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ACCURACY, ALARM LIMITS AND RISE TIMES OF TWELVE OXYGEN ANALYSERS

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SUMMARY

The Comité Européen de Normalisation (CEN) recently proposed a new standard for "particular requirements of oxygen monitors for medical use". The accuracy of alarm activation and the oxygen display value (during continuous flow and during and after cyclic pressure) as well as the rise time during rapid concentration changes have been tested in the following 12 analysers according to the stated criteria in the proposed standard: Datex Capnomac II™ and Servomex 570A™ (measuring principle: paramagnetic); Brüel & Kjaer 1304™ (magnetoacoustic); Criticare Poet II™, Multinex™, Dräger Oxydig™, Dräger PM 8030™, Megamed 046A™, Ohmeda 5120™, Spacelabs Multigas™, Teledyne TED 200™ (all galvanic) und Kontron M 810™ (polarographic). All the tested analysers showed an oxygen reading within ± 3 percentage volume fraction (vol%) oxygen of the actual oxygen levels of the test gases. Some of the tested devices showed more than 2 rel% of deviation between their alarm activation and the preset alarm limits. Only the Kontron M810, the Megamed 046A and the Spacelabs Multigas fulfilled the CEN proposal in all tested O_2-concentration levels. In the following three analysers a cyclic pressure of between -1.5 to + 8 kPa did not result in a deviation of the O_2-display: Brüel & Kjaer 1304, Datex Capnomac II and Servomex 570A. The remaining ones however, showed - depending on their measuring principle - an inaccuracy of the display of between -1 to +6 vol% O_2. After exposure to high pressure all oxymeters worked normally. The time required by the oxygen analyser to display the rise from 29 to 92 vol% after a sudden change of concentration from 21 to 100 vol% O_2 is defined as rise time and must not - according to the

CEN standard proposal - exceed the manufacturers' declaration more than 1.15 times. Brüel & Kjaer and Poet II did not comply with this requirement, although their rise time was among the shortest. We conclude that the standards concerning accuracy are generally fulfilled when continous flow is used; under cyclic pressure, however, the standard is not always met, as well as in the accuracy of the alarm activation. These deviations from the norm are small and not clinically relevant.

Keywords: Oxymeters, accuracy, rise time, alarm limit

INTRODUCTION

Monitoring the oxygen concentration allows for early detection of malfunctions or errors in the oxygen supply system thus improving safety in anaesthesia [1,2,3]. Earlier studies investigated the influence of longterm oxygen exposure, high humidity, high temperature and the presence of N_2O on the oxygen display of O_2-analysers[4,5,6,7]. A recent CEN proposal[8] defined the following standards: The accuracy of the measurement of medically used oxygen analysers shall be within ± 3 vol% in the whole measuring range under continuous flow as well as after cyclic pressure exposure of between -1.5 to +10 kPa during 10 min at 10 cycles/min. The difference between the alarm limit set and the alarm activation must not exceed ± 2 rel%. The rise time shall not be greater than 1.15 times the value stated by the manufacturer. The rise time is defined as the time required by the oxygen analyser to display a rise from 29 to 92 vol% after a sudden change of O_2-concentration from 21 to 100 vol%.

The aim of this study was to test the feasibility of the proposals and to check the accuracy of 12 oxygen analysers presently on the market according to the aforementioned criteria. Oxygen sensors with the following measuring principle were tested: galvanic[9], polarographic[10], paramagnetic[11] and magnetoacoustic[7] (Tab. 1)

