PRECISION AND ACCURACY OF PULSE OXYMETER

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SUMMARY

The use of pulse oxymeters in perioperative monitoring and in Intensive care is becomming more and more routine. The aim of this study was to compare the accuracy and precision of five pulse oxymeters.

Measurements of oxygen saturation (SaO2) were made on 52 patients using the five pulse oxymeters simultaniously as well as direct arterial blood analysis.

3 patients had repeated measurements done, initialy 20 recordings were done at 5 minute intervals (probes taken off between the recordings) and secondly 20 recordings were done at 2 minute intervals (probes left in place between the recordings). The patients lung function was monitered by direct arterial blood analysis.

We used the statistical method described by Bland et al. (11) for assesing the difference between pulse oxymetry and direct arterial blood gas analysis.

The results confirm that pulse oxymeters are very reliable for monitoring arterial blood oxygen saturation but a single value cannot be used for clinical diagnosis.

The use of pulse oxymeters in perioperative and intensive care monitoring is discussed.

KEYWORDS

Measurement techniques, pulse oxymetry

Oxygen, arterial saturation

Equipment, pulse oxymeters

Pulse oxymetry was first described in 1975 (1). The method allows the continuos non invasive monitoring af arterial oxygen saturation (SaO_2). In recent years the avialability of various pulse oxymeters from many manufactorers has enhanced the use of this technology in the perioperative period (2,3) and in intensive care (4).

All pulse oxymeters work on a similar principle, namely absorption spectroscopy. Considerable differences exist in the way different manufacturers obtain and process the data. These differencesoccur in the light emitting diodes, sampling frequency, microprocessor algorithms and constants used in the calculations. The principles are well described elsewhere (2). Manufacturers˘ specifications of accuracy for pulse oxymeters are all similar in the clinical usefull range ($\pm$ 1-2%).

Papers have been puplished to support this (2,5-7). A report (8) has found that the readings obtained from two pulse oxymeters (Ohmeda BIOX 3700 and Nellcor N 100 E) in cyanosed chrildren differed significantly from arterial blood measurements using radiometer OSM-2 co-oxymeter.

In these patients the error of both machines axceeded the manufactures` claims. Kagle et al. (9) found that the 99% confidence limits for Ohmeda BIOX 3700 was $\pm$ 8%, a result unacceptable for clinical diagnostic use. Another study (10) performed in critically ill chrildren showed a large error (range +8,2% to -9.7%) for Nellcor N 100 E.

The aim of this study was to compare the accuracy and precision of five pulse oxymeters.

METHODS

The study was approved by the local ethical sommitee. All patients gave informed consent.

52 patients from the Hospital Clinic for Pulmonary Diseases were admitted to the study. Patients with jaundice were excluded.

Five pulse oxymeters were used: Criticare CSI 501, Criticare 502 (Simonsen and Weel), Nellcor N 100 (Draeger), Satelite (Datex) and Novametrix 500 (Vickers).

Each af these pulse oxymeters has a choice of probes, for example for earlobes or fingers, only the fingerprobes were used in order to reduce variation.

The probes were placed an a finger on the same hand. Saturation readings were recorded when each oxymeter indicated a good perfusion signal, the reading was stable and no other malfunction warning was displayed. An arterial blood sample was withdrawn from the radial artery on the other arm simultaneously with the recording af the pulse oxymeter readings. The blood was stored in crused ice and analysed withinn 15 minutes in an ABL 3 (Radiometer Copenhagen).

Secondly 2 patients and 1 healthy volunteer, all with stable pulmonary function, had repeated measurements done.

Initialy 20 saturation recordings were made with 5 minute intervals on each patient the same way described above.

The probes were taken off between the recordings.

After this, 20 saturation recordings were done with 2 minute intervals, the probes were left in place between.
The stability of the patients pulmonary function were ensured by analysing arterial blood 3 times, at the beginning, after 50 minutes and after 100 minutes, as described above.

STATISTISCAL ANALYSIS

Measurement agreement was estimated as described by Bland et al. (11). A plot of the differences between the two methods against their mean is more informative than the correlation coefficient. We calculated the lack of agreement by calculating the bias, estimated by the mean difference $\bar{x}$ and the standard deviation of the differences SD. If we assume that the differences are normally distributed (gaussian) 95% of differences will lie between $\bar{x} \pm 2$ SD and 99% between $\bar{x} \pm 1$ SD.
The precision is expressed as the SD of differences between pulse oxymeters and ABL 3 recordings.
By using the results of the repeated recordings of SaO2 on 3 stable patients we were able to calculate total standard deviation SD_t (probes off between recordings), standard deviation within measurements (probes left on the finger between recordings) SD_w. We could then calculate standard deviation between recordings, SD_b, using the formula $SD_t^2 = SD_w^2 + SD_b^2$. In the same way we could calculate CV_t (total coefficient of variation), CV_w (coefficient of variation within measurements) and CV_b (coefficient of variation between measurements).

