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TECHNICAL MEMORANDUM

title: Neurophysiological Equipment Susceptibility Test Program [by]

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INTRODUCTION

CEL will perform susceptibility tests on neurophysiological equipment commonly used in Naval Hospitals at a selected contractors facility in the Washington DC area.

These tests are designed to determine the vulnerability of the neurophysiological equipment to ultra-low frequency electric and magnetic fields which may reasonably be expected in the hospital environment. By using controlled laboratory experiments, the susceptibility of the equipment under test (EUT) may be accurately specified for both radiated electric/magnetic fields as well as conducted signals on the power lines.

From the test data, an engineering analysis will be made to determine the shielding and filtering requirements for proper location, layout and design of the neurophysiology departments of Naval Hospitals.

BACKGROUND

Clinical neurophysiology is the medical science of obtaining and interpreting tracings of the minute biological potentials of the body and brain. While this is not a new science, it is emerging as an important medical diagnostic tool in the treatment of certain illnesses, such as epilepsie, muscular dysfunction and other nervous disorders. The primary reason for the surge of interest in neurophysiology is the recent application of modern electronics to the measurement of the extremely small biopotentials. Accurate reproduction of biopotentials as small as one millionth of a volt is now well within the state of the art. The biopotentials of interest however, occur at ultra low repetition rates, (.5-50PPS) and as a result, specialized equipment has been developed and named for each particular medical specialty.

These specialities are:

(a) Electroencephalography (EEG). Graphic recording of biopotentials developed in the brain, by electrodes applied to the scalp, to the surface of the brain, or placed within the brain.

(b) Electromyography, (EMG). Graphic recording of the biopotentials associated with muscle tissue by electrodes placed within the muscle or on the skin surface directly over the muscle being monitored.

(c) Electro-oculography, (EOG). Graphic recording of the biopotentials associated with movements of the eyeball, by electrodes placed on the skin near the eye.

This clinical equipment is extremely sensitive and the requirement of placing multiple probes over wide areas of the body (each with an individual conducting wire) causes the equipment to be susceptible to stray electric and magnetic fields. Normally this problem could be avoided by

simply installing conventional shielded rooms, however, the ultra low frequency range renders conventional shielding and filtering techniques virtually useless as a means of providing the proper environment.

As a result, a test program is proposed to quantify and qualify the susceptibility of this equipment in engineering terms, so that by analysis and deduction an effective environment may be specified for Naval Hospitals which have neurophysiology departments and facilities. In view of the increasing use of clinical neurophysiology as a medical diagnostic tool, it is now necessary that Naval architects and designers incorporate the proper environmental criteria into future hospital design.

TEST ITEMS

The items to be tested are typical samples of modern neurophysiological equipment. At least three samples of each type are required. The three samples of each type will be from different manufacturers if possible, but will be provided from Navy equipment presently in use or in storage. Recent models of each type are preferred as samples to reflect the present state-of-the-art in equipment. A list of preferred equipment is presented below.

A. Electroencephalographs:

- Medcraft, Mark III, 8 channel EEG
- Grass Instrument Co., Series 8 EEG

B. Combintaion EEG, EMG and EOG's

- Beckman Dynograph, 8 channel Recorder
- Nicolet Instrument Co., CA-1000 system
- TECA, TE-4 Electromyograph

C. Audio and Visual evoked response stimulators

- Medcraft PS II, Photic stimulator
- Nicolet NIC-1006 Visual stimulator
- Nicolet Audio tone and click stimulator
- Grass PS-22 or PS-33 photic stimulator

A study of reference texts (1 and 2) on the subject of neurophysiological pulse wave forms shows a frequency spectrum for each category as depicted in Figure 1. The equipment manufacturers have designed their signal input amplifiers to pass all frequencies indicated without attenuation. Therefore, the susceptibility tests must extend from .1hz to 5Khz.

The patient/machine interface will be simulated by utilizing a life-size styrofoam ball for the patients head with 5 Kilohm resistors between connection points as shown in Figure 2. The exact connection points to be used will vary for each test depending upon the recommendations of a practicing neurologist just prior to start of the tests.

PROCEDURE

The susceptibility tests will be conducted in a selected contractors shielded room on sample neurophysiological equipment borrowed from Navy supplies.

