

Risk of skin reaction when using ECG electrodes



Ambu A/S has been developing electrodes for electrocardiography (ECG) for the last 30 years. There are several phases in the process of developing the electrodes. One of the most important phases is the biocompatibility testing of the electrodes, which assures that the materials selected for the electrodes are compatible with the human skin (unless biocompatibility can be documented otherwise). Every time a new electrode is developed or considerably changed, new tests have to be performed. Biocompatibility testing of the electrodes is a requirement of the International Organization for Standardisation (ISO) 10993 – Biological Evaluation of Medical Devices. The tests required for surface electrodes are:

- Sensitization study to evaluate the potential of the electrode to cause delayed dermal contact sensitization.
- Cytotoxicity study (in vitro) to determine the electrode's potential of causing cell death.
- Primary skin irritation to evaluate whether the topical application of the electrode can cause skin irritation.

While several tests and precautions are taken to assure that the materials selected are biocompatible, it is impossible to guarantee that no patients will eventually react to a certain substance contained in the gel or medical adhesive.

What does Ambu do when a patient reports a skin reaction?

Ambu has a special procedure to handle complaints. Every complaint received is highly prioritised and analysed by a team, that depending on the nature of the complaint, can involve professionals from the Quality Assurance, Regulatory Affairs, Clinical Research, Research and Development, and Process Development Departments.

After receiving the complaint-form from a customer, a handling process is started. The first step is to identify whether the problem was caused by a defect in the electrode. If the customer sent samples of the device that caused the problem, tests are performed on those devices; otherwise, electrodes from the same batch are localised for testing.

Finally, production registrations and inspection registrations are checked to localize any abnormality during the production of the batch.

If it is proved that the electrode was not defective, the next step is to find out whether the electrode was used properly or whether the patient was particularly allergic or sensitive to any materials contained in the electrode. The procedure followed will depend on the type of reaction, situation, electrode-type, patient, etc. The next section presents an overview of all the complaints that Ambu has received during the last 6 years in relation to skin reactions following the use of Ambu ECG electrodes.

The review shows that the most typical causes are:

- The patient was allergic to a certain material contained in the electrode. Neither the patient, nor the doctors knew of the allergy.
- The electrodes were used incorrectly (periods longer than those recommended, in a wrong group of patients, etc).

Statistics

Ambu has received on average less than 5 complaints per 100 million units of electrodes sold (average calculated within the period 2001 - 2007).

Typical cases

Redness of the skin

After removing the electrodes, redness of the skin may appear if the patient skin is sensitive to some of the materials contained in the electrode or due to the mechanical stress when removing the electrode. Despite Ambu performs the mentioned in-vitro, in-vivo (animal), and clinical testing of the electrodes during the developing phase, it may happen that few patients are allergic or sensitive to certain chemicals, which normally would not cause adverse reactions. This risk increases if the skin of the patient is damaged, or if the electrode has been used for very long periods of time.

Sometimes it can be difficult to analyse these cases. Especially when the description of the situation is insufficient or if the customer has not sent samples of the electrode that caused the problem. One important aspect is to analyse whether the reaction was caused by the hydrogel or the adhesive.

Usually, patients and doctors want to know which materials are contained in the hydrogel and adhesive. Under certain circumstances, Ambu can disclose information regarding the substances contained in the hydrogel.

Skin irritation due to wrong skin preparation or use

Sometimes, skin reactions may occur after long-term use of some electrodes. Further investigation revealed that the electrodes were used for longer periods (3 to 7 days) than they are recommended for. Other cases revealed that before applying the electrodes, the skin was unnecessary prepared using sandpaper, which caused severe skin irritation due to epidermal stripping. In the some electrodes, the outer adhesion-ring is designed such that the adhesion of the ring increases over time. By stripping the skin right before placing the electrodes, the electrode adhesion increases even more causing skin irritation by itself or by mechanical reaction when removing the electrode. Moreover, the hydrogel contains components, which can penetrate deeper skin-layers if the skin is stripped before electrode application, increasing the risk of irritation.

If it is necessary to prepare the skin, it is common practice to use alcohol wipes and letting the alcohol evaporate before placing the electrodes. However alcohol may increase skin impedance and is therefore not recommended. When the electrodes have to be removed, it is helpful to use a few drops of water, which act dissolving the adhesive and helping removal of the electrodes.

Particular cases

Allergic reaction

It is a rare possibility to observe an allergic reaction after electrodes removal.

Allergic reactions are sensitivities to a specific substance, called an allergen, which in this case is contacted through the skin. Most reactions happen soon after contact with the allergen. Substances that do not bother most of the people (such as venom from bee stings, some types of foods, and pollens) can trigger allergic reactions in some people. While first-time exposure may only produce a mild reaction, repeated exposures may lead to more serious reactions. Once a person is sensitised (has had a previous sensitivity reaction), even a very limited exposure to a very small amount of allergen can trigger a severe reaction.

If the patient or the doctors do not know that the patient is allergic to a certain chemical substance, it is very difficult to prevent these situations.

Skin burn

It may be a rare situation to observe the patient's

skin burnt under the electrodes, when they are used in Magnetic Resonance (MR).

Ambu Blue Sensor MRX-electrodes can be used safely during MR and X-ray procedures. A general consideration when working with MR-scans is that any conductive material, which will be inside the scan and in contact or close to the patient during the scan, should not form conductive loops. This means that, for example, the electrode wires should not be placed forming a loop. If the wires are forming a loop, the strong magnetic field of the scanner will generate an electric current in the wires that will heat the electrodes and consequently burn the patient skin. In these cases it was important to investigate the following issues: Did the burn occur during the MR scan? Was the patient connected to other electric devices, which could have caused the burns before the MR-scan? Was the patient ECG-monitored during electric-surgery? (If the patient is incorrectly grounded, electricity from the electric scalpel can run through the ECG electrodes to the ground, burning the patient skin).

After the case was investigated, it was concluded that the burning was caused because the electrode wires were forming a loop.



Example of a skin burn under the electrode



General recommendations

Based on the reviewed cases, it is suggested that the users are always reminded about the following considerations:

- In case of skin reaction, keep samples of the electrode that caused the problem. This will help Ambu analysing the case.
- In case of skin reaction, take pictures of the

affected skin areas and write detailed descriptions of the case. This will help Ambu analysing the case.

- Use the electrodes as suggested in the Directions for Use.
- Do not use electrodes for adults in children.
- Blue Sensor MRX-electrode: do not make cable loops inside MR-scans.
- If skin preparation is needed, avoid using sandpaper.
- If the electrode is strongly adhered to the skin, use drops of water to facilitate electrode removal.

Conclusion

Despite Ambu electrodes are developed and tested to assure that the materials are biocompatible, it is impossible to guarantee that no patients can eventually react to a certain substance contained in the gel or medical adhesive.

It is important to understand that patients' allergic reactions are not caused by a defect in the

electrode, but because a few people may be allergic or sensitive to a certain substance. Sometimes, hospitalised patients may be more vulnerable to certain substances that normally would not cause any type of reaction, especially if they have been under medication for long periods. Finally, simple recommendations like the ones listed above may help to avoid some undesirable situations.

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