A comparative wear test of two adhesives on the Unilect™ Biotab short term monitoring electrode

Year: 2012

Location: ConvaTec Ltd Global Development Centre, First Avenue, Deeside Industrial Park, Deeside, Flintshire CH5 2NU, UK.

Aim: The aim of this wear test was to evaluate the safety in relation to the skin and performance of the Unilect™ Biotab gel electrode following a design change related to the adhesive component to the electrode compared to the currently marketed solid gel electrode (0415M).

Number of volunteers: 20

Summary: A single center, randomized, comparative, wear test was conducted. Investigator performed a basic 12 lead ECG on volunteers at the start of the investigation. If the ECG trace was normal, they were allocated a subject number and randomized to receive either the test or marketed electrodes. Electrodes were applied and a baseline ECG trace was taken. The electrodes remained in place for 30 minutes and another ECG trace was taken after the 30 minutes then ease of removal was assessed. 24 hours later, investigator assessed the subjects' skin around each electrode.

Skin conditions, adhesion and signal quality was assessed. All electrodes (100%) in both groups remained in place for the intended 30 minutes and provided adequate ECG signal after 30 minutes of wear. All electrodes (100%) in the marketed product group provided excellent security during the 30 minutes of wear. 108 out of 110 electrodes (98%) in the test product group provided excellent security while the remaining 2% provided fair security. All electrodes (100%) allowed for either excellent or good ease of removal with 71% of the marketed product providing an excellent ease of removal and 65% for the test group. No skin reactions were recorded after 24 hours of follow up.

In conclusion, the adhesion of the electrodes and acceptability of ECG trace was comparable between the two groups (marketed and test products) on application and after 30 minutes (the intended period of use) of wearing the electrodes.