
Performance of Ambu Blue Sensor NEO X

A New Electrode for ECG-Monitoring of Preterm Neonatal Patients

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ABSTRACT

Objective: To assess the use and performance of the new Ambu Blue Sensor NEO X electrode for ECG-monitoring of premature neonatal patients.

Method: Neonatal Intensive Care Units (NICUs) in Spain, Germany and Denmark participated in an evaluation of the Blue Sensor NEO X ECG electrode. The NICUs evaluated the use and performance of the NEO X electrode as part of the normal ECG monitoring routine. After approximately 2-3 weeks of use, the participating nurses were asked to fill-in an evaluation form each regarding the use and performance of NEO X. The electrode, normally used in the department, was used as the reference electrode for comparison.

Results: More than 70 neonatal patients, aged between 24 and 39 weeks of gestational age, were ECG monitored using the Blue Sensor NEO X electrodes. A total of 37 participating NICU nurses each filled-in and returned the NEO-X evaluation form. Compared to the reference electrodes, the NICU nurses evaluated the NEO X electrode positively. In particular, the ability to stay attached to the skin of the neonate for an extended period of time and the adhesive properties in high humidity incubators were regarded as superior. Additionally, the flexible NEO X wire was appreciated for its softness compared to the wires of the reference electrodes. The "ease of removal" of the NEO X electrode was evaluated as reduced compared to the reference electrodes. However, the benefits derived from a reliable long-term adhesion outweighed the extra care needed during active electrode removal, since the majority of the nurses in Spain, Germany and Denmark recommended to buy the NEO X electrodes for use in NICUs.

Conclusion: Compared to the reference ECG electrodes, the Blue Sensor NEO X electrode was evaluated to be superior for long-term ECG monitoring of preterm neonatal patients placed in high humidity incubators. The decrease in "ease of electrode removal" was outweighed by the increased benefits from consistent, long-term skin attachment.

INTRODUCTION

Infants receiving neonatal intensive care comprise a vulnerable patient population often demanding continuous monitoring of vital functions for long periods of time. The majority of the patients admitted to the NICU are premature neonates [1]. A premature neonate is defined as a child born before 37 weeks of estimated gestational age (GA). The most extremely premature neonates are born between week 22 and week 28 GA [2]. Extremely premature neonates have a functional immaturity of many organ systems inversely proportional to their gestational age. The skin of the extremely premature neonates is one of the organ systems affected by a high degree of immaturity [3;4].

One of the major functions of the skin is to provide a barrier against the outside world. The skin barrier function is essential for survival in that it prevents excessive water loss across the skin and inhibits systemic invasion of surface microbes. Compared to the skin of full-term neonates, extremely premature skin is thinner and markedly less effective in preventing water loss and systemic microbial infections. The immature skin of the extremely premature neonates is also characterized by a reduced cohesion between the upper most skin-layer, the epidermis, and the second skin-layer, the dermis. As a result, the skin of the extremely premature neonate is very fragile with a high degree of susceptibility to mechanically induced skin injury [3-6].

ECG monitoring of the neonatal patients is a standard routine procedure at most NICU departments [1]. Due to the incomplete skin development, the extremely premature neonatal patient has some special requirements to the ECG monitoring electrodes. To reduce water loss over the immature skin barrier, the extremely premature babies are often placed in incubators with a high relative humidity (60% – 80% rH) [3]. The high humidity environment makes it difficult for standard ECG electrodes to stay

attached to the skin for longer periods of time [1]. As a consequence, the electrodes often fall off, resulting in frequent disturbances of the neonatal patient during re-application of detached electrodes. In general, disturbances of the extremely premature neonatal patient shall be reduced to a minimum to ensure a "stress-free" environment. Another challenge, related to the ECG monitoring of extremely premature neonates, is the highly fragile skin, which easily tears and breaks leaving painful open sores and increased risk for infections. Consequently, the removal of adhesives from the immature skin is related to a risk of skin trauma, pain and infections [7-9]. Thus, the ideal ECG electrodes for the extremely premature neonates display extended adhesion to the skin even in a high humidity incubator environment while still being sufficiently easy to remove to reduce the risk of skin trauma to a minimum.

