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MACRODUCT  
SWEAT COLLECTION  
SYSTEM

*Model 3700 SYS*

**instruction/service manual**

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SECTION 1  
INTRODUCTION



## 1.1 *User's Manual Overview*

This manual covers the complete laboratory procedure for the laboratory diagnosis of cystic fibrosis through examination of sweat electrolyte concentration. The steps preliminary to sweat analysis—sweat stimulation and collection, are accomplished using the Macroduct® Sweat Collection System.

### *CAUTION!*

**Never attempt sweat collection until you are thoroughly familiar with the procedures and cautionary information detailed in this manual. Abbreviated instructions printed elsewhere are provided for reference only and should not be used as a substitute for the complete information contained in this manual.**

## 1.2 To Our Valued Customer

Thank you for purchasing the Macroduct Sweat Collection System. We are confident that this is the finest sweat testing system in the world. As the acknowledged world leader in sweat testing products for the laboratory diagnosis of cystic fibrosis, Wescor is dedicated to providing customer support in all aspects of the use of this product and sweat testing theory and practice.

From the beginning, our goal has been to identify problems in sweat testing, delineate the precise cause of false diagnosis, and then to devise innovative solutions. We have accomplished this with the added benefit of vastly simplifying procedures while remaining within the strict boundaries of acceptable accuracy.

Wescor is ready to help you resolve any difficulty with the operation or performance of the Macroduct system. If you cannot resolve a problem using the information in this manual, please contact us.

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**PLEASE NOTE:**

Wescor's Authorized European Representative for matters relating to the Medical Device Directive is:



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## 1.3 Important User Information

### APPLICATION:

The Macroduct System is intended for laboratory use by qualified personnel for stimulation and collection of sweat for analysis in the diagnosis of cystic fibrosis.

**Anyone operating Macroduct must be thoroughly familiar with the procedures and cautionary information detailed in this manual before attempting to use this equipment.**

### SPECIFICATION OF SAFE USE:

Using this device in a manner not specified by Wescor, Inc may impair the safety protection designed into the equipment and may lead to injury. Do not use where flammable anesthetic is present or in any oxygen-enriched environment.

### STATEMENT OF ENVIRONMENTAL LIMITS:

This equipment is designed to be safely operated at 5° to 35 °C, maximum relative humidity 80%.

### EXPLANATION OF SYMBOLS FOUND ON EQUIPMENT:

I Run

O Stop



International Attention Symbol.  
Calls attention to important information and instructions in the user's manual.



Type BF equipment complying with Medical Equipment Safety Standard EN60601-1.

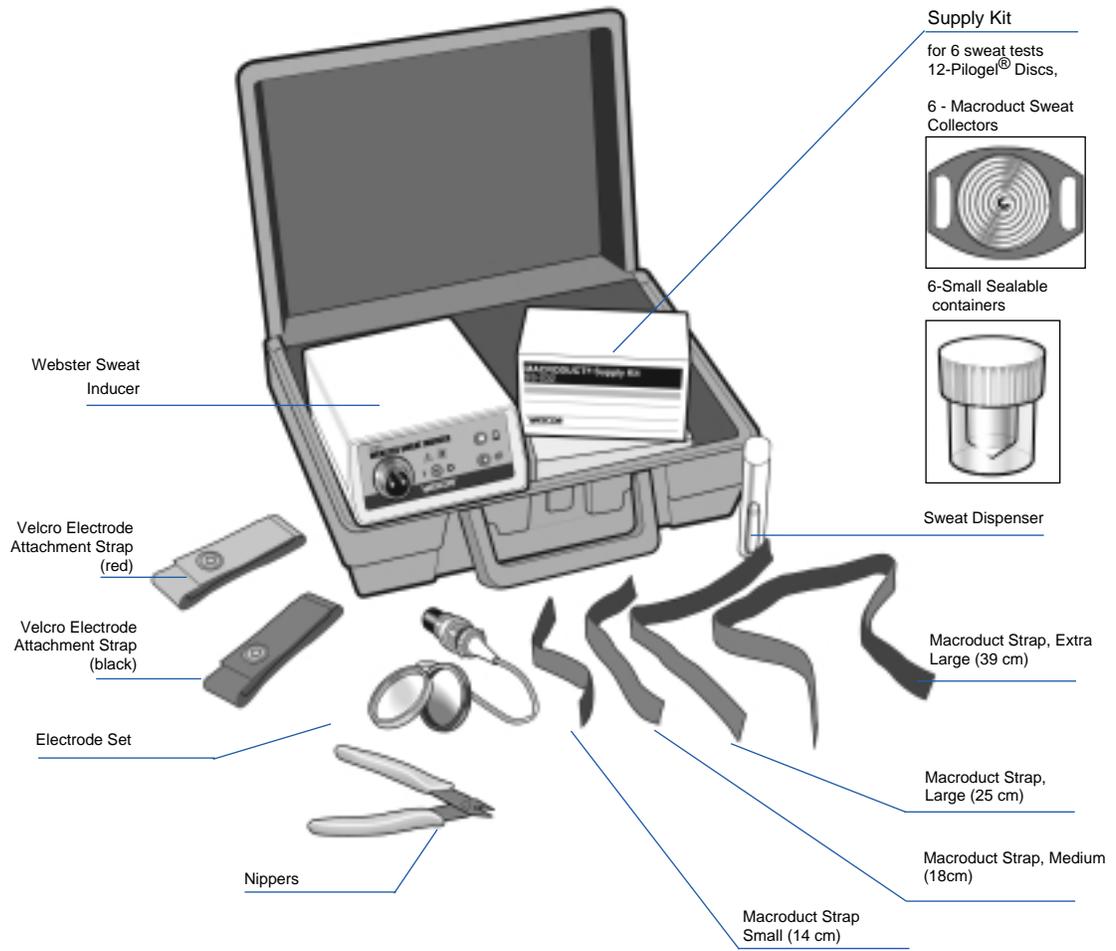


Current Flow Indicator



Low Battery Indicator

# 1.4 System Components

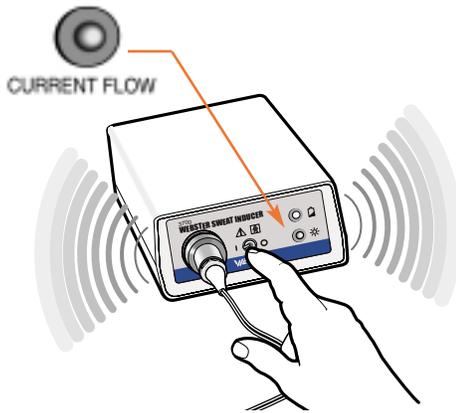


## *1.4 System Components*

### **CATALOG NUMBER 3700-SYS**

DESCRIPTION	UNIT	CATALOG NO.
Webster Sweat Inducer	1 each	Model 3700
Electrode Set	1 each	320566
Electrode Attachment Strap (red)	1 each	RP-044
Electrode Attachment Strap (black)	1 each	RP-045
Supplies kit for 6 sweat tests (12-Pilogel <sup>®</sup> Discs, 6-Macroduct Sweat Collectors, 6-Small Sealable containers)	1 each	SS-032
Sweat Dispenser	1 each	RP-065
Nippers	1 each	RP-066
Macroduct Strap, Small (14 cm)	1 each	SS-128
Macroduct Strap, Medium (18 cm)	1 each	SS-129
Macroduct Strap, Large (25 cm)	1 each	SS-130
Macroduct Strap, Extra Large (39 cm)	1 each	SS-131

## 1.5 Webster Sweat Inducer



The Webster Sweat Inducer is an integral part of the Macroduct Sweat Collection System. Its design is based on years of clinical experience, research, and product development, with patient safety and comfort given paramount importance. It is a fully automatic unit featuring advanced electronic circuitry and many fail-safe and operator convenience features.

