GE Entropy Sensor

Comparative Study

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INTRODUCTION

The purpose of this study was to compare the GE Entropy Sensor P/N M1038681 (test) to the Entropy Sensor P/N 8002858 (reference). Performance variables included Entropy™ values, EEG signal, interference tolerance, electrode impedance, electrode adhesive performance and overall usability of the sensor.

METHOD

The comparative studies were carried out in Finnish University Hospitals from September to November 2005. Data from 26 adult and 13 pediatric subjects were collected during three different studies, including general, neurological and pediatric surgeries. The Entropy sensors were applied to the subjects according to instructions. The test sensor was applied on one side of the forehead and the reference sensor on the opposite side (Figure 1). Entropy was measured from the subject using both test and reference sensors which were connected to an M-Entropy module in Datex-Ohmeda S/5 Compact Anesthesia Monitors. Data were entered into a computer.

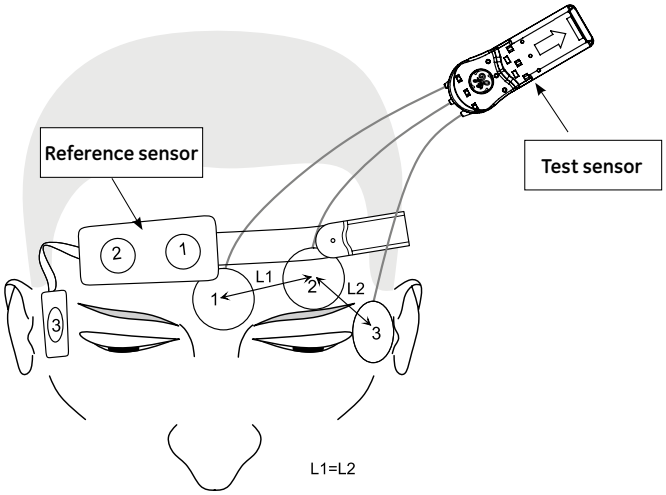

Figure 1. Position of both the test sensor and reference sensor during a study.

RESULTS

Entropy values

State Entropy (SE) and Response Entropy (RE) values from the test and reference sensors were compared by calculating correlation coefficients. Mean test-reference differences in Entropy values were compared with the Wilcoxon signed rank test. Criteria for substantial similarity were set at a correlation coefficient of at least 0.8 and mean differences either < 5 units or without statistical significance at the 0.05 level. The results met all criteria. Correlations were > 0.8 (Table 1). There were no statistically significant differences from the Wilcoxon signed rank test. Mean differences were < 5 units (Table 2).

	SE	RE
Study 7	0.928	0.922
Study 8	0.942	0.949
Study 10	0.986	0.977

Table 1. Correlation coefficients for test-reference comparisons of SE and RE values during different studies

	SE	RE
Study 7	-0.7	-0.2
Study 8	0.7	1.2
Study 10	-0.1	0.8

Table 2. Mean differences for test-reference comparisons of SE and RE values during different studies

EEG SIGNAL

The EEG signal was compared with calculations of the spectral EEG from the test and reference sensors during awake, medium anesthesia, and deep sleep, and when Burst Suppression Ratio (BSR) was > 0.5 to show differences in the noise levels measured during EEG suppression. In each comparison, medians of the amplitude spectrum of low EEG frequencies, high EEG frequencies and two EMG frequency bands were calculated. The means of the spectrum (in decibels) were calculated from the test and reference frequency ranges and were compared with the Wilcoxon signed rank test. The signal levels were considered substantially similar if the difference in values was not statistically significant at the 0.05 level, or if the median difference was < 3 dB. The results indicated that there were only small differences between the median amplitudes. A few statistically significant differences could be coincidental because of the large numbers of comparisons.

INTERFERENCE TOLERANCE

Interference tolerance was evaluated by comparing the raw EEG data and the calculated Entropy values between the test and reference sensors. The studies were performed in normal operating room conditions for exposure to typical levels of interference. The interference tolerance of the test and reference sensors was substantially similar because there were no significant differences for raw EEG and calculated Entropy values.

