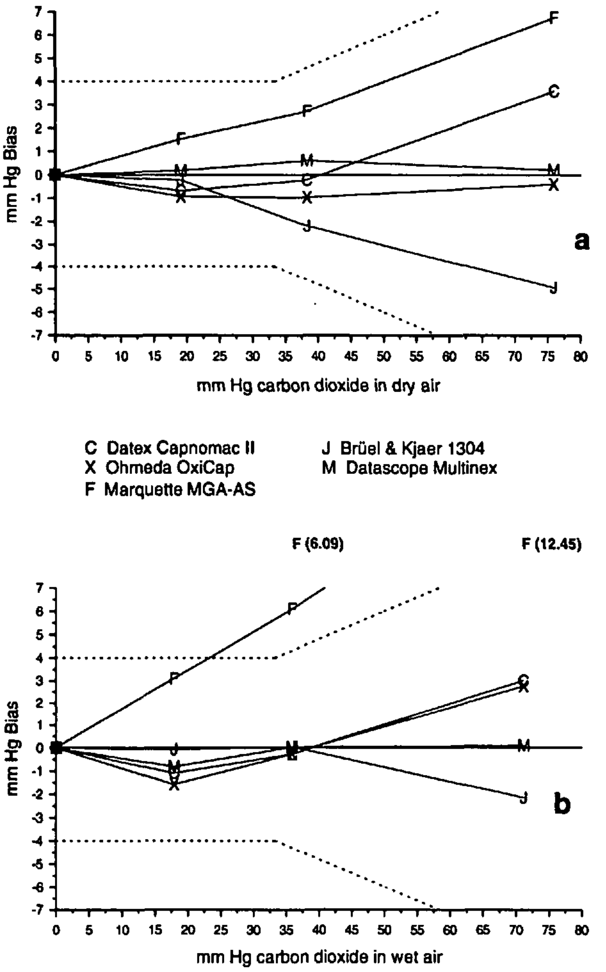


FIGURE 3 Bias (mean of four measurements) of the monitors display values to the (a) dry and (b) wet test gas values, balance air, in S1-type CO_2 analysers (respiratory cycles not demanded). The dotted lines denote the DIS limits. Standard deviations for (a) $\leq \pm 0.54$ mmHg, (b) $\leq \pm 0.60$ mmHg, except F: $\leq \pm 0.98$ mmHg.

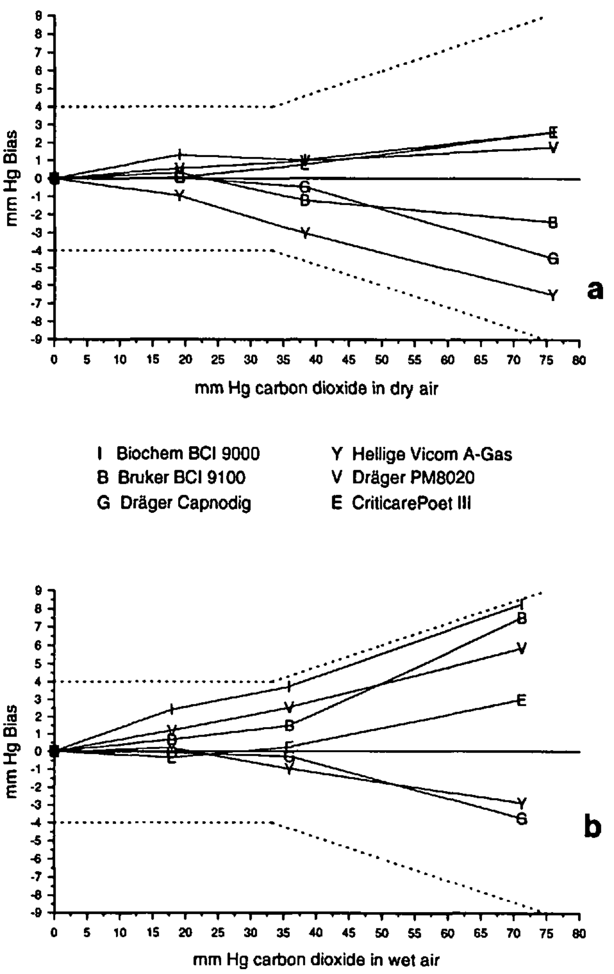


FIGURE 4 Bias (mean of four measurements) of the monitors display values to the (a) dry and (b) wet test gas values, balance air, in S2-type CO_2 analysers (respiratory cycles demanded). The dotted lines denote the DIS limits. Standard deviations for (a) $\leq \pm 0.53$ mmHg, (b) $\leq \pm 0.60$ mmHg.

