

Date: 6/26/2017

Re: Model 3300 LATITUDETM Programming System: Tune Up Procedure

The Guidant Corporation (a wholly owned subsidiary of Boston Scientific Corporation doing business as Boston Scientific Cardiac Rhythm Management) Model 3300 LATITUDETM Programming System is a programmer/recorder/monitor (PRM) for BSC cardiac rhythm implantable pulse generators such as pacemakers and defibrillators. The LATITUDETM Programming System is used by trained medical professionals in hospitals and clinics during CRM device implantation and follow-up procedures.

The Model 3300 LATITUDETM Programming System is a new product for the Guidant Corporation. The Model 3300 PRM provides radio frequency (RF) telemetry in the 402 – 405 MHz MedRadio band, 902 – 928 MHz ISM band, and the 869.7 – 870.0 MHz European SRD band (not used in the US) for use with radio frequency (RF) enabled BSC implantable pulse generators. Near field inductive telemetry is available using a sub-100 kHz band. The Model 3300 also provides wireless connectivity through a pre-certified embedded Bluetooth and Wi-Fi (2.4 and 5 GHz bands) module.

The Model 3300 Programmer frequency and power for all radios (including the Part 95I radio) are verified to be within limits during device manufacturing. There is no tune up procedure for the device.