	Low EEG frequencies 1-8 Hz Difference/dB	**High EEG frequencies** 8-30 Hz Difference/dB	**EMG frequency band** 55-95 Hz Difference/dB	**EMG frequency band** 105-145 Hz Difference/dB
Study 7				
Deep sleep	1.1*	0.5	-0.3	-0.7
Medium sleep	0.9*	1.0*	0.5	0.0
Awake	1.2	1.1	0.0	-0.4
BSR	-1.2	-0.0	0.5	-0.0
Study 8				
Deep sleep	-1.1	-0.6	-0.6	-0.1
Medium sleep	-0.8	-0.5	-0.6	-0.7*
Awake	-0.9	-1.1	-1.9	-1.8
BSR	-1.4	-1.2	-0.1	0.1
Study 10				
Deep sleep	0.7	0.4	0.6	0.2
Medium sleep	-0.2	0.2	-0.2	-0.3
Awake	1.1	0.5	-0.4	-1.2
BSR	3.2	2.9	0.6	-0.4

Table 3. Signal amplitude median differences between test and reference sensors (dB)

*= P<0.05 (Wilcoxon signed rank, no Bonferroni correction)

ELECTRODE IMPEDANCE

The electrode impedances were manually recorded in the computer. On average, the impedance for the test sensor was approximately 1 kOhm lower than for the reference. The impedance for the test sensor seemed to decrease after application while it generally stayed the same for the reference. The confidence level for meeting the initial impedance requirements was 96 percent; two test sensors did not meet the impedance requirement. Figure 2 illustrates the electrode impedance distributions for test and reference sensors at initial application, as an average over the whole test case and at the end of the test case.

ELECTRODE ADHESIVE PERFORMANCE

The adhesive material was evaluated for adherence to skin, removal from skin, and skin reaction. The adhesive performance was excellent. No adhesive failures and no skin reactions were reported during hospital use and three 24-hour, in-house tests. The confidence levels for skin compatibility of the electrodes and sufficient adhesion were 99 percent. The sensor could be removed easily after use. The adhesive left very little residue on the skin after sensor removal.

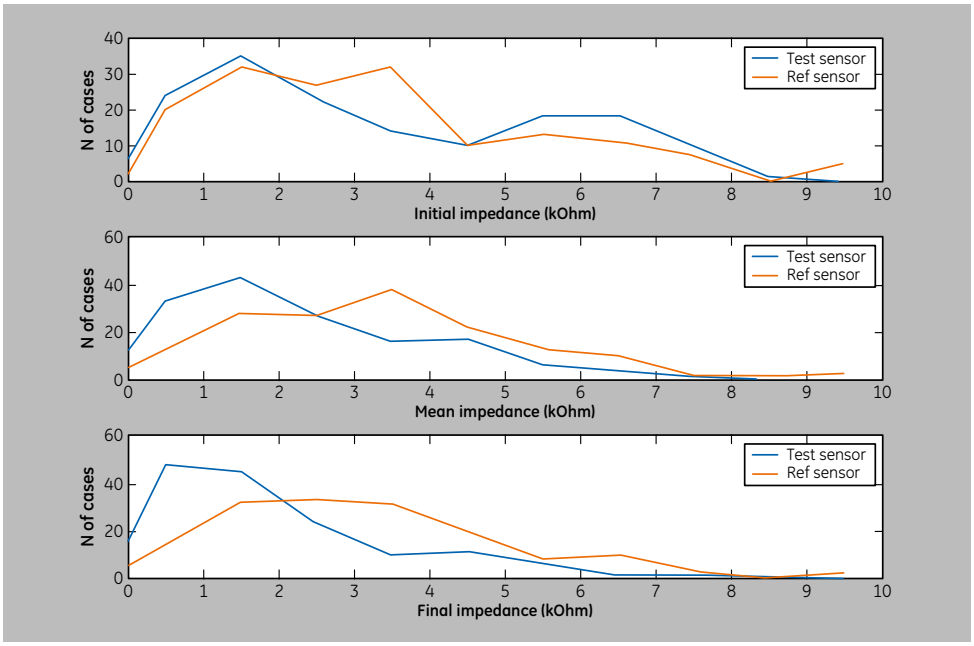

Figure 2. Electrode impedance distributions for test and reference (Ref) sensors

OVERALL USABILITY OF THE SENSOR

Overall usability involved sensor application (skin preparation and positioning of the individual electrodes) and sensor fit. Based on feedback from the clinicians, the test sensor was about as easy to apply and remove as the reference, and the preparation method produced sufficient impedances, once the use of the sensor had become routine. There were no reports in which the test sensor would not fit on the forehead of the subject.

SUMMARY

In this study, SE and RE values, EEG signal, interference tolerance, electrode impedance, adhesive performance, and overall usability were compared and no differences of significance were found.

NOTE: Always refer to the Instructions for Use document which accompany the device.

Imagination at work

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