Accuracy for saturated gas measurements

The sidestream monitors: BCI 9000, BCI 9100, PM 8020 showed great biases and reached the maximal tolerated deviations as proposed by the DIS especially with 10 vol% CO_2 (Figure 4b). The MGA-AS even exceeded the limits with 5 and 10 vol% CO_2 (Figure 3b, Table I). The accuracy of the mainstream monitors was well within the limits of the DIS and Passport showed the least MAB (0.25 mmHg ± 0.29) of all tested monitors. The greatest bias was found in the Capnogard: 4.2 mmHg at 10 vol% CO_2, balance N_2. The difference (N_2-air) of MAB showed that accuracy was slightly better (≤ 1 mmHg) with test gases containing air, especially at full range.

The direct effect of humidity on the readings could be demonstrated in all the monitors except in the Servomex. The readings with humid gases were generally slightly lower showing a dry/wet ratio of >1, except in the two monitors, Brüel & Kjaer 1304 and BCI 9000, where the ratio was <1 (Table II). The table also shows to what extent the gas samples are dried in relation to the laboratory environment.

Temperature and moisture measurements of the breathing and sampling system in clinical conditions

At fresh gas flows of 1 $L \cdot min^{-1}$ the airway gases were mostly saturated. When the fresh gas flow rate was kept at 3 $L \cdot min^{-1}$ the moisture reached lowest values after four hours of ventilation: 60.4% relative humidity at the mainstream (Y-piece) and 53% at the inlet of the sidestream monitor (Table III).

TABLE II Temperature and humidity of the test gases measured behind the monitor sensor units and of the laboratory environment. The dry/wet ratio shows the water vapour interference

	Sample exhaust at the monitor outlet		*Laboratory environment*		*Mean dry/wet ratio of the mean* $P_{ET}CO_2$ *reading over the full scale corrected to 760 mmHg*
	Temp (° C)	*Humidity (% rel)*	*Temp (° C)*	*Humidity (% rel)*	
S1-type monitors (respiratory cycles not demanded)					
Brüel & Kjaer 1304	23.0	43.0	22.0	50.2	0.982
Capnomac II	25.3	82.0	24.5	34.0	1.052
MGA-AS	23.5	98.6	21.0	38.0	1.012
Multinex	24.2	94.6	22.0	50.0	1.073
OxiCap	24.5	48.5	23.5	34.0	1.038
Servomex*	23.5	48.0	22.0	49.4	1.000
S2-type monitors (respiratory cycles demanded)					
BCI 9000	24.0	52.3	23.2	34.0	0.968
BCI 9100	25.2	37.5	24.6	34.0	1.005
Capnodig	25.0	91.0	24.2	34.0	1.023
PM 8020	21.5	50.0	21.0	53.0	1.016
Poet II	25.5	83.5	24.6	34.0	1.044
Vicom A-GAS	23.3	44.0	22.0	46.0	1.016

	Test gases passing the sensor cuvettes		*Laboratory environment*		*Mean dry/wet ratio of the mean* $P_{ET}CO_2$ *reading over the full scale corrected to 760 mmHg*
	Temp (° C)	*Humidity (% rel)*	*Temp (° C)*	*Humidity (% rel)*	
Mainstream monitors					
Capnogard	37.0 ± 2	100.0	21.3	36.0	1.081
HP M1166A	37.0 ± 2	100.0	23.0	37.0	0.866
	30.0 ± 1	100.0	22.0	41.5	1.060
Passport	37.0 ± 2	100.0	22.5	36.5	1.064
Tramscope12	37.0 ± 2	100.0	23.0	36.0	1.075
Ultracap	37.0 ± 2	100.0	23.0	38.6	1.089
Vicom ETC	37.0 ± 2	100.0	22.0	37.6	1.081

*No intrinsic drying system, external Nafion tube used.

