

K93502A

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SUMMARY.

The ESI-5000 ultrasound system main applications are in general radiology, obstetrics/gynecology, cardiology, and peripheral vessel 2D imaging, spectral Doppler analysis, and color Doppler imaging.

It is a multi function real time ultrasound imaging system, featuring 2D imaging, M mode, Spectral Pulsed and CW Doppler, and Color Flow, using a variety of linear array, curved array, annular array, and mechanical sector probes, in the frequency range of 3.5 MHz. to 10 MHz.

Regarding safety and effectiveness, the main features of the ESI-5000 are compared to the main features of the following predicate ultrasound systems:

ESI-1000 manufactured by Elscint Ltd.

ESI-2000 manufactured by Elscint Ltd.

ESI-3000 manufactured by Elscint Ltd.

128 XP manufactured by Acuson.

UM-9 manufactured by ATL.

Acoustic output compliance:

Since the ESI-5000 includes "Fetal Doppler" examination capabilities, the ultrasound system-transducer combination conforms with the out put display standard, and is designed to comply with the maximum intensity levels for track 3:

The absolute maximum intensity is limited to SPTA=720 mW/cm², and SPPA=190 W/cm². In addition the intensity is limited to the operator selected, application specific limit, which is always below the allowed absolute maximum.