

#7 Narrative Statement describing experiment

For the two locations::

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

The purpose of performing PG RF and system level testing at both the Guidant St. Paul Minnesota facility and the Charles River Oseloa Wisconsin facility is to test the European RF frequency of 869 MHz. The Guidant animal studies at the St. Paul facility and the Charles River Laboratories facility will consist of design testing and GLP testing. The design testing portion focuses heavily on the RF telemetry system between Frontier I PG and the NGP 3120 PRM to determine how well it performs in the clinical environment both in tissue simulators and in actual tissue. The purpose of this testing is to ensure that the PG system meets the product requirements. The GLP testing proves the safety and efficacy of the US and European PG systems, including RF telemetry.

Charles River Laboratories site has been chosen due to the minimal amount of interference that may be caused to the PG-PRM system. At this location, interferers such as cell phone towers, repeaters, and services, are far away from the testing site. Charles River Laboratory's location reduces the amount of 869 MHz cell phone interference to an acceptable level.

It is anticipated that it will take 2 days at each location to complete the testing.