Clinical Trial Report of Medical Device

Product Name: Pulse Oximeter

Sample Type: MD300C

Sponsor: Beijing Choice Electronic Technology Co., LTD

Investigational site: Beijing Friendship Hospital

Clinical Trial Catagory: Validation Test

Principal investigator:

Date: Oct. 24th, 2006

General Clinical Information: (the source of subjects , the number of subjects and inclusion/exclusion criteria)

86 subjects are sampled this hospital, 1 data is excluded from the analysis because the functional saturation was 57% SaO2. The valid data is 85. The age of subjects is from 25 years to 91 years, which have 39 male and 46 female; The finger size is from 41mm to 59mm. The study includes 85 subjects with suitable finger sizes to test SpO2 by the pulse Oximeter and SpO2 values ranged between 70% and 99%. 30 subjects' values of SpO2 are in the range between 100% and 90%, 30 subjects' values 89% and 80%, 25 subjects' values 79% and 70%. The pulse rate of subjects is from 42 to 170 bpm.

The study protocol: (including the setting of data pairs)

The study protocol is subjected to ISO 9919:2005 Annex EE. Procedures of testing required in EE4.1 are adopted. SpO2 readings of the pulse oximeter equipment are compared with values of SaO2 determined by a CO-oximeter.

The protocol: Those whose values of SpO2 are in the range between 70% and 100% in the emergency ward are selected as subjects. The subjects should lie on beds. The pulse oximeter probes to be evaluated are clipped to the subjects' middle fingertips or little fingertips. Pulse oximeter probes should be covered with opaque material to prevent optical interference. The measuring value which is stabilized for more than 1 minute can be considered as an endpoint. The readings of SpO2 and pulse rate should be recorded. When above testing is going on, blood samples of subjects is withdraw from the radial artery in the same side of the pulse oximeter equipment by the disposable blood collection tools. The blood samples are analyzed by AVL OMNI 3 CO-Oximeter and the values of SaO2 are recorded. All the procedures should be conducted under a good environment. Keep the finger warm to enlarge the ability of micro-circulation.

Evaluate criteria and/or statistical method:

Evaluate criteria: the result of the clinical trial should be compliance to the specification of SpO2 accuracy claimed by manufacturer. The specification is described as follows: values ranged between 100% and 80%, Arms<±2%; and between 79% and 70%, Arms<±3%.

Statistical method: accords to the data analysis stated in ISO9919, and Arms is calculated using the formula as following:

$$Arms=\sqrt{\frac{\sum_{i=1}^{n}(SpO\ 2i-S_Ri)^2}{n}}$$

The result of the clinical trial:

There are 155 blood samples totally in two hospitals. The values of %SaO2 are in the range between 70% and 100%, which are compared with %SpO2. There are 85 male subjects and 70 female subjects in the total 155 subjects aged from 16 to 92. 49 samples' values of %SaO2 are in the range between 70% and 80%, 53 samples' values of SaO2 are in the range between 80% and 90% and 53 between 90% and 100%. The Average Difference, Standard Deviation and ARMS of the 155 samples are listed as following:

Table 1 The accuracy of MD300C

MD300C	Data Pairs Analyzed/Excluded	Average Difference	Standard Deviation	ARMS	Specification
	155/2	0.31	1.68	1.70	±2

Accuracy of each testing range:

Samples	ARMS
22 samples' SaO2 ranged 70%-75%	2.10
27 samples' SaO2 ranged 76%-80%	2.25
27 samples' SaO2 ranged 81%-85%	1.80
26 samples' SaO2 ranged 86%-90%	1.47
32 samples' SaO2 ranged 91%-95%	1.18
21 samples' SaO2 ranged 96%-100%	1.10

SpO2-SaO2 relevant Figure:

The figure of the relationship between SpO2 and "golden standard" SaO2 is listed in

Annex A Figure 1.

It is shown from the result that the accuracy of the MD300C pulse Oximeter is compliance to the specification claimed by the manufacturer. There is no failure during the trial.

The adverse event and side effect during the clinical trial and the relevant disposal:

There no adverse event and side effect observed during the study.

Result analysis:

It can be determined from the result of the study that the accuracy of the MD300C pulse Oximeter equipment is compliance to the specification claimed by the manufacturer compared with "Golden Standard" Co-Oximeter.

Conclusion of clinical trial:

The accuracy of MD300C pulse oximeter equipment is compliance to the requirement, and the product is safe during the use. It can be used in the clinical environment. It is substantially equivalent to other pulse oximeter product with the same effectiveness and safety.