### How It Works

When the RUN/STOP switch is moved to the "I" position, a brief tone signals that external electrode circuit resistance is acceptable and that the instrument has begun to deliver iontophoretic current. Current delivery is confirmed by a green CURRENT FLOW INDICATOR. The tone sounds again briefly at the completion of iontophoresis.

Iontophoretic current rises to 1.5 mA during a 17-30 second interval, remains at 1.5 mA for 5 minutes, then decreases in the final 6 seconds to zero, at which time the instrument switches off. This "profiling" of iontophoretic current prevents the sensation of electrical shock that results when current changes abruptly. The CURRENT FLOW indicator is wired in series with the electrodes.



During the complete iontophoretic sequence, the total electrical charge delivered to the positive electrode is approximately 450 millicoulombs or 78 millicoulombs/cm<sup>2</sup>. Due to impurities in the agar, Pilogel discs contain sodium and other cations in total molar concentrations approximately equal to that of the pilocarpinium ion. These therefore compete with each other for transport of electrical charge which produces an approximately 50% reduction in the amount of pilocarpine that would have been delivered to the glands in the absence of such salts. However, sufficient drug is transported to produce maximal sweat stimulation.

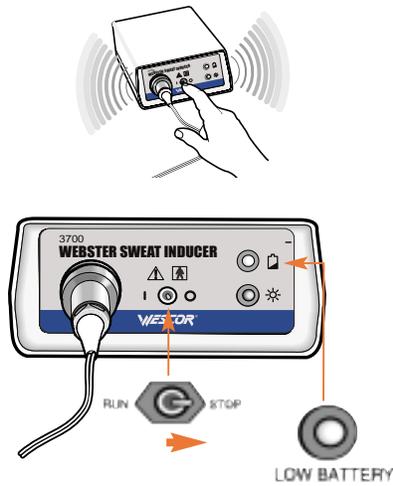
## *1.5 Webster Sweat Inducer*

### **FAULT CONDITIONS**

To maximize safety, the inducer continuously monitors the current. If an unexpected condition is detected the current turns off and an alarm sounds. This alarm continues until you move the switch to STOP **(0)**.

A fault condition can occur if one of the electrodes becomes detached. An alarm may also be due to low batteries, (see next page). See Section 4 for more detail of fault conditions and alarms.

## 1.5 Webster Sweat Inducer



### LOW BATTERIES

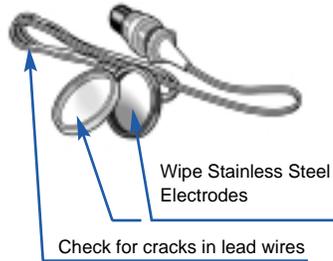
The alarm sounds if the batteries are low when the switch is moved to RUN (I). In this case, the amber LOW BATTERY indicator will also be illuminated, and the inducer will not start. The alarm continues until the control switch is moved to the STOP (0) position.

If batteries get low during iontophoresis, the instrument completes the cycle using remaining power in the batteries, but at the end of the cycle, the tone sounds and the LOW BATTERY indicator flashes. To disable the LOW BATTERY alert, push the switch to the STOP (0) position.

Replace batteries before attempting another iontophoresis cycle. See Section 4.3.

## 1.5 Webster Sweat Inducer

### ELECTRODES



The high-grade stainless steel electrodes require only minimal maintenance. This consists of cleaning them with purified water after each use so they will be ready for the next procedure (See Section 4.2). Lead wires should be periodically inspected for breaks or cracks in the insulation. If electrode wires, insulation, or the plastic electrode housing exhibit cracks or breaks the electrode set should be replaced.



#### NOTE:

*If you activate the run switch while the electrodes are not attached to the patient's limb, an "open circuit" alarm will sound. To disable the open circuit alarm, push the switch to the STOP position.*

## 1.6 Pilogel® Iontophoretic Discs



The traditional reagent solutions for pilocarpine iontophoresis are pilocarpine nitrate and sodium nitrate. These have been applied either to absorbent fabric (such as gauze) or to discs of thick paper that are then interposed between the electrode surfaces and the skin. Such reagent reservoirs have always presented problems to both operators and patients.

Pilogel iontophoretic discs were developed specifically to overcome these and other problems. They consist of a solid agar gel that is 96% water, into which is dissolved 0.5% pilocarpine nitrate and a trace of antifungal compounds.

The discs are approximately 6 mm thick and sized to fit snugly into the standard Wescor recessed electrodes. Pilogel is supplied in a resealable vial containing 12 discs intended for one-time use (sufficient for 6 iontophoretic sweat stimulations). Discs are used in both positive and negative electrodes. Sweat stimulation occurs under the positive electrode, while the disc under the negative electrode completes the electrical circuit.

The Pilogel system provides monumental improvements in patient safety, efficiency of sweat stimulation, and convenience to the operator.

## 1.6 Pilogel® Iontophoretic Discs

### EFFICIENT SWEAT PRODUCTION

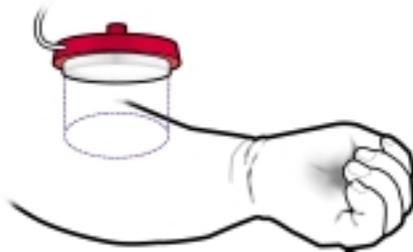
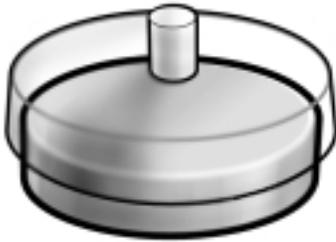
Reliable, uniform, gel-to-skin contact ensures delivery of pilocarpine over the whole skin area, thus providing total gland stimulation and maximal sweat yield.

Despite being mostly water and presenting a "wet" surface to the skin, Pilogel discs do not exude fluid even under the pressure applied during limb attachment. This eliminates any possibility of "bridging". Gel-fitted electrodes may be placed in close proximity without risking a short circuit, a great advantage when dealing with neonates.

Pilogel eliminates the need to apply gauze or paper pads. The discs are immediately ready for use. There is no need to prepare or store reagent solutions. With Pilogel, the electrodes, once fitted, require no further attention during iontophoresis.



## 1.6 Pilogel® Iontophoretic Discs



### ENSURING PATIENT SAFETY

The Macroduct system represents a dramatic improvement in patient safety over previous sweat induction and collection methods.

