EVALUATION OF UNITAS EQUIPMENT EFFECTS ON THE HUMAN EEG

M.B. Sterman, Ph.D. and D.A. Kaiser, Ph.D.

CONFIDENTIAL

INTRODUCTION

This research study was initiated as the result of a contract between Unitas, a Cayman Island Corporation, and M Barry Sterman, Ph.D., a private scientific contractor. Dr Sterman is also a Professor, School of Medicine, University of California, Los Angeles The study was conducted in Los Angeles, California at the offices of EEG Spectrum, a private research and clinical facility.

The objective of this study was to provide an initial but scientifically rigorous evaluation of the effects of Unitas electromagnetic flux conditioning equipment on the electrical activity of the human brain, as measured by the electroencephalogram, or EEG. While the research staff was familiar with the literature addressing the medical concerns of electromagnetic flux exposure and the general theoretical perspective of the Unitas equipment developer, no comprehensive technical information was provided as to the nature of this equipment or the basis for its potential effects on human alertness or performance

METHODS

Preliminary Evaluation

A preliminary evaluation was carried out to assure that the various items of Unitas equipment described below would have no disruptive affect on the functioning of the sensitive EEG recording equipment to be used in this study. This evaluation found no electronic interactions between these devices and the EEG recording equipment. Any effects on the subsequently recorded human EEG data could thus be attributed to biological variables.

Subjects and Preparation for EEG Recording

Three adult subjects were studied. Two were female and one was male. Ages ranged from 27-34 years. All had at least a college level education and were in good physical and mental health. All were required to review and sign an approved Institutional Human Subjects form.

Referential EEG recordings were obtained using a standardized, pre-measured electrode cap with 19 recording sites estimating placements specified by the International 10/20 System. These included all prefrontal, frontal, central, temporal, parietal, and occipital recording sites. Each site was referenced to linked earlobes. A ground lead was located anterior to the mid-frontal placement. Impedance readings below 5K were required before recording was initiated. EEG data were subjected to a 2 Hz high-pass and a 30 Hz low-pass filter, with rolloffs of 12 and 48 dB/octave, respectively. Data were digitized at 128 samples/sec. and stored on a hard disc for subsequent analysis.

Cognitive Testing

A modified computer version of the Continuous Performance Task, or CPT, was used. The CPT test presented a continuous sequence of 200 individual roman letter stimuli in the middle of a video screen during an 10 minute trial. These letter stimuli were exposed for 200 msec. and appeared once every 3000 msec. The subject was instructed to press the space-bar on a computer keyboard whenever designated "target" stimuli appeared in the letter stream. Target stimuli used here were the second of 3 paired sets of letters, with the first letter serving as a prime. Thus, the subject had to recall 3 designated letter pairs in order to accurately identify targets, and to disregard all other stimuli.

Seven letters were selected as stimuli on the basis of comparable shapes and sizes. This limited number of letters was chosen also to increase the short-term recall difficulty of the task, since many of the same letters were used in different combinations. These letters were arranged in a sequence which provided 20 randomized replications of each target pair, or 60 designated targets, among the 200 stimuli presented.

The letter stream was presented at the center of a black monochrome screen placed approximately 3 feet in front of the seated subject. The letters were light gray and 2.75 x 1.80 cm in size. All subjects were given an initial 3 min. practice session with target letters different from those used in the test condition. The program automatically scored reaction times and the accuracy of test performance in terms of percent correct responses.

Setting and Equipment

The study was conducted in a room measuring 8 by 10 feet. Lighting was normal and of moderate intensity. A padded leather reclining chair was placed in the rear right-hand corner of this room in front of a small table holding a 12 inch computer monitor and a keyboard to be used for cognitive testing. A Unitas physio-regulatory relaxation mat, measuring 24 by 72 inches, was placed over the surface of the chair and attached at the top. This mat was flexible and easily conformed to the contours of the chair. It was connected at the bottom to a cable trailing off under the small table. A computer desk, holding a 486 IBM-compatible personal computer and monitor, was placed between the chair and the room entrance. The operator sat at this desk throughout each trial and directed the sequence of test events while reviewing and structuring data acquisition. Data were acquired to this computer from a 24 channel quantitative EEG system (Lexicor NRS 24, Boulder, CO). A small table was placed behind this desk and held a second 486 computer that was used to control the cognitive test monitor facing the subject.

