NOTE

Due to continuing product innovation, specifications in this manual are subject to change without notice. The information in this manual applies to ApexPro software version 4 or later and the CARESCAPE Telemetry T14 transmitter.

NOTE

For technical documentation purposes, the abbreviation GE is used for the legal entity name, GE Medical Systems *Information Technologies*.

CE marking information

Compliance

The ApexPro telemetry system bears CE mark CE-0459 indicating conformity with the provisions of the Council Directive 93/42/EEC concerning medical devices, and fulfills the essential requirements of Annex I of this directive. The product is radio-interference protection class A in accordance with EN 55011.

The country of manufacture can be found on the equipment labeling.

The product complies with the requirements of standard EN 60601-1-2 “Electromagnetic Compatibility-Medical Electrical Equipment.”

The safety and effectiveness of this device has been verified against previously distributed devices. Although all standards applicable to presently marketed devices may not be appropriate for prior devices (i.e. electromagnetic compatibility standards), this device will not impair the safe and effective use of those previously distributed devices.

Exceptions

The CIC Pro Clinical Information Center and ApexPro Telemetry Server are suitable for use in the specified electromagnetic environment. For more information, refer to the appropriate service manual.

R&TTE directive

The ApexPro 420-460 MHz transmitters and receiver bear the CE mark CE 0123 indicating conformity to R&TTE Directive 1999/5/EC.

The product complies with the requirements of standard EN 300 220-1 [ETSI 300 220-1 v1.2.1]: “Electromagnetic Compatibility and Radio Spectrum Matters (ERM); Short Range Devices (SRD); Part 1: Technical Characteristics and Test Methods”.

For more information, refer to the appropriate service manual.

General information

- This manual is an integral part of the product and describes its intended use. It should always be kept close to the equipment. Observance of the manual is a prerequisite for proper product performance and correct operation and ensures patient and operator safety.
- The symbol ⚠ means ATTENTION: Consult accompanying documents.
- Information which refers only to certain versions of the product is accompanied by the model number(s) of the product(s) concerned. The model number is given on the nameplate of the product.

- The warranty does not cover damages resulting from the use of accessories and consumables from other manufacturers.
- GE is responsible for the effects on safety, reliability, and performance of the product, only if:
  - assembly operations, extensions, readjustments, modifications, or repairs are carried out by persons authorized by GE;
  - the electrical installation of the relevant room complies with the requirements of the appropriate regulations; and,
  - the device is used in accordance with the instructions for use.
- All publications conform with the product specifications and applicable IEC publications on safety and essential performance of electromedical equipment as well as with applicable UL and CSA requirements and AHA recommendations valid at the time of printing.
- The quality management system complies with the international standards ISO 9001 and ISO 13485, and the Council Directive on Medical Devices 93/42/EEC Annex II.

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