Accuracy of alarm activation

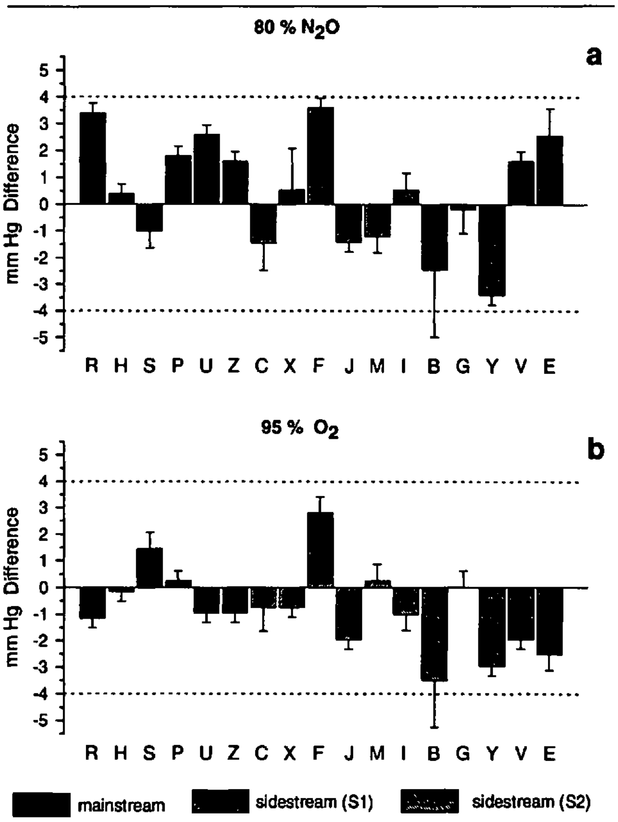
All tested analysers complied with the accuracy of alarm activation proposed by the DIS (≤0.2 vol%), except the Capnodig where the bias reached 1.75 mmHg for the upper alarm limit. The average (low and high) of MAB (mmHg) was in M-type: 0.42 ± 0.49, S1-type: 0.28 ± 0.36 and S2-type: 0.52 ± 0.57. The difference between the CO_2 readings of the Servomex and those of the monitors at alarm activation was ≤6 mmHg and well within the accuracy of CO_2 readings proposed by the DIS. Alarm activation of the non-clinical CO_2 analyser, the Servomex, was not tested.

Effect of nitrous oxide and oxygen

The CO_2 readings with the interfering gases O_2 and N_2O were well within the limits stated in the DIS (≤12%) in all tested monitors. Measuring the effect of oxygen, the best accuracy was found in the Capnodig, the mean difference being 0.00 mmHg. The greatest difference was found in the BCI 9100 (−3.49 mmHg). For N_2O, again, the Capnodig was found to have the smallest difference (−0.20 mmHg). The greatest deviation was found in the MGA-AS (3.60 mmHg), the Vicom A-GAS (−3.40 mmHg) and the Tramscope 12 (3.39 mmHg) (see Figure 5). The average of MAB showed that M-type analysers are less disturbed by O_2 (0.81 mmHg ± 0.52) than S1- (1.30 mmHg ± 1.05) and S2-type (1.98 mmHg ± 1.30) monitors and N_2O had a higher effect in all monitors (but equal in all types: 1.74 mmHg ± 1.22). A two-hour period of continuous exposure to the test gases before the measurements had no influence (difference 0.00 mmHg) on the results and could therefore be omitted.

