

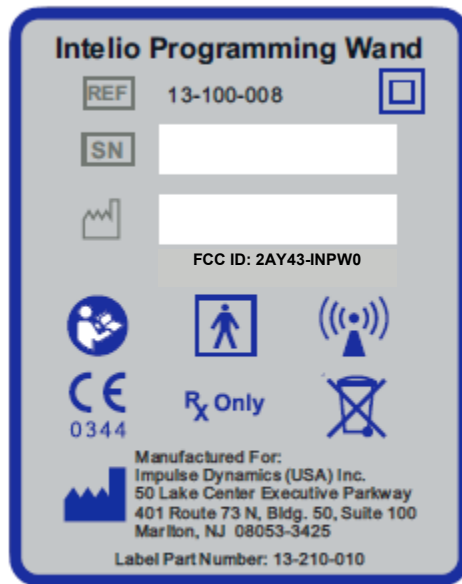


Figure 1: Picture of the Commercial Intelio Programming Wand back label.

Figure 2: Label location placed on the Intelio Programming Wand enclosure

Label Durability:

All labeling for the Intelio Programming Wand have been tested and verified in according with clause 7.1.3 of standard 60601-1 for Medical Devices for durability of markings and protection from humidity during storage or handling in accordance with EN 45502-1 section 10.2. To test for durability the label was exposed to the following test procedure:

1. Rub the label by hand, without undue pressure for 15 seconds, with a cloth rag soaked with distilled water
2. Rub the label by hand, without undue pressure for 15 seconds, with a cloth rag soaked with 96% ethanol
3. Rub the label by hand, without undue pressure for 15 seconds, with a cloth rag soaked with isopropyl alcohol
4. Inspect the label and **verify** that the label has not worked loose or become curled at the edges.
5. Inspect the label and **check** if it is still clearly legible.

Compliance with these standards deems the Intelio Programming Wand labeling will survive for the intended lifetime of the device.