A new ECG-monitoring electrode, the Ambu Blue Sensor NEO X electrode, has recently been developed. The NEO X electrode is specifically designed for long-term ECG monitoring of extremely preterm neonatal babies placed in high humidity incubators. Previously, a comparative in vivo study in premature newborn pigs was performed to evaluate the capacity of NEO X for long-term adhesiveness in a high humidity environment. Compared to standard marketed ECG electrodes, the NEO X electrode adhered firmly to the skin of the pigs for longer periods of time even at a relative humidity of 75%-80%. Despite the firm attachment to the skin, the NEO X electrode was evaluated to be sufficiently skin-friendly during active electrode detachment.

The purpose of this evaluation is to assess how the nurses at NICU's evaluate the performance and suitability of the NEO X electrodes for ECG monitoring of premature neonatal patients.

METHOD

Participating NICUs

A total of 6 hospitals distributed in 3 European countries participated in the NEO X user evaluation: Denmark: Odense University Hospital; Germany: Sana Berlin Lichtenberg and Anonymous*; Spain: Hospital La Paz in Madrid, Hospital Gregorio Marañón in Madrid and Hospital Sant Joan de Déu in Barcelona.

ECG Electrodes

The Ambu Blue Sensor NEO X electrode is based on a hydrophobic adhesive suitable for long-term adhesion in both humid and non-humid environments. NEO X is designed with thin, flexible wings which easily adapt to the body contours of the small preterm neonatal babies. To optimize the patient comfort during use, the NEO X electrode includes a soft cable insulation. The cable insulation is PVC-free and phthalate-free. To ensure adequate skin attachment, gentle pressure, as described in the Instruction for Use, must be applied on the transparent wings of the NEO X electrode during skin application. NEO X is a single-use ECG electrode which is not suitable for re-positioning.

Test Period and Evaluation Form

The NICUs evaluated the NEO X electrodes as part of the normal ECG monitoring routine. The involved nurses were instructed to leave the electrodes on for long-term use and not to remove the electrodes actively during the first 72h unless necessary for clinical reasons. After approximately 2-3 weeks of use, each of the participating nurses were asked to fill-in an evaluation form regarding the use and performance of the NEO X electrode. Various electrode parameters were scored on a 5-point scale: 1: Unacceptable; 2: Limited; 3: Average; 4: Good; 5: Excellent. The electrodes normally used in the NICU's were used as the reference electrodes setting the baseline for comparison to the NEO X electrodes. The reference electrodes differed between the various NICU's: Denmark: Ambu Blue Sensor BR and Unomedical Unilect; Spain: Ambu Blue Sensor BR and Telic K/KS-140; Germany: Ambu Blue Sensor NF electrodes.

The user evaluation was discussed with the local ethical committees in Denmark, Spain and Germany who deemed that it did not need formal ethical approval.

*Approval for writing the hospital name was not obtained from the ethical committee.

RESULTS AND DISCUSSION

During the user evaluation, more than 80 neonatal patients were ECG monitored using the NEO X electrodes. A total of 37 participating nurses each filled-in and returned the NEO X evaluation form. For each of the involved countries, the number of participating nurses which completed the NEO X evaluation form were distributed as follows: Denmark: 6 nurses; Germany: 13 nurses; Spain: 18 nurses. The age of the neonatal patients ranged from 24 to 39 weeks of gestational age. In all 6 participating centers, extremely premature neonates (< 28 weeks GA) placed in high humidity incubators were included in the user evaluation.

The average scores for the various performance parameters of NEO X and reference electrodes are listed in Table 1.

When asked to compare with the reference electrodes, the NICU nurses evaluated the NEO X electrode highly positively. In all three countries, the general opinion of NEO X was rated higher than the average reference electrodes. In particular, the ability to stay attached to the skin of the neonate for longer periods of time and the superior adhesive properties in high humidity incubators was rated very positively. The scores for the ECG trace were around or better than the scores for the ECG trace normally achieved for reference electrodes. The higher ECG trace score for NEO X is likely to be related to the increased level of adhesiveness.

