MACRODUCT ®
Sweat Collection System

U.S. Patent Number 4,542,751
U.K. Patent Number 2,116,850
Other Patents Pending

ABBREVIATED INSTRUCTIONS FOR USE

DO NOT TOUCH OR OTHERWISE CONTAMINATE
THE CONICAL SURFACE OF MACRODUCT

1. Attach the appropriately-sized strap to the MACRODUCT collector with proper orientation for subsequent attachment to limb.

2. Thoroughly clean and dry the stimulated skin area.

3. Apply the conical surface of MACRODUCT precisely over the stimulated area.

4. Fix MACRODUCT very tightly in position using the strap.
MACRODUCT REMAINS ATTACHED DURING STEPS 5 THROUGH 8.

5. The protective transparent cover over the spiral microbore tube may be removed by inserting a pointed tool under one of the cut-out sections and prying upward. (The nippers may be conveniently employed for this operation.) It can be removed immediately after attachment of the MACRODUCT unless an elastic bandage or other overwrap is to be used.

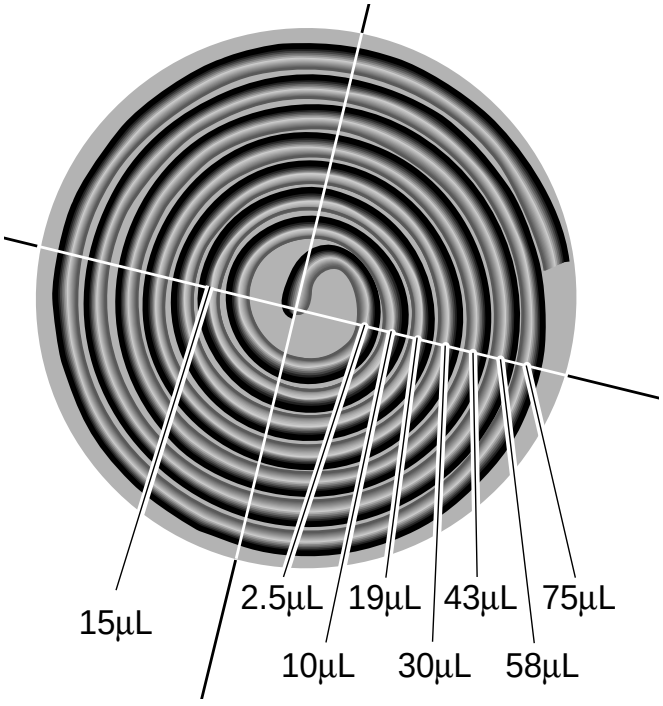
6. When sufficient sweat has accumulated,* connect the free end of the microbore tube to the needle of the sweat dispenser or blunt end needle on a syringe. Grasp the end of the microbore tube (not the dispenser or syringe) and carefully lift the tube away from the adhesive surface until its entire length is free.

7. Use the nippers to sever the attached end of the microbore tube as closely as possible to the upper surface of the MACRODUCT collector body.

8. Immediately transfer the sweat to the sealable microsample cup by gently and continuously squeezing the dispenser to expel the sweat from the microbore tube, or connect the tubing to the nipple of the conductivity cell.

9. Remove the MACRODUCT collector body from the patient's limb; retain the attachment strap and discard remainder.

*The bore of the collecting tube is controlled to contain at least 2.7 µL/cm, corresponding to the volumes indicated in the diagram below.



INFORMATION FOR PARENTS:

SWEAT TESTING POSES A REMOTE RISK OF MINOR SKIN BURNS

There is an element of risk inherent in all medical procedures, no matter how simple. The sweat test has been an important laboratory tool since the 1950s. It provides a quantitative test result to confirm or exclude a clinical diagnosis of cystic fibrosis. Unfortunately, the test has been accompanied by occasional minor burns.

The sweat test consists of three sequential procedures: (1) sweat stimulation, (2) sweat collection, and (3) sweat analysis. The first procedure is known as pilocarpine iontophoresis. It is universally accepted by medical authorities as a safe and effective method of stimulating sweat glands. A sweat-inducing drug, pilocarpine, is delivered from the surface of the skin through the watery pathways of the sweat ducts into the sweat glands by a small electric current that is made to flow through the dermal layers. The electric current is supplied by a battery-powered device through a pair of electrodes fitted to the limb of the patient.

Minor skin burns have been an unwelcome, adverse side-effect of pilocarpine iontophoresis from the beginning. Some types of iontophoretic apparatus are prone to cause burns, particularly if there is procedural error. Fortunately, such burns are extremely rare with the Wescor iontophoretic system. It uses a sophisticated microprocessor current controller and a very low delivery current of only 1.5 milliamperes. Pilocarpine is contained in unique Pilogel gel drug reservoirs that are 96% water. These features substantially reduce, but do not totally eliminate, the possibility of skin burns.

Burn descriptions vary from “tiny black pinholes in the skin” to “crater-like, third-degree burns two to three millimeters in diameter.” In most of the incidents reported, the children have exhibited no sign of pain or discomfort during iontophoresis, and the burn was not discovered until the electrodes were removed.

Most individuals exhibit a sensitivity to pilocarpine that is typically manifested as mild erythema (redness) of the skin at the electrode locations. In some cases, one or more blister-like welts may also form. These are often mistaken as burns, but they are simply the reaction of the skin to pilocarpine. Such “blisters” invariably disappear within 2 to 3 hours, leaving no after-effects.

Based on current data and reported events, the apparent burn rate is less than 1 in 50,000. Wescor prescribes proper test procedures which minimize the risk of burns from its equipment. It is highly unlikely that your child will suffer a burn during the sweat 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 injuries are minor and there are no lasting effects. The burns usually heal completely within one to two weeks with little or no scarring.

WESCOR®

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