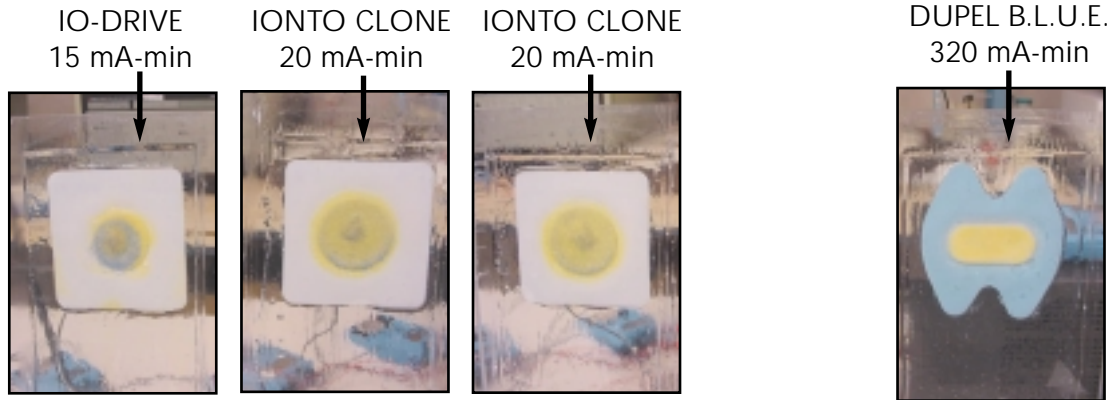


# TECH NOTE



Your Partner in Rehabilitation Outcomes

## Dupel B.L.U.E. Quality Testing



Safety is an important factor when determining the quality of any Iontophoresis electrode. Below is a list of quality testing that is performed on Dupel Iontophoresis electrodes. A brief description of each test is provided.

Testing Performed	Numbers Tested per Lot per Test	Time for Completion per Lot
1. pH Mapping	Maximum of 20 electrodes	4-6 hours
2. Bulk Electrical Resistance	Maximum of 10 electrodes	1-2 hours
3. Carbon Layer Resistance	Maximum of 10 electrodes	1 hour
4. Resin Extraction (active only)	Maximum of 5 electrodes	4 hours

### TEST DESCRIPTIONS

**pH Mapping:** 10 electrodes are tested in the positive polarity and 10 in the negative polarity. The pH Mapping test will detect localized pH failures on the electrode surface. Each Dupel electrode is monitored for pH failures throughout 160mA-min product specification and beyond (480mA-min maximum). 480mA-min represents a 6x safety factor. NOTE: FDA cleared to 80 mA-min treatment. pH Mapping is used to eliminate the possibility of unsafe pH changes (chemical burns). A yellow chemical solution is applied to the electrode. Base pH failure is represented when the chemical solution turns blue which starts to occur at a pH of 8. As noted in the photo above, the Dupel electrode shows no sign of pH failure.

**Bulk Electrical Resistance:** 10 electrodes are tested and the overall electrical resistance of the electrode measured. This test tells if the electrode is functioning electrically or not.

**Carbon Layer Resistance:** 10 electrodes are tested. The carbon layer is tested for resistance and in essence is a measure of conductivity.

**Resin Extraction:** 5 electrodes are tested. Each electrode is broken down and buffering resin is extracted from all layers containing buffering resin. The collected buffer is weighed to ensure the manufacturing resin coat weight specification is within range. This also is a factor in eliminating the possibility of pH problems.