

Summary of EMC Review Findings

The electromagnetic compatibility (EMC) testing and results information is contained in Volume 11, pages 174 to 231 of the PMA submission from Independence Technology. The information contained in these pages of the submission represents a summary of the EMC testing and results on several IBOT devices in several different operating modes. The device has at least five different modes: standard, 4-wheel, balance, remote, and stair climbing. The IBOT device incorporates several unique functions that make it different from other powered wheelchair devices, and consequently raises different concerns about hazards that might be the result of electromagnetic interference (EMI). The balance mode is unique to the IBOT device and the stair-climbing mode is different from other devices. Since the IBOT user may be at significant risk from the effects of EMI in these modes, and since existing wheelchair standards do not address devices that operate in all of these modes, a thorough evaluation of EMI performance is particularly important with this device.

EMC testing was performed by Radiometrics Midwest Corporation, primarily according to requirements in the existing EMC standards applicable to powered wheelchairs. In addition, several additional immunity tests were performed at test levels higher than those called out in the standards. The test results indicate that the IBOT device performed without degradation due to electromagnetic interference (EMI) for all of the tests, including emissions with the battery charger in-place. No modifications were added to the IBOT devices in order to pass the EMC tests. However, one test sample device failed the emissions testing. The sponsor performed an analysis of this failure, but the results of the failure analysis were reported as "inconclusive". The reports do not fully explain the IBOT modes that were tested, or how these tests address EMI concerns for these modes. For each functional mode of the IBOT device (i.e., standard, 4-wheel, balance, remote, and stair climbing), the sponsor should provide a brief summary of the functional mode and how they have addressed the EMI concerns for that functional mode. This information should include the following:

- A clear summary of all EMC testing (emissions and immunity) of the IBOT device with the test results and data to support their claims for immunity to EMI.
- A brief explanation of how each EMC test was performed and how the testing for each mode addresses the risks for EMI and demonstrates EMC to the claimed levels.
- Reference to appropriate EMC testing standards (such as the CDRH recognized ANSI/RESNA WC/Vol. 2-1998 standard Section 21).
- The pass/fail criteria for each of the EMC tests, how these were quantified and measured, and justifications for these criteria.
- In addition, if any there were any deviations from the referenced standards or modifications to the device under test these must be explained and justified.