

Ambu WhiteSensor ECG Electrodes Performance

Year: 2006

Location: Unomedical A/S Kongevejen 2 3460 Birkerød, Denmark.

Products: 4560M, 0415M, 0615M, 4570M, 4535M, 4540M, 4500 series, 4440M

Number of volunteers: 23 volunteers

Summary:

Performance of the Ambu WhiteSensor ECG electrodes were evaluated through a clinical trial in which adhesion and signal quality of the electrodes was measured. This study was conducted in accordance to the Association for the Advancement of Medical Instrumentation (U.S.A.)'s standard ANSI/AAMI EC 12:2000 sec 5.4 and approved by The Ethics committee and The Data Protection Agency.

Methods: Volunteers were separated into 2 groups: Short-term and long-term applications. Volunteers in the short-term group were enrolled in the test for 3 whole days while long-term group were enrolled for 6 whole days. The participant's skin was prepared accordingly as in normal ECG practice to obtain results similar to actual clinical usage. In the short term group, ECG was performed immediately after electrode application, and 1 hour, 24 hours and 48 hours after. In the long-term group, the ECG was also measured after 72 hours, 96 hours and 120 hours. Although the recommended application times were 24 hours for short-term electrodes and 48 hours for long-term electrodes, prolonged application time were tested to assess the potential of the electrode to adhere and provide clear ECG signals past their recommended application times.

Eighty-three percent of 0415M, 0615M electrodes stayed attached and provided an acceptable signal within 24 hours. Eighty-two percent of 4440M stayed attached within 72 hours. This is partly due to the small number of participants (n=12 for short-term, n=11 for long-term) where two electrodes affected would lead to failure. More than 90 % of all other electrodes stayed attached and provided good signal quality throughout the whole testing period: 48 hours for electrodes 4560M, 4570M, 4535M, 4540M and 4500 series. Thus the attachment and signal quality provided was demonstrated for periods longer than their respective applications times.

Conclusion: This clinical investigation showed that Ambu WhiteSensor ECG electrodes are able to meet the high standards of quality and performance within and for longer periods than their respective recommended application times. All the electrodes meet the demands of The Association for the Advancement of Medical Instrumentation (U.S.A.)'s standard ANSI/AAMI EC 12:2000 sec 5.4.