The shielded room will then be outfitted to so that a standard magnetic field of known magnitude and direction can be generated to flood the machine/patient interface test sample. The frequency of the magnetic field will be varied from .1hz to 10Khz for three dimensional orientations of the test sample. The response of the test sample to the incident magnetic field will be recorded along with the magnetic field strength and sample orientation. This procedure will be repeated for all samples.

The shielded room will then be outfitted to so that a standard electric field of known magnitude and direction can be generated to flood the machine/patient interface test sample. The frequency of the electric field will be varied from .1hz to 10Khz for three dimensional orientation of the test sample. The response of the test sample to the incident electric field will be recorded along with the electric field strength and sample orientation. This procedure will be repeated for all samples.

For those machines which are too large to be placed inside the standard magnetic field generator, a small magnetic field search coil will be used to search the case of the machine incrementally.

As a final test, all test samples will be subjected to a conducted susceptibility test to determine whether or not power line filters are required. The conducted susceptibility test will consist of spike voltages, of 100 volts in accordance with MIL-STD-462.

It is estimated that the test program will not exceed two week in duration. Preliminary significant results will be forwarded to the sponsor informally during the tests. However, a fully documented technical memorandum will be submitted to the sponsor through official channels upon completion of the test program.

MEASUREMENTS

The neurophysiological equipment susceptibility will be determined by performing the following series of measurements on each test sample.

a. Electric field susceptibility levels, (.1hz-10Khz) of the simulated patient/machine interface.

b. Magnetic field susceptibility levels, (.1hz-10Khz) of the simulated patient/machine interface.

c. Magnetic field susceptibility, (.1hz-30Khz) of the machine case.

d. Conducted spike susceptibility of the machine power supply and lines.

The electric field susceptibility test set up for the simulated machine/patient interface is shown in Figure 3. It is the purpose of this test to determine the level of electric field, in volts/meter, required to cause a deflection of the recorder pens equal to that caused by a normal biopotential. At least one data point will be taken for each octave of frequency between .1hz and 10Khz. The simulated patient head and leads will then be rotated and the test repeated to obtain information from all three directions of electric field orientation.

The magnetic field susceptibility test set up for the simulated machine/patient interface is shown in Figure 4. It is the purpose of this test to determine the level of magnetic field strength in gauss required to cause a deflection of the recorder pen equal to that caused by a normal biopotential. At least one data point will be taken for each octave of frequency between .1hz and 10Khz. The simulated patient head and leads will then be rotated and the test repeated to obtain information from all three directions of magnetic field orientation.

The magnetic field susceptibility of the machine itself will be determined as shown in Figure 5. The search coil (loop) is a standard coil with construction details as shown in Figure 6. The coil generates a standard magnetic field of .5 gauss/amp at the base of the coil form.[3] The coil will be placed on each face (top and sides) of the machine, and the current through the loop will be increased until a deflection of the recorder pen equal to that of a normal biopotential occurs. At least one data point for each octave of frequency between .1hz and 20Khz will be taken. The current through the coil will be monitored by measuring the voltage across the 1 ohm resistor in the lead as shown in Figure 5.

The conducted susceptibility of the machine power lines/supply will be measured using the test setup shown in Figure 7. A standard spike voltage, shown in Figure 8, which represents a broad spectrum of signals, will be injected into the AC power lines to determine susceptibility quickly. Most neurophysiological equipments contain a power line filter and therefore susceptibility to the spike voltage is not expected. In the event susceptibility is demonstrated, the spike generator will be replaced with a power sinewave oscillator to determine the filtering requirements. These requirements will be recorded as test data.

INTERFACING

At the request of the Naval Bureau of Medicine and Surgery (BUMED), the Naval Facilities Engineering Command (NAVFAC) undertook a study to determine whether or not Electromagnetic shielding should be incorporated into the design of the neurophysiological monitoring areas of Naval Hospitals. The responsibility of conducting the engineering study and test program was delegated to the Civil Engineering Laboratory (CEL) and is being executed under work unit YF53.534.091.01.107 entitled, "Shielding Requirements for Clinical Neurophysiological Equipment in Navy Hospitals". Along with its request, BUMED has agreed to provide typical samples of neurophysiological equipment for test purposes and medical advice from practising neurologists and technicians as necessary to expedite the tests described herein.[4] The necessary contacts and liaison with practising neurologists and technicians has been established at the Naval Regional Medical Center, Bethesda, Maryland. It is intended that the test program be conducted in a selected contractors shielded room in the immediate vicinity of the medical center to maintain very close liaison and expedite the exchange of equipment.