RESULTS

Measurements were made on 52 patients. The SaO2 range was 60 - 99%.

Figure 1 shows a plot of mean SaO2 against the difference (pulse oxymeter - ABL 3). The mean and mean $\pm$ 2 SD are plotted.

As mentioned above 95% of the values will lie between these values. As seen from the figure this interval is rather wide in all pulse oxymeters. The interval is smallest for CSI 502, - 2.7% to + 4.7% SaO2, and biggest for Novametrix 500, - 5.3% to + 3.5% SaO2.

In table I the accuracy of the pulse oxymeters is expressed as the mean of differences between pulse oxymeter and ABL 3 readings. Four pulse oxymeters had a slight tendency to overestimated the SaO2, only Dates Satelite underestimate the value. Generally the accuracy is very good and fully acceptable.

Table II shows the precision of the pulse oxymeters expressed as SD of differences between pulse oxymeter and ABL 3 recording. These values are generally close to the values stated by the manufacturers.

In table III the five pulse oxymeters are ranged according to accuracy and precision: Novametrix 500 has the lowest accuracy and precision.

Table IV and V give the results of the repeated measurements on the two patients and the healthy volunteer. In 2 instanses the SD_t and CV_t were smaller than SD_w and CV_w and therefore made the calculation of SD_b and CV_b impossible. All pulse oxymeters show impressingly low SD_t and CV_t, all in the range stated by the manufacturers.

The possible error in placing the probe is very small as shown by SD_w and CV_w. The reading obtained has little relation in placing the probe on the finger.

CSI 501 has the highest SD_t and CV_t. CSI 502 has the lowest SD_t and CV_t in the present study.

DISCUSSION

Our result show that both the accuracy and precision were within the manufacturers` claims.

The results confirm that pulse oxymeters are very suitable for monitoring arterial blood oxygen saturation.

If, however, we look at a single measurement, the 99% confidence limits are ± 5.5% for CSI 502 as a minimum and ± 6.8% for Novametrix 500 as a maximum. This means that in the 60 - 99% SaO2 range one can be 99% certain that arterial saturation will differ by no more than 5.5% with CSI 502 and 6.8% with Novametrix 500. This makes the pulse oxymeters unacceptable for clinical diagnostic use.

Our study confirms the result by Kagle et al. (9), by demonstrating a very wide 99% confidence limit for single SaO2 readings.

Undoubtly pulse oxymeters will be part of standard monitoring equipment in anaesthesia and intensive care in the future. The measurements of SaO2 has several advantages over the transcutaneous oxygen tension measuring. It works fast and requires no warming op period, calibration is automatic, there are no problems with heating op the skin, and the response time is very short.

Clinical comparison of pulse oxymetry and transcutaneous oxygen tension measurement has not been conclusive which is complained by the fact that different things are measured (1).

There are a few limitations in the use of pulse oxymetry. There has to be a good pulsation in the finger or earlobe, which means that hypotension, hypothermia and the use of vasoconstrictive drugs may interfere with the measurements. A study by Lawson et al. (13) demonstrated that the blood flow must be reduced to approximately 10% before the readings of pulse oxymeters is unreliable. Should finger or earlobe measurements be impossible, some pulse oxymeters have probes, which can be placed over the nasal septal artery, a branch of the internal carotid artery. The pulsation of this artery tends to persist during periods of hypotension or periferal vasoconstriction.

The presence of abnormal hemoglobin such as carboxyhemoglobin, methemoglobin and sulfhemoglobin also interferes with the measurement (14).

Similary abnormal high levels of bilirubin in the blood may be a problem.

The use of pulse oxymeters may be of great value in routine perioperative monitoring, especially in patients with known risk of hypoxia (one lung ventilation, bronchoscopy) and patients with known preoperative hypoxia.

It is useful when acces to the patient is limited, and in training of anaesthetist. A study (3) demonstrated a fall in anesthetic disasters by routine use of pulse oxymeters.

In intensive care pulse oxymetry may be of great value in respiratory failure, IPPV and when weaning patients off the ventilator. It may also be beneficial in evaluation patients in sleepapnoe studies.

Also in intensive care the use of pulse oxymetry undoubtly will be routine in the future.

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Table I

Accuracy of pulse oxymeters compared to usual method, ABL 3 Radiometer.

	Deviation % SaO2
CSI 501	+ 0,3
Nellcor N 100	+ 0,3
Datex Satelite	- 1,0
Novametrix 500	+1,4
CSI 502	+ 1,0

Measurement range 60 - 99% SaO2

Table II

Precision of pulse oxymeters expressed as SD of difference between pulse oxymeter and ABL recordings.

	SD of difference
CSI 501	2,16
Nellcor N 100	2,19
Datex Satelite	1,94
Novametrix 500	2,25
CSI 502	1,84

Measurement range 60 - 99% Sa02

Table III

Ranging of pulse oxymeters according to accuracy and precision.

