

BIOTRONIK Comments on Draft FDA Guidance – Radio Frequency Wireless Technology in Medical Devices

			Date April 2, 2007	Document RF Wireless in Medical Devices
Clause/ Subclause	Paragraph Figure/ Table/Line No.	Type of comment (General/ Technical/ Editorial)	COMMENTS	Proposed Language on each comment submitted
2. Scope	Page 5, first paragraph		The list should include further classes of devices. Also additional parts of CFR 47 should be mentioned (e.g. Part 95 I - MICS)	Remove paragraph or add more technologies.
4. Concerns	Page 7, first full paragraph		The limits as defined by FCC should be accepted by FDA. Most manufacturers will use the maximum FCC allowed power to improve performance.	Remove paragraph, possible replacement “FCC requirements regarding RF output and potential interference shall be followed to ensure compatibility.”
4. Concerns	Page 7, last full paragraph		The nature of wireless RF communications requires that you mitigate possible times of interference. It is impossible to ensure that they always “operate safely...” We need to provide the best possible assurance that products meet the FCC guidelines which should ensure safety, but not effectiveness.	Remove “...and effectiveness” Replace: “...will operate...” With: “...will operate or not be negatively affected...”
4. Concerns	Page 8, Bullet list		There are several CFR 47 parts / technologies missing: e.g., Part 95 I devices such as MICS	Add more examples.
4. Concerns	Page 8, last full paragraph		This document does not provide any suggestions that would solve the quality of service concern.	Add acceptable solution examples to Section 6, Design and Development.
4. Concerns	Page 8, last bullet		“Critical medical alarms”, no definition for critical	Add definition for “critical”.
4. Concerns	Page 9, third bullet		“Time critical medical telemetry”, no definition for time-critical	Add definition for “time-critical”.
6. Design & Development	Page 12, first bullet list		Many of these specifications are already defined by the FCC. FDA should work closely with FCC to ensure the needs and requirements of both agencies are met. FDA should define the extent of wireless coexistence testing that is required. It is impossible to test all current and future sources of interference.	N/A

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6. Design & Development	Page 13, second full paragraph		This will lead to additional documentation required for FDA submissions and may increase the number of simple manufacturing changes that require submissions. The amount of EMC-related device shielding and filtering is irrelevant if the devices pass the EMC performance testing as required by the third full paragraph of page 13.	“FDA recommends that you control any shielding and filtering designed to protect against EMI as part of your normal Quality System and ensure that any modified devices also pass the required testing.”
6. Design & Development	Page 15, first bullet list, 3 rd bullet		In addition to severity, probability of occurrence should also be considered.	Change third bullet from: “severity of harm” To: “Severity of harm and probability of occurrence”
6. Design & Development	Page 15, last full paragraph		Whether or not certain functions should be made wireless is determined at the time of product definition. Such statements are irrespective of reality.	Remove: “Because RF wireless systems are inherently less reliable than hardwired ones, we recommend you identify which device functions should be made wireless and which should not.”
7. Design & Development Verification	Page 17, last full paragraph		Including the RF wireless and EMC testing in the device labelling intended for the physician is unnecessary and most likely not understood by the user. Testing should be summarized in the premarket submission with adjustments in the labelling for any user instructions or precautions that should be followed as a result of conclusions drawn from the testing.	Remove: “...and labeling”
8. Design & Development Validation	Page 19, second paragraph		It is not clear how we are to determine what type of in-band sources may be present now and in the future. Again, FCC limits should ensure that in-band interference is held to a minimum.	Remove: “We recommend this testing be conducted in the presence of the number and type of in-band sources at the expected proximity specified for the device.”

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9. Labeling	Page 19, first paragraph and bullet list		Including the complete equipment and system specifications for RF wireless technology is unnecessary and provides no value to the majority of physician users. Limited information regarding frequencies used and power levels is sufficient for all users. EMC and telecommunications standards are also of very limited value, the physician is not interested or trained to understand this information. Again, test results in the device labeling intended for the physician is unnecessary and most likely not understood by the user. Testing should be summarized in the premarket submission with adjustments in the labelling for any user instructions or precautions that should be followed as a result of conclusions drawn from the testing. Standards change continuously, therefore labeling will become outdated without notice.	Remove: first three bullets Incorporate: fourth bullet into paragraph after "...include"
9. Labeling	Page 19, second paragraph		See above, the second sentence contradicts the need for discussion of design, standards and test results in the labeling. The warnings and precautions should be included.	Delete: "...supplement design, testing and risk control measures to address RF wireless issues and..." Replace with: "...must include any precautions that your users should take regarding RF wireless issues."
9. Labeling	Page 19, last paragraph and bullets		This requirement for labeling to include conformance to standards, how testing was competed and susceptibilities discovered has proven of little benefit for our users in the CE region. The associated and resulting precautions would be most beneficial.	Remove: all three bullets
9. Labeling	Page 20, first two paragraphs with bullets		This requirement for labeling to include details on the transmission characteristics has proven of little benefit for our users in the CE region. The associated and resulting precautions would be most beneficial.	Remove: two paragraphs with bullets

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9. Labeling	Page 20, last paragraph		This requirement for labeling to include details on the transmission characteristics has proven of little benefit for our users in the CE region. This section of IEC 60601-1-2: should not be required by FDA. Recognition of a standard by FDA does not make it a requirement.	Remove first sentence of last paragraph: “FDA recommends you document evidence of compliance with the standard’s labeling provisions. (See IEC60601-1-2:2001)”
Appendix B: Reference Standards	Page 27, first section		List should be updated, ETSI EN 300683 has been withdrawn, moreover several standards are missing	Remove: ETSI EN 300683 Add: Other appropriate Standards and “The following are provided as examples.”