Pilogel discs provide an air-free continuous conduction medium and even distribution of current over the stimulated skin area, reducing the possibility of electrical burns to the skin.

The Pilogel disc fits snugly into the recess of the electrode, preventing disc separation from the electrode. This virtually eliminates any possibility of a burn from direct metal-to-skin contact.

### BURNS DURING IONTOPHORESIS

The Macroduct Sweat Collection System has become perhaps the most frequently used system in hospitals and clinics worldwide.

While the Macroduct system is clearly superior to previous methods, burns during iontophoresis have not been totally eliminated. Based on reports from practitioners, we estimate a frequency of 1 burn in 50,000 iontophoretic procedures.

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 reported cases the children have exhibited no sign of pain or discomfort during iontophoresis, and the burn was not discovered until the electrodes were removed.

Parents must be informed and allowed to read the “Information for Parents” included with the Macroduct supply kit. You should also have them sign an appropriate release form before performing this procedure.

If the procedures outlined in the manual are followed correctly, burns should be extremely rare.

## 1.6 Pilogel® Iontophoretic Discs

**We strongly recommend the following burn prevention procedures:**



**1** Do not use Pilogel discs that have an unusual appearance (fractures etc.). See Section 3.

**2** Electrode strap pressure should promote firm contact between the skin and the gel disc. Straps should not be tight enough to crush the disc between skin and electrode.



**3** Leave skin slightly wet after washing the area where the electrode will be attached

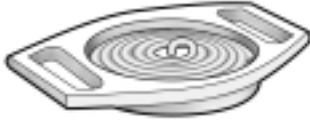
**(OR)**

Add a drop of water to either the skin or the pilogel surface (after installation in the electrode).

### NOTE:

*Although these recommendations are designed to prevent burns during iontophoresis, there is no guarantee they will not occur. Any institution providing sweat tests should thoroughly explain this possibility to parents and obtain a written waiver from them prior to iontophoresis. Besides limiting liability from an unfortunate incident, parents thus warned can make an informed decision about testing their child and are less likely to be upset if a burn occurs.*

## 1.7 Macroduct Sweat Collector



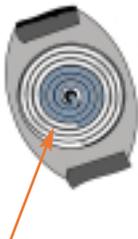
The Macroduct Sweat Collector is a **disposable** plastic device with a shallow concave underside that covers the skin area previously stimulated by pilocarpine iontophoresis. The collection surface is contoured such that when firmly applied to the stimulated area, the skin bulges into the concavity, leaving no air space. At the apex of the conical surface, a tiny orifice leads to a small-bore plastic tube or duct, having an inside diameter of approximately 0.64 mm, and coiled into a spiral.

The base of the sweat gland is 2 to 3 mm beneath the surface of the skin. Fluid secreted by the gland creates hydraulic pressure that moves the fluid upward through the sweat duct to emerge from the skin as sweat. When sweat surfaces beneath a Macroduct collector, this same hydraulic pressure forces it into the air-free interface between the skin and the concave surface of the collector. Since the pressure of the skin against the collector surface is greatest at the rim and decreases inwardly toward the center, the secreted sweat is directed to the orifice and into the plastic "macroduct."

After attachment, sweat becomes visible in the spiral tube of Macroduct within one to four minutes, depending upon the relative elasticity of the skin and the subject's sweating rate.

### NOTE:

*For best results, the stimulated skin area should cover deep flesh such as reasonably thick musculature. Thin skin sections overlaying palpable tendons or bony structures are not suitable as collection sites.*



**BLUE COLORED SWEAT**

The emergent sweat is turned blue by contact with a small amount ( 10 nanomoles) of blue water-soluble dye (FDC certified food color) applied to the Macroduct collection surface. This allows easy assessment of the volume produced at any time during collection.

This dye does not interfere with sweat chloride assay by colorimetry. The dye contributes slightly to the osmolality and sodium content of the sweat sample. Even with a low sweat yield of only 20  $\mu\text{L}$ , this contribution will not exceed 1.5 mmol/kg or 1.0 mmol/L, respectively, and is negligible.

The spiral collection tube capacity is approximately 85 microliters. This is adequate for average sweat production levels (50 to 60 microliters) in thirty minutes of collection. This volume is sufficient for all current methods of sweat analysis (see Notes Regarding Sweat Yield p.17).

At the end of the collection period, the collector must remain on the limb until the pristine sweat specimen is removed by severing the plastic tube at its attachment point. See complete instructions in Section 2 before attempting this procedure.

## 1.7 Macroduct Sweat Collector

### Advantages of Macroduct

- (a) By preventing any exposure to an air space the collected sweat is not subject to condensate error.
- (b) Evaporation of sweat can only occur at the advancing meniscus in the plastic collecting duct. This has been found by measurement to produce a negligible loss of 0.1 microliters per hour.
- (c) The operator can gauge the amount of sweat produced at any time, a unique and unprecedented feature that eliminates guesswork in deciding the duration of the collection period.
- (d) The patient has complete mobility during the collection period. (The collector can be over-wrapped with an elastic bandage to keep curious young fingers from causing mischief.)
- (e) Macroduct collects sweat passively and automatically, driven by the same hydraulic pressure that causes sweat to move from the base of the sweat gland to the skin surface.

There is no "harvesting" procedure during which the integrity of the sweat specimen is liable to be compromised by human error or other factors.

### Notes Regarding Sweat Yield

Technologists experienced with the Gibson and Cooke pad absorption method of sweat collection often raise the question of the "100 mg Rule," or some variation, which requires a minimum sweat volume for the analytical result to be valid. To the extent that such requirements were imposed to mitigate the error possibilities of the pad absorption method, they may be disregarded, since Macroduct collection is free of such errors.

On the other hand, some authorities have suggested that the minimum yield rules were promulgated because low sweating rates are associated with anomalous electrolyte concentrations, and therefore may give rise to a misleading diagnostic result. In order to establish an equivalent minimum yield threshold for Macroduct, one must take into account the differences in electrode size (area) and the recommended collection times for the two methods.

Applying these ratios shows that an average collection of 50  $\mu\text{L}$  in 15 minutes using Macroduct is equivalent to a yield, in terms of sweating rate, of approximately 350 mg by the pad absorption method. Conversely, the sweat yield with Macroduct corresponding to the "100 mg Rule" is approximately 15  $\mu\text{L}$ .



SECTION 2  
SWEAT INDUCTION AND COLLECTION



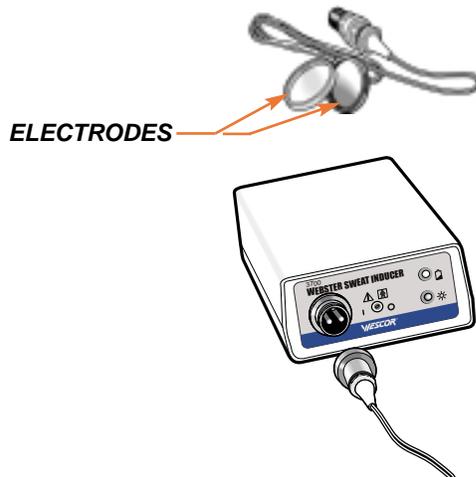
## 2.1 Inducing Sweat

### WARNING!

Due to the possibility of an explosion, never attempt iontophoresis on a patient receiving oxygen-enriched respiratory therapy in an enclosed space. With medical approval, remove the patient from that environment during iontophoresis.