	Accuracy	Precision
CSI 501	1	3
Nellcor N 100	1	4
Datex Satelite	3	2
Novametrix 500	5	5
CSI 502	3	1

Table IV

SD_t, SD_w and calculated SD_b for pulse oxymeters.

	Patient	SD_t	SD_w	SD_b
CSI 501	A	1,35	1,21	0,60
	B	0,83	0,22	0,80
	C	2,46	1,90	1,56
Nellcor N 100	A	1,36	1,35	0,17
	B	0,44	0,00	0,44
	C	1,72	0,98	1,41
Datex Satelite	A	0,98	1,32	?
	B	1,02	0,49	0,90
	C	1,88	1,02	1,58
Novametrix 500	A	1,47	0,79	1,20
	B	0,47	0,67	?
	C	1,95	0,70	1,82
CSI 502	A	0,81	1,11	?
	B	0,50	0,31	0,39
	C	1,15	1,06	0,45

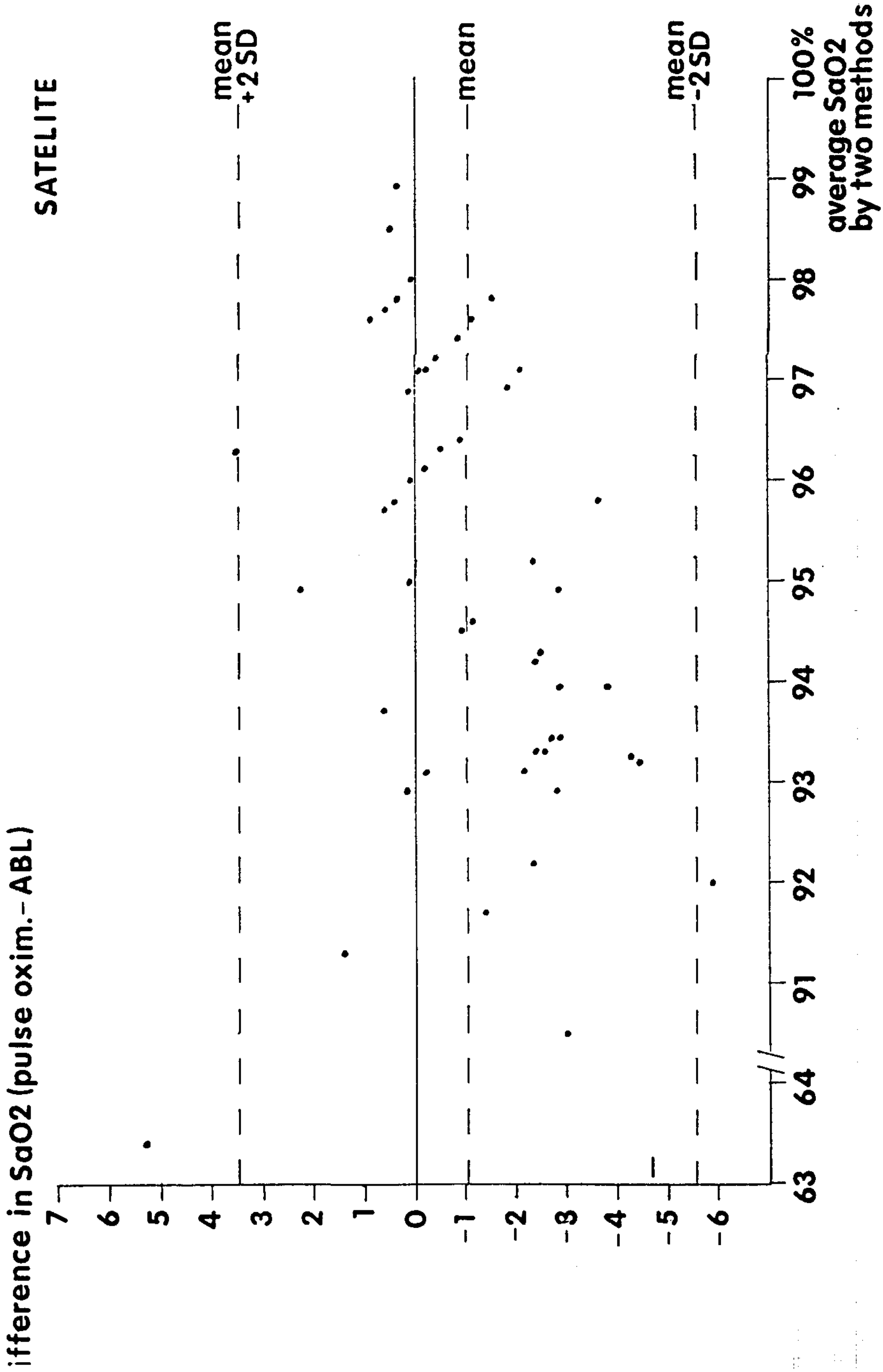
Table V

CV_t, CV_w and calculated CV_b for pulse oxymeters.