REFERENCES

1. Graf, R. F. and Whalen, G. J. the Reston Encyclopedia of Biomedical Engineering Terms. Reston Publishing Co., Inc., A Prentice Hall Co., Reston, VA, 1977.

2. Geddes, L. A. and Baker, L. E., Principles of Applied Biomedical Instrumentation, John Wiley and Sons, New York NY 1975.

3. MIL-STD-461/463/463, "Electromagnetic Interference Characterists," 21 November 1968.

4. BUMED ltr, BUMED-416-ls of 6 January 1978.

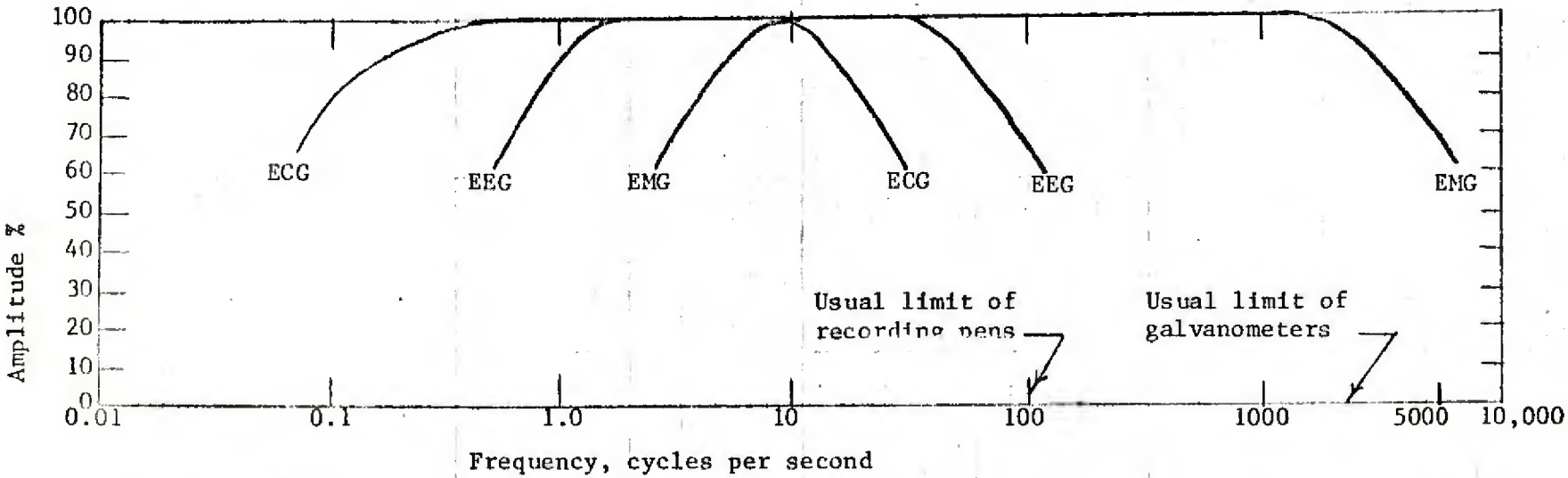


Figure 1. Frequency Spectrum of Clinically Recorded Bioelectric Events

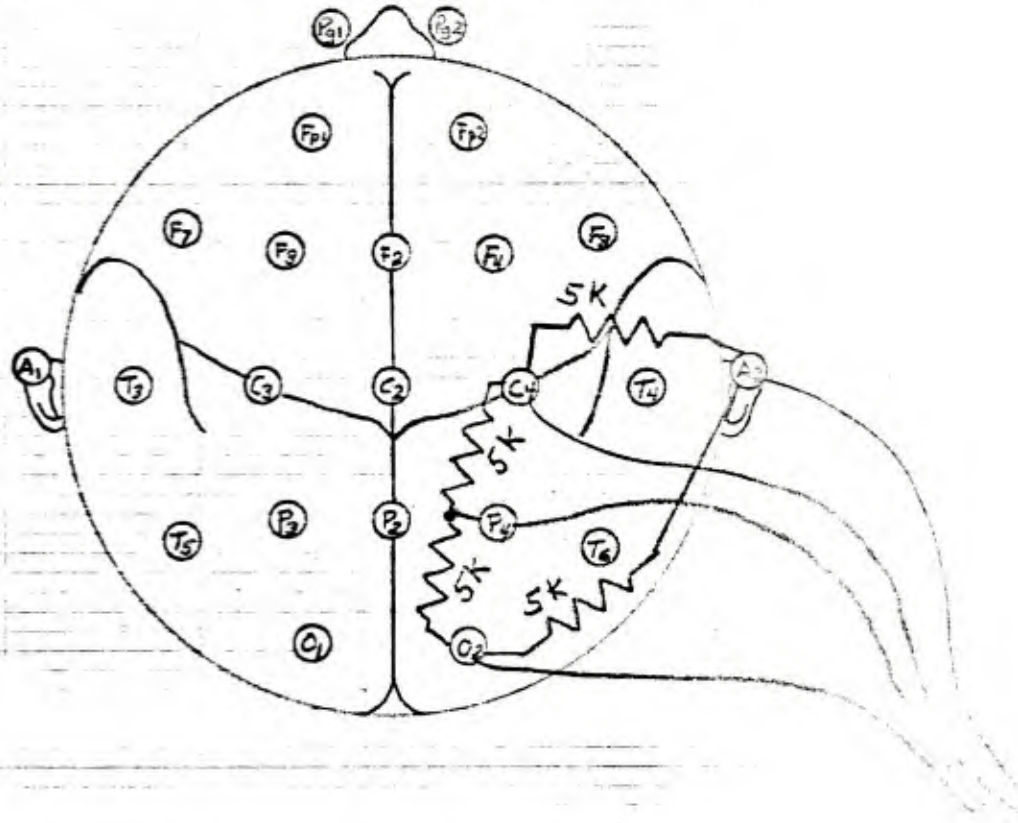


Figure 2. Patient/Machine simulation using a life-size styrofoam ball for the head and resistors between connection points for skin resistivity.