- 1 ASSEMBLE EQUIPMENT AND SUPPLIES**  
 Make certain everything is on hand for the complete procedure. In addition to the complete Macroduct Sweat Collection System you will need a supply of pure water, alcohol, and cotton balls or gauze pads.

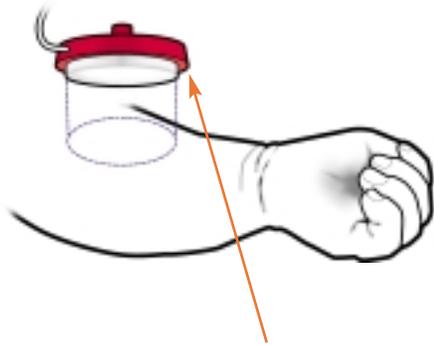


- 2 INSPECT ELECTRODES AND CONNECT TO INDUCER**

Clean the electrodes if necessary (see Section 5.2). Check wires and insulation for cracks or fraying. **Replace electrodes if wires, insulation, or plastic housing are cracked or frayed.**

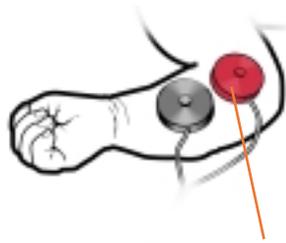
Press the electrode plug into the jack on the sweat inducer panel. You must engage the positive/negative alignment pins correctly to do so. Tighten the locking ring to secure the connection.

## 2.1 Inducing Sweat



**RED  
ELECTRODE**

### TINY INFANT PLACEMENT



**RED  
ELECTRODE**

### 3 CLEAN THE SELECTED SKIN AREAS

The positive (RED) electrode must be placed correctly for successful sweat collection. Locate it on an area of skin with a high density of sweat glands for optimum sweat yield. The preferred site is the lower portion of the flexor aspect of the forearm. This generally has a very high density of sweat glands, provided the limb is not so small as to prevent proper attachment of the Macroduct collector.

#### NOTE:

*Do not place the electrode so close to the wrist that tendons or bone are palpable just beneath the skin. Reasonably thick musculature is necessary for a proper interface with the Macroduct collector.*

If the limb is tiny, place the red electrode on the upper portion of the flexor aspect of the forearm (nearer the elbow) or even the upper arm. If the entire arm is too small to attach the collector (such as a premature infant), use the inner thigh. In this case, constrain the infant from flexing the knee during collection to avoid a loss of interface between the skin and the collector.

Attach the negative (BLACK) electrode at any other convenient position on the arm, or to the leg (**on the same side of the body**).

## 2.1 Inducing Sweat

The selected site must be free of breaks, fissures, or observable abnormality in the skin. There should be no sign of inflammation. Apart from exacerbating the complaint, there is the possibility of contamination of the sweat by serous exudates. The area must be as wrinkle-free and hairless as possible.

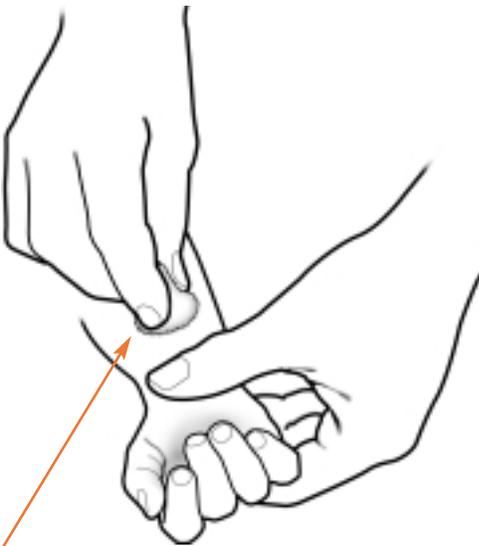
Clean the skin at the selected sites to remove dirt, fatty material and loose dead cells, to minimize the electrical impedance of the skin. To do this:

**a** Swab the area vigorously with alcohol, then with plenty of purified water.

**b** Leave the skin wet where the Pilogel disc is to be attached (**OR**):

Place a drop of water on the skin or on the surface of the Pilogel disc just before attachment.

This will ensure uniform contact over the area and reduce the possibility of a burn.



1 SWAB WITH ALCOHOL

2 SWAB WITH PURIFIED WATER

**NOTE:**

*Be sure that you are familiar with the precautions found in Section 1.6.*

## 2.1 *Inducing Sweat*



### 4 INSTALL PILOGEL DISCS ON BOTH ELECTRODES

Pilogel discs have a diameter slightly larger than the inside diameter of the electrode skirt to provide a tight fit. Be sure to press firmly all around the outer perimeter of the disc to achieve uniform, air-free contact with the electrode. This may shave small slivers of gel from the outside of the disc as it is seated against the electrode. This is normal.

Do not be concerned if the Pilogel disc has a tendency to bulge away from the stainless steel electrode at the center. Attachment to the limb will flatten it against the electrode.

#### **WARNING!**

Pilogel discs should be refrigerated at 2 to 8 °C. **DO NOT FREEZE.** Never use discs that have been frozen or that are cracked.

#### **WARNING!**

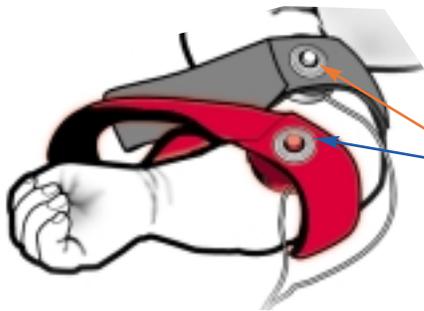
Never attach an electrode to the skin without Pilogel. Direct skin-to-metal contact will burn the patient. Refer to Section 1.6 for additional information.

## 2.1 Inducing Sweat

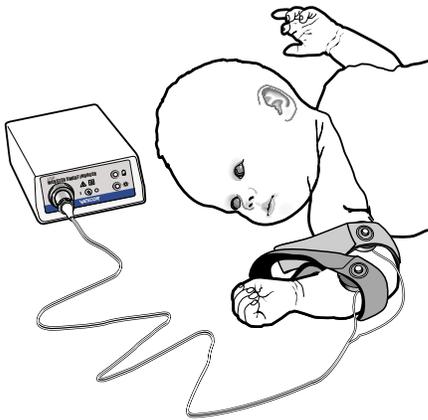
### 5 ATTACH THE ELECTRODES TO LIMB



Place each strap so that the stud of the electrode protrudes through the rivet of the strap, with the “hook” portion of the short tab facing upward, away from the skin. Secure the electrode firmly so that the gel surface is pressed flat against the skin. There should be moderate pressure to minimize discomfort, but do not tighten enough to crush the gel disc.



