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ELECTRICAL SAFETY IN IONTOPHORESIS

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The first ActivaTekNote concerns electrical safety. The emphasis on safety was a precondition to the founding of ActivaTek. No products will be made by ActivaTek that do not exceed industry standards for safety, as well as efficacy. The following topics were included in ActivaTek's formal risk assessment and risk management that governed the design evolution of the Trivarion iontophoresis electrode system. Safety was designed into the Trivarion electrode.

MODERATING PH SHIFTS DUE TO HYDROLYSIS

Iontophoresis uses a low amplitude electrical current to drive ionic drug molecules through the skin. The applied electrical current will split water into H+ and OH- in a process known as hydrolysis. A method of buffering the pH changes due to hydrolysis is necessary in all iontophoresis electrodes.

The Trivarion electrode system uses a novel oxidation-reduction carbon-silver chloride pH control system that constrains the pH shifts due to hydrolysis. The pH control system keeps the native pH of the drug solution relatively constant. This is important as the charge of the drug may be altered with pH shifts. Since it is the charge that propels the drug in an electrical field, the efficiency of delivery is altered by any changes in the polarity of the drug molecule.

The Trivarion electrode system was tested for pH changes over the course of delivery of a maximal dose of 80 mA*minutes. A chemical indicator was used to detect pH changes every two minutes over a treatment duration of 20 minutes. Figure 1 shows the pH excursion relative to the initial pH as a function of the treatment period. The current setting was 4.0 mA and the electrode polarity was positive. The pH excursions expected from uncontrolled hydrolysis are towards the acidic (negative) side of the scale. A random sample of six electrodes was tested and each pH measurement was plotted. Through the entire 80 mA*minute treatment session, the pH was constrained to within a half pH value of the starting pH.

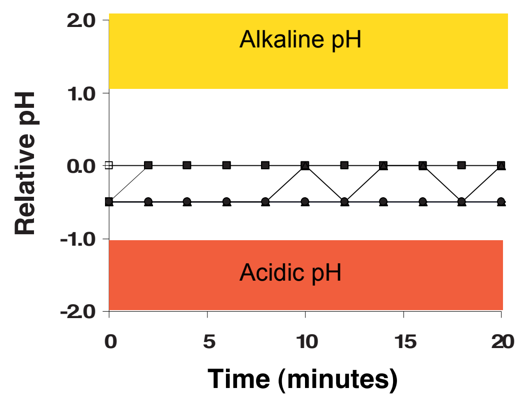

Figure 1: *Timecourse of pH excursions relative to the starting pH for six electrodes. Electrode polarity was positive, total dose was 80 mA*minutes.*

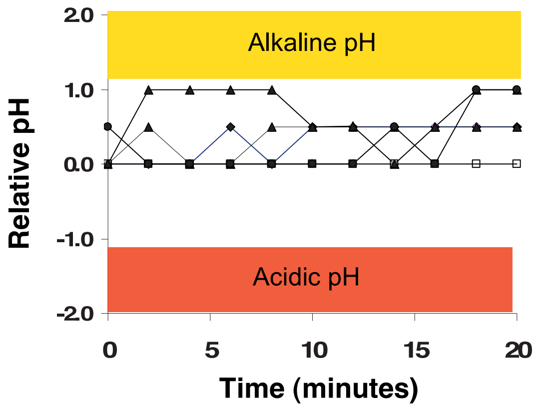

Figure 2: *Timecourse of pH excursions relative to the starting pH for six electrodes. Electrode polarity was negative; total dose was 80 mA*minutes*

The pH excursions for the same 80 mA*minutes dose using negative electrode polarity were also determined for six randomly sampled electrodes. Figure 2 shows the relative pH excursions over the course of treatment. The pH excursions expected from uncontrolled hydrolysis are towards the alkaline (positive) side of the scale. Through the entire 20 minute treatment course, the pH was constrained to one pH value in the alkaline direction.

AVOIDING INTERNAL HIGH CURRENT DENSITIES

Whenever the path of electrical current (mA) is constrained or constricted, the current density (mA per cm2) increases. Increases in current density may cause skin irritation or burns.

High current densities may occur internal to the electrode if the drug reservoir is not uniformly wet. As only the wetted areas of the reservoir conduct current, if the wetted area is small a high current density results. The Trivarion drug reservoir was chosen for its extreme absorbency. However, any dry spots noted while adding the drug solution should be touched up with additional drug solution (see the Instructions for Use included with the electrodes).

High current densities may also occur if the adhesive seal of the electrode with the skin does not adhere well and leaks. Again, the drug reservoir may become nonuniformly wet, resulting in high current densities. The unique shape and adhesive materials of the Trivarion were designed to conform to the complex surfaces of the fingers, wrist, elbow, knee, and ankle.

The collaboration of careful design, manufacture and clinical practice ensures a high degree of patient safety.

AVOIDING EXTERNAL HIGH CURRENT DENSITIES

High current density conditions outside of the electrode generally occur as local short circuits and as a result of inadvertent externally applied pressure over the drug delivery and/or ground electrode(s).

High current densities caused by a short circuit are often the result of (metal) jewelry worn in the vicinity of the electrode. Metal provides a low resistance channel for current to be routed away from the lead, snap, or electrode. If the metal also touches the skin, a high current density pathway is created that may result in a skin burn.

High current densities caused by externally applied pressures such as hot packs, cold packs, elastic bandages, etc. are the result of compressing the conductive element within the drug delivery and/or ground electrode(s). The compression over the electrode causes uneven current distribution, which may cause skin irritation or burns. Never tape, bind or compress either electrode during an iontophoresis procedure.

(See the Instructions for Use included with the electrodes)

The Trivarion iontophoresis electrode system has been tested to the conventionally used dose of 80 mA*minutes. This dose has been cleared for the Trivarion by the Federal Drug Agency (k061522). The Trivarion drug delivery electrodes are compatible with FDA cleared constant current Iontophoresis devices.

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