Measuring principle	polarographic	galvanic								paramagnetic		magneto-acoustic
Unit	M 810	Oxydig	PM 8o3o	046A	Oxygen Monit 512o	TED 2oo	Spacelabs Multigas	Poet II	Multinex	Capnomac II	570A	Anaesthesiagasmonitor 1304
Manufacturer/Agent	Kontron	Dräger	Dräger	Megamed	Ohmeda	Teledyne	Spacelabs	Criticare	Datascope	Datex	Servomex	Brüel u. Kjaer
Country of origin	CH	BRD	BRD	CH	USA	USA	USA	USA	USA	SF	GB	DK
Accuracy of display (according to manufacturer)	Error < ±5 rel%	±3 Vol%	1-5 Vol% depending on measuring range	-	-	±1 Vol%	±2Vol%	±3 Vol%	±3Vol%	2Vol%	0-3 rel%	I rel%
Response time (T90) [sec]	25-40	< 20	< 20	20	< 15	< 8	-	0.125	60	<0.450	<7.5	<0.2ms
Range of display [Vol%]	0-100	5-100	5-100	0-99	0-100	0-100	0-99	0-99	0-99	0-100	0-100	0-100
Operation temperature [°C]	15-40	15-40	15-40	15-45	5-40	0-40	0-40	-	10-35	1-35	0-50	10-40
Analog output	no	no	no	yes	yes	no	no	yes	yes	optional	yes	optional
Sensor position	non-diverting						diverting					

Table 1 The 12 tested oxygen analysers

MATERIAL AND METHODS

All the analysers in evaluation were factory-new. They were calibrated according to instructions of the manufacturers. The **test gases** containing 15, 40 and 60 vol% oxygen in nitrogen were gravimetrically produced by Carbagas (Bern, Switzerland) according to the ISO Norm 6142 regulation[12]. The accuracy of the test gases ($\pm$ 0.5 rel%) complied with the proposed CEN standard ($\pm$ 0.5 vol%)[8]. The gas mixture with 18 vol% of oxygen, which was used for the determination of alarm activation was obtained by mixing oilfree compressed air (Jun Air 2000, Norresundby/DK) with the test gas containing 15 vol% of O_2. When measuring the accuracy of the alarm activation and cyclic pressure the oxygen concentrations were checked with a Servomex 570A (Servomex, Crowborough/UK) with external pump, which has served previously as a reference[13,14] for O_2-measurements. The gas- and ambient temperature (20° C $\pm$ 0.5) were within the required limits of the CEN proposal. The pressure of the compressed gases was reduced from 15 MPa to 300 kPa using reduction valves (Gloor, Burgdorf/CH). The gasflow was limited to 5 ℓ/min using rotameters (Wisag AG, Zürich/CH) independent of viscosity. Each measurement was carried out 4 times and the mean value was computed. In order to determine the accuracy of the measurement during constant pressure the test gases were - adjusted according to their density - dosed using a N_2O-rotameter, whereas oxygen and compressed air were dosed using original rotameters. After calibration all oxymeters were simultaneously exposed to 15 vol% O_2 followed by 21, 40, 60 and 100 vol%

O_2. After an exposure time of 5 min. the displayed O_2-values were read and recorded.

The **accuracy of alarm activation** was investigated using the above mentioned measuring system at O_2-concentrations of 18, 21, 40 and 60 vol%. On all concentration levels 100 vol% of oxygen was mixed with the respective test gas until the resulting O_2-concentration was 20 vol% above the alarm limit to be tested. After a time intervall ($\geq$ 5 x rise time specified by the manufacturer) the O_2-concentration was reduced until the alarm was activated.

The deviation of the alarm activation was defined as follows:

$$D = 100 \times \frac{C_A - C_m}{C_A} \tag{1}$$

where

D = relative deviation [%]

C_A = set alarm limit [vol%]

C_m = O_2-concentration measured by Servomex at the time of alarm activation [vol%]

In order to produce a **cyclic pressure** of between -1.5 to 8kPa a Spiromat 650 ventilator (Drägerwerke AG, Lübeck/BRD) was used, which was connected to a lungsimulator (Ohmeda, USA) via a y-piece. A resistance of 26.6 $kPA \cdot \ell^{-1} \cdot min$ and a compliance of 1 $ml \cdot kPa^{-1}$ was chosen on the lungsimulator; a respiratory pattern with negative endexpiratory pressure, with a minute volume of 6 ℓ/min, a frequency of 10/min, an I:E-ratio of 1:2 and a fresh gas flow of 10 ℓ/min were set at the respirator . In order to avoid any ambient air to be sucked into the Servomex through the probe during the negative pressure phase we secured the opening with a Heimlich one-way-valve[15]. The measurements were only started if the O_2-concentration measured by the reference analyser at atmospheric pressure corresponded to that of the test gases (21, 50 and 100 vol% O_2) which were flowing through the fresh gas inlet into the Spiromat ventilator. The O_2-readings of the monitor displays were manually recorded. Having exposed the analysers to cyclic pressure we read the displays only after an interval of three rise times.

