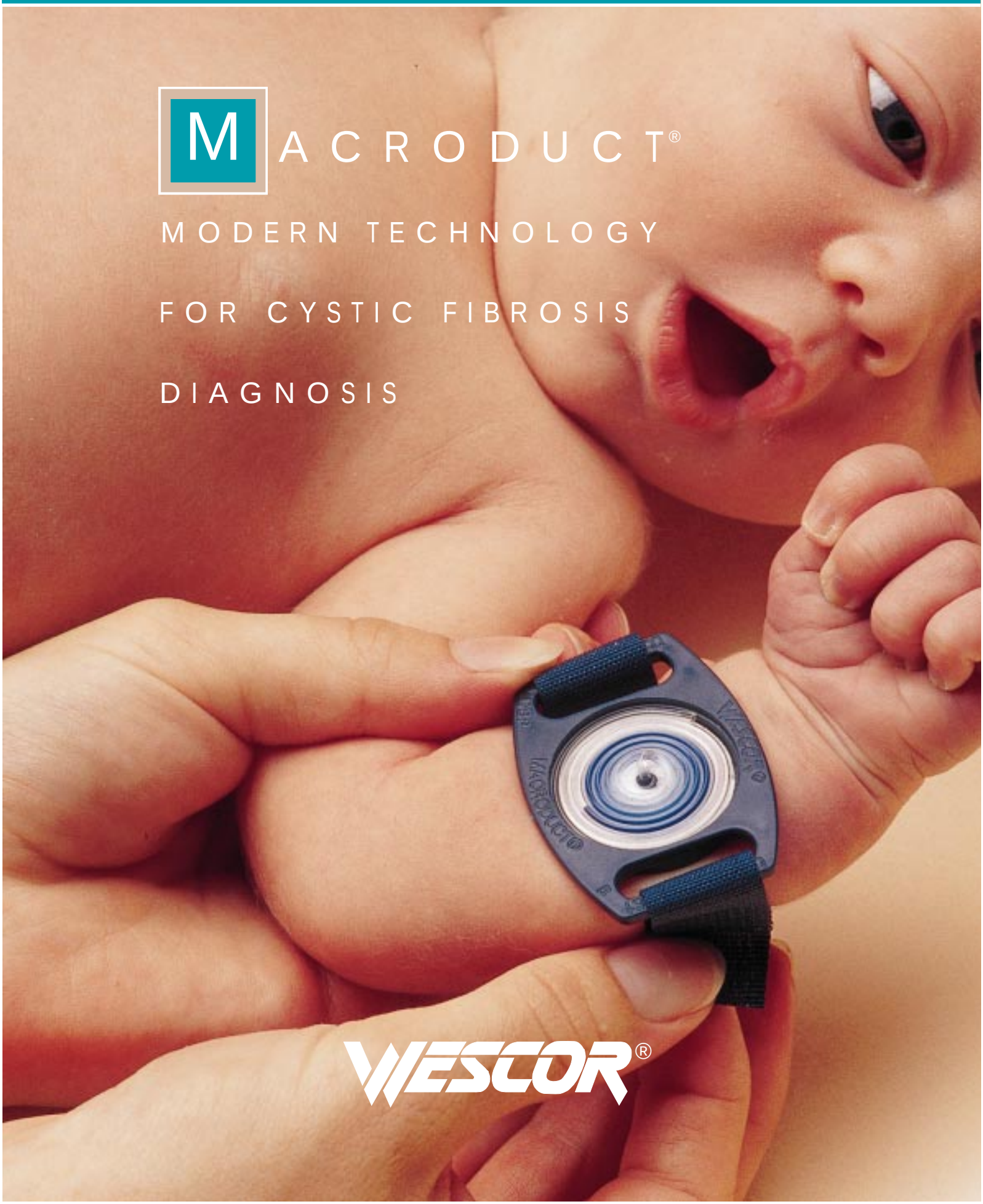
MACRODUCT®

MODERN TECHNOLOGY FOR CYSTIC FIBROSIS DIAGNOSIS



BACKGROUND

Wescor is the world leader in products for the laboratory diagnosis of cystic fibrosis. The landmark Macroduct*System has forever transformed sweat testing by eliminating the errors inherent in many previously used methods.

The sweat test has three phases: stimulation, collection, and analysis. Unfortunately, sweat testing has often produced false diagnostic results due to intrinsic errors during collection and/or human error during analysis.



"To be blunt, Macroduct and Sweat-Chek can prolong lives."

–Dr. Lewis Gibson

The 1959 pad absorption method of Gibson and Cooke,[1] which introduced pilocarpine iontophoresis for sweat stimulation is generally regarded as the reference method for sweat testing. Although relatively free of intrinsic error, the long and tedious procedures invite human error. The need for a simpler method spawned many innovations from 1959 to the mid-1970's, but these "simplified" systems actually increased the occurrence of false diagnoses and triggered a storm of criticism in the professional literature. [2,3,4,5]

Since 1978 Wescor has systematically freed sweat testing of intrinsic sweat collection errors, and achieved the lowest possible potential for human error with a series of groundbreaking innovations. The Webster sweat inducer [6] and Macroduct sweat collector [7] provide a "pure" specimen of eccrine secretion for analysis, [8] with the unprecedented advantage of visual quantitation of sweat as it is being collected. The Sweat-Chek analyzer gives a simple and accurate analysis of the specimen. Together they form the Macroduct Sweat Testing System, which has been adopted by thousands of labs worldwide. It has become the new world standard.