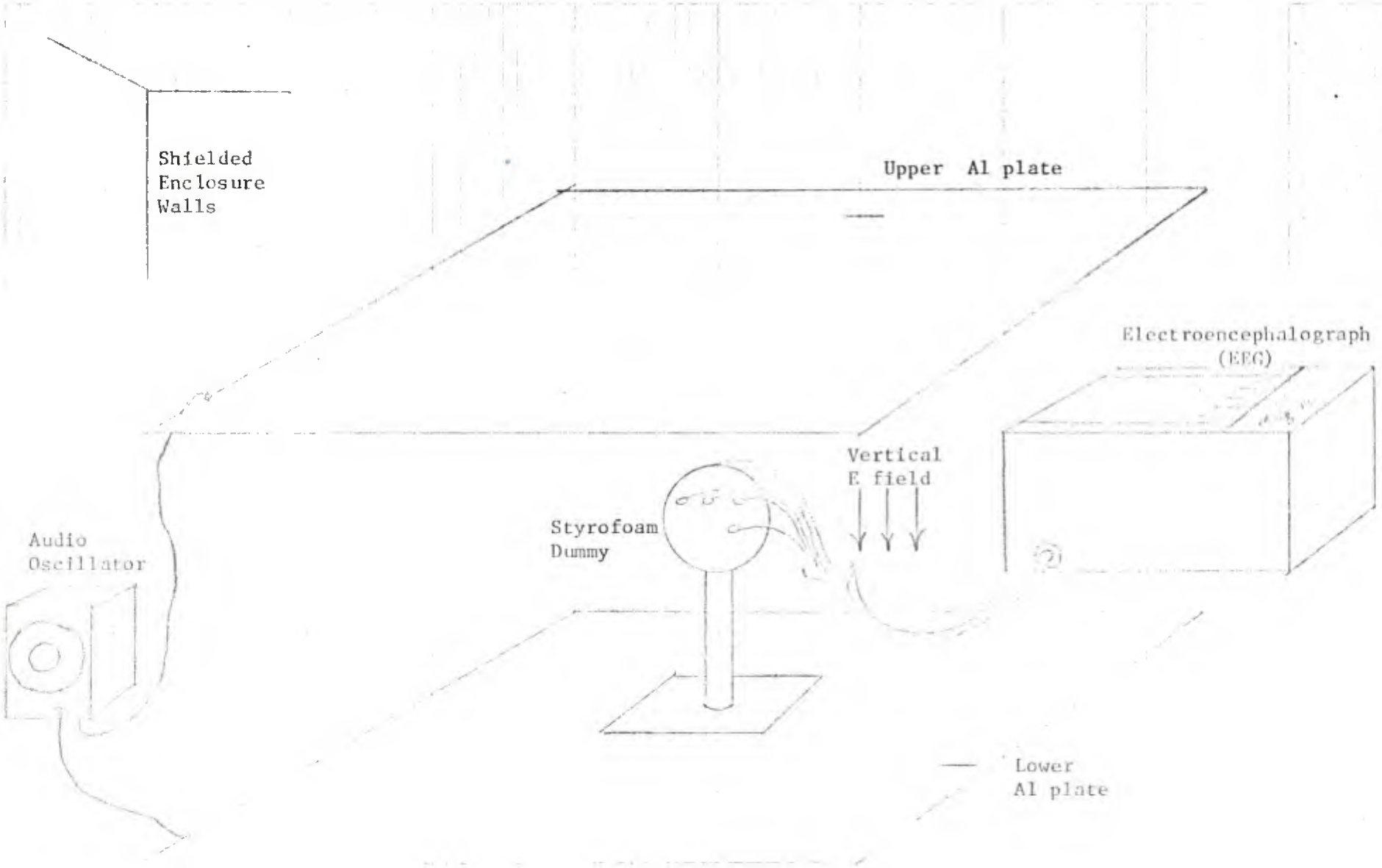


Figure 3. Test set up for electric field susceptibility of EEG machine/patient simulation