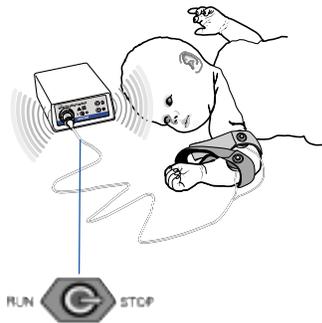
**ELECTRODE STUD**



#### NOTE:

*Individuals vary in their sensitivity to iontophoretic current. Most subjects feel nothing more than a slight prickling sensation during iontophoresis. If a child complains or if an infant shows signs of distress, tighten the strap to increase pressure against the skin.*

## 2.1 Inducing Sweat



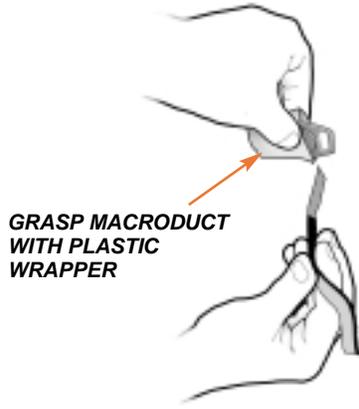
### 6 ACTIVATE IONTOPHORESIS

Push the control switch to the RUN (**I**) position and hold momentarily until you hear a short “beep.” A steady tone indicates excessive external circuit resistance, a break in the line, or weak batteries. If this occurs, move the control switch to STOP (**0**) and correct the fault condition before proceeding (Section 4).

If everything is normal, the CURRENT FLOW indicator reaches full brightness in approximately 20 seconds, and diminishes in brightness during the last 5 seconds of iontophoresis as the current is reduced to zero.

If the circuit is broken even briefly during iontophoresis, current flow ceases and the alarm sounds. If this occurs, switch the inducer to STOP (**0**). Check leads and electrodes for fissures, breaks, etc. See Section 4 for complete information.

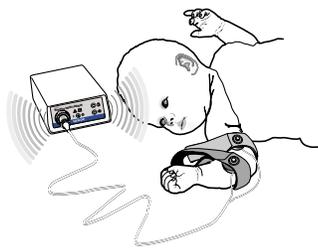
## 2.2 Collecting Sweat



**GRASP MACRODUCT WITH PLASTIC WRAPPER**

### 1 PREPARE MACRODUCT SWEAT COLLECTOR DURING IONTOPHORESIS

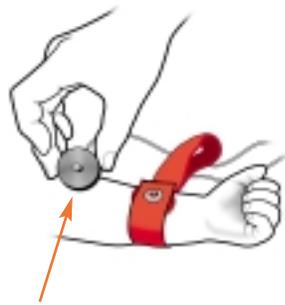
Open one end of the plastic wrapper and slide the Macroduct sweat collector slightly out of the package and thread a Macroduct strap of suitable size through one slot so that the “hook” side of the strap faces away from the Macroduct collection surface. **DO NOT TOUCH THE COLLECTION SURFACE.**



### 2 REMOVE ELECTRODES AT COMPLETION OF IONTOPHORESIS

Iontophoresis proceeds automatically for approximately 5 1/2 minutes after RUN is activated. At completion, an audible tone sounds briefly and the instrument turns itself off.

Remove the negative (black) electrode first and then clean the exposed area of skin. Before removing the positive (red) electrode, mark around the stimulated area with an alcohol-based felt marker to ensure proper placement of the Macroduct sweat collector.



**REMOVE THE BLACK ELECTRODE FIRST**

Remove the positive (red) electrode.

## 2.2 Collecting Sweat



### 3 CLEAN THE SKIN UNDER THE POSITIVE (RED) ELECTRODE

Clean the stimulated skin and the surrounding area thoroughly with purified water to remove salt, then blot dry. There should be a distinct redness under the red electrode. Proceed to Step 4 **immediately**.



### 4 ATTACH MACRODUCT SWEAT COLLECTOR FIRMLY TO LIMB

Apply the concave surface of the Macroduct collector precisely over the area of skin contacted by the Pilogel disc. (The red-dened area of skin will generally be larger than the sweat-stimulated area.)



Thread the free end of the strap around the limb and through the opening. Then tighten the strap until the collector is very firmly attached, with strap pressure pulling as evenly as possible from each end of the collector.

Check for collector displacement during attachment, and adjust if necessary.

## 2.2 Collecting Sweat

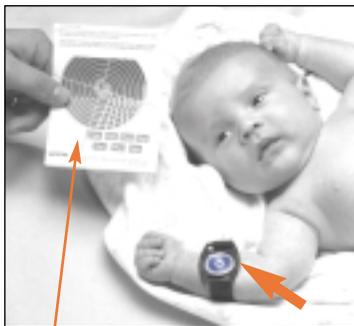
If a child attempts to disturb the collector, overwrap the device with an elastic bandage.

For neonate sweat collections, where the limbs are extremely small, overwrap the collector firmly with a 2 or 3 inch-wide elastic bandage. This ensures a continuous and firm contact between the collector and the skin, and greatly improves the probability of a successful collection.

Macroduct allows you to visually assess sweat production at any time by reference to the spiral tube calibration diagram. A 30 minute collection time usually yields 50-60 microliters of sweat, although variance among individuals is extremely wide. You can vary collection time to maximize the sweat yield, but with most individuals, very little additional sweat can be collected after 45 to 60 minutes.



**BLUE COLORED SWEAT**



**SPIRAL TUBE  
CALIBRATION DIAGRAM**

## 2.2 Collecting Sweat



**NOTE:**

*Inadequately tightened collector straps can be detected simply by pressing the collector very firmly against the skin. If the advancing meniscus of sweat in the spiral tube moves by more than 2-3 millimeters, attach the strap more firmly.*

### 5 REMOVE AND STORE SWEAT SAMPLE

**NOTE:**

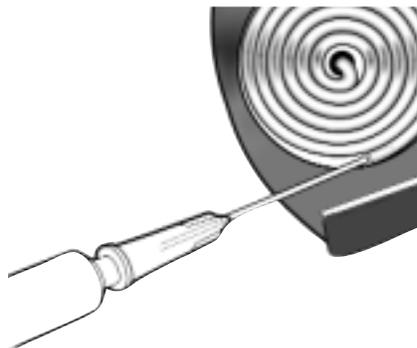
*The following procedure must be done while the Macroduct collector is still firmly strapped to the limb. Removing the complete device before detaching the tubing may create a vacuum that will draw the collected sweat from the tubing and seriously reduce sample volume.*

**FOLLOW THESE INSTRUCTIONS CLOSELY:**

**a** Remove the protective transparent cover by inserting a pointed tool into one of the cut-out sections and prying upward. (The nippers supplied with the Macroduct system will work well.)