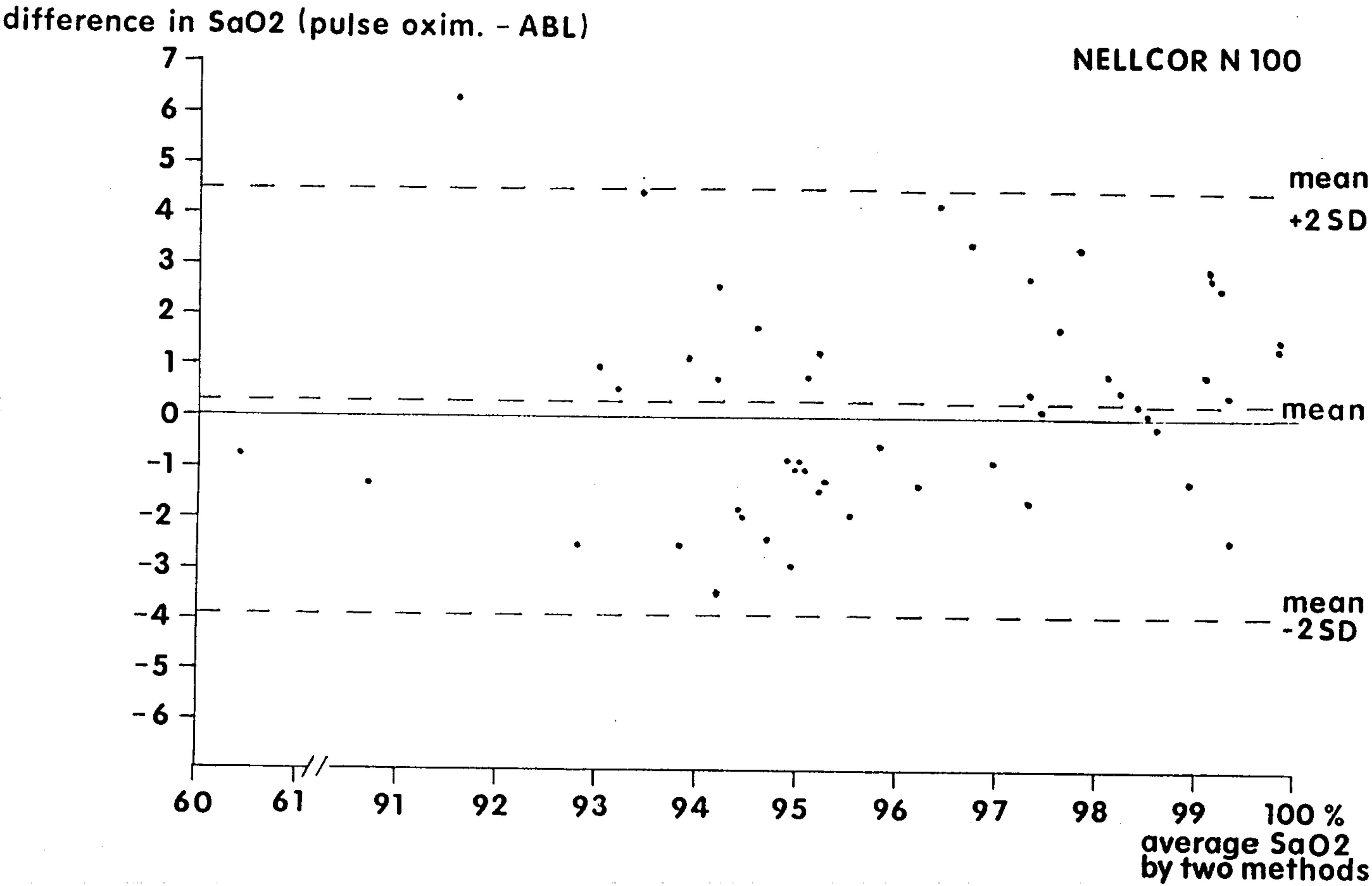
	Patient	CV_t%	CV_w%	CV_b%
CSI 501	A	1,50	1,30	0,70
	B	0,84	0,22	0,80
	C	2,70	1,97	1,80
Nellcor N 100	A	1,46	1,43	0,29
	B	0,44	0,00	0,44
	C	1,86	1,04	1,54
Datex Satelite	A	1,06	1,40	?
	B	1,05	0,50	0,92
	C	2,09	1,12	1,76
Novametrix 500	A	1,56	0,82	1,32
	B	0,48	0,68	?
	C	2,06	0,72	2,05
CSI 502	A	0,86	1,18	?
	B	0,51	0,31	0,40
	C	1,21	1,11	0,48