All of this equipment was connected to AC power by one of two routes. One was a standard AC power strip. The other was through a Unitas signal conditioning unit to a Unitas power conditioning strip. When the Unitas equipment was used for the computers the signal conditioning units were placed between the computer monitors and the CPUs and these were connected to the power conditioning strips. The NRS-24 EEG data acquisition equipment was also connected to one of the Unitas strips. When this system was not used the normal monitor cables were replaced and the CPUs and EEG acquisition equipment were connected to standard power strips. The mat had only one cable which was connected to a power conditioning strip through a signal conditioning unit, and was either plugged to (during Unitas evaluation) or unplugged from (during the control condition) the AC power source. All power strips and signal conditioning units were placed under the tables, which were draped, and were not visible to the subjects.

Experimental Design

Each subject participated in four test trials administered over the course of a six hour period commencing at 10 AM. All test trials were the same as far as procedure was concerned. After the initial preparation for recording, as described above, the subject was seated on the reclining chair. The chair was maximally reclined (60 degrees from vertical), placing the subject in a semi-prone position. Subjects were asked to close their eyes and attempt to clear their minds and relax. They remained in this condition for 30 minutes. After this period was completed the subject was placed in a comfortable upright position in the chair and the monitor table rolled forward over their legs so that they could access the keyboard. A five minute break period was then allowed. During the first of these the subject was instructed about the conduct of the CPT test and given a practice trial. During subsequent breaks the subject chatted with the operator. The 10 minute CPT test was then administered. When this was completed the subject's recording cap cable was disconnected from the equipment and they were allowed to stretch, eat, or visit the restroom, depending on their needs or the time of day, with the cap in place. This break was restricted to 30 minutes in the mid-morning and mid-afternoon. One hour was allowed for eating at lunch time. They then returned to the reclining chair and the next trial was initiated. Excluding the initial EEG electrode hook-up period, each trial lasted for approximately one hour and was followed by either a 30 or 60 minute break interval.

A double crossover, four-trial design was employed, using 3 different configurations to provide a control for order effects. During what was designated as condition "A" all equipment, including the mat, was connected through Unitas signal conditioning units and power strips. During condition "B" all equipment was connected through standard cables to standard power strips and the mat was disconnected. The three configurations used were: **ABAB, BABA, and ABBA** Lunch breaks were allowed between the first and last two trials.

EEG Data Analysis

Digital EEG data were subjected to both automatic and visual artifact removal. The automatic program deleted data sequences of atypical amplitude (6 x local 10 sec mean). Visual inspection of these deletions assured that no viable EEG data were lost and provided for the selected manual deletion of any residual artifacts. Less than 5 percent of these data were lost due to artifact in the initial resting condition. For the cognitive testing condition zero values replaced deleted data to maintain temporal continuity but these were not included in the computing method, as described below. Corrected digital EEG files were then exported to custom, seamless FFT software.

Analysis of Data from the Initial Resting Phase: The first 5 minutes of the 30 minute period during which the subjects were reclined and resting was deleted to allow for adaptation to the situation, a need demonstrated in previous studies. The FFT analysis program generated a sequence of one minute averages over the subsequent 25 minute period for each recording site and in each of five 2 Hz frequency bands between 5 and 13 Hz. A 6th band at 15-18 Hz was also evaluated. These sequential one-minute averages were subjected to z-score transformation within subject, and averaged by condition (Unitas vs. Standard power source) across subjects. Trends in EEG spectral magnitude were then compared between conditions.

Analysis of Cognitive Testing Data: As noted above, the performance data for this test included mean reaction time and percent response accuracy. These measures were automatically calculated by the CPT program. For analysis of corresponding EEG data Event-Related EEG Response Profiles (EERPs) were generated by our special software program. EERPs resemble evoked response potentials but are generated by EEG frequency changes rather than amplitude modulation (Pfurthscheller and Aranibar, 1977; Sterman et al, 1996). Our software program applied a series of 1 sec. cosine tapering functions, each overlapping the next by 87.5%, to FFT calculations. This method maintained edge protection while preserving an updated temporal resolution of 125 msec. If more than 10% of the digital samples in a given second were zeros that sec. was discarded. Such omissions were rare, and had little effect on outcomes, particularly since mean temporal profiles were obtained by averaging event-related EEG responses within subjects and across conditions.

Spectral voltage (square root of power) estimates were calculated for the 6 designated frequency bands. Actual voltage (magnitude) was used in place of power because previous findings have shown that the power transform of EEG spectral data seriously distorts distribution characteristics (Pollock et al. 1990; Sterman et al, 1994). An event marker provided by the CPT program identified the timing of stimulus presentations.