Indication, scope, Contraindication and caution:

The MD300C pulse oximeter is appropriate to adult in the hospital and home.
It can not be used in the environment with flammable anesthetic gas.
It can not be used during the MRI and CT scanning.
The MD300C pulse oximeter is intended for use only as an adjunct in patient assessment.
It must be used in conjunction with clinical signs and symptoms.

Problem that exists and improving advice:

None

Investigator	Duty	Title	Section
Yang Lipei	Director	Professor of Treatment	Emergency Ward
Wang Guoxing	Vice Director	Professor of Treatment	Emergency Ward
Zhang Bin	Doctor	Professor of Treatment	Emergency Ward

Suggestion of Governing Body of Investigational site

(Sealed)

Date: Oct. 24th. 2006

Annex A

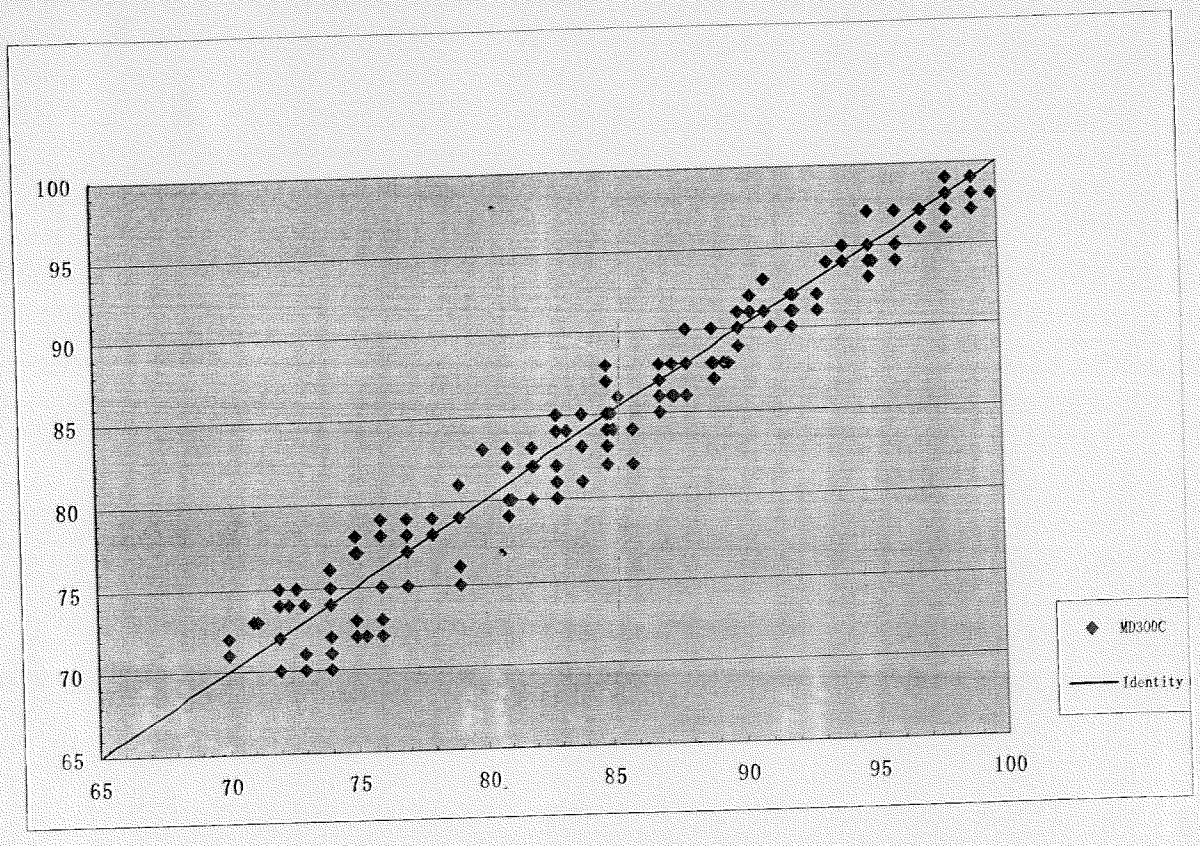

Figure 1

Figure1 Graphical representation of the desaturation data for the MD300C compared with an AVL OMNI 3 CO-Oximete. The X axis is presented for Functional saturation (%-SaO2), The Y axis is presented for Oxygen saturation (%-SpO2). The identity line is presented for evaluation of the data.