

# PRODUCT CHANGE NOTIFICATION

## 3-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.

There are several streamlining changes coming to our 3-lead ECG leads & trunk cables product line as outlined below. Overall, we are standardizing the lead & cable mating connectors to the more common “HP-AAMI” style. Our current metallic lead sets & trunk cables for nuclear medicine already utilize this style connector, but the carbon/radiotranslucent lead sets & trunk cables used for CT do not, so these will be changing. ***This means that both the leads and the trunk cables need to be upgraded together initially when ordering replacement ECG leads for the first time.*** The trunk cables will also move to a “universal” dual AHA/IEC configuration, eliminating the need for separate trunk cables for AHA vs IEC, as well as for nuclear medicine vs. CT. Lastly, we will be discontinuing certain seldom used configurations of the trunk cables or leads.

### 1) ECG Lead Sets – Metallic (3-Lead)

- Products affected: **590411 (IEC), 590413 (AHA)**
- Anticipated commercial implementation: **Q2 2021**
- Details
  - Elimination (End-of Life) of the 40”/1m length leads; transition to 36” length instead (590489, 590490)

### 2) ECG Lead Sets – Carbon/Radiotranslucent (3-Lead)

- Products affected: **590256, 590318, 590319, 590341, 590376, 590377, 590398, 590399**
- Anticipated commercial implementation: **Q2 2021**
- Details
  - The contract manufacturer of our carbon leads has been acquired, and the production facility is moving to a new location. There is no change in materials or performance; Minor changes to labeling are required.
  - In addition, the mating end of the lead set will change from the current “D” style to the standard HP-AAMI style connector, and will mate with the new universal ECG trunk cables referenced in section (3) below.

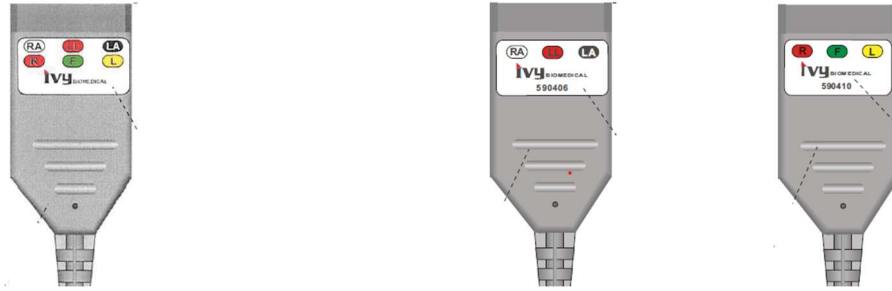
Old P/N	New P/N	Description	Termination
590318	590483	24” RT (carbon) lead wires (AHA)	HP-AAMI style termination replaces older “D” style termination
590376	590484	24” RT (carbon) lead wires (IEC)	
590341	590485	30” RT (carbon) lead wires (AHA)	
590377	590486	30” RT (carbon) lead wires (IEC)	
590319	590487	36” RT (carbon) lead wires (AHA)	
590256	590488	36” RT (carbon) lead wires (IEC)	
590398	Discontinued	40” RT (carbon) lead wires (AHA)	
590399	Discontinued	40” RT (carbon) lead wires (IEC)	



**HP-AAMI Style Connector** → replaces → **older “D” Style connector**

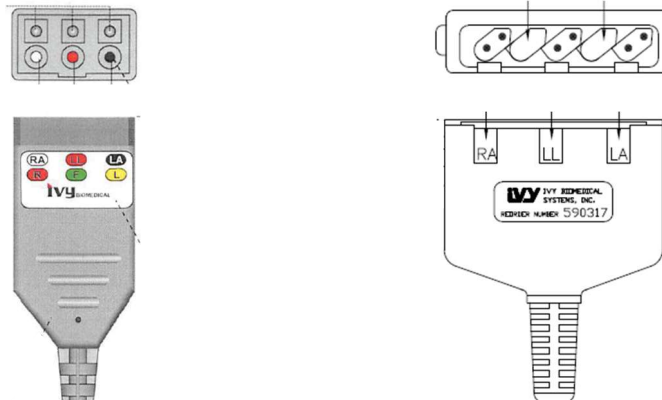
### 3) ECG Trunk Cables (3-Lead)

- Products affected: **590317, 590323, 590366, 590375, 590381, 590397, 590406, 590408, 590410, 590412**
- Anticipated commercial implementation: **Q2 2021**
- Details
  - Introduction of new “universal” dual AHA/IEC color coded trunk cable configurations available in 10ft (590476), 5ft (590491), and 40”/1m (590481) lengths (labeling change only)



**“Universal” Label** → **replaces both** → **AHA** & **IEC**

- Standardization on HP-AAMI style ECG Lead connectors/termination for all carbon lead sets (used primarily in CT). The yolk is also significantly smaller in overall size, making it more manageable. This will involve a change in materials and construction in the new trunk cable relative to the old “D” style cable.



**HP-AAMI style connector** → **replaces** → **“D” Style connector**

Old P/N	Description	New P/N	Description
590317	ECG Trunk Cable, LN, 3 Lead, AHA, 10ft	590476	ECG Trunk Cable, 3-Lead, Universal (AHA/IEC), HP-AAMI style lead termination, 10ft
590375	ECG Trunk Cable, LN, 3 Lead, IEC, 10ft		
590323	ECG Trunk Cable, LN, 3 Lead, AHA, 10ft, 1K		
590381	ECG Trunk Cable, LN, 3 Lead, IEC, 10ft, 1K		
590406	ECG Trunk Cable, Shld, 3 Lead, AHA, 10ft		
590408	ECG Trunk Cable, Shld, 3 Lead, IEC, 10ft		
590366	ECG Trunk Cable, LN, 3 Lead, AHA, 40”/1m	590481	ECG Trunk Cable, 3-Lead, Universal (AHA/IEC), HP-AAMI style lead termination, 40”/1m
590397	ECG Trunk Cable, LN, 3 Lead, IEC, 40”/1m		
590412	ECG Trunk Cable, Shld, 3 Lead, AHA, 40”/1m		
590410	ECG Trunk Cable, Shld, 3 Lead, IEC, 40”/1m		
N/A	N/A	590491	ECG Trunk Cable, 3-Lead, Universal (AHA/IEC), HP-AAMI style lead termination, 5ft