**b** Insert the blunt needle approximately 5 mm into the open end of the Macroduct microbore tubing using a twisting motion (see illustration). Alternatively, lift the open outer end of the micro-bore tubing and pull one or two inches of the tube free from the adhesive base before attaching the tube to the blunt needle of the syringe. **Position the plunger at mid point before inserting it into the tubing.**

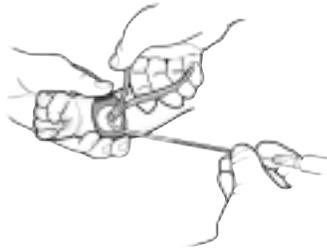
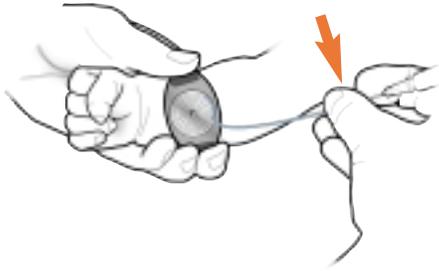
Do not squeeze the dispenser or syringe body or move the syringe plunger at any time during attachment or during the following procedure.



**USE TWISTING MOTION WHILE INSERTING BLUNT NEEDLE INTO THE END OF THE MICRO-BORE TUBING.**

## 2.2 Collecting Sweat

**HOLD THE TUBING WHERE IT ATTACHES TO THE SYRINGE NEEDLE**



**c** Grasp the tubing where it is attached to the needle and pull the tubing away from the collector body until the tubing is completely uncoiled and extending outward from the point of attachment. Use the provided nippers to sever the tube as close as possible to the collector surface.

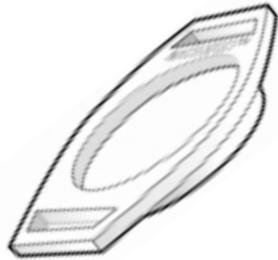
**d** Immediately after severing the tubing, carefully draw the sweat into the tube one or two inches. This is to prevent any loss of sweat from the cut end due to expansion of air in the syringe body. It also allows you to cut-off the tightly coiled end of the microbore tubing for easier handling.

**OR**

If using the Sweat Check™ Analyzer, attach the end of the tube to the Sweat Chek intake for analysis. Refer to instructions in the Sweat-Chek instruction manual.

**e** Expel the sweat specimen into the cup and immediately install the cover to protect the specimen.

## 2.2 Collecting Sweat



### 6 REMOVE AND DISCARD COLLECTOR BODY

Detach the collector body from the patient's limb. Retain the strap, and discard the collector body.



### 7 CLEAN THE ELECTRODES

Remove and discard the Pilogel discs. Clean the electrodes with purified water and wipe dry. See Section 4.2.

## 2.3 Abbreviated Instructions

**CAUTION!**

These instructions are intended for reference only. Never attempt sweat induction and collection until you have read and thoroughly understand the complete procedures detailed in the instruction manual.

- 1 ASSEMBLE EQUIPMENT AND SUPPLIES
- 2 INSPECT ELECTRODES AND CONNECT TO INDUCER
- 3 CLEAN THE SELECTED SKIN AREAS
- 4 INSTALL PILOGEL DISCS IN BOTH ELECTRODES
- 5 ATTACH THE ELECTRODES TO LIMB
- 6 ACTIVATE IONTOPHORESIS
- 7 PREPARE MACRODUCT SWEAT COLLECTOR DURING IONTOPHORESIS
- 8 REMOVE ELECTRODES AT COMPLETION OF IONTOPHORESIS
- 9 CLEAN THE SKIN UNDER THE POSITIVE (RED) ELECTRODE
- 10 ATTACH MACRODUCT SWEAT COLLECTOR FIRMLY TO STIMULATED SKIN SITE
- 11 REMOVE AND STORE SWEAT SAMPLE
- 12 REMOVE AND DISCARD MACRODUCT RESIDUE
- 13 CLEAN ELECTRODES



SECTION 3  
SWEAT ANALYSIS



### 3.1 An Overview to Sweat Analysis

The procedures described up to this point in the manual provide the laboratorian with an undiluted sweat sample. By virtue of the specific safeguards against condensation and evaporation error, the sample is fully representative of the patient's secretion and is therefore a valid specimen for analysis.

#### Sodium and/or Chloride Analysis

These are the traditional sweat test analytes. Sodium may be measured on Macroduct samples by adding an aliquot of the sweat sample (5 or 10  $\mu\text{L}$ ) to an appropriate volume of lithium sulphate diluent and directly aspirating this solution into a flame photometer that does not automatically predilute. Sodium assay in itself is not a reliable method in CF diagnosis, because there is some overlap between normal and abnormal groups. It is usually performed together with chloride, which has in the past been determined using micro-titration with mercuric nitrate, an old method that requires prohibitively large sample volumes for acceptable accuracy. In recent times coulometric titration requiring as little as 10  $\mu\text{L}$  is often used. Ion-specific electrodes can be employed but these usually require sample dilution to a point where sensitivity is compromised. A simple colorimetric method is available that requires only 5  $\mu\text{L}$  of undiluted sweat, and is not affected by the minute amount of dye that is present in Macroduct specimens.

#### Osmolality

A modern approach to diagnostic sweat analysis that is more rapid, and more sensitive is the measurement of osmolality using the Wescor Vapro® Vapor Pressure Osmometer. This instrument can provide an osmolality value on a little as 5  $\mu\text{L}$  of undiluted sweat within 1.5

minutes. Since osmolality indicates total solute concentration, which in sweat is made up almost completely of electrolytes, it provides a convenient single-measurement assessment of sweat electrolyte level. Extensive trials with hospital patients have shown that the normal range in children is approximately 50 to 150 mmol/kg and the CF patients show values in excess of 200 mmol/kg with an average of 270 mmol/kg.

#### Electrical Conductivity

Wescor's Sweat Chek Sweat™ Conductivity Analyzer was designed to measure conductivity of Macroduct collected samples. Field testing in clinics in the U.S.A and in the United Kingdom, testify to its simplicity, economy, and accuracy in the diagnosis of cystic fibrosis. The results show clearly that conductivity, osmolality, and chloride have equal capacity to distinguish between normal and CF subject groups, and are therefore equivalent as diagnostic indicators.

A detailed account of the nature of sweat conductivity, the clinical trial results, and its status in the international clinical laboratory scene is presented in the Sweat-Chek User's Manual.



SECTION 4  
MAINTENANCE AND  
TROUBLESHOOTING



## 4.1 Troubleshooting

Aside from electrode cleaning, there is no regular periodic maintenance required in the Model 3700 Webster Sweat Inducer.

If the system appears to malfunction, use the following information to identify and remedy the problem.

### SYMPTOM

### PROBABLE CAUSE/SOLUTION

Nothing happens when switch is pushed to RUN (I).

High circuit resistance (will be accompanied by an audible alarm). Completely dead batteries. Check and replace if necessary.

Low battery light comes on and alarm sounds when switch is pushed to RUN.

Low batteries. Replace batteries. See Section 4.3.

Alarm alternates from high to low pitch.

Open Circuit. Make sure the electrodes are clean and unmarked. If necessary, clean or replace electrodes. See Section 5.2.

Make sure electrodes are strapped securely to the patient's limb. If alarm continues, arrange a short circuit at the inducer connector by holding the two electrodes (with Pilogel disks installed) against each other. The Pilogel disks should be facing each other and touching. If the unit still does not operate, check electrodes and wires for open connections. If the inducer will not function with the connector shorted, return it to Wescor for service.