Sixty target letter pairs appeared randomly during the 10 min. recall task. A temporal profile of successive EEG spectral magnitudes was generated for each of these, with data points at 0.125 sec intervals for a period from 0.25 sec prior to stimulus presentation to 1.75 sec afterwards. Spectral magnitude values for the resulting 17 data points associated with each target stimulus were then averaged within each condition for each subject. These data were normalized (z-score transform) within subject to reduce between-subject variance, and the normalized values averaged across subjects for each condition separately.

The small number of subjects tested here precluded meaningful statistical analysis. Given that each subject experienced each condition twice, it was possible to combine performance data for all three in order to achieve a preliminary "sign test" evaluation of CPT performance variables. Further, since normalized EEG data were expressed in terms of standard deviations from condition means it was possible to estimate significance on the basis of established probabilities.

RESULTS

Initial Resting Phase

Findings: Plots of EEG trends across the 25 minutes of data evaluated during the initial resting period disclosed 3 major differences between A (Unitas equipment on) and B (Unitas equipment off) conditions. Posterior cortical activity in the 7-9 Hz band increased progressively during the off condition but remained essentially stable during the on condition (fig. 1A). While values were generally lower in the off condition for the first 15 minutes they reached parity and then surpassed on condition values during the last 10 minutes of this period. By the termination of the resting phase off condition values exceeded values in the on condition by approximately 1.5 standard deviations. Although statistics are questionable with such a small number of subjects, probability theory suggests that such a difference would occur by chance only 10% of the time.

Activity in the 9-11 Hz band in this same posterior region was essentially identical in both conditions during the first 12 minutes but diverged afterwards (fig. 1B). In the equipment off condition the relative magnitude in this frequency band decreased progressively, while during the equipment on condition it was unchanged. The characteristic difference between conditions for the 7-9 and 9-11 Hz frequency bands was the relative stability of spectral magnitudes during the on condition in the second half of the period, as contrasted with the divergent changes seen when the equipment was off. The probability of these combined differences occurring by chance is only 5%. These differences have meaningful functional significance, as discussed below.

The third difference noted was in the higher frequency bands (13-15 & 15-18 Hz) over anterior cortical leads. Trends in the two conditions were very different across the entire resting period (fig. 1C). In the on condition activity was increased over the first 10-12 minutes and then declined. In the off condition activity was lowest initially, increased to comparable levels by 10-12 minutes, and then increased markedly thereafter. During this last 10 minute period differences between conditions again reached the 10% level of chance probability.

Discussion: Recent scientific evidence has indicated that the 8-12 Hz dominant alpha rhythm in the human posterior cortical EEG is actually made up of two functional different components (Klimesch et al. 1988; Pfurtscheller and Klimesch 1991, Sterman et al. 1996). Thus, increased activity in the 7-9 Hz, or "lower alpha" band reflects a reduction in non-stimulus bound general attention, while increased activity in the 9-11 Hz, or "upper alpha" band indicates reduced stimulus-bound cognitive processing. Further, since a common thalamic mechanism underlies the generation of these frequencies it would be expected that certain functional changes would be reflected by reciprocal changes in these two bands. One such functional change is the progression into drowsiness and sleep. The reduction in general attention associated with this progression tends to shift frequency dominance to the lower band. Such a shift was seen here in the off condition but not in the on condition.

Increased higher frequencies in the anterior EEG, when accompanied by reduced 9-11 Hz activity posteriorally, is associated with general alertness. However, increases in these higher frequencies accompanied by a decrease in 9-11 Hz and an increase in 7-9 Hz rhythms indicates a very different cognitive state. Such a pattern suggests that the increased higher frequencies reflect the onset of a characteristic EEG pattern known as sleep spindles. If this is in fact the case, the combined increase in slower frequencies, decrease in intermittent frequencies, and increase spindle activity argues strongly for the conclusion that subjects were progressing into sleep towards the end of the off condition. Such a progression, however, did not occur when the Unitas equipment was turned on.

The implications of this interpretation are significant. They suggest that the Unitas equipment countered changes in the brain that normally promote drowsiness and sleep onset during a sustained period of inactivity. Accordingly, by mechanisms as yet unknown, this equipment appeared to support general attention and suppress the urge to drowsiness and sleep, even when the eyes were closed for a prolonged period. This provocative conclusion is certainly worthy of further investigation.

