

Further Argument for 200 Equipment Units

The units needed reflect the current anticipated needs of the company to support the development and integration of RF telemetry into our implantable medical devices and supporting devices. It is not believed that the quantity could be reduced without having a deleterious effect.

Terms used to describe system:

1. PG – Pulse generator. Term used that indicates a pacemaker or implantable defibrillator.
2. NGP – Next Generation Programmer. Term used to indicate the tool a doctor uses to communicate with a PG to set functional parameters and evaluate the patient and device status.
3. Repeater – Term used to indicate a tool that performs home monitoring functions of the patient and PG status.
4. RRP – Raw Register Programmer. A tool used to interface with prototype and production PGs. It provides access to the internal operation of a PG.
5. Production Testers – Tools used to verify functionality of PGs under construction.
6. Protocol Testers – Tools used to develop and verify the operation of the RF Telemetry communication protocol.

The use of the equipment units can be broken down into three stages: Field, Production, and Development.

A. Field: At this point, radiating devices would be distributed commercially.

Qualified physicians implant the PGs. The physician would interact with the implanted PG using the NGP in both the implant room and during scheduled patient follow-ups in a clinical setting. The patient could be either given or sold a Repeater to use in their home. The Repeater would communicate with the implanted PG at scheduled intervals and to report any abnormalities. Since the RF telemetry system will be exported, this activity will occur in those foreign countries that allow radiators in the frequency band selected for operation. Therefore, these equipment units are not considered in the total needed.

B. Production: At this point radiating devices are being built for commercial distribution.

The PGs are tested during four levels of PG construction. At each level of construction, tests would be performed to ascertain various functional parameters and proper operation of the PG transceiver. Each test level would utilize stand alone Production Testers. Multiple fixtures are used at each level to maximize PG construction throughput. To get accurate results, these tests on the production floor will utilize a combination of a direct connection between the PG and the Production Tester or the PG and Production Tester will be enclosed in a shielded container. This way adjacent Production Testers can be in use at the same time without interfering with one another.

C. Development: This is the initial phase of integration of RF telemetry into our devices. None of the devices in this phase would be commercially available.

The integration can be further broken down into Feasibility Studies, Protocol Development, PG Prototypes, RRP Development, NGP Development, Repeater Development, and Production Tester Development. Feasibility Studies and Protocol Development occur separate from the other development processes. They would use customized tools that would have little reuse value, as they would be specifically designed to perform individual tasks.

1. Feasibility Studies. This testing would occur first before any subsequent development effort is undertaken. These studies include testing of RF propagation through various tissue models and characterization of transceiver performance. Validating bit error rates for a potential RF telemetry link will be important to the subsequent protocol development. Since these test are specific in nature, different prototypes would be developed for each test. An estimated 20 equipment units will be used for these tests. 10

of each transceiver type. After this testing is completed, these equipment units will no longer be in active service, but will be maintained to provide the ability to do additional testing if required.

2. Protocol Testers. These devices would be transceivers connected to PCs through a custom interface. This configuration allows the communication protocol to be tested in a realistic environment where various end cases of the protocol can be evaluated. An estimated 12 equipment units will be required for these tests. 6 of each transceiver type.

There will be two different PGs developed, a pacemaker device, and an implantable defibrillator device. Due to the differences between the two PGs, two different transceivers are targeted for each application. At various stages of the PG development cycle, the PG will need to have its RF telemetry link tested with the RRP, NGP, Repeater, and Production Testers. The RRP will have to be developed before completing any PG prototypes. The NGP, Repeater, and Production Testers will be developed along parallel time lines as the PGs, but by different project teams. Since all of these devices to be developed utilize application specific hardware and software, multiple prototypes are constructed to allow efficient verification of hardware and software functions. Typical minimum builds are 10 units. Prototypes that are found to have defective hardware are usually discarded after a failure analysis is completed.

1. PG Prototypes. The PGs under development are prototyped at three stages, in each stage a higher level of system integration is achieved. Typically, the first two prototype builds are in smaller quantities than the final prototype build. The prototypes once built usually remain in service until the product development cycle is completed. Other project teams, for example the NGP, Repeater, and Manufacturing Test teams, would usually use the earlier prototypes as test fixtures. An estimated total 64 equipment units will be required. 32 units for each PG platform.
2. RRP Development. The RRP would be developed once and used throughout the PG development cycle. The RRP is used for hardware validation and software verification. An estimated 40 equipment units will be required. 20 units for each PG platform.
3. Manufacturing Tests Development. Production Testers will be developed for 4 levels of PG construction tests. Once the design is finalized and reviewed, these testers would become the Production Testers. An estimated 24 equipment units will be required. 12 units for testing each of the PG platforms.
4. Repeater Development. The Repeater will communicate with the PG using the RF telemetry link and then upload the data via some other communication link to provide patient and device status remotely to the physician. An estimated 20 equipment units will be required. 10 units for each PG platform.
5. NGP Development. The NGP is designed to support all existing devices as well as being extensible to any future devices. Therefore, the NGP will need to support both PG platforms and as a result will have both types of transceivers included in its design. An estimated 20 equipment units will be required. 10 units of each transceiver.