

K962308

Hitachi EUB-905 Ultrasound Electronic Scanner  
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ATTACHMENT 11

SUMMARY OF SAFETY AND EFFECTIVENESS  
Hitachi EUB-905 Ultrasound Electronic Scanner

Device Description

The Hitachi EUB-905 Ultrasound Electronic Scanner is Track1 diagnostic ultrasound system capable of the following operating modes: B, B/M and M mode. Probes available with the EUB-905 are intended for the following general clinical uses: Abdominal, Cardiac, Intra-operative, Fetal, Pediatric, Small organ, Peripheral Vascular, Trans-rectal and Transvaginal.

Safety

With respect to limits on acoustic outputs, the Hitachi EUB-905 Ultrasound Electronic Scanner comply with the guideline limits set in the April 14, 1994, Revision of 510(k) Diagnostic Ultrasound Guidance as a Track1 ultrasound system.

With regard to general safety, the Hitachi EUB-905 Ultrasound Electronic Scanner is designed to comply with the international standards IEC 601-1 (1988) Medical Electrical Equipment, Part1, General Requirements for Safety.