

RADIOMETER MEDICAL A/S



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May 7, 2002
KER/KCH

Re: **Docket No. 01D-0577: Class II Special Controls Guidance Document: Cutaneous Carbon Dioxide (PcCO₂) and Oxygen (PcO₂) Monitors; Draft Guidance for Industry and FDA**

Gentlemen:

We hereby submit our comments to the above Draft Guidance.

We welcome the FDA's issuance of this draft guidance document, which will help to remove the regulatory uncertainty that has been prevalent in this field for years. We are concerned, however, that the draft guidance does not reflect current standards applicable to devices subject to this guidance. Specifically, the draft guidance refers to a number of standards that have been discontinued, replaced, or amended and, in some cases, fails to refer to the current standards in the field. In order that the Guidance will reflect the state of the art, we have proposed several revisions, as described below.

1. *Reference to Standards and Guidance Documents*

The Draft Guidance refers to the following standards/guidance documents that either have been discontinued, replaced, or amended:

Standard Id.	Year	Title	Status
ASTM F 984-86	1986 (reapproved 1992)	Standard Specifications for Cutaneous Gas Monitoring Devices for Oxygen and Carbon Dioxide	Discontinued 8/10/99 without replacement
IEC 60601-1-2	1993	Medical Electrical Equipment, Part 1: General Requirements for Safety, 2. Collateral Standard: Electromagnetic Compatibility - Requirements and Tests	Obsolete, Second Edition issued 2001; 2001 Edition is an FDA Recognized Consensus Standard

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Standard Id.	Year	Title	Status
IEC 60601-3-1	1996	Medical electrical equipment - Part 3-1: Essential performance requirements for transcutaneous oxygen and carbon dioxide partial pressure monitoring equipment	FDA Recognized Consensus Standard Now included in IEC 60601-2-23 (1999)
IEC 60601-2-23	1993	Medical electrical equipment - Part 2: Particular requirements for the safety of transcutaneous partial pressure monitoring equipment	Obsolete. Second Edition issued Dec 1999
IEC 61000-4-2	1999	Electromagnetic Compatibility (EMC)-Part 4-2: Testing and measurement techniques- Electrostatic discharge immunity testing	Amended 2000
IEC 61000-4-3	1995	Electromagnetic Compatibility (EMC)-Part 4-3: Testing and measurement techniques- Radiated, radio frequency, electromagnetic field immunity test	Amended 2000
IEC 61000-4-11	1994	Electromagnetic Compatibility (EMC)-Part 4-11: Testing and measurement techniques- Voltage dips, short interruptions and voltage variations immunity tests	Amended 2000
IEC 61000-4-4	1995	Electromagnetic Compatibility (EMC)-Part 4-4: Testing and measurement techniques- Electrical fast transient/burst immunity test	Amended 2000
IEC 61000-4-8	1993	Electromagnetic Compatibility (EMC)-Part 4: Testing and measurement techniques-Section 8: Power frequency magnetic field immunity test	Amended 2000

2. *State of the Art Standards and Guidances*

IEC 60601-2-23: "Medical Electrical Equipment - Part 2-23: Particular requirements for the safety, including essential performance, of transcutaneous partial pressure monitoring equipment" has been issued as a second edition in Dec. 1999. As noted above, this second edition cancels and replaces the first edition published in 1993 and also covers the scope of IEC 60601-3-1 published in 1996.

The 1999 edition of IEC 60601-2-23, together with the set of IEC publications listed below, defines controls for all the risks identified in Section 4 of the Draft Guidance, except Toxicity and Tissue Reactivity:

- IEC 60601-1:1988, Medical Electrical Equipment - Part 1: General requirements for safety, amendment 1, amendment 2;
- IEC 60601-1-2:1993, Medical Electrical Equipment - Part 1: General requirements for safety - 2. Collateral Standard: Electromagnetic compatibility - Requirements and tests; and
- IEC 60601-1-4:1996, Medical Electrical Equipment - Part 1: General requirements for safety - 4. Collateral Standard: Programmable electrical medical systems.

In addition, the 1999 edition of IEC 60601-2-23 is an FDA Recognized Consensus Standard.

For that reason, Radiometer recommends that compliance with the 1999 edition of IEC 60601-2-23 should be the recommended mitigation measure for the risks of electrical shock, electromagnetic interference, burns and inaccurate measurement.

For the risks related to Toxicity and Tissue Reactivity, demonstration of compliance with the relevant parts of ISO 10993, "Biological Evaluation of Medical Devices" would appear to be adequate mitigation. The ISO 10993 Series is also an FDA Recognized Consensus Standard. Indirectly, the FDA supports compliance with ISO 10993 by referring to General Program memorandum G95-1, but Radiometer would recommend a more direct reference to ISO 10993.

3. *Other Comments*

- a. Sections 1 and 5 of the Draft Guidance refer to the traditional 510(k) and the abbreviated 510(k) procedure. We believe that there should be a reference to the special 510(k) procedure as well.
- b. MIL standards are developed for use by defense and aerospace related organizations. The compliance with the MIL standards referred to in the Draft Guidance and listed below should not be mandatory for normal situations and environments but only for such special uses requiring extreme reliability of the devices.

Standard Id.	Year	Title
MIL-STD 461D	1993	Requirements for the Control of Electromagnetic Interference, Emissions and Susceptibility
MIL-STD 462D	1993	Measurement of Electromagnetic Interference Characteristics

- c. Provided that the 1999 edition of IEC 60601-2-23 be relied upon as the primary risk mitigation measure we do not see any reason for maintaining a reference to the 1990 IFCC guidance document, Guidelines for Transcutaneous PO₂ and PCO₂ Measurement (1990). We understand the IFCC guidance document is cited only as support for the statements of Section 12.1 of the Draft Guidance and that no further compliance with the IFCC Guidance is requested. The 1999 edition of IEC 60601-2-23 has detailed provisions in Section Seven - Protection against Excessive Temperatures and other Safety Hazards - to ensure against skin burns, making reference to the 1990 IFCC guidance document superfluous. If the reference to the 1990 IFCC guidance document be maintained it should be clarified that the reference serves only to support the statements of Section 12.1 of the Draft Guidance.
- d. For devices intended to be used in hyperbaric facilities Radiometer recommends that the FDA considers including a reference to NFPA 99-1999, Standard for Health Care Facilities CHAPTER 19 - Hyperbaric Facilities, or to the previous 1996 issue which is an FDA recognized consensus standard.

On the basis of the above comments, Radiometer recommends that the Draft Guidance be redrafted so as to clarify what are the appropriate standards. The Company believes that such clarification will be very useful for the industry and ensure more relevant, consistent controls to mitigate any risks associated with cutaneous carbon dioxide and oxygen monitors.

Radiometer appreciates the opportunity to provide these comments on the Draft Guidance. Because the Draft Guidance relies heavily on complicated international standards, Radiometer stands prepared to discuss in further detail any and all of these standards as part of the final guidance drafting process. We encourage the FDA to contact us in this regard and we also will be following up with the Agency on these issues. In the meantime, please feel free to contact us at +45 3827 3390 in the event that you should wish a clarification of any of our comments.

Best regards,
RADIOMETER MEDICAL A/S



Kirsten Rønø
Director of Quality

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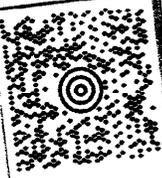
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