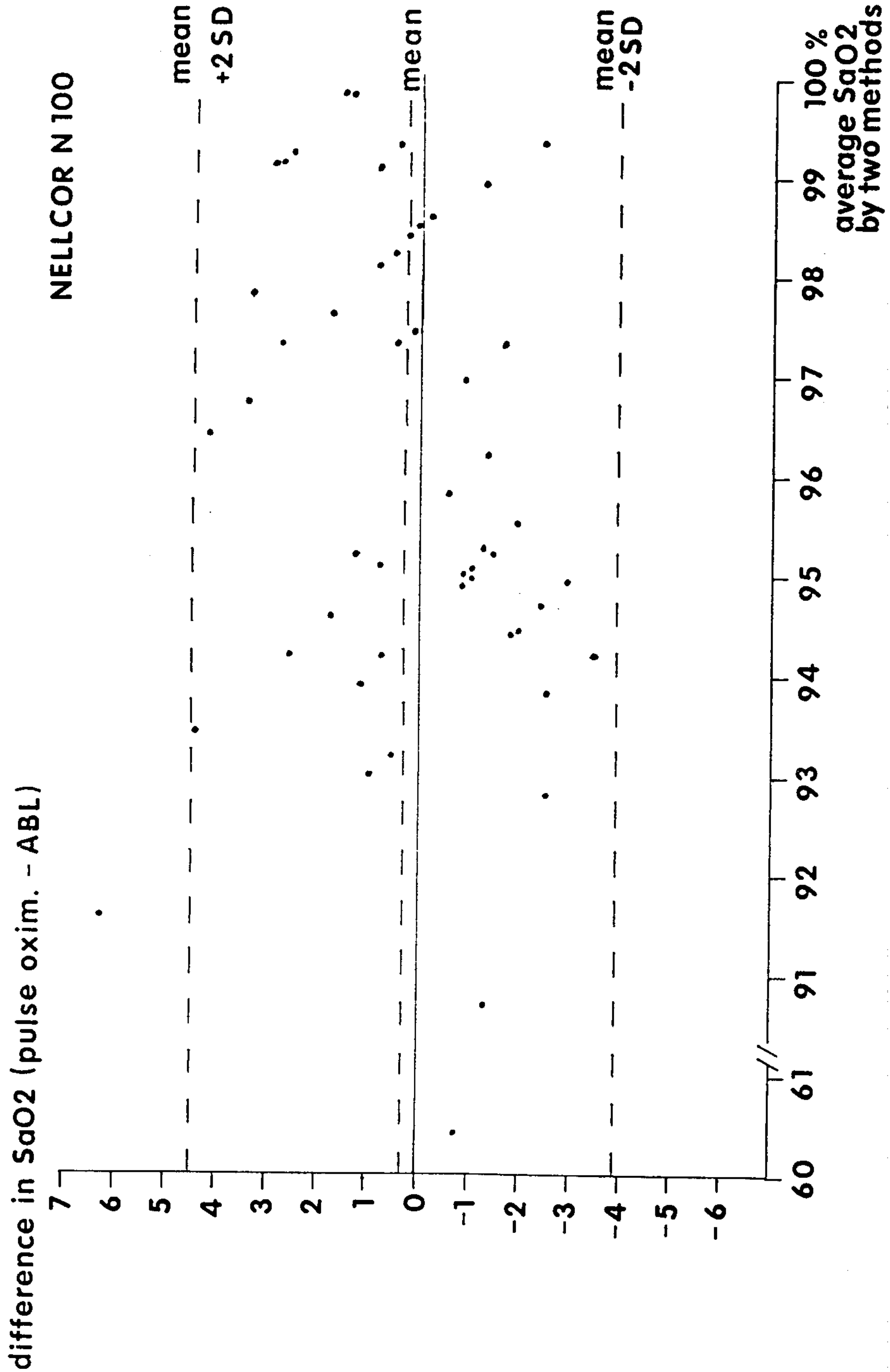
Figure 1

Mean SaO_2 (average by two methods) against difference in SaO_2 (pulse oxymeter - ABL 3) for five pulse oxymeters.

