NANODUCT™

Neonatal Sweat Analysis System

U.S. Patent Number: 6,198,953 B1

ABBREVIATED INSTRUCTIONS FOR USE
(Consult the instruction manual for detailed procedure)

Pilocarpine Iontophoresis

1. Attach the two holders to selected sites on the limb. They will remain in place during the entire procedure.
2. Clean the skin within the holder rings with isopropyl alcohol and water and allow the skin to remain moist.
3. Insert a gel disc into each iontophoretic electrode (discs are identical).
4. Insert each electrode into the appropriate color-coded holders.
5. Connect the cable to the socket of the Inducer/Analyzer and press **ON**.
6. Default selection will be “Iontophoresis”. Press **ENTER**.
7. After completion of iontophoresis, remove the anode (red) electrode but leave both holders and the black electrode in place.

Analysis

Do not touch or otherwise contaminate the conical surface of the sensor.

1. Remove a conductivity sensor from its protective bag.
2. Attach the sensor to the sensor connector on the cable.
3. Wash the stimulated skin area with deionized water and thoroughly dry.
4. Without delay, insert the sensor into the red holder. (see instruction manual for details).
5. Program the Inducer/Analyzer for Sweat Analysis.

Nanoduct Conductivity Sensors are intended for single use only. Discard after use.

INFORMATION FOR PARENTS

SWEAT TESTING POSES A REMOTE RISK OF MINOR SKIN BURNS

The sweat test has been an important hospital laboratory procedure since the 1950's. It provides a quantitative test result to confirm or exclude a diagnosis of cystic fibrosis. Unfortunately, occasional minor burns have accompanied the test.

The sweat test is based on a laboratory analysis of the concentration of salt in the sweat. As performed with the Nanoduct System the test consists of two sequential procedures: (1) sweat stimulation, and (2) sweat analysis. The first procedure is to stimulate an isolated area of skin to produce sweat. This is accomplished by the electrical transport of a sweat-inducing drug, pilocarpine, into the upper layers of the skin. It is universally accepted by medical authorities that pilocarpine iontophoresis is a safe and effective method of stimulating the sweat glands. The electrical current is supplied through a battery current-regulating circuit and a pair of electrodes fitted to the patient's limb.

Minor skin burns have been an unwelcome, adverse side-affect of pilocarpine iontophoresis from the beginning. Unusual sensitivity to pilocarpine has sometimes been assumed to be the cause of "burns" but there is no firm evidence for this contention. Majority opinion seems to support the proposition that some types of stimulating apparatus are prone to cause burns, particularly when associated with procedural error.

Such burns are extremely rare with Wescor Sweat Stimulating Systems. They use a sophisticated microprocessor controller and a very low total delivery current (0.5 milliamperes in the Nanoduct System). Pilocarpine is contained in unique gel reservoirs. The gels also include compounds that further protect the patient from skin damage by preventing acid accumulation, by minimizing the risk of gel breakage and by substantially reducing the time of electrical drug transport. These features markedly reduce, but do not entirely eliminate, the possibility of skin burns.

Most individuals exhibit a mild erythema (redness) at the skin stimulation site. In some cases one or more blister-like welts may also form. These are often mistaken for burns, but are more likely to be a temporary reaction to the passage of electrical current. Such "blisters" invariably disappear within 2 or 3 hours, leaving no after-effects.

Based on current data and reported events, the apparent burn rate using Wescor instruments is less than 1 in 50,000. The low rate is due to Wescor's insistence on proper test procedures together with built-in equipment safety provisions that minimize the risk of even mild skin injury. It is highly unlikely that your child will suffer a burn during the stimulation phase of the sweat test.

We realize these statistics will be of scant comfort to the parents of a child who has the misfortune of suffering the "one burn in 50,000". However, experience has shown that when burns do occur, the injury is minor with little or no scarring.

WESCOR®

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