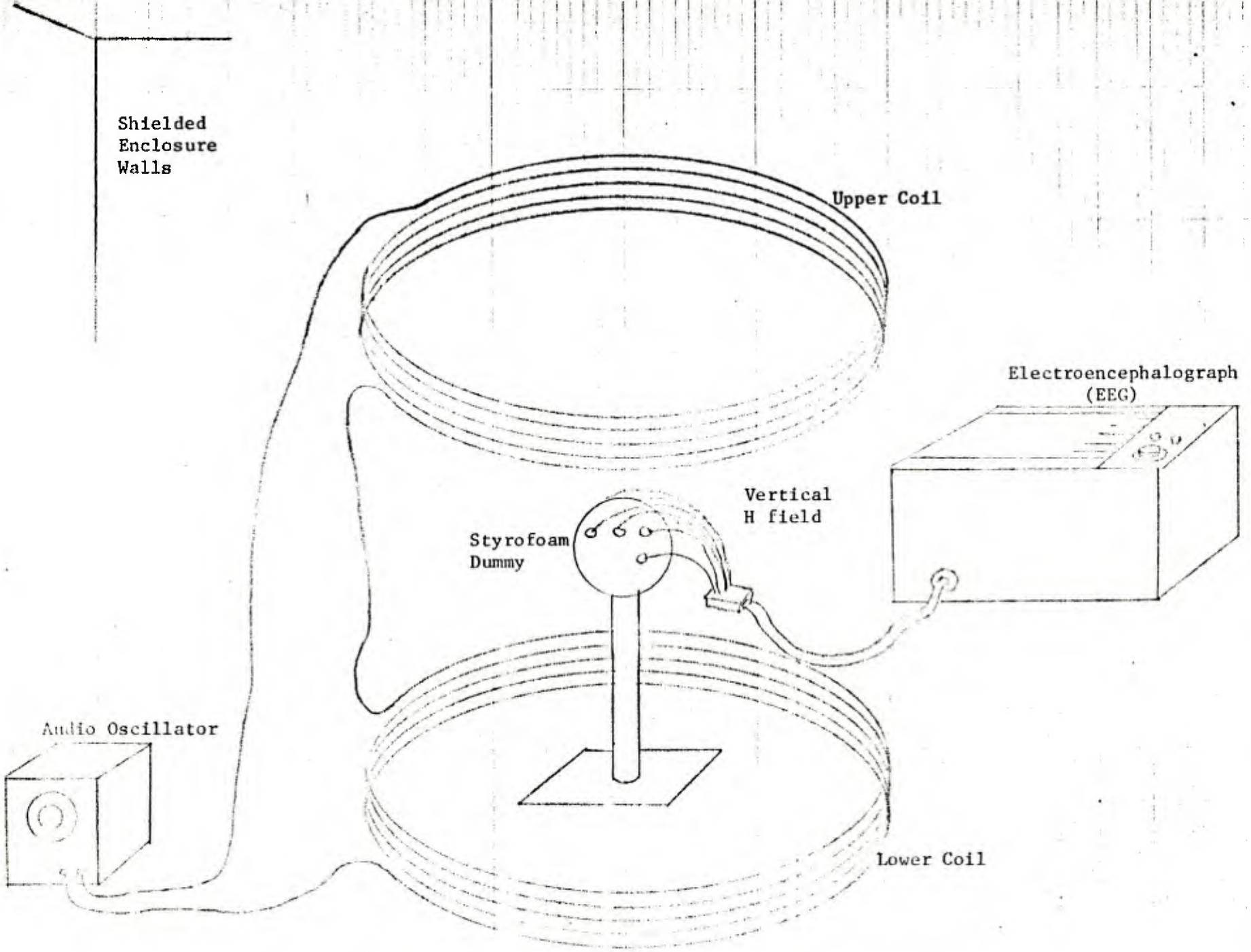


Figure 4. Test set up for magnetic field susceptibility of EEG