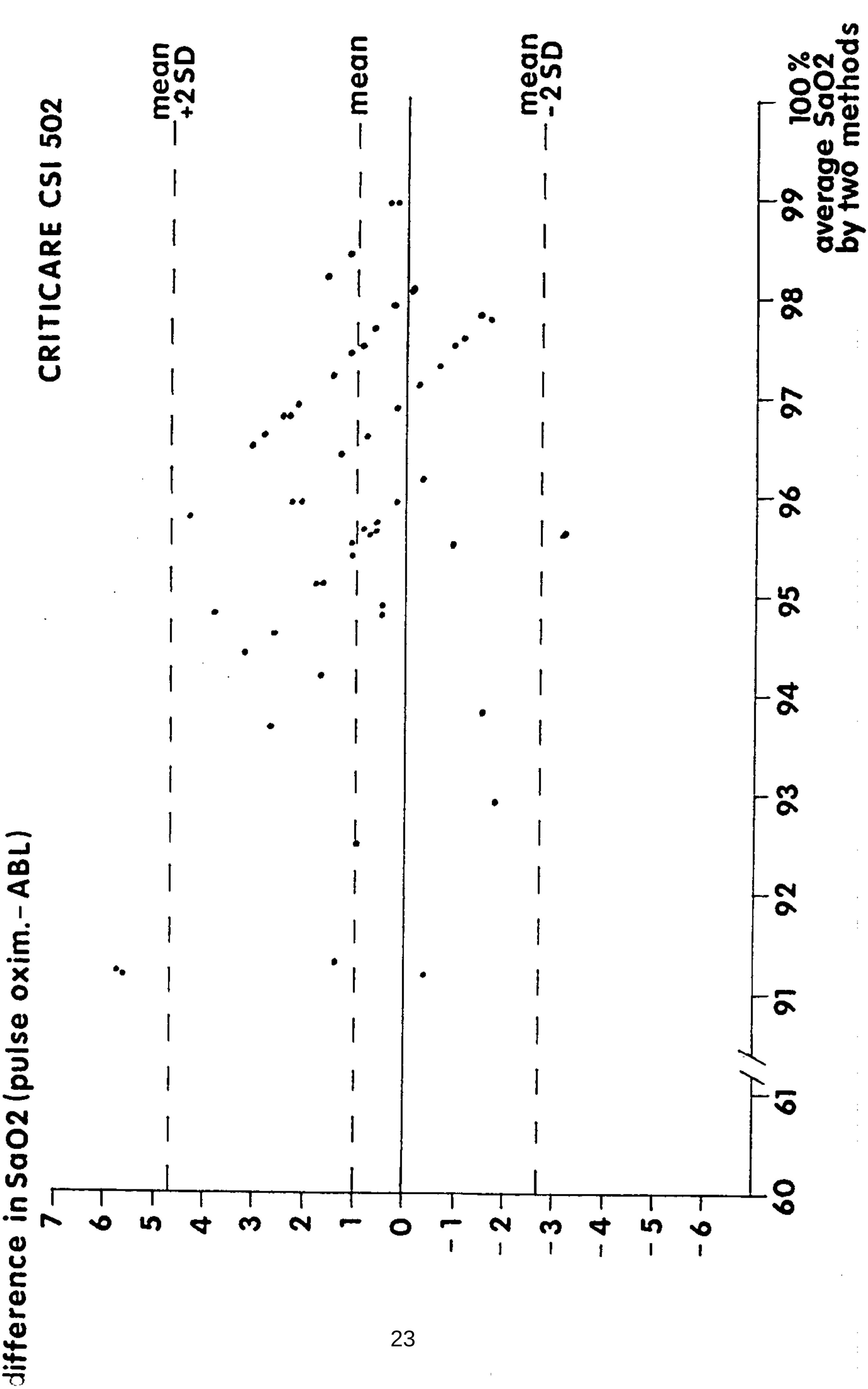


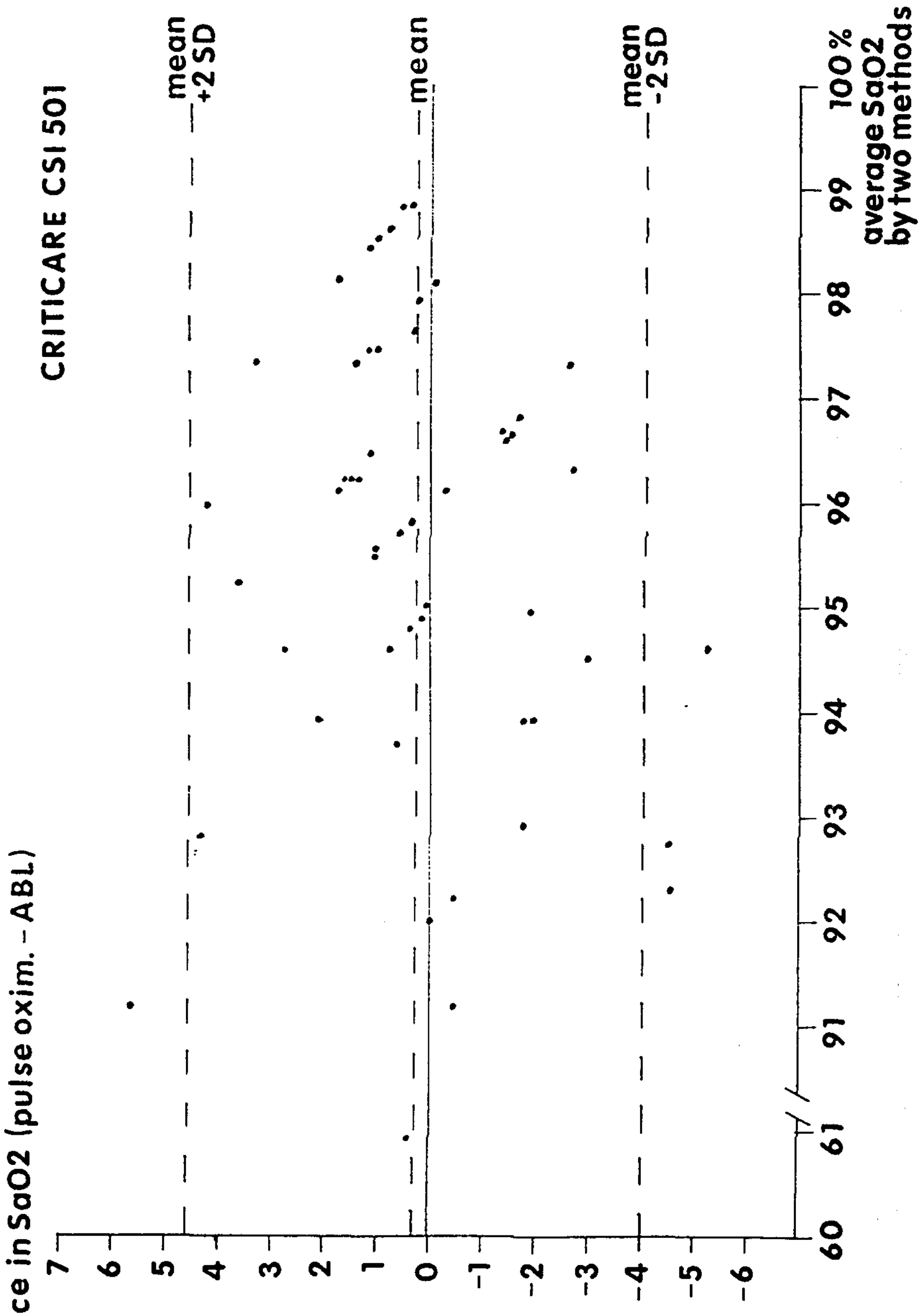
SATELITE
ifference in SaO2 (pulse oxim.- ABL)
mean +2SD
mean
mean -2SD
7
6
5
4
3
2
1
0
-1
-2
-3
-4
-5
-6
63
64
91
92
93
94
95
96
97
98
99
100%
average SaO2 by two methods