A well-attached electrode will provide a better and more reliable ECG trace than a less well-attached electrode.

Additionally the extremely soft non-PVC based NEO X cable was appreciated compared to the cables of the reference electrodes.

The preservation of skin integrity is essential in the management of the extremely preterm infant [7;8]. The ideal ECG electrode adhesive shall be strong enough to retain the ECG electrode in place while still permitting removal without causing severe skin trauma.

If the adhesive is too aggressive, then skin damage may occur upon removal. On the other hand, insufficient adhesion leads to an unacceptable level of false alarms and frequent disturbances of the neonatal patient. Therefore, it is important to balance the need for skin-friendly removal with the need for continuous reliable ECG monitoring.

Table 1. Results from the Ambu Blue Sensor NEO X user evaluation.

Electrode Features	Spain	Germany	Denmark	Average	Average
	NEO X	NEO X	NEO X	NEO X	Reference ^A
Ease of Placement	4.3	4.1	4.2	4.2	4.5
Adhesion Quality	4.4	4.6	4.5	4.5	2.6
Long-term Use	4.3	3.4	4	3.9	2.7
Use in High Humidity	4.5	3.8	4.6	4.3	2.3
ECG Trace	4.3	3.8	4	4.1	3.7
Flexibility of Cables	N/A	3.9	4.5	4.2	2.6
Ease of Removal	3.3	2.6	3.7	3.2	4.1
General Opinion	4.1	3.7	4.4	4.1	3
Recommend to buy NEO X	Yes: 68%; N/A: 11%; No: 21%	Yes: 69%; N/A: 23%; No: 8%	Yes: 83%; N/A: 17%; No: 0%	Yes: 70%; N/A: 19%; No: 11%	

N/A: No Answer

A: Average scores for reference electrodes in Spain and Denmark. No scores for reference electrodes in Germany were reported.

Scores: 1: Unacceptable; 2: Limited; 3: Acceptable; 4: Good; 5: Excellent.

The ease of removal of the NEO X electrodes from the skin was evaluated to be less easy compared to the reference electrodes. This is expected, since an increase in the level of adhesion will inevitably lead to a decrease in the ease of removal of the electrode from the skin. However, even though the average scores for ease of removal are lower for NEO X, the effort needed for removal is not evaluated to be unacceptable since the average scores are all well above 2. No skin trauma/skin injury was reported. Only a few cases of skin irritation were described. Skin irritation is also commonly reported for reference electrodes.

The level of skin-attachment of most ECG electrode adhesives will increase to a maximum level within a certain time and then gradually decrease [10]. Most ECG electrode adhesives will, at some point, lose their adhesion making them easier to remove. Guidelines for the use of adhesives in neonatal patients have been developed in order to reduce the risk of skin damage. It is suggested that active tape removal should be avoided or at least delayed until after expected peak of adhesiveness [8]. The NEO X is designed for long-term skin attachment. Due to a high level of adhesion, active removal of the NEO X electrode during the first 72h hours of attachment is not recommended on a routine basis. When allowed to stay attached to the skin for longer periods of time, the risk for skin irritation during active removal of NEO X will be minimal. Thus, the NEO X electrodes are suitable for use in clinical settings where reliable long-term ECG monitoring is needed.

CONCLUSION

Finding the right balance between suitable adhesion and adequate skin friendliness must be the focus when designing ECG-monitoring electrodes for preterm neonatal patients. The ECG electrodes must be capable of adhering to the skin for a suitable amount of time in both normal and high humidity environments. In addition, it is an essential requirement that the electrodes can be taken off without damaging the delicate skin of the extremely premature children.

Compared to the standard ECG electrodes, the NEO X electrode was evaluated to be superior for long-term ECG monitoring of preterm neonatal babies placed in high humidity incubators. The ease of removal of the NEO X electrode from the skin was evaluated as reduced compared to the reference electrodes. However, the benefits derived from a reliable long-term adhesion outweighed the extra care needed for active electrode removal, since the majority of the nurses in Spain, Germany and Denmark recommended to buy the NEO X electrodes for use in NICUs.

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