For the determination of the **rise time** 100 vol% of oxygen and compressed air were dosed via rotameters. The sudden change from 21 to 100 vol% O_2 (and vice versa) was achieved using a Herion-5/2-switchvalve (Vektor AG, Volketswil/CH; change-over time <100 ms). No influence of the switching on flow and pressure could be found. In order to create equal flow conditions for all non-diverting O_2-sensors we constructed a special connector between sensor and gasflow (Fig. 1). Using a pressure probe of 6 mm in diameter (HM 18, Thommen, Waldenburg/CH) it could be shown that the pressure near the placement of the O_2-sensor corresponded to ambient pressure. The voltage which corresponded to a certain O_2-concentration was measured either at the wire of the sensor (Dräger Oxydig and Dräger PM 8030, Kontron M 810, Teledyne TED 200) or from the analogue output of the analyser (i.e. remaining six analysers) and was recorded with a thermal chart recorder (Watanabe Linear Recorder Mark VII, Tokio/Japan; linewidth 1 mm, reading accuracy

0.5 mm) (Fig. 2). The charting speed was adjusted according to the respective instructions of the manufacturers in order to achieve reading errors of below 5 rel%.

The following definitions are used (Fig 3):

Delay time	=	$T_1 - T_0$
Rise time of output (RTo, readable as analogue signal)	=	$T_2 - T_1$
Rise time of display (RTd, readable as display signal)	=	$T_4 - T_3$
Total system response time	=	$T_4 - T_0$

where

R_1	=	100		[vol% O_2]
R_2	=	21		"
R_3	=	$R_2 + 0.1(R_1 - R_2) = 28.9$		"
R_4	=	$R_2 + 0.9(R_1 - R_2) = 92.1$		"
T_0	=	time where 5/2-valve is switched		[sec]
T_1	=	time where O_2 = 28.9 vol% (R_3)	} at display	"
T_2	=	time where O_2 = 92.1 vol% (R_4)		"
T_3	=	time where O_2 = 28.9 vol% (R_3)	} at display	"
T_4	=	time where O_2 = 92.1 vol% (R_4)		"

