

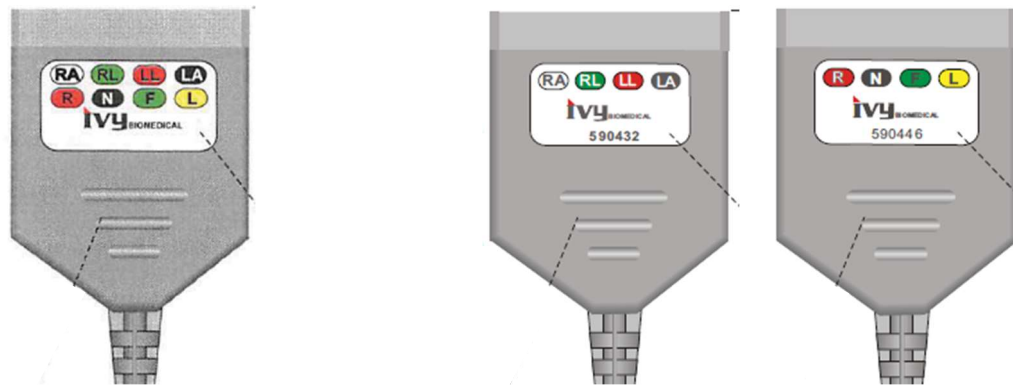
PRODUCT CHANGE NOTIFICATION

4-Lead ECG Accessories

In a continual effort to provide our channel partners with high quality innovative products and compliance with industry regulations, Ivy Biomedical Systems is pleased to inform you of several product enhancements we will introduce in the coming months. Additional information is available upon request.

1) ECG Trunk Cables

- Products affected: **590432, 590446**
- Anticipated commercial implementation: **on or about Dec 1, 2020**
- **Details**
 - Introduction of new “universal” dual AHA/IEC color-coded trunk cable configurations will simplify inventory and ordering, and will replace both current individually color-coded trunk cables:



“Universal” → replaces both → AHA & IEC

- Both current 10ft trunk cables, 590432 (AHA) & 590446 (IEC), replaced by new “universal” 590478
- Introduction of two new “universal” trunk cable lengths: 5ft (590477), and 40”/1m (590479)
- Alternate cable construction based on UL Style Sheet vs. UL registered wire; UL approved
- There is no change in performance or biocompatibility

2) ECG Lead Sets (Carbon/Radiotranslucent)

- Products affected: **590435, 590442, 590451, 590452**
- Anticipated commercial implementation: **on or about Oct 1, 2020**
- **Details**
 - The contract manufacturer for our carbon lead sets has been acquired, and the production facility is moving to a new location
 - There is no change in materials, construction, or performance; Minor changes to labeling are required

3) EU-MDR Compliance

- Products affected: **All**
- Anticipated commercial implementation: **on or about Jan 1, 2021**
- **Details**
 - In our continued efforts for worldwide regulatory compliance, we are making minor changes to product labeling and our IFU as required by the EU-MDR directive.