Cognitive Testing Phase

Findings: Performance on the CPT test was evaluated automatically by the program. Measures of mean reaction time and percent response accuracy were provided for both the on and off conditions. These measures are shown for each subject in figure 2. Reaction time data, which are based on correct target responses only, are presented in the top graph. These data indicate that 2 of the 3 subjects responded more quickly to the target stimuli when the equipment was on. Both subjects HE and TH showed a reaction time decrease of approximately 20%. Subject TT, however, showed a comparable reaction time increase. Response accuracy data are shown in the bottom graph. Subject HE was 100% accurate in both conditions. Subject TH showed a 17% improvement in accuracy when the equipment was on, while subject TT showed an improvement of only 3%. Excluding the comparable accuracy values for subject HE, 4 of the 5 remaining reaction time and accuracy differences among the tree subjects indicated improved performance on the CPT test during the on condition A sign test would attribute such a result to a real difference 80% of the time.

Corresponding event-related EEG response profiles showed consistent difference that were limited to alpha band frequencies at recording sites over the anterior and posterior right temporal lobe of the brain. Response profiles in both the 7-9 low alpha and 9-11 Hz high alpha bands tended to show a more rapid activation response (called an "event-related desynchronization" or ERD in this context) during the on condition (figs. 3 and 4). Further, at both of these sites and for both of these frequency bands the subjects showed a more sustained ERD and a more delayed recovery to baseline when the equipment was off.

Discussion: Despite the tentative nature of these findings they are surprisingly consistent from a functional perspective. The performance data suggest that both sustained attention and the related ability to recall target stimuli were possibly enhanced when the equipment was on. This conclusion was in fact supported by the finding that alpha frequency event-related EEG responses were more brief and recovered more quickly selectively in the right temporal lobe during the on condition. This structure in the brain is well documented as the seat of pattern memory. Further, brief and facilitated ERD responses at these frequencies and in this area have been systematically associated with superior attention and memory performance (Sterman et al. 1996).

The consistency of these two observations with each other and with the findings from the initial resting phase is indeed provocative. Despite the fact that few subjects were studied and that findings were at best modest the overall picture that emerges is surprisingly consistent with the conclusion that the Unitas equipment had a meaningful and positive effect on the subjects ability to sustain attention. Such a finding was both unpredicted and unexpected.

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FIGURE LEGENDS

Figure 1. Mean smoothed trends in normalized EEG spectral magnitudes for three subjects across the final 25 minutes of the initial resting phase of this study. The lower and higher components of the dominant posterior alpha rhythm band are shown in the top 2 graphs The bottom graph instead shows activity found to be characteristic of the higher 13-18 Hz range at anterior recording leads. The observed pattern in these 3 bands and locations during the latter portion of the off condition is indicative of a progression into sleep. This pattern was not seen in the on condition.