machine/patient simulation

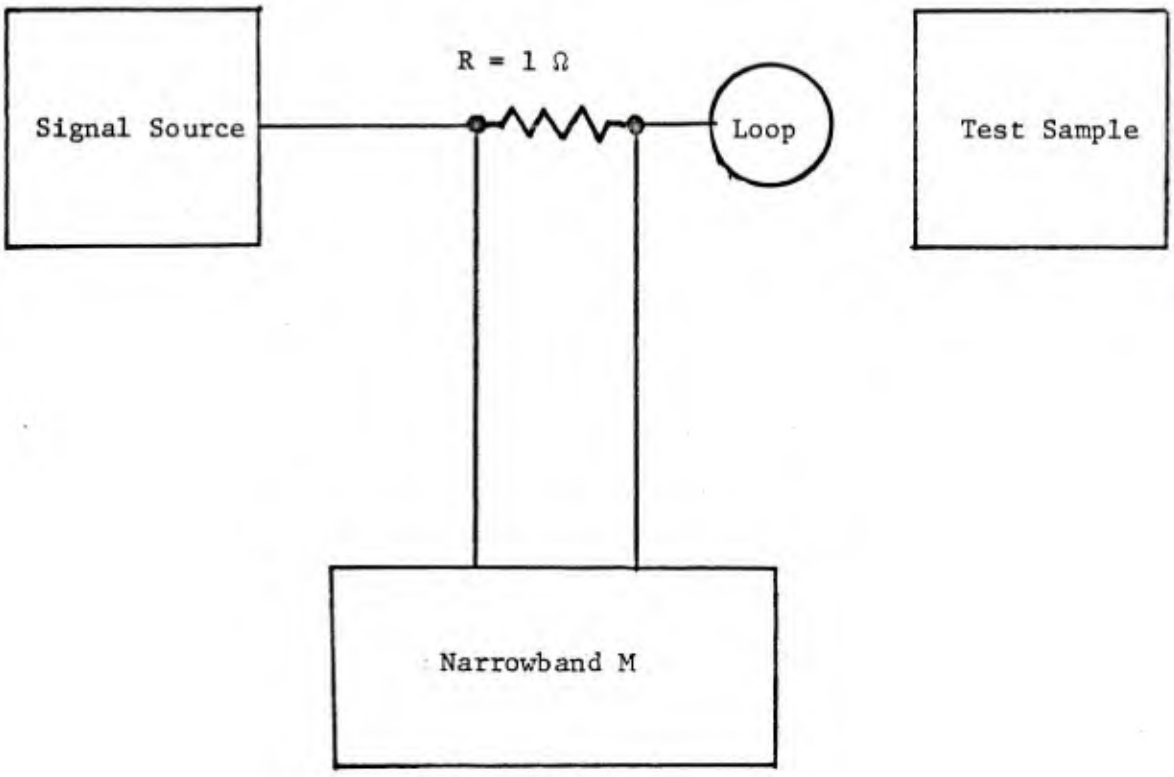
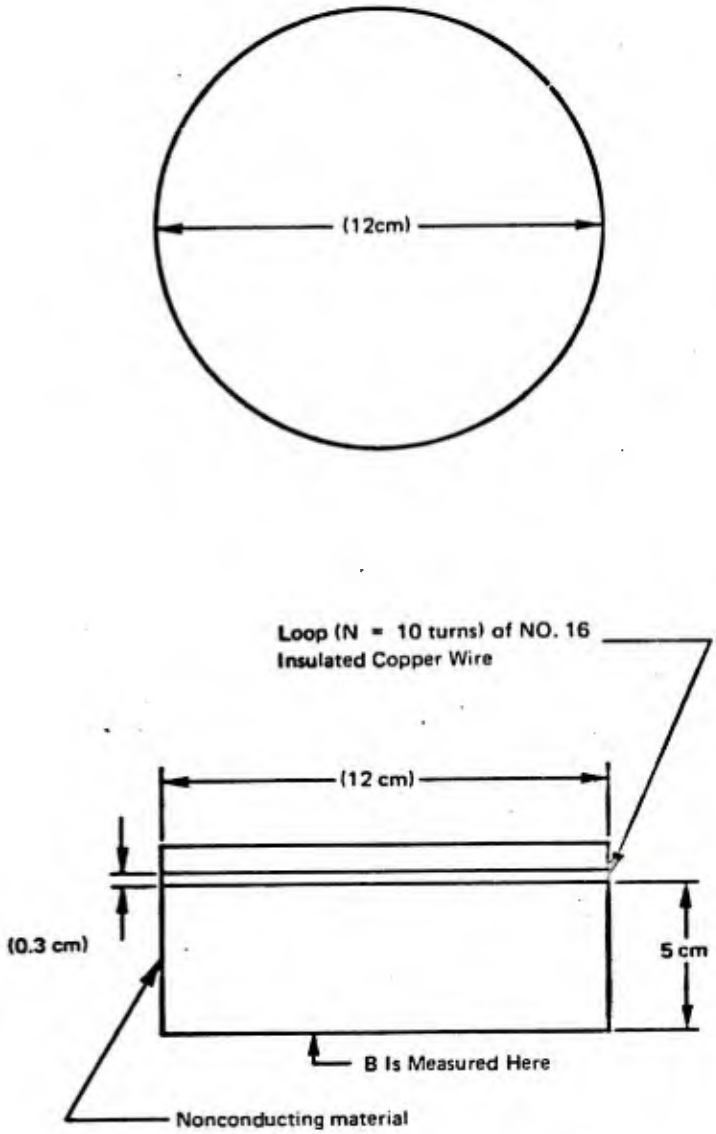


