



Charles S. Farlow
Senior Program Manager, Systems Engineering
Medtronic Cardiac Rhythm Disease Management
8200 Coral Sea Street NE, MVC83
Mounds View, MN 55112

January 20, 2012

Mr. Paul Nikolich
Chair, IEEE 802 LAN / MAN Standards Committee
18 Bishops Lane
Lynnfield, MA 01940
p.nikolich@ieee.org

Subject: Appeal Brief, IEEE 801.15.6 Decisions

Dear Paul,

This letter constitutes an Appeal Brief for two recent decisions related to draft standard IEEE 802.15.6 (Body Area Networks): a) 22 Dec. 11 EC decision to submit the draft to RevCom, and b) 21 Dec. 11 decision of the IEEE 802.15.6 Ballot Resolution Committee (BRC) for comments r03-03, r03-04, r03-05, and r03-06.

1. The "Resolution Detail" of "Group can not reach concensus." for four rejected comments (r02-06, r02-07, r02-08, r02-09) as documented in 15-11-0868-01-0006 is not valid.

Ignoring, for the moment, the spelling error, the text entered in the "Resolution Detail" field for comments r02-06, r02-07, r02-08, r02-09 is a status of Ballot Resolution Committee's deliberation, not a "resolution" in any sense of the word. The "Resolution Detail" does not provide any feedback to the commenter. There is no allowance for this type of response in any IEEE-SA policy or procedure.

2. Selected IEEE 802.15.6 Ballot Resolution Committee (BRC) voting results exceeded a 30% abstention rate; therefore, these BRC votes are not valid.

IEEE 802.15.6 BRC voting results exceeded a 30% abstention rate for r02-06, r02-07, r02-08, and r02-09 comments as documented in 15-11-0872-01-0006. Paragraph 5.4.3.5 of the IEEE-SA Standards Board Operations Manual states "In the event that 30% or more of the returned ballots are *Abstentions*, the standards balloting process shall be considered invalid." Notwithstanding the IEEE-SASB Operations Manual's requirement, in one case, the number of "Abstentions" equaled the sum of "Yes" and "No" votes (e.g., r02-06, Yes: 4, No: 2, Abstain: 6.). Clearly, this vote is not valid by any modern standards development metric.

3. IEEE 802.15.6 TG6 PAR paragraph 7.3 was not updated as required by the IEEE-SA Standards Board Operations Manual.

The IEEE 802.15.6 TG6 PAR, paragraph 7.3, was not updated to reflect the safety concerns expressed by the Advanced Medical Technology Association, European Telecommunications Standards Institute (ETSI), and ISO/TC 150/SC 6 - IEC/SC 62D JWG 1. As stated in paragraph 5.2 of the IEEE-SA Standards Board Operations Manual, "It is important for standards-writing committees to examine the approved PAR periodically in order to make certain that its information is current as shown on the form. This will minimize delays in obtaining approval of final submittals."

4. Four rejected comments (r03-03, r03-04, r03-05, r03-06) and their predecessors were not addressed with sufficient technical rigor, as evidenced by the lack of documentation indicating serious consideration of said comments.

This comment is self-explanatory; many comments submitted during the Sponsor Ballot phase received little consideration by proponents of Clause 11 technology. Particularly, for r03-03, r03-04, r03-05, r03-06 (and predecessor comments), proponents of the technology specified in Clause 11 refused to provide any technical justification in their response(s). As stated in paragraph 5.4.3.3 of the IEEE-SA Standards Board Operations Manual, "Sponsors shall provide evidence of the consideration of each comment via approved IEEE Standards Association balloting tools."

5. The conditional approval of draft standard IEEE 802.15.6 is not consistent with the IEEE Code of Ethics.

In the IEEE Code of Ethics (first paragraph) members agree "to accept responsibility in making decisions consistent with the safety, health, and welfare of the public, and to disclose promptly factors that might endanger the public or the environment." Faced with three letters indicating a risk to patients with Active Implantable Medical Devices (AIMDs), the IEEE 802 Executive Committee (EC) still provided conditional approval of the draft IEEE 802.15.6 standard. The conditional approval of draft standard IEEE 802.15.6 is not consistent with the IEEE Code of Ethics nor does the IEEE 802 EC possess the medical expertise required to render a valid decision.

If there are any questions related to this appeal, please contact me at charles.s.farlow@medtronic.com (+1 763 742 5158).

Respectfully,

// submitted electronically //

Charles S. Farlow

cc:

Richard Hulett, Chair, Standards Board, IEEE Standards Association

Bob Heile, Chair IEEE 802.15

Art Astrin, Chair IEEE 802.15.6