Philips Medical Systems



To: Federal Communications Commission, Washington, DC 20554

Attention: Ms. Diane Poole

Date: October 28, 2004

From: Barry Wyshogrod, Philips Medical Systems, Andover, MA Subject: Reply to Correspondences, References #27856, #27857

731 Application #EA936855

Dear Ms. Poole and FCC Reviewers,

On 25-Oct-04, you e-mailed me the following request:

Please add the FCC statement on the label as in 15.19 (a) of the FCC rules to the product.

Philips Medical Systems' response:

The PQCM4841A device is relatively small, about the size of an adult hand. It includes numerous regulatory markings (product identification, safety, emissions, consult product documentation, etc.). In addition, it includes controls and connector labels, and clinical graphics reminding the user how to correctly connect and use the device. These labels and graphics are very important for the clinical user. However, the regulatory markings are not important to the clinical user; rather, they are important to the bioengineering and installation professional.

Therefore, so as to optimize the use of the limited space on the device, Philips Medical Systems hereby requests that the PQCM4841A device itself be exempted from bearing the FCC Part 15.19(a)(1) statement*. Instead, we have placed the statement on the cover page of both the Instructions For Use (IFU) and the Service Guide. As such, we believe that we have targeted the message to the appropriate professional, while simplifying the markings on the device itself, thus making a small contribution to reducing potential confusion in the clinical environment.

Diane, I hope that this will be acceptable to the FCC. For any further discussion or issues, I can be reached at **(978) 659-7383** or by e-mail to: barry.wyshogrod@philips.com. If I am not available, please contact Ms. Denise Haley at **(978) 659-4358** or by e-mail to: denise.haley@philips.com.

Sincerely yours,

Barry Wyshogrod, Regulatory Engineer Signature already on-file at the FCC

^{* &}quot;This device complies with part 15 of the FCC Rules. Operation is subject to the condition that this device does not cause harmful interference."