Alarm with steady tone.

High skin resistance. Since the inducer has a fixed limit for acceptable resistance, try using another area of skin that may offer lower resistance, or scrub the skin vigorously to remove as much dead epithelial cell material as possible. See Appendix B.

## 4.1 Troubleshooting

### **SYMPTOM**

Alarm has multiple alternating pitches, much like a siren.

### **PROBABLE CAUSE/SOLUTION**

Overcurrent indication. Do not use inducer until it has been checked. Return to Wescor for service if needed.

LOW BATTERY light flashes after iontophoresis and audio warning signal sounds.

Low batteries. Replace batteries. See Section 4.3.

If the malfunction has been traced to a faulty electrode, replacement parts can be ordered from Wescor (APPENDIX B).

If the malfunction has been traced to the electronics or cannot be isolated following the above procedures, the inducer and electrodes should be returned to Wescor for inspection and repair.

## *4.1 Troubleshooting*

**DO NOT OPEN** the case and attempt repairs during the one year warranty period except when authorized and instructed by Wescor service personnel. To do otherwise will void the inducer warranty. We strongly recommend that you return any malfunctioning unit to Wescor for service even after the warranty has expired. Repairs made by electronic technicians who are not completely familiar with the fail-safe features of this device may render such features inoperable.

Since the instrument is small enough to be shipped by airmail or UPS, factory repair service will inevitably be the fastest and least expensive method of repair.

## 4.2 Cleaning the Electrodes



Electrodes must be cleaned following each iontophoresis procedure.

- 1 Remove remaining Pilogel disc material from electrodes.
- 2 Use a cotton ball or swab with purified water to thoroughly clean each electrode.
- 3 If the electrode appears dirty after an extended idle period or will not clean with steps 1 and 2, try using a small round piece of light duty cleaning pad (such as 3M Scotch Bright™#7445) to buff the electrode surface.

### **CAUTION!**

**Never use harsh abrasives such as steel wool, sandpaper or emery cloth to clean electrodes. Never scrape electrodes with metal tools.**

### **NOTE:**

*When needed, the instrument case and electrode cable can be cleaned using a damp cloth soaked in a 10% household bleach or mild soap solution. Avoid excessive moisture to the instrument.*

### 4.3 Replacing Inducer Batteries

The battery compartment for the Webster Sweat Inducer is on the bottom of the unit. To access and replace the batteries:

- 1 Slide the battery access panel out and away from the case.
- 2 Remove the foam spacer from the end of the batteries.
- 3 Carefully remove each battery from its connectors. Dispose of batteries properly, (see below).

**NOTE:**

*Always replace both batteries at the same time.*

- 4 Insert two new 9 volt batteries (type EDA/ANSI 1604A). Be sure the batteries are correctly aligned and seated in the connectors.
- 5 Replace the foam spacer at the end of the batteries.
- 6 Replace the battery compartment lid.

#### BATTERY CARE AND DISPOSAL

**WARNING!**

Do not connect improperly, charge, or dispose of in fire. Batteries can explode or leak. Do not carry batteries loose in your pocket or elsewhere as burn injury may result.

Dispose of in accordance with applicable laws and ordinances.



APPENDIX A  
SPECIFICATIONS



## Specifications

### MODEL 3700 WEBSTER SWEAT INDUCER

<b>Power Supply</b>	2 x 9 V alkaline batteries, EDA/ANSI 1604A.
<b>Iontophoresis Current</b>	1.5 mA (automatic).
<b>Iontophoresis Time</b>	5 minutes 25 seconds maximum (automatic), at operating current.
<b>Current Control</b>	(a) Current profile-controlled, 20 second rise time, 5 second fall time. (b) Provides full current at resistance up to 20,000 ohms. (c) Fail-safe limited by circuit design.
<b>Fault Indication</b>	Audible tone.
<b>Current Flow Indicator</b>	Green LED, series-connected with the electrodes.
<b>Low Battery Indicator</b>	Amber LED.
<b>Electrode Set</b>	Jacketed stainless steel, premium-quality instrumentation lead wires, polarized locking connector.
<b>Case</b>	High impact polystyrene.
<b>Dimensions W x H x D</b>	9.3 cm x 4.5 cm x 15.5 cm (3.7 x 1.77 x 6.10 inches).
<b>Weight</b>	434 grams (0.96 lbs).



A P P E N D I X B

# SUPPLIES AND REPLACEMENT PARTS



### *Supplies and Replacement Parts*

UNIT	DESCRIPTION	CATALOG NO
1 ea.	Electrode Set (red, black)	320566
1 ea.	Red Electrode Attachment Strap	RP-044
1 ea.	Black Electrode Attachment Strap	RP-045
1 ea.	Sweat Dispenser	RP-065
1 ea.	Nippers	RP-066
1 ea.	Supply Kit (materials for 6 sweat tests) Containing: 12 ea. Pilogel Discs 6 ea. Macroduct Sweat Collectors 6 ea. Small Sealable Containers	SS-032
1 ea.	Macroduct Strap, Small (14 cm)	SS-128
1 ea.	Macroduct Strap, Medium (18 cm)	SS-129
1 ea.	Macroduct Strap, Large (25 cm)	SS-130
1 ea.	Macroduct Strap, Extra Large (39 cm)	SS-131
1 set	Macroduct Strap Set, 1 ea (Small, Medium, Large, Extra Large)	SS-132
1 ea.	Macroduct Sweat Collector	SS-142



A PERSPECTIVE ON  
THE SWEAT TEST



## *A Perspective on the Sweat Test*

The "sweat test" provides laboratory confirmation of the clinical diagnosis of cystic fibrosis. It originated in the early 1950's following the discovery that children afflicted by the disease are prone to acute hyponatremia during hot weather. This occurs because of an abnormally high salt concentration in their eccrine sweat, ranging from three to five times higher than that of normal children.

The prospect of obtaining a sweat specimen for analysis of its salt (or electrolyte) content is conceptually simple, but practical obstacles to accomplishment of the diagnostic objective have made sweat testing one of the most controversial and criticized of all laboratory procedures. This stems mainly from the fact that the test has traditionally been associated with a large number of false results, most of which fall into the equivocal (borderline) or positive range. Complications connected to sweat testing resulted in some fatalities<sup>1</sup> (in the early days), and include numerous incidences of skin burns to patients and minor allergic reactions.

Vociferous debate has raged among clinicians and researchers as to the efficacy of various sweat testing methods, often with little apparent regard for the concerns of the beleaguered individual who must actually conduct the test. As a result, the sweat test generally ranks as one of the least popular laboratory procedures that a medical technologist must administer.

The sweat test is actually a composite of three separate, sequential procedures that must be accomplished without interventional error. In order, they are (1) Sweat Stimulation, (2) Sweat Collection, and (3) Sweat Analysis. The 1959 pad absorption method of Gibson and Cooke<sup>2</sup> introduced pilocarpine iontophoresis as a preferential method of sweat stimulation, replacing the dangerous practice of sweat stimulation by induced hyperpyrexia. The method is also known as the "Quantitative Pilocarpine Iontophoresis Test," or QPIT.