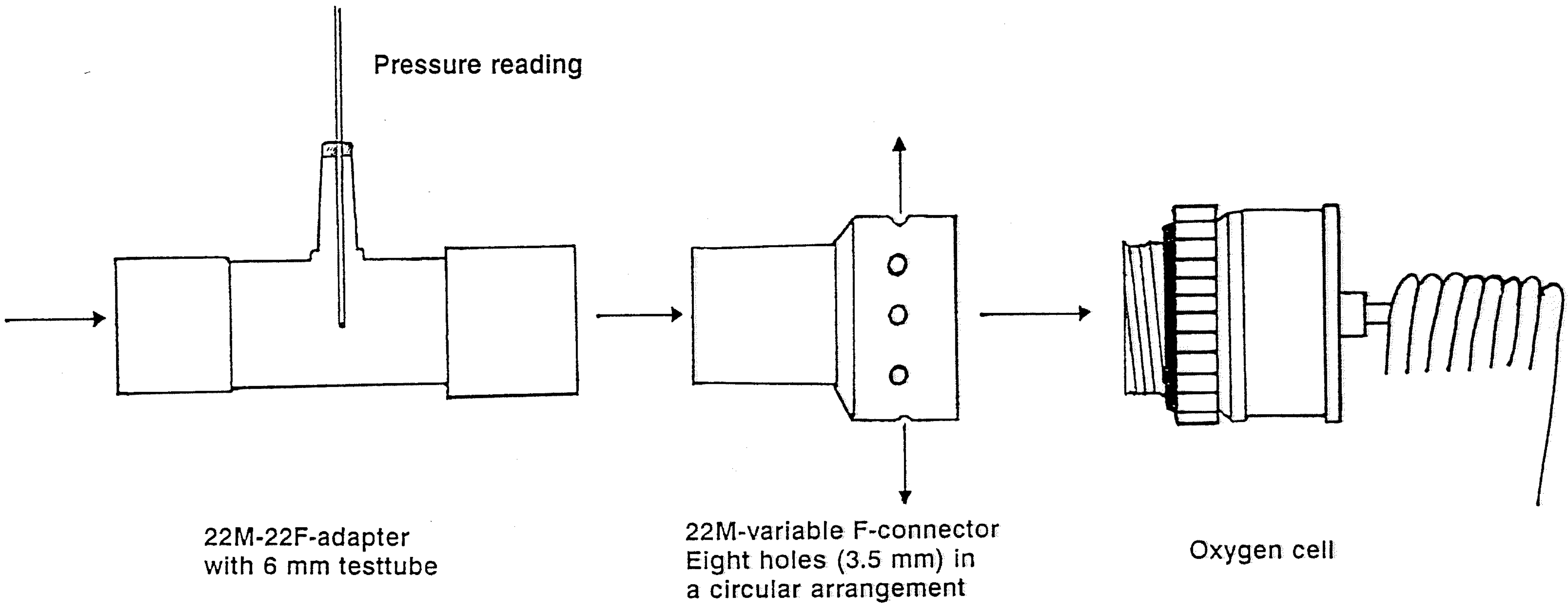

Fig 1: Standardconnector for rise time measurement of O_2-cells

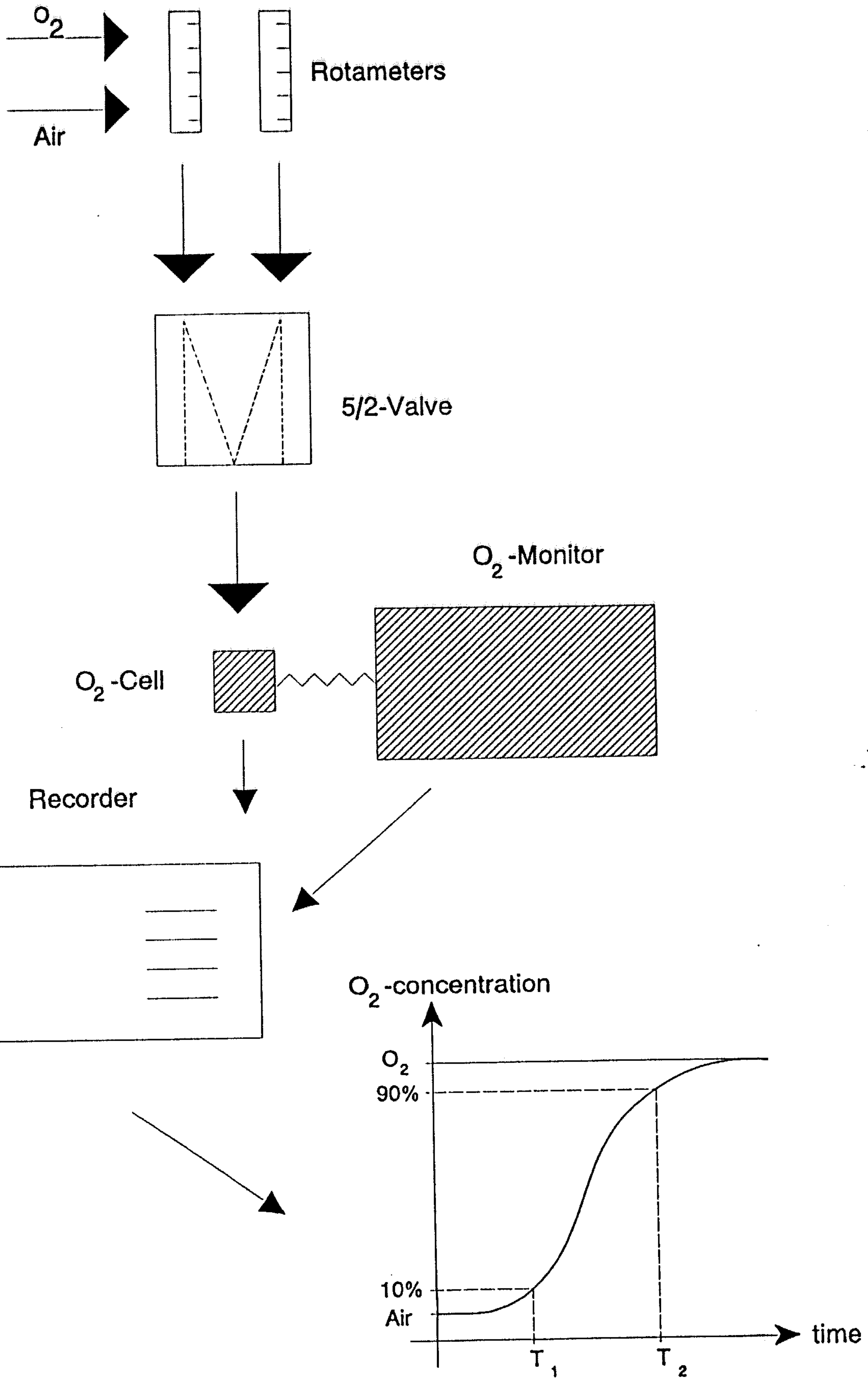

Figure 2 :
Schematic measuring arrangement for determing the rise time

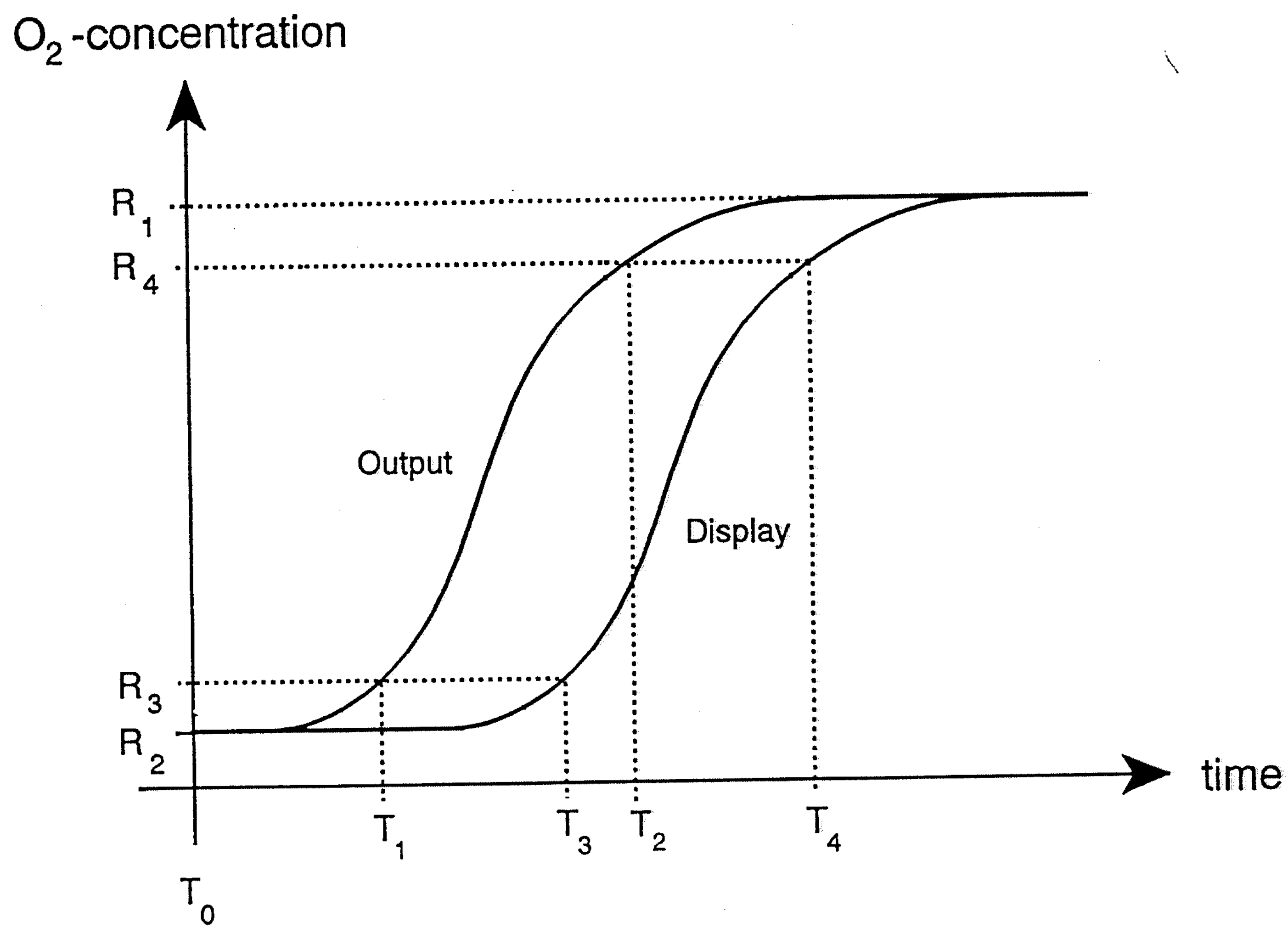

Figure 3 : Delay time, rise time and total system response time after a sudden gas concentration change (legend see text)

RESULTS

All analysers complied with the **accuracy** of ± 3 vol% as required by the CEN in the whole measuring range. With increasing concentrations, however, measuring errors of up to 2.25 vol% were found (Tab. 2).

The following analysers kept the accuracy of the **alarm activation** of ± 2 rel% of the preset minimal oxygen concentration at all O_2-concentration levels as required by