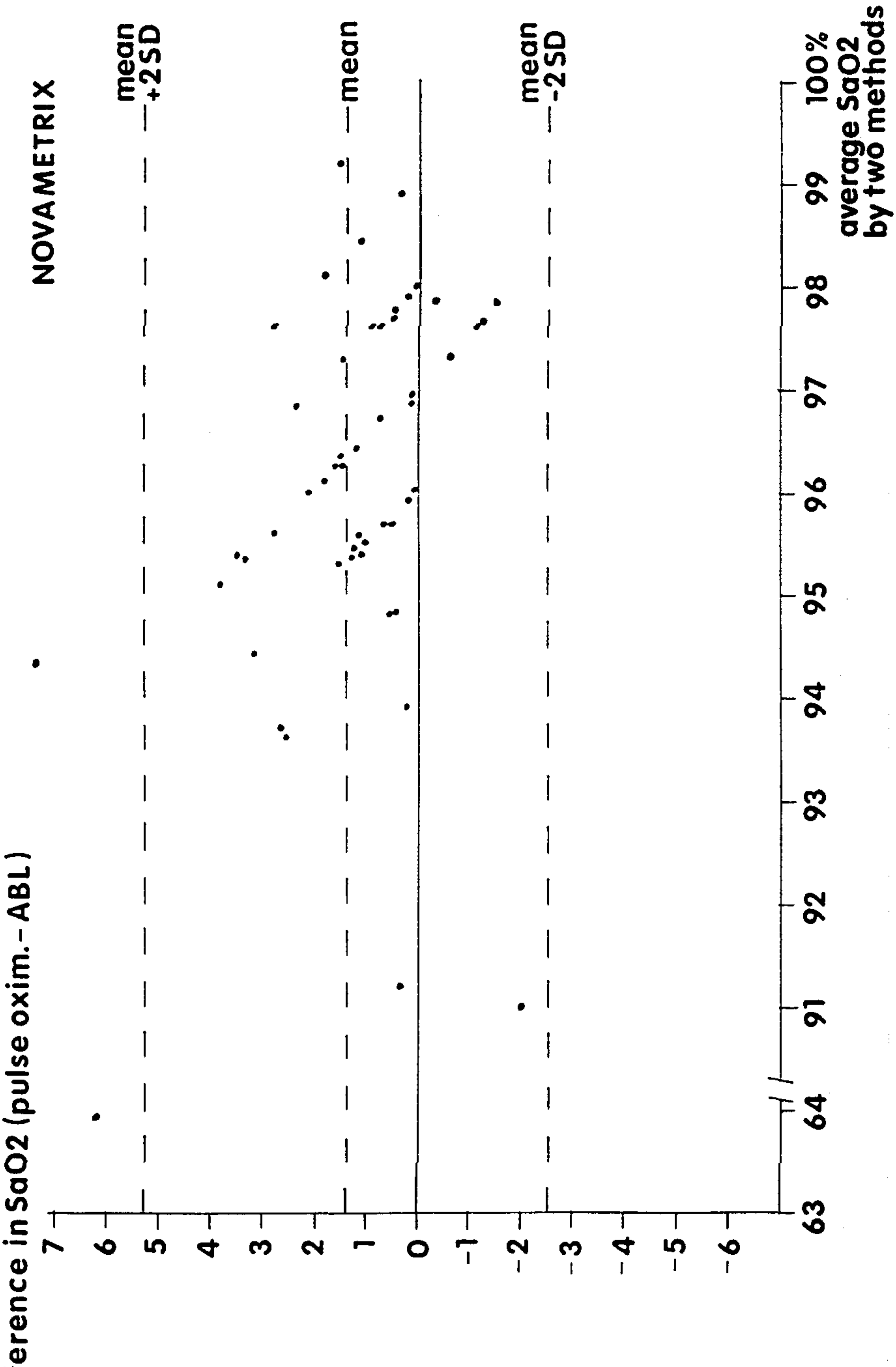

difference in SaO2 (pulse oxim. - ABL)
NELLCOR N 100
7
6
5
4
3
2
1
0
-1
-2
-3
-4
-5
-6
mean
+2 SD
mean
mean
-2 SD
60
61
91
92
93
94
95
96
97
98
99
100 %
average SaO2
by two methods



NELLCOR N 100
difference in SaO2 (pulse oxim. - ABL)
mean +2SD
mean
mean -2SD
7
6
5
4
3
2
1
0
-1
-2
-3
-4
-5
-6
60
61
91
92
93
94
95
96
97
98
99
100 %
average SaO2 by two methods


CRITICARE CSI 502
difference in SaO2 (pulse oxim. - ABL)
7
6
5
4
3
2
1
0
- 1
- 2
- 3
- 4
- 5
- 6
mean +2SD
mean
mean -2SD
60
61
91
92
93
94
95
96
97
98
99
100%
average SaO2 by two methods


CRITICARE CSI 501
difference in SaO2 (pulse oxim. - ABL)
7
6
5
4
3
2
1
0
-1
-2
-3
-4
-5
-6
mean +2 SD
mean
mean -2 SD
60
61
91
92
93
94
95
96
97
98
99
100%
average SaO2 by two methods


NOVAMETRIX
difference in SaO2 (pulse oxim. - ABL)
mean +2SD
mean
mean -2SD
7
6
5
4
3
2
1
0
-1
-2
-3
-4
-5
-6
63
64
91
92
93
94
95
96
97
98
99
100%
average SaO2 by two methods

	Weight (kg)	Accuracy @ 85%	Physical Design	Screen Readability	Status Messages	Control Layout	Pulse Indicator	Pulse Sound	Alarm Sound	Alarm Features	Alarm Setting	Weak Sgnl. Performance	Cautery Rejection	Motion Rejection	Xenon Arc Lamp	BP Cuff	Probes (adult)	Probes (pediatric)	Portable Use	Trending	Averaging Intervals
Ohmeda 3700	3.9	-0.50	++	0[d]	++	++	++	++	-	+	+	++	+	0	+	++	+	+	0	+	3-6
Invivo 4500	3.0	-0.05	+	++	++	+	0	++	++	++	++	+	0	-	+	--	+	N/T	+	++	3-12
Nellcor N-200	3.6	+0.41	0[b]	+	--	+	-	++	0	+	++	+[h]	+	+[i]	--	+	++	++	-	+	3-15
Datascope Accusat	4.5[a]	+2.41	-	+[e]	++	++	+[g]	++	+	++	+	+	++	++	0	--	-	--[j]	-	0	Auto
Criticare 501+	0.5	+0.81	0[c]	0	0	+	--	--	--	-	-	+	+	++	+	--	+	+	++	0	Auto
Physiocontrol 1600	6.1	+0.07	0	++	--	++	-	++	+	-	+	0	+	--	N/T	--	0	++	--	-	Auto
SARA Oximeter	2.0	+0.81	-[c]	0	0	+	0[g]	--	--	-	-	+	+	++	+	--	+	+	N/A	+[k]	Auto
SensorMedics	2.8	-1.50	--[c]	--	0	-[f]	0	++	++	--	++	+	-	++	--	--	+	-	+	+	0-30
Catalyst MiniOx 100	4.5	-0.56	+	++	+	--[f]	0	-	++	0	+	-	-	-	0	+	-	+	-	-	Auto

Notes:
- a--6.4 kg with battery
- b--clumsy junction box
- c--external power supply
- d--view angle control under unit
- e--status message screen (LCD) hard to read
- f--power switch on rear
- g--when used with external monitor
- h--slight improvement with ECG synchronization (C-lock)
- i--total body movement (e.g. shivering) may fool C-lock
- j--temperature may exceed 38° C
- k--when used with SARA system

**Oximeters are listed in order of estimated overall performance. Choice among the top four oximeters should be based upon the specifics of your application.

++ + 0 - --
best worst

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