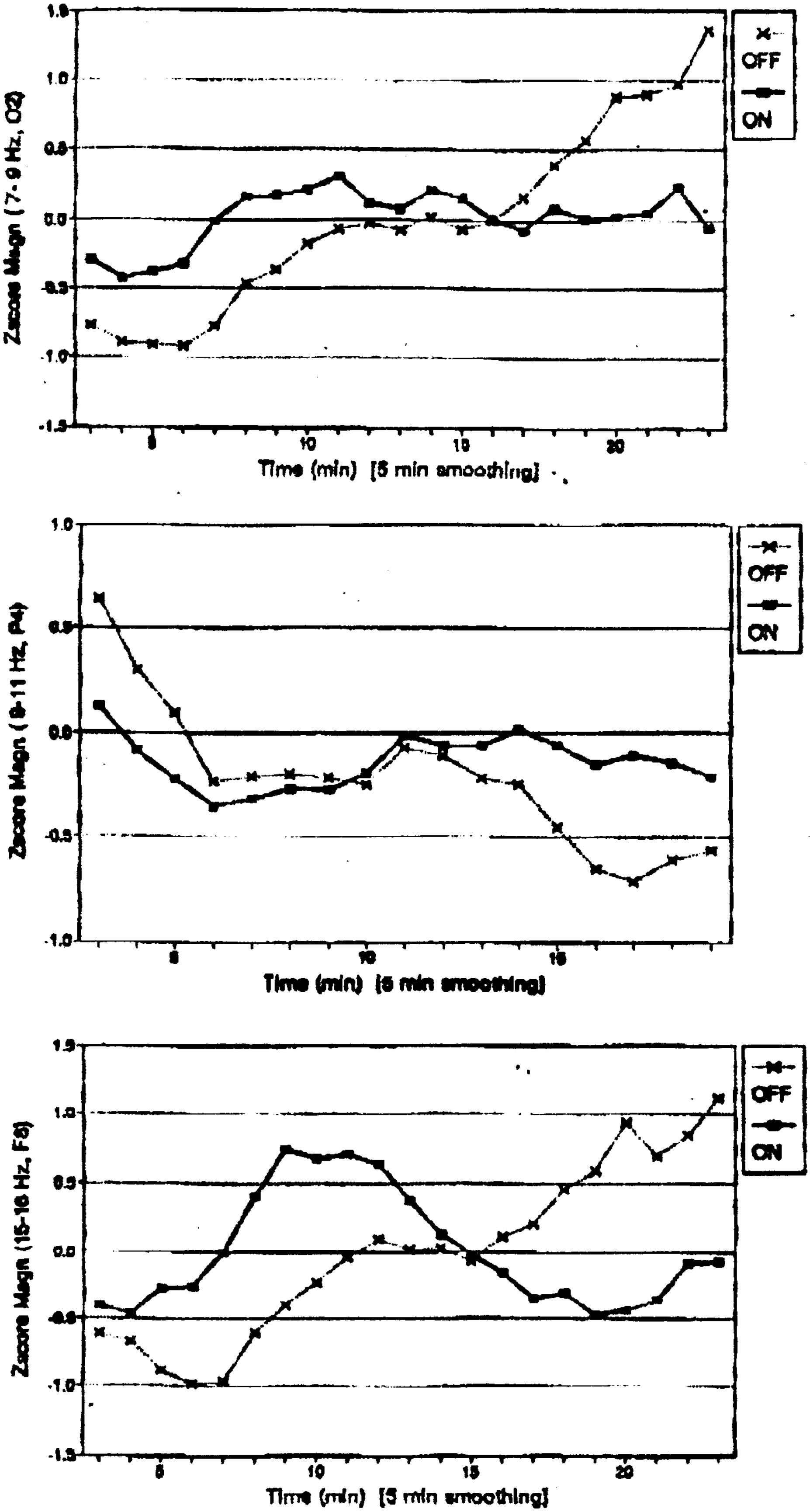
Figure 2. Reaction times (top) and percent response accuracy (bottom) scores from the Continuous Performance Test are shown here for each subject during the on and off conditions of this study. These scores were generated by the test software. They suggest that performance was improved during the on condition in 2 of the 3 subjects.

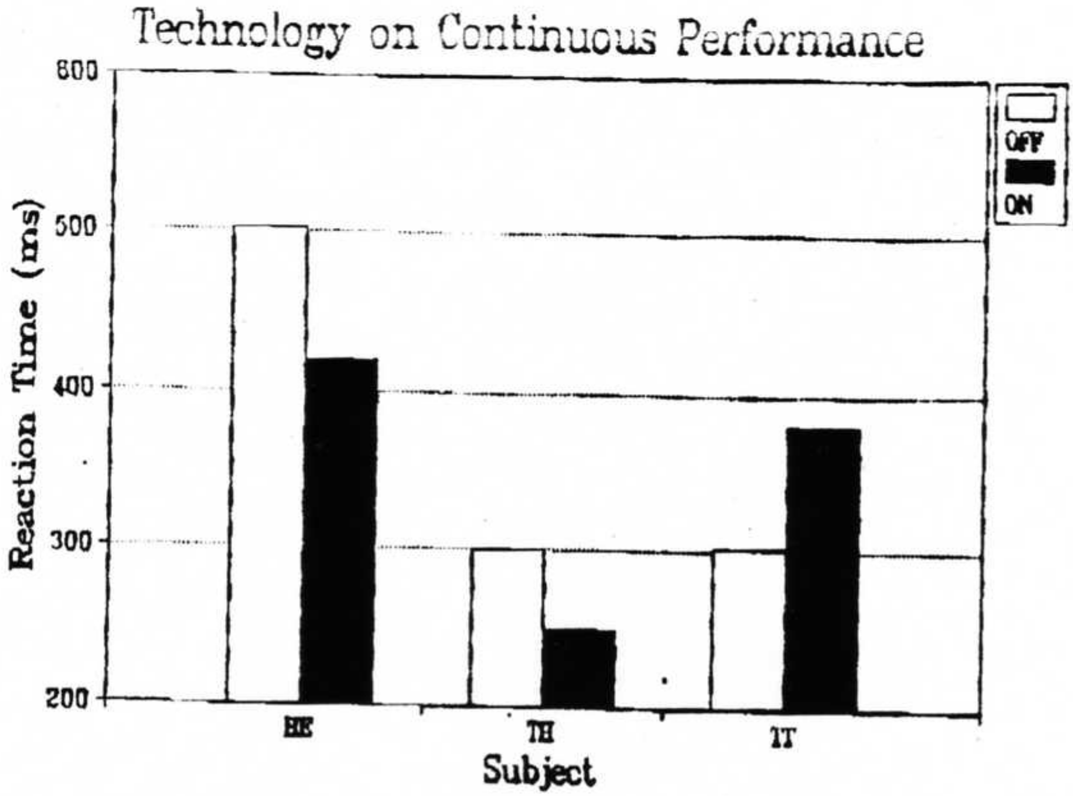
Figure 3. Normalized and averaged Event-Related EEG Response profiles at anterior and posterior temporal cortex recording sites are compared here for the 7-9 Hz frequency band during the on and off conditions. Temporal Position refers to the dimension of time from just prior to and after target stimuli appeared on the screen at time 0.00. The activation response, or Event-Related Desychronization, was longer and recovery slower during the off condition. See text for details.