Because the pad absorption method has withstood the test of time, it is considered by many to be the reference method for sweat testing. Unfortunately, the method is long and tedious, requiring many steps where human error can intervene. Laboratorians in C.F. centers who specialize in this method of sweat testing develop the requisite skills to maintain consistently accurate results; but in outlying clinics and hospitals where the test is requested only on an

## *A Perspective on the Sweat Test*

occasional basis, the chances of obtaining a false result have proven to be unacceptably high.

The need for a simpler method spawned the development of alternative procedures during the late 60's and early 70's. Principally among these were the cup-collection systems which used electrical conductivity as the analytical procedure, and the direct-skin chloride electrode system. These methods were highly innovative, were procedurally simpler than the Gibson and Cooke method and were commercially successful. They nevertheless failed in their objective to eliminate false diagnostic results. Wide adoption of the new sweat testing methods exacerbated the problem, evoking a storm of criticism in the professional literature with calls for a return to the pad absorption "reference" method.<sup>3,4</sup> In the United States, C.F. referral centers operating under accreditation of the Cystic Fibrosis Foundation were forbidden to use any sweat testing method other than the QPIT.

These early attempts to produce a simplified sweat testing system failed for two principal reasons: (1) error intrinsic to the method of collection and beyond the control of the operator, or (2) extreme susceptibility to variations in operator technique. Further progress was stymied until these factors had been fully investigated and identified through research findings published in the late 70's.<sup>5,6</sup>

In 1978, Wescor introduced the Model 3500 Webster Sweat Collection System.<sup>7</sup> Its unique, heated collection cup\* operated at a temperature slightly warmer than the skin. This prevented the condensate error that was intrinsic to all previous cup collection systems. It was the first "simplified" sweat collection method worthy of comparison to the Gibson and Cooke method, and it enjoyed considerable commercial success.

The Webster system was a significant breakthrough in the effort to develop a modern sweat collection system worthy of displacing the venerated method of Gibson and Cooke. Despite the fact that the heated cup solved the most significant problem connected to cup collection of sweat, it was nevertheless burdened by a problem common to all cup collection systems, i.e., the need to "harvest" sweat accumulated under the cup during the collection period. Wescor's commitment to resolve this problem eventually led

\*U.S. Patent No. 4,266,556

## *A Perspective on the Sweat Test*

to a significant breakthrough in the collection phase of the sweat test—the invention of the Macroduct<sup>®\*</sup> Sweat Collector.

Vested in Wescor's scientific and engineering staff is a combination of many years experience in laboratory sweat testing and in the development of modern electronic laboratory instrumentation. These professional talents were marshalled in support of the company's commitment to achieve objectives that it believed were essential to advancing laboratory sweat testing from the era of the 1950's to the present day:

- 1 Eliminate all intrinsic sources of error concomitant to previous collection methods.
- 2 Ensure impeccable accuracy in the diagnostic result by reducing human error potential to the lowest possible level.
- 3 Maximize patient safety and comfort.
- 4 Maximize operator convenience within the strictures imposed by objectives 1, 2, and 3.

During the development of the Macroduct system, Wescor's research team conducted a comprehensive and detailed review of every aspect of the sweat test, with the object of simplifying the procedure to the greatest degree possible. Laboratory research and experimentation led to a better understanding of the parameters governing stimulation by pilocarpine iontophoresis, and ultimately, to the development of a fully automatic electronic sweat inducer that requires no judgmental decisions or adjustments by the operator. A review of all currently available methods for sweat analysis was made in order to identify the procedure(s) most suitable for use with the unique new method of collection.

With the introduction of the Model 3600 Macroduct Sweat Collection System in 1983, all of the comprehensive objectives had been successfully accomplished. Paramount among the system's several unique and novel features was the innovative Macroduct disposable sweat collector.<sup>8, 9, 10, 11</sup>

\*U.S. Patent No. 4,542,751 U.K. Patent No. 2116850

## *A Perspective on the Sweat Test*

The Macroduct sweat collector preserves absolute integrity in the collected sweat specimen and gives the unprecedented advantage of visual quantitation of the volume of sweat collected at any time during the collection period. Other unique features of the system include the unique Pilogel<sup>®\*12</sup> pilocarpine reagent reservoirs that provide maximum protection from burns, eliminate the problem of "bridging," and are extremely simple and easy to use.

Macroduct sweat collection, combined with a modern, single-step, micro-analytical procedure, provides a diagnostic result having the highest confidence level in the history of laboratory sweat testing.

The Macroduct Sweat Collection System has been unequivocally approved by the U.S. Cystic Fibrosis Foundation for sweat stimulation and collection.

In keeping with Wescor's commitment of excellence, still further improvements have now been made in the Macroduct system. The new Model 3700 Webster Sweat Inducer has all of the fail-safe and convenience features of its predecessor, the Model 3600, but does not require a separate charging unit or access to AC power for recharging. It is powered by a pair of ordinary 9 volt alkaline batteries that have sufficient capacity for up to a thousand separate iontophoretic procedures.

Additional descriptive details and information covering each of the Macroduct Sweat Collection System components are found throughout this manual.

\*U.S. Patent No. 4,383,529

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A P P E N D I X D

PROCEDURE FOR  
HIGH SKIN RESISTANCE



## *Procedure for High Skin Resistance*

Almost all of the electrical resistance in an iontophoretic circuit is provided by the two skin areas involved, and is due to the relatively dry dead cell layer of the epidermis, which varies in thickness according to body position and also between individuals. When iontophoresis begins, the resistance is high, but rapidly reduces as the ducts begin to carry salt containing sweat to the skin surface. In the great majority of cases, the standard pre-cleaning procedure of a brisk rub with alcohol and water to remove excess skin oils, a vigorous wash to remove as much dead cell material as possible, and a final wetting of the involved areas just before applying Pilogel will lower resistance to satisfactory levels.

### **Special Procedure for Exceptional Resistance**

Iontophoretic shut down by the 3700 Sweat Inducer due to very high resistance is quite rare. However, the physiological literature contains many references to high resistance in certain racial types where the skin is highly pigmented. In field sweat testing, such problems could arise where children of these racial types are involved. In such cases the unusually thick stratum corneum and dryness of the skin often confers electrical resistance sufficient to shut down the circuit. In the past, with simple battery and rheostat devices, the operator could increase the applied voltage to dangerously high levels in order to overcome this resistance and reach the desired current level, thus greatly increasing the possibility of a serious burn. This is not possible with Wescor's 3700 Sweat Inducer.

Laboratories that frequently experience these high skin resistance characteristics should use a specially modified Model 3700 Inducer delivering 1.0 mA current. This allows the applied voltage to remain safely below the shut down level. The iontophoretic time on this modified Sweat Inducer is extended to 7.5 minutes to maintain the pilocarpine delivery characteristics for maximum sweat yield. **Contact Wescor for further information and to have this specially modified loan instrument sent to perform the sweat test.**



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