## #7 Narrative Statement describing experiment

1) ***For locations #1 through #16 as listed in the locations list:***

Both the acute studies below (GDT1000 and GDT2000) are performed after the leads have been implanted, but before the Guidant CRM device is implanted. The Acute Study box (external version of the PG implantable hardware) is connected to the implanted leads. The programmer (and inductive telemetry link of 102.4 kHz) is used to first download various patient heart parameters into, and then to transmit e-gram and marker information from the Acute Study box to the programmer. This study at all hospital locations will be completed in approximately one year.

**GDT1000 (Sensing) & GDT2000 (RV Autothreshold)**

The purpose of these feasibility studies is to characterize the performance of a re-engineered sensing algorithm and the performance of the Guidant RV Auto Threshold feature in humans. These features will be implemented in future Guidant devices. The inductive telemetry frequency of 102.4 kHz will be used for less than 10 minutes for the GDT1000 trial and less than 20 minutes for the GDT2000 trial.

2) ***For locations #17 and #18 above, as listed in the locations list:***

These studies will consist of testing the interference effects on the RF link (902-928 MHz band) of the 1st Generation PG system, hereby consisting of the implantable cardioverter defibrillator – 1st Generation PG and the Programmer (PRM). Hospital rooms including the Cardio-thoracic Operation Theatre and clinical follow-up rooms are now beginning to use wireless equipment more regularly. Any interference of this equipment on Guidant's PG-PRM RF link causing reduction in functioning, needs to be monitored and recorded.

Here, inductive telemetry frequency of 102.4 kHz will be used for a few seconds only, at the start of the interference test. This is in order to initiate the PG using the wand/PRM.

A pictorial depiction of the relationship between 1st Gen-PG and PRM is shown below. This illustrates a typical scenario in which the 1st Gen-PG is being implanted into a patient while certain physiological parameters are being monitored by the PRM.

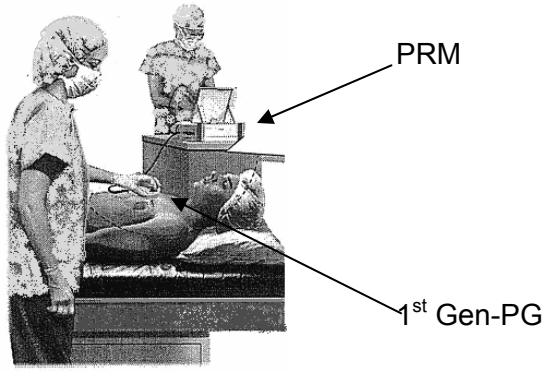


**Figure 1: Pictorial depiction between 1st Gen-PG and PRM**

The duration of this study is only 1-2 days at each hospital setting.