TABLE III Temperature and humidity measured in clinical conditions in 15 patients (SD = standard deviation)

Temperature (° C)	*Max*	*Min*	*Mean*	*SD*
Operation room	22.6	20.9	21.2	1.1
Patient (rectal)	38.4	35.2	36.3	0.9
Tube connection	31.1	27.3	29.9	1.4
Y-piece at sample connection (after bact filter)	29.2	23.5	25.6	2.0
End of sample tube (monitor inlet)	25.9	21.7	23.3	1.3
Humidity (% rel)				
Operating room	45.7	33.2	40.2	5.4
Tube connection	100	93.7	98.9	2.6
Y-piece at sample site (after bact filter)	100	60.4	85.7	19.8
End of sample tube (monitor inlet)	100	53.0	83.5	15.5
Other parameters				
Fresh gas flow ($L \cdot min^{-1}$)	3.0	1.0	2.2	0.8
Sample rate ($ml \cdot min^{-1}$)	200	200	200	0.0
Sample tube length (cm)	300	180	250.8	38.0
Time between intubation and end of measurement (min)	345	50	120.8	77.1



R Marquette Tramscope 12
H Hewlett Packard HPM1166A
S Datascope Passport
P Novametrix Capnogard
U Nellcor Ultra Cap N-6000
Z Hellige Vicom SMU 611/612 ETC Modul
C Datex Capnomac II
X Ohmeda OxiCap
F Marquette MGA-AS

J Brüel & Kjaer 1304
M Datascope Multinex
I Biochem BCI 9000
B Bruker BCI 9100
G Dräger Capnodig
Y Hellige Vicom A-Gas
V Dräger PM 8020
E Criticare Poet II

FIGURE 5 Effect of interfering dry gas mixtures on CO_2 reading: (a) 5 vol% CO_2 80 vol% N_2O balance N_2, (b) 5 vol% CO_2, 95 vol% O_2. The dotted lines denote the DIS limits.

Discussion

To test gas analysers for accuracy, either precisely premixed test gases or an established reference method for gas analysis like mass spectrometry, refractometry,[20] chromatography and probably other methods are needed. Since premixed gases are expensive, an accurate gas analyser to test and calibrate clinical gas monitors would be of advantage. The Servomex 2500 is a single-beam multiwavelength infrared CO_2 analyser designed for industrial purposes. This instrument was used as a reference in this study because it fulfilled the manufacturer's accuracy claims (Appendix, Table VI) and its accuracy was almost comparable with those of the test gases used in this study. Although the accuracy limits proposed by the DIS are more tolerant than those used by the manufacturers (Table I) they satisfy clinical requirements entirely. The manufacturers' information on the accuracy for the Capnomac II, i.e., error <1.5 mmHg over the full scale and on the nonlinear error of the Brüel & Kjaer 1304 of 2% relative are too optimistic. However, at clinical CO_2 concentrations the Capnomac II complied with the strictest limits set by the manufacturer whereas the Brüel & Kjaer 1304 complied only at 10 vol% CO_2 wet.

Accuracy with dry test gas

The DIS accepts a CO_2 reading of ±12% relative to the actual test gas value or ±4 mmHg, whichever is greater over the full range of capnometer readings (2.5 vol% CO_2: 19 ± 4 mmHg, 5 vol%: 38 ± 4.56 mmHg, 10 vol% CO_2: 76 ± 9.12 mmHg). Bias was smaller with test gases containing air than those containing N_2. As in clinical conditions O_2 is always present, test gases containing O_2 (air) are therefore more realistic than those with N_2 as balance. We have therefore omitted the test results we obtained with N_2.

Temperature and moisture measurements of the breathing and sampling system

When using a low-flow technique, inspired gas may be almost completely saturated in contrast to when the semi-open Mapelson or Bain systems are used (Table III).[21,22] The monitors are thus exposed to gases of highly variable humidity. The manufacturers of the mainstream devices assume the gases to be water saturated at 28-33° C. Many sidestream sensor units are provided with drying systems (Nafion tubing) equilibrating water vapour pressure to ambient conditions (Appendix, Table IV). Others do not dry the sampling gases at all (see sample exhaust, Table II). Reading errors of the true PCO_2 resulting from the moisture present in the sample tubings have been calculated in previous studies.[16,19] They were in the magnitude of 0.5 mmHg when the gas had been dried and of 1 mmHg, if not. The sensors inserted in the mainstream at the tube connection are exposed to an average water vapour pressure of 29 mmHg (temperature = 30° C; relative humidity = 90%; Table III), resulting in a difference to the lung value of 0.9 mmHg at 5 vol% CO_2 and 100% water vapour saturation in the lungs ($0.05 \cdot (P_b\text{-}29) - 0.05 \cdot (P_b\text{-}47) = 0.9$). In previous evaluations of the monitors Brüel & Kjaer 1304 and the Datex Capnomac by McPeak *et al.*, water vapour seemed to have no effect on the gas measurements.[23,24]