Figure 4. Normalized and averaged Event-Related EEG Response profiles at anterior and posterior temporal cortex recording sites are compared here for the 9-11 Hz frequency band during the on and off conditions. Findings were similar to those for the 7-9 Hz band in figure 3.

Figure 1

Effect of Quantum Wave Mat
Eyes Closed Test




Technology on Continuous Performance
Reaction Time (ms)
600
500
400
300
200
OFF
ON
HE
TH
TT
Subject

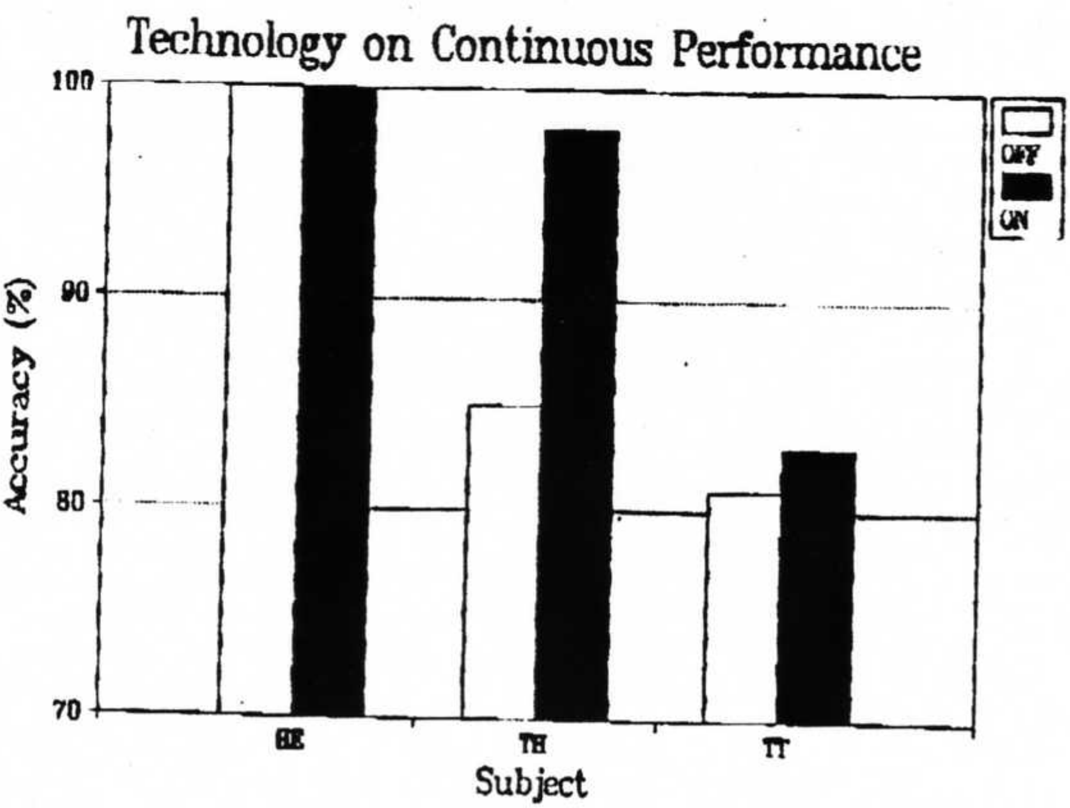

Technology on Continuous Performance
Accuracy (%)
100
90
80
70
OFF
ON
HE
TH
TT
Subject