Figure 5. Magnetic field radiated susceptibility, (5 Hertz to 30 kHz) of the neuro-physiological equipment



Note: (a) B = 5×10^{-5} tesla/amp at 5 cm from wire turns

(b) Loop self-resonant frequency shall be greater than 100 kHz
1 tesla = 1 Weber/M^2 = 10^4 gauss

Figure 6. Loop used for radiating local magnetic fields.

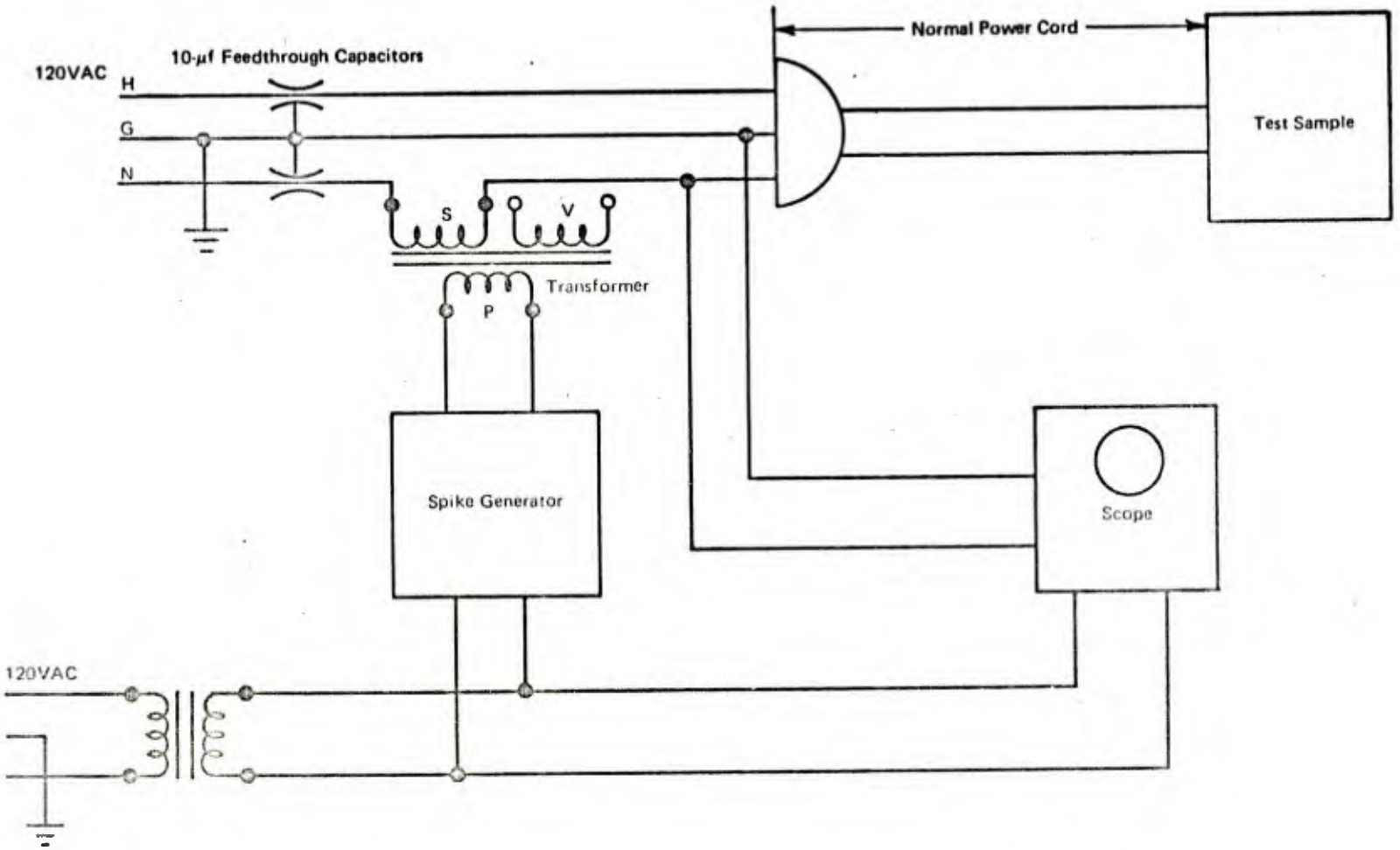
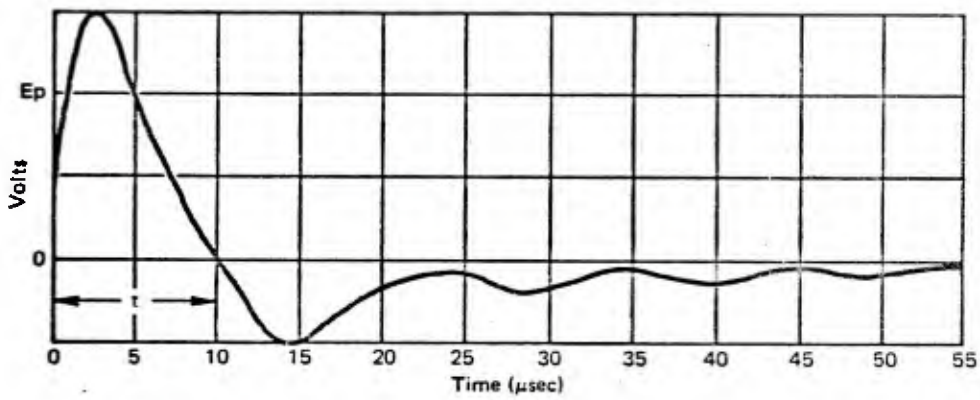


Figure 7. Test setup for conducted susceptibility, spike, on AC power leads.



Note: (a) Ep = Two times lines voltage or 100 volts, whichever is less
(b) $t \leq 10\,\mu sec$

Figure 8. Applied spike voltage for conducted susceptibility, spike, tests.