Interference by water vapour

The water vapour has three effects on the readings: dilution of the CO_2, increase of the readings by the phenomenon called "collision broadening" and absorption of some of the bands of infrared light used to measure CO_2. Independent of the physical effect of the water vapour on the CO_2 measurement, the water vapour pressure should be taken into account by the instruments (in clinical conditions: $FCO_2 \times (Pb\text{-}47)$) if a true ("deep lung") value for PCO_2 of the patient sample is to be expected on the display. If this correction is present, the reported values are expressed at body temperature and pressure saturated (BTPS). Without a water vapour correction the values for PCO_2 are reported at ambient temperature and pressure dry (ATPD) (Appendix, Tables IV and V). The error in reporting at ATPD when it should be reported at BTPS is 2.35 mmHg at 5 vol% CO_2 and 4.7 mmHg at 10 vol% CO_2. To make sure that the CO_2 monitor in use reports a correct PCO_2 value, Severinghaus describes several methods to perform empirical calibrations.[19]

Selecting mmHg, the wet measuring mode was automatically selected in the monitors with a water vapour compensation allowing for the PCO_2 readings at BTPS. The operators manuals of the Brüel & Kjaer 1304, the Ultra Cap N-6000 and the Vicom A-GAS declare that if vol% is selected the displayed value is reported at ATPD. This dry measuring mode is not selectable in the HP M1166A. If $P_{ET}CO_2$ values were converted to BTPS values and displayed accordingly, a comparison between arterial and mixed venous blood values would be possible.[25] Severinghaus therefore strongly recommended that respiratory PCO_2 analysers report their results corrected for water vapour pressure.[19]

During the saturated gas testing (at 37° C), the water vapour did condense in the windows of the cuvette of the HP M1166A. However, when decreasing the saturated test gas temperature to 30 ± 2° C the results were within the DIS limits and even showed the least MAB (0.23 mmHg ± 0.27) of all tested monitors (Figure 2b). The motor and filter of the CO_2-transducer (HP 14360A) is heated to 41.7° C (manufacturers' specifications), giving the window and the adapter a temperature of about 33° C, which seems to be high enough to avoid condensation during clinical conditions where temperatures are rarely above 30° C at the tube connection (Table III). This is the only mainstream sensor which is made of metallic material heated to 33° C, whereas all the other mainstream sensors are non-metallic and are heated to ≥42° C. Since the metal airway adapter loses temperature faster than a plastic airway adapter, Hewlett Packard developed a new plastic airway adapter (HP M1465A) and CO_2-transducer (HP M1460A). This adapter has been available since September 1994 and has no more condensation problems, as we found when testing it during the revision phase of this manuscript.

Effect of N_2O and O_2

In spite of the unusually high levels of the interfering gases, 95 vol% O_2 and 80 vol% N_2O, the monitors fulfilled the accuracy proposals for 5 vol% CO_2 (medium range) most satisfactorily. The Capnodig monitor was least influenced by the interfering gases. According to the manufacturer, the sampling gas is radiated from a selective IR source, a plasma radiator needing no spectral filters. This monitor does not have an incorporated correction software. In the devices, which display the interfering gases (Appendix, Tables IV and V), the CO_2 values are automatically corrected based on the inspiratory values. Since respiratory cycles are simulated with air in this study, proper correction was achieved after an apnoea time allowing the analyser to shift to the expiratory values. There is no O_2 cell in the Poet II (model 602-1), BCI 9100 and PM 8020, thus correction did not take place. Although O_2 does not absorb IR radiation, CO_2 readings are affected by collision-broadening altering the readings by up to −2.5 mmHg, depending on O_2 concentrations.[16] The HP M1166A was the mainstream monitor which allowed the simultaneous use of the O_2 module to obtain an automatic correction with an error of $< \pm 1\%$ according to the manufacturer.