Figure 2

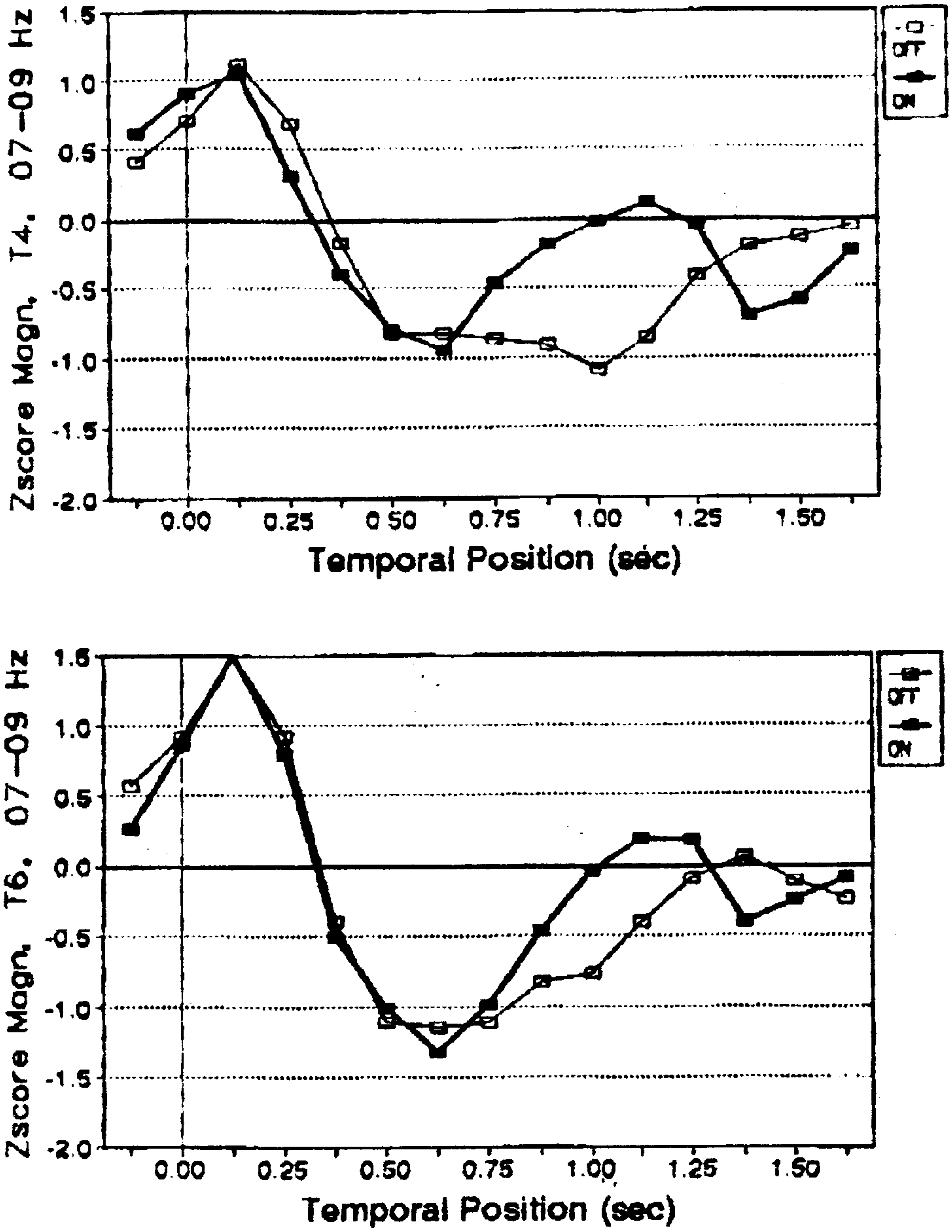
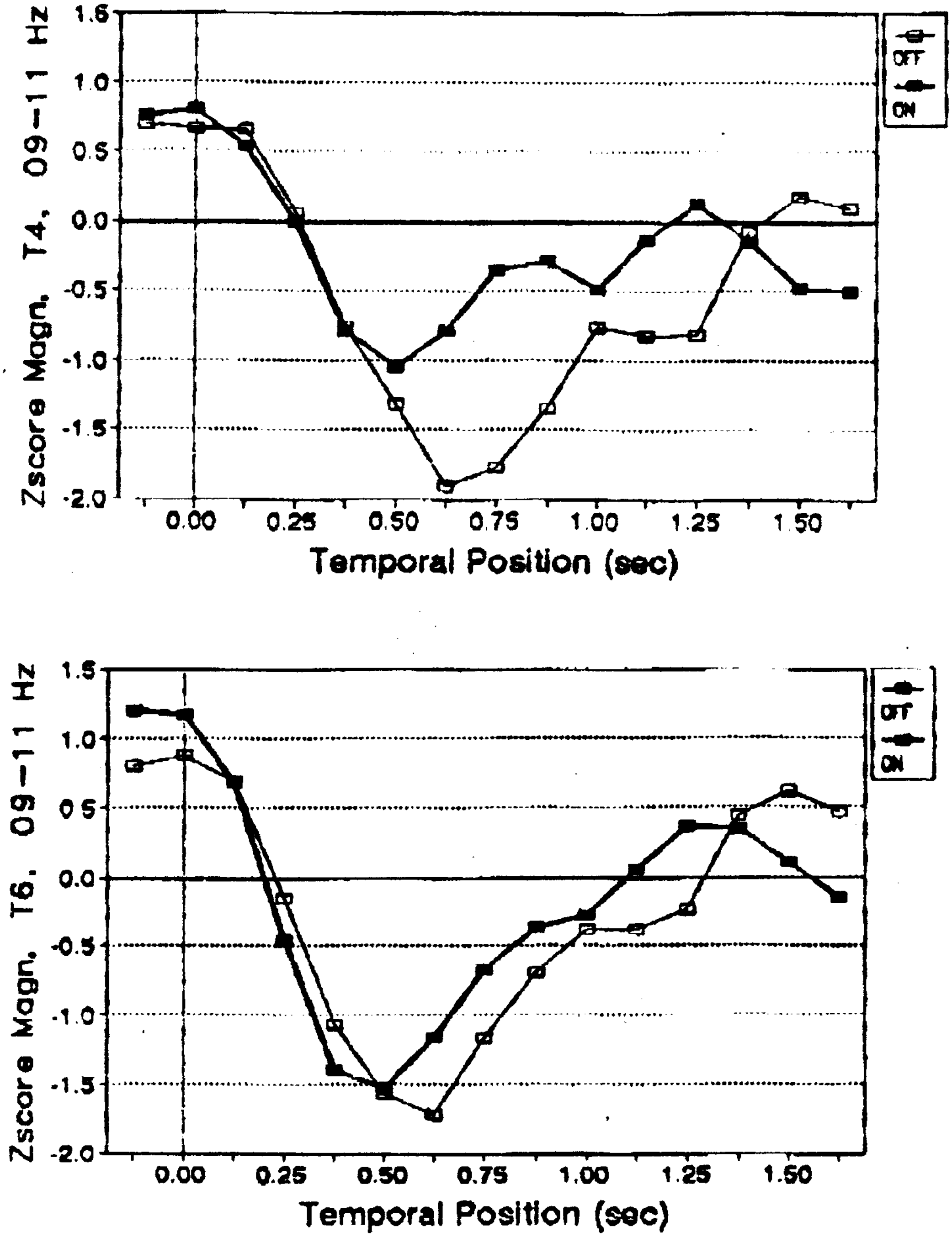

Zscore Magn. T4. 07–09 Hz
1.5
1.0
0.5
0.0
-0.5
-1.0
-1.5
-2.0
0.00
0.25
0.50
0.75
1.00
1.25
1.50
Temporal Position (sec)
OFF
ON
Zscore Magn. T6. 07–09 Hz
1.5
1.0
0.5
0.0
-0.5
-1.0
-1.5
-2.0
0.00
0.25
0.50
0.75
1.00
1.25
1.50
Temporal Position (sec)
OFF
ON

Figure 3



Zscore Magn. T4, 09–11 Hz
Temporal Position (sec)
OFF
ON
Zscore Magn. T6, 09–11 Hz
Temporal Position (sec)
OFF
ON

Figure 4