March 29, 2001

Joe Dichoso
Office of Engineering and Technology Laboratory
Federal Communications Commission
7435 Oakland Mills Rd
Columbia MD 21046-1609

Re: Given Imaging
Application EA99991
Corres. Ref. # 18593

Dear Mr. Dichoso:

Following are revisions to the User's Manual submitted as an exhibit to the above-referenced application. These revisions are provided in response to the correspondence reference number above.

The changes deal with the instruction to the physician regarding the brief period of time between when the physician takes the M2A™ Capsule out of its packaging and the Capsule being ingested by the patient. These changes reflect our conversation on this subject in response to the correspondence referred to above, and this letter serves as our response to this aspect of your correspondence, as well as our confirmation that the revisions shown on the following pages will be implemented in Given's User's Manuals and other future documentation, if any, where similar language or instruction appears.

Please contact either Michele Farquhar or me with any questions or further requests for information or revisions. Thank you.

Sincerely

Ronnie London
Counsel for Given Imaging

Attachments

The M2A™ Capsule starts immediately after its removal from the proximity of the magnet in the blister and the consequent closing of the magnetic switch in the capsule.

~~After a brief (less than one minute) test by the physician to verify that the capsule is active, the capsule is ingested by the patient.~~

**In order to minimize the potential for radiofrequency interference from the device after removing it from the blister package and until it is ingested by the patient, the M2A™ capsule should be tested as quickly as possible. After verification that the M2A™ capsule is operational – it should be immediately ingested by the patient.**

While active, the capsule transmits images at a rate of 2 images per second. For each image, an illuminating light flash of 100ms is applied with the illuminating LEDs. When the battery power is depleted, the transmitter disables the imager and switches the M2A™ Capsule off.

For specification and technical parameters of the M2A™ Capsule, refer to *System Specifications* on page *15*. For Indications and Contraindications, refer to *Indications and Contraindications* on page 9.

The Data Recorder LED starts blinking green.

5. Instruct the patient to take the M2A™ Capsule out of its holder.

6. Ask the patient to put the M2A™ Capsule in his/her mouth, and to hold it under the tongue WITHOUT INGESTING.

7. If after a short adjustment period, with the M2A™ Capsule in the patient's mouth, the green light keeps on blinking, ask the patient to ingest the capsule with a sip of water.

**Note:**

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|  | ~~The time elapsed between capsule activation and ingestion should usually not exceed 1 minutes.~~**In order to minimize the potential for radiofrequency interference from the device after removing it from the blister package and until it is ingested by the patient, the M2A™ capsule should be tested as quickly as possible. After verification that the M2A™ capsule is operational – it should be immediately ingested by the patient.** |

8. In the Event Form, write down the ingestion time of the M2A™ Capsule.