With nitrous oxide the greatest deviations were observed in the Tramscope 12 and in the MGA-AS. Nitrous oxide strongly influences PCO_2 measurements by direct influence and collision-broadening altering the readings by up to 6.5 mmHg. Correction factors for the presence of commonly used N_2O concentrations have been incorporated in the monitors software,[12,26,27] although errors might be mostly reduced by calibrating the instruments with a gas mixture containing N_2O.[14,27,28] Several capnometers are calibrated for low O_2 compensation, assuming a reference state of 0 vol% N_2O and 20 vol% O_2 (air), even though the user's calibration is carried out with CO_2 only (Ultra Cap N-6000). We do not think that clinical monitor testing should be done with O_2-free gases.

Accuracy of alarm activation

The suggested procedure in the DIS for the accuracy of the alarm limit ("... for each CO_2 reading, adjust the alarm set point so that the alarm is deactivated. Incrementally adjust the alarm set point until the alarm is activated and record ...") is not feasible since in some monitors the alarm can only be set in steps of 5 mmHg whereas in others respiratory cycles have to be registered. With the technique used in this study it is possible to read the difference between the alarm set point and the reading on the display when the alarm is activated. We believe that varying the level of CO_2 until the alarm is activated produces a better simulation of the clinical reality than varying the alarm set point. The DIS does not ask for a minimal accuracy between the CO_2 reading and a corresponding test gas for a given alarm set point nor for clinically relevant levels of humidity present in the gas, which may affect the performance. We decided not to test the accuracy of alarm activation with wet gases because changing the CO_2 concentration step by step was much easier with dry gases. In a few monitors the alarm is activated as soon as the displayed CO_2 value equals the set alarm limit (Passport, BCI 9000, BCI 9100, MGA-AS) whereas in the others the displayed value must exceed the limit by 0.5 mmHg (displayed only in the Brüel & Kjaer 1304) or by 1.0 mmHg (HP, Poet II, Ultracap, PM 8020).

Conclusion

In CO_2 readings (dry, wet gas and effect of N_2O and O_2) the accuracy (average of MAB) was better in M-type monitors than in S1- or S2-type analysers. Accuracy of alarm activation showed less bias in S1- than in M- or S2-type monitors. But in none of these comparisons could a statistical (or clinical) difference be detected and all tested analysers were found to be safe for clinical use, except those failing DIS limits. Most manufacturers work within stricter limits than those stated in the DIS.

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Appendix

TABLE IV Manufacturers' specification of the tested sidestream infrared carbon dioxide analysers (auto = automatically, man = manually, cal = calibration, sel = selectable, baro = barometer)

	S1-type monitors (respiratory cycles not demanded)				
Monitoring unit	*Type 1304*	*Capnomac II*	*MGA-AS*	*Multinex*	*4700 OxiCap*
Country of origin	Denmark	Finland	USA	USA	USA
Manufacturer	Brüel & Kjaer	Datex	Marquette	Datascope	Ohmeda
Accuracy of display in mmHg or otherwise stated at different scale ranges according to manufacturer	Nonlinear error 2% and 1% full scale Zero error <0.1%	<0.2 vol% <1.5 mmHg	0–40 = ±1.5 41–60 = ±2.5 61–76 = ±4	0–20 = ±1.5 20–40 = ±2.0 40–60 = ±2.5 60–76 = ±3.0	0–7% = ±2.2 7–9% = ±5
Calibration interval	3 mo	6 mo	6 mo	No user cal	Weekly
Zero calibration	Not required	Auto/man	Auto/man	Auto	Auto
Span calibration	Cal mixture	Cal mixture	Cal mixture	No user cal	Cal mixture
Display range and units for ETCO$_2$	0.0–10.0% mmHg/kPa	0–10% 0–76 mmHg	0–10%, kPa mmHg	0–76 mmHg 0–9.9%/kPa	0–14% mmHg
Multigas analyser	Yes	Yes	Yes	Yes	No
Insp. CO$_2$ display	Yes	Yes	Yes	Yes	Yes
Barometric pressure-compensation [mmHg]	Auto 540–840	Auto 500–800	Auto	Sel 760 mm or local baro	Auto 500–800
Compensation: N$_2$O	Auto	Auto	Auto	Auto	Auto
Display N$_2$O	Yes	Yes	Yes	Yes	Yes
Compensation: O$_2$	Auto	Auto	Auto	Auto	Auto
Display O$_2$	Yes	Yes	Yes	Yes	Yes
Correction for water vapour 47 mmHg	Yes	No	No	Sel no 47 mmHg corr	No, error ≤2 mm
Sample gas drying	Yes	Yes	No	No	Yes
Continuous digital display for CO$_2$ (respiratory cycles not demanded)	Yes	Yes	Yes	Yes	Yes
Sample flow (ml · min^{-1})	90	200	50, 150, 250	50, 100, 150, 200	300
Operation temp. [°C]	10–40	10–35	10–30	10–35	15–40
Warm up time [min]	1 min	2		15 min	1.5
Analogue output	Optional	Yes	Optional	Yes	Yes