CEN: Kontron M 810, Megamed 046A and Spacelabs Multigas (Tab. 3), although the Kontron M810 allows only a minimal alarm setting of 18.5 vol%. In the Megamed 046A an exact control of the alarm limits via digital display was not possible. The accuracy of the alarm activation of the Datascope Multinex can be tested only when in use, i.e. under controlled respiration depending on CO_2-production. The Servomex 570A does not have adjustable alarm limits.

Under cyclic pressure deviations of up to 6 vol% can occur (Tab. 4). Paramagnetic monitors showed less deviations than galvanic and polarographic monitors. When the accuracy was measured **after exposure to cyclic pressure** - as suggested by the CEN proposal - , all investigated monitors fulfilled the CEN requirements.

The **rise time** after a sudden change of oxygen concentration from 21 to 100 vol% exceeded the CEN standards in the Brüel&Kjaer and Criticare Poet II monitors ($p < 0.05$, tab. 5).

	O_2-concentration of the test gases [vol%]				
	15	21	40	60	100
Brüel & Kjaer I304	15	21	40	59.75	98
Criticare Poet II	15	21	40	60.25	98.75
Datascope Multinex	15	21	40	59.5	97.75
Datex Capnomac II	15	21	40	60.75	101
Dräger Oxydig	15	21	40.5	59.5	100
Dräger PM 8030	15	21	40.25	60.25	100.75
Kontron M 810	15	21	40	60	100.75
Megamed 046A	15	21	40	60	100
Ohmeda 5120	15	21	39.75	59.75	99
Servomex 570A	15	21	40	60	100
Spacelabs Multigas	15	20.75	40	59	97.75
Teledyne TED 200	15	21	40.5	61	101.75

Table 2 O_2-display readings [Vol%] compared to the actual concentration of the five test gases

