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AN EVALUATION PROGRAMME FOR ULTRASONIC DIAGNOSTIC EQUIPMENT

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The rapid growth in the application of ultrasonics in biology over the past decade has stimulated industry into manufacturing a wide range of sophisticated equipment. Some of this equipment is designed either to assist fundamental studies or to make unique clinical measurements. One example of such a unique clinical observation is in neurology where it is possible to diagnose the existence of a pathological condition as a result of measuring a displacement of the mid-line structure of the brain. This employs the pulse echo technique, with the reflected pulses being displayed as a vertical deflection on a single trace, of a CRT, calibrated in terms of tissue depth and known as an "A" scan.

The Department of Health and Social Security (Health) commissioned a programme of evaluation and comparison of a number of the "A" scan type of instrument, selecting them from foreign as well as British manufacturers. The engineering and applied physics aspects being assessed by staff of the UKAEA at AWRE, with the clinical trials being co-ordinated by a Consultant Radiologist, United Sheffield Hospitals and Physicists of the Sheffield Regional Hospital Board. Although any one "A" scan system may have a range of applications the terms of reference dictated that the evaluation should be mainly directed towards the system's ability to detect a displacement of the mid-line structure.

The complete programme evolved took the interests of the following parties into consideration:-

1.	Patient	Electrical safety, degree of discomfort and preservation of dignity
2.	Clinician	Electrical safety, ease of use, time taken for a satisfactory examination, system, accuracy, reproducibility and reliability.
3.	Manufacturer	Quality assessment.
4.	Hospital Administration	Economics.
5.	Technician	Maintenance of standards.

Electrical and mechanical engineering aspects were assessed together with measurements, made under controlled conditions, to ascertain the functional performance. The latter included the ability to identify two interfaces both longitudinally and laterally, overall system sensitivity, depth accuracy, transducer beam profiles and average acoustic output power.

It was clear from the onset that it would be extremely difficult to simulate the complex, structures and network of interfaces likely to be encountered in biological specimens. However, where practical, materials whose acoustic parameters bore a relationship to those of the skull were employed, the number of interfaces and types of material being limited to the minimum required for objective results. Similarly, as it was unreasonable to consider all permutations of reflecting object parameters, the methods adopted attempted to define the effect of single variables when applied independently. One of these variables is the angle of incidence of the ultrasonic beam to the target surface, or in practical terms, the degree of tilting of the transducer which produces a significant attenuation in echo amplitude. Measurements were generally made with the transmitted power and receiver sensitivity at a maximum in order to reduce the number of variables from system to system. When this

is done, the overall system sensitivity can, ideally, be defined by a single parameter, namely, the distance at which a specified target can be detected within a medium, such that the amplitude of its echo has fallen to the lower limit of the system dynamic range.

In order to isolate system parameters and measure them under controlled conditions it was necessary to devise suitable test facilities. Their design was preceded by a series of investigations into materials which could act as substitutes for body fluids, tissue and bone. Castor oil was finally selected for the main medium in the test tank with water being used for a number of tests external to the tank. Suitable targets were constructed from rubber, perspex, brass, steel and copper wire. The effect of introducing bone into the beam was investigated using two samples of fresh skull bone, from the temporal/parietal region, which had been encapsulated in epoxy resin.

A test tank was manufactured from sheet perspex, dimensions 60 x 15 x 16 cm. A specimen carrier, capable of traversing the length of the tank supports a frame on "gymbal" bearings which can be adjusted to maintain reflector surfaces in a plane normal to the ultrasonic beam axis. A tracking device locates a test object or detecting crystal at any point in the beam. The problem of mounting transducers of widely different geometrical shapes was overcome by casting them in cold curing rubber with the resultant uniform shape only requiring a single clamping system. Other test equipment included a device which generates a continuously variable thickness target, with parallel faces, and was employed to measure longitudinal resolution and depth accuracy.

The test findings gave a basis for comparison with other machines tested under similar conditions, although in the absence of an accepted standard specification they can, for the present, be offered only as factual results. Most evaluation programmes are open to criticism in that, the sample investigated was inadequate, too few or too many tests were carried out or in this specific case

that the detection of simple geometric shapes is no substitute for the complex structures likely to be encountered within the skull. While it is agreed that technical evaluation must not detract from the only valid criterion, that of safe and efficient clinical applicability, the choice of tests in this programme resulted in there being considerable agreement between the clinical observations and the laboratory results. This was particularly so when the instruments were given an overall rating, ie Order of Merit, by those involved in the investigation. Correlation of these results could assist later in the formulation of a basic specification.