	S2-type monitors (respiratory cycles demanded)					
Monitoring unit	*BCI 9000*	*BCI 9100*	*Capnodig*	*PM 8020*	*Poet II*	*Vicom-sm SMU 611/612 A-GAS*
Country of origin	USA	USA	Germany	Germany	USA	Germany
Manufacturer	Biochem	Bruker	Dräger	Dräger	Criticare	Hellige
Accuracy of display in mmHg or otherwise stated at different scale ranges according to manufacturer	0–50 = ±2	0–50 = ±2	0–38 = ±4 38–76 = ±10% of display	0–40 = ±1.5 40–60 = ±2.5 60–80 = ±4.0	±2	0–20 = ±3.5 21–40 = ±3.7 41–60 = ±4.8 61–80 = ±6.7
Calibration interval	6 mo	100 hr auto	6 mo	6 mo	6 mo	6 mo
Zero calibration	Auto	Auto/man	Auto	Auto	Auto	Auto
Span calibration	Cal mixture	Cal tank	Cal mixture	Cal mixture	Cal mixture	Cal mixture
Display range and units for ETCO$_2$	0–100 mmHg	0–100 mmHg	0–10%, kPa mmHg	0–80 mmHg 0–9.9 kPa	0–90 mmHg	0–80 mmHg vol%
Multigas analyser	No	Yes	No	Yes	No	Yes
Insp. CO$_2$ display	Yes	Yes	No	Yes	Yes	Yes
Barometric pressure-compensation [mmHg]	Auto	Auto	Man 600–1200	Auto	Auto 0–990	Auto 500–800
Compensation: N$_2$O	Auto	Auto	No (0–80%)	Auto	Sel	Auto
Display N$_2$O	Yes	Yes	No	Yes	No	Yes
Compensation: O$_2$	No	No	No (0–75%)	Auto	No	Auto
Display O$_2$	No	No	No	No	No	Yes
Correction for water vapour 47 mmHg	No	No	No	No	No	Yes
Sample gas drying	Yes	Yes	Yes	Yes	No	Yes
Continuous digital display for CO$_2$ (respiratory cycles not demanded)	No	No	No	No Yes if >5 mmHg and >20 sec	No, only as meter	No
Sample flow (ml · min^{-1})	140	140	≤150	50, 200	50, 150	125, 250
Operation temp. [°C]	10–40	10–40	15–40	15–40	10–40	15–45
Warm up time [min]			3	15	3	5
Analogue output	Yes	Yes	Yes	No	Yes	No

TABLE V Manufacturers' specification of the tested mainstream infrared carbon dioxide analysers (auto = automatically, man = manually, cal = calibration)