Preset alarmlimit ($Vol\%\ O_2$)	18	21	40	60
Brüel & Kjaer I304	*	*	*	+ 3.5%
Criticare Poet II	- 2.8	- 4.0	- 3.2	+ 2.5
Datascope Multinex	IPPV-conditions required for testing			
Datex Capnomac II	*	*	- 2.2	*
Dräger Oxydig	*	-3.3	*	*
Dräger PM 8030	-2.8	-3.3	*	*
Kontron M 810	*	*	*	*
Megamed 046A	*	*	*	*
Ohmeda 5120	- 2.8	- 2.4	*	*
Servomex 570A6	no alarm system			
Spacelabs Multigas	*	*	*	*
Teledyne TED 200	+ 5.5	*	+ 2.5	*

Table 3 Deviations of alarm activation from the preset alarm limits in rel%. (* Deviations $\leq$ 2 rel%, i.e. CEN-standard fulfilled)

	During cyclic pressure						After cyclic pressure		
O_2-concentration in freshgas-flow [vol%]	21		60		100		21	60	100
Pressure [kPa]	+8	-1.5	+8	-1.5	+8	-1.5	continuous flow		
Brüel&Kjär 1304	0	0	0	0	0	0	0	0	0
Criticare Poet II	0	0	0	0	-5	0	0	0	-1
Datascope Multinex	-1	0	+2	0	-5	-2	0	0	-1
Datex Capnomac	0	0	0	0	0	0	0	0	0
Dräger Oxydig	0	0	+1	0	0	-1	0	0	0
Dräger PM 8030	0	0	+2	0	0	-1	0	0	0
Kontron M 810	0	0	+1	0	0	-3	0	0	-1
Megamed 046A	0	0	+4	0	+3	+1	0	0	-1
Ohmeda 5120	0	-1	+2	-1	+3	-2	0	0	0
Servomex	0	0	0	0	0	0	0	0	0
Spacelabs Multigas	0	0	-1	-1	-2	0	-1	0	-1
Teledyne Ted 200	+3	0	+4	-1	+6	-4	0	+1	0

Table 4 Deviation of O_2-display during and after cyclic pressure of +8 kPa and -1.5 kPa. According to the CEN standard proposal deviations of up to ±3 vol% after pressure exposure are tolerated (n = 4).

Unit	Response Time [sec] (mean ± SD)	Manufacturers information [sec]	CEN-standard fulfilled ($p<0.05$)
Brüel & Kjaer 1304	0.765 ± 0.059	< 0.250	no
Criticare Poet II	1.2 ± 0.04	< 0.500	no
Datascope Multinex	4.9 ± 0.14	none	-
Datex Capnoac II	0.481 ± 0.022	< 0.450	yes
Dräger Oxydig	12.2 ± 0.2	< 20	yes
Dräger P 8030	8.7 ± 1.4	none	-
Kontron 810	3l.7 ± 0.4	25-40	yes
Megamed 046A	15.3 ± 0.4	T_{90} = 20	yes
Ohmeda 5120	8.7 ± 0.2	< 15	yes
Servomex 570A	4.2 ± 0.1	< 7.5	yes
Spacelabs Multigas	4.8 ± 0.2	none	-
Teledyne Ted 200	3.0 ± 0.14	< 10	yes

Table 5 Rise time (mean value, based on four measurements of increasing and decreasing O_2-concentration changes) compared to manufacturers information.

DISCUSSION

According to the CEN standard proposal the **accuracy** of a factory-new oxygen analyser should be within ± 3 vol% of the actual oxygen concentration, including all errors arising from the oxygen sensor, the electric circuit, the display and the calibration. All tested analysers complied with this limit. We could not detect a difference in accuracy caused by the measuring principle, although the two analysers with the greatest deviation (at 100 vol%: Datascope Multinex, Spacelab Multigas 2.25 vol%) are multigas analysers and were equipped with galvanic detectors.

The suggested procedure in the CEN standard proposal for testing the accuracy of the **alarm limits** ("...with a stable oxygen reading ... adjust the alarm limit control until the alarm is activated..") is not feasible as only in 6 analysers the alarm limit can be adjusted to a precise value whereas the others only have an approximate scale on a knob which, however, is sufficient for clinical use. Even with these monitors precise dialing of a few well defined values such as 18, 21, 40 and 60 vol% is possible. In order to expose all the tested oxygen analysers to the same conditions for the determination of the alarm accuracy, we altered the procedure as described in "Material and Methods". With this technique it is possible to read the difference between alarm set point and limit on the display of a reference oxymeter which is more accurate and reproducible than estimating a knob position against its scale marks. Therefore we propose to alter the suggested procedure in the CEN standard proposal.

