‘Standards’ for Home Healthcare

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The following standard must be met for all medical products intended to be used in the home: IEC 60601-1-11, which is “Medical Electrical Equipment—Part 1-11: General Requirements for Basic Safety and Essential Performance—Collateral Standard: Requirements for Medical Electrical Equipment and Medical Electrical Systems Used in the Home Healthcare Environment.” Based on the requirements of the standard, following are key obstacles that make home healthcare products challenging to design.

- All home healthcare products need to be classified as Class II equipment if they are connected by a cord, which means the use of a protective earth conductor is not allowed as a means of protection. This is due to the fact that some homes still don’t have a reliable protective earth connection and without any protection provided by it, it would be disabled in the home healthcare environment.
- The means to prevent accidental or unauthorized changes to controls will be provided. This needs to be more stringent in the home healthcare environment then in a hospital since children could be around the device and possibly change a setting that would affect its basic safety and essential performance.
- The risk of strangulation or suffocation is increased in the home healthcare environment since children and/or pets may be near a device. One way to help reduce this hazard is to provide a retention device.

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