Monitoring unit–Modules	*Capnogard*	*HP M1166A CO_2 module (HP M1016A)*	*Passport*	*Tramscope 12 CO_2 module*	*Ultra Cap N-6000*	*Vicom-sm SMU 611/612 ETC-Modul*
Country of origin	USA	Germany	USA	USA	USA	Germany
Manufacturer	Novametrix	Hewlett Packard	Datascope	Marquette	Nellcor	Hellige
Accuracy of display (mmHg) at different scale ranges according to manufacturer	0–40 = ±2 41–100 = ±5% of reading	0–40 = ±2.2 40–100 = ±5.5% of reading	0–40 = ±4	±2 or ±5% of reading, whichever is greater	0–40 = ±2 41–99 = ±5% of reading	0–39 = ±2 40–79 = ±5% of reading 80–99 = ±10% of reading
Calibration interval	Weekly or if switching adapter type	If required, on reference cells	Weekly or if switching adapter type	Annually	Annually, no user calibration required	Bi-annually
Zero and span calibration	Quick checks any time on reference cells	Quick check any time on reference cells	Quick check any time on reference cells	Checks every 3 mo calibration gas	Checks if required with test gases	0 and 10% CO_2 test gas air balanced
Display range and units	0–100 mmHg mmHg	−4 to 150 mmHg mmHg/kPa	0–100 mmHg mmHg/%/kPa	0–13%/0–99 mmHg mmHg/%/kPa	0–99 mmHg mmHg/%/kPa	0–99 mmHg mmHg/%
Display insp. CO_2	No	Yes	No	Yes	No	Yes
Barometric pressure compensation (mmHg)	Auto/man adjustable 550–780	Man setting altitude 0–4600 m	Man 500–800	Man setting for cal auto adjustment	Auto 0–3048 m	Auto 540–810
Compensation for N_2O	Selectable 50–70%	Selectable	Selectable	Selectable	Selectable	Selectable
Compensation for O_2	Selectable ≥60%	FiO_2 driven or assumed 45%	Selectable 0, 21, 40, 60, 80, 100%	No	Selectable >60%	Selectable ≥50%
Correction for water vapor pressure (47 mmHg)	No	Yes	No	No	Yes (mmHg and kPa) No (vol %)	Not yet, a correction will be considered
Continuous digital display	No	Yes, but only in the cal mode	No	No	No	Yes
Airway adapter reusable	Yes	Yes (metallic, new plastic)	Yes	No	No	No
Dead space (ml)	≤5	15 (new 7), neonatal 2	<5, <0.5 neonatal	7	<6	≤5
Sensor temperature (°C)	42	41.7 (motor), 33 (window)	42	42	42	42
Sensor chopped	No	Yes, with cal memory	No	Yes	Yes	Yes, with cal memory
Operation temperature (°C)	10–40	17–38	10–40	10–35	10–40	10–40
Warm up time (sec)	30	20 min full accuracy	300 min	30	45	≤120
Analogue output	Optional	Optional	Optional	No	Yes	No

TABLE VI Manufacturers' specification of the tested non clinical carbon dioxide analyser used as a reference device

Product	*Servomex 2500 Infrared Analyser*
Country of origin	Great Britain
Manufacturer	Servomex
General Description	The Servomex 2500 is a single beam, multiwavelength infrared to soft UV process analyser suitable for monitoring single components or a component group in a gas or liquid sample stream. It is supplied configured to the customers' precise analytical requirements for a stated analysis in a background stream.
Uses	
Environment	Designed for 24 h/day continuous operation for industrial environments.
Intrinsic error (under reference conditions)	Less than ±1% of full scale deviation (fsd) (1-100%)
Calibration	Factory calibration for the measurement required (CO_2). It contains a zero constant, a span constant and a linearising function. Adjustments to each of these, using the calibration routines, is possible. Test gas for zero and span required.
Repeatability/linearity error	±0.5% fsd/less than 1% fsd
Output fluctuation (noise)/response time	Less than 1% fsd (peak-peak) at T63 = 1 sec
Short term zero drift	Less than ±1% fsd per week
Ambient temperature/humidity	0-55% (with heated cells above 100°C)/0-95%, non-condensing
Warm-up time/cell temp	Typically 2-10h, depending on application and environment./60°C
Response time (T63)	User adjustable from 1-60s (electronic only, excludes sampling)
Unit/range/resolution	Percent/0-100%/0.01% (actual span calibration: 10% CO_2)
Sample flow max/min (no internal pump)	0.1-1.0 $L \cdot min^{-1}$ (liquid applications) 0.2-2.0 $L \cdot min^{-1}$ (gas applications)
Sample pressure/temperature stability	±1.5% fsd for a ±1% change in sample pressure/±0.3% fsd for ±1°C
Power supply effects: voltage/frequency	Less than ±1% fsd for 10% (110/220 VAC)/<1% fsd for 47-53 Hz or 57-63 Hz change.
Analogue output	Each analogue output can be scaled across the whole measurement range (e.g., 0-100%)