The influence of **cyclic pressure** was measured after exposure according to the CEN standard proposal and, additionally, during exposure because this also appeared as clinically relevant. Patients suffering from respiratory distress syndrome (ARDS) or asthma may require ventilation with peak pressures near 8 kPa[16,17] and therefore the exposure of the O_2-sensors to peak pressures is justified, whereas ventilation using negative endexpiratory pressure (NEEP) is being questioned nowadays due to the induction of localised myocardial ischemia and because it decreases ejection fraction in patients with coronary artery disease (CAD)[18]. Furthermore, negative intrathoracic pressure (the so called Mueller manoeuvre) can produce pulmonary edema[19]. The CEN standard proposal of exposing the test devices to a negative endexpiratory pressure (- 1.5 kPa) is difficult to carry out and unnecessary, as such situations do not occur anymore. Instead of using peak pressures of +10 kPa as suggested by the CEN-proposal we used peak pressures of 8 kPa only as higher pressures could not be achieved with our equipment. Furthermore only the paramagnetic and magnetoacoustic measurement principle is pressure independent. As the standard does not specifiy the contour of the pressure wave curve except for the frequency we chose a clinically relevant setting.

In order to determine the **rise time**, it was necessary to construct reproducible measuring conditions as the proposal does not provide any suggestions (".. expose the sampling site to a test gas mixture..."). Using original adapters for the O_2-sensors in nondiverting type analysers resulted in rise times which were up to three times longer than declared in the manufacturers' manuals. This is due to a delayed change of the O_2-concentrations at the sensor site, because in most adapters the O_2-sensor is placed in a T-Piece at the periphery of the gas stream. We therefore constructed an adapter which leads the gasflow vertically on to the sensor membrane and then enables it to escape from the test system via openings near the membrane (Fig. 1). By doing this we got very reproducible results. We only measure the rise time of the output (RTo), while the CEN proposal asks for the rise time indicated by the display (RTo + RTd) of the test device (Fig. 3). Only the manufacturer is able to provide information on the difference between the RTo and the RTd, which includes the conversion time of an analogue to a digital signal plus the rise time of the visualising part (LCD's have rise times of about 200 to 300 ms). It is therefore his responsibility to provide this information and this requirement should be formulated as a fixed regulation.

The CEN standard proposal does not ask for a minimal rise time but for a comparison between the rise time we measured and the rise time declared in the manufacturers' document. In two cases a significant difference was found. The fast, magnetoacoustic Brüel&Kjaer does not comply with the standard although it has the fastest rise time of all analysers. Using a different technique (solenoid valve for change of O_2-concentration) MacPeak[7] achieved rise times between our and the manufacturers' results; they are, however, still slower by more than 1.15 times than the manufacturer claims. The information of the manufacturer of Poet II is too optimistic. The measured rise times of the remaining analysers did not exceed the values given by the manufacturers, which does not necessarily mean that all these analysers are very quick in responding but rather, that the manufacturers were very careful in their statements. Despite the difference between ours and the manufacturers results the Poet II is still one of the fastest.

Calibration was very user-friendly in the following analysers: Servomex, Dräger Oxydig and PM8030, Kontron M 810, Megamed 046A, Ohmeda 5120. Often, however, only a close study of the manual enables the user to calibrate his analyser. An observation which - although not part of this study - seems worth mentioning.

In conclusion, we found that most of today's oxygen analysers are very accurate and comply with the CEN standards. Oxymetry seems to be a well developed technology.

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LEGENDS FOR FIGURES

Figure 1

Standardconnector used in the rise time measurement of O_2-cells

Figure 2

Set-up for the determination of the rise time

Figure 3

Delay time, rise time and total system response time after a sudden gas concentration change (legend see text)