



PHILIPS

Philips Medical Systems

Federal Communications Commission
Experimental License Division
Washington, DC 20554

March 29, 2002

Dear Sir or Madam,

This Experimental License Application is for the demo use only of a portable Fetal Telemetry System (medical device) for sales training and industry exhibition in June 2002 (RF transmission range <10 km, RF output 1 mW). This device is similar to its granted predicate, FCC ID: PQCM1310A, except that the transducers in the device are now wireless (vs. cabled). We anticipate submitting the full FCC Grant application for this updated model sometime in the June-August timeframe when the full product (hardware) design is finalized.

The demo use intention of this device for this license is for sales training, customer exhibition, and to gather information on user preferences in design. It will not be used for any clinical purpose.

Location 1: Chicago Hilton and Towers, Chicago (June 1-8, 2002)--Philips sales training

Location 2: Hynes Convention Center, Boston (June 21-26, 2002)--Customer/industry exhibition and convention.

Intended Use of Final Approved Device:

Continuous cordless fetal monitoring in connection with a fetal monitor for resting or ambulating patient, also usable during hydrotherapy, for antepartum testing, and labor and delivery (intrapartum). The target patient population: pregnant women from about 22 weeks of gestation on through delivery. For use under the supervision of healthcare professionals in hospitals, clinics, and physicians offices.

Project Scope:

This device is a cordless transducer system for fetal monitoring that when cleared for marketing will be used by a healthcare professional in a hospital or clinic. The device transmits fetal heart rate signals (ultrasound Doppler or ECG signal), uterine contraction signals, and maternal heart rate signal (with ECG as optional). The transmission range is up to 100m line of site. This experimental device will be used for demonstration only and will not be used on patients or for clinical purposes.

Principle of Operation:

Transducers: these are the front end components of the fetal telemetry system that gather patient signals (heart signals from ultrasound Doppler or ECG, uterine activity (Toco transducer), A/D conversion for Toco, digital status and ID information. The device uses FSK modulated digital information added to analog heart signals in the 430 MHz or 610 MHz range. It uses service/manufacturing programmable RF channels that are synthesizer controlled. The transducers are powered by a rechargeable Li-Ion battery.

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Base Station: the base station has 3 RF receiver channels that are synthesizer controlled with signal demodulation. The received signals are transmitted as analog or digital signals to the fetal monitor where they are processed, displayed and printed. The base station is mains powered and serves as a battery charger for the transducers when they are not in use.

1 Fetal Telemetry System can have up to 3 transmitters--

Model M2725A Toco transmitter
Model M2726A Ultrasound transmitter
Model M2727A ECG transmitter

There is one receiver unit: Model M2720A

Other details on the RF characteristics of this device are contained within the FCC Form 442, and upon licensure the labeling requirements of 2.803 (c) will be met.

Please feel free to contact me should you have any questions or require additional information.

Thank you.

Sincerely,

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