Macroduct makes collecting an error-free sweat sample a simple reality. Sweat-Chek makes the analytical phase equally simple and reliable. The result is that routine neonatal testing is now considered practical.[9] Dr. Lewis Gibson, originator of the pad absorption method says, "The primary reason I have advocated the Macroduct System is simply that I believe it is obvious that an accurate sweat test should be available in any hospital that admits children. Children with CF live longer if they are diagnosed early and to do this one must test a lot of children with even slightly suggestive symptoms. To be blunt, Macroduct and Sweat-Chek can prolong lives."

Macroduct is approved for sweat collection by the Cystic Fibrosis Foundation, and is rapidly replacing the pad absorption method everywhere. At last, with the complete Macroduct System, there is a method of sweat testing that is both accurate and simple.[10]

*U.S. Patent Number 4,542,751. U.K. Patent Number 2,116,850 German Patent (DBP) 33 09 273

Macroduct Sweat Collection

Model 3700-SYS, contains all components and accessories necessary for stimulation and collection, conveniently packed in a lightweight portable case.

A starter supply kit (SS-032) is included with each system.







Webster Sweat Inducer

The Webster Sweat Inducer is an improved, lightweight unit that accomplishes pilocarpine iontophoresis simply by activating a start switch. It automatically delivers a safe and optimal quantity of pilocarpine for gland stimulation (equivalent to five minutes iontophoresis at 1.5 mA).



The Model 3700 has integral fail-safe circuitry to limit the applied voltage and warn of open circuits. Current is brought up slowly to a plateau and reduced slowly at completion of iontophoresis to minimize patient discomfort. Power is supplied by two standard 9 volt batteries.

STIMULATION







Pilogel® iontophoretic discs* are unique gel reservoirs of pilocarpinium ions that bring unprecedented simplicity and safety to the iontophoretic stimulation of sweat. There are no electrolyte solutions to prepare or to keep track of, and no messy electrolyte pads that must be saturated with separate solutions. Instead, a pilogel disc is simply inserted into each of the recessed stainless steel electrodes. The discs have a rubbery consistency. They do not exude fluid under normal attachment pressures, but are nevertheless constituted of 96% water and present a “wet” surface to the skin and to the electrode.

*U.S. Patent Number 4,383,529.

Macroduct Sweat Collector

The Macroduct sweat collector is a unique disposable plastic device having a shallow, concave under-surface. The Macroduct is placed precisely over the stimulated area and firmly attached by means of a hook and loop strap.



The skin bulges into the concavity, leaving no air space between the skin and the collection surface. At the apex of the conical surface, a small aperture leads to a spiral of microbore plastic tubing.



Sweat secreted by the sweat glands is forced from the ducts under hydraulic pressure and flows between the skin and the concave undersurface of the Macroduct collector. The flow is in the direction of least resistance toward the central aperture and into the microbore spiral. A small amount (10 nanomoles) of water-soluble blue dye on the collection surface marks the advancing column of sweat for easy assessment of the accumulated volume by reference to the furnished chart.

COLLECTION









After a sufficient volume of sweat has accumulated, a sweat dispenser, or blunt needle on a tuberculin syringe, is connected to the open outer end of the tubing. The tubing is then uncoiled from the body of the Macroduct and severed at the point of attachment. The sample can then be expressed into a supplied sealable micro cup or directly into the analytical instrument.

Sweat production will vary considerably from patient to patient, but the average individual will produce approximately 60 microliters of sweat during a 30 minute collection interval. Low sweat production will be evident early in the procedure, and, if necessary, the collection can be continued for as long as one hour to maximize the sweat yield.

ANALYSIS



Sweat samples are collected in Macroduct using the normal procedure. A syringe is attached to the end of the microbore tubing before the tubing is uncoiled and severed from the collector body. The end of the microbore tube is then attached to the inlet nipple of the Sweat-Chek conductivity cell.



A separate length of clean microbore tubing is attached to the outlet nipple of the cell to act as a take-up reservoir.

The specimen is transferred into the cell by moving the syringe plunger into its barrel. When the specimen contacts both cell electrodes (less than 10 microliters are required), the conductivity of the specimen is measured, converted to equivalent NaCl molarity, and the result displayed.



The conductivity cell is temperature-controlled for stable calibration. A stable reading obtains in about 10 seconds as the specimen equilibrates to the cell temperature. The digital readout is calibrated in units of molarity (mmol/L) representing the molar concentration of a NaCl solution equivalent in conductance to that of the sample.

The specimen can be drawn back into the cell for repeat measurement, or it can be expressed into a storage cup for subsequent corroborative analysis by any microanalytical procedure including anion assay, cation assay, osmolality assay[15], or electrical conductivity if desired.

SPECIFICATIONS

Webster Sweat Inducer Model 3700

Iontophoresis Current	Profiled ramp up and ramp down, equivalent to 1.5 mA for 5 minutes (1.5 mA maximum)
Current Control	Fail-safe circuitry, controlled rate-of-change, circuit fault interrupt and alarm
Iontophoresis Electrodes	Stainless steel, recessed, color-coded
Power Supply	Two standard 9 volt batteries (ANSI c18.Im-1992)
Size and Weight	9.2 cm x 4.5 cm x 15.5 cm, 0.4 kg

To order complete sweat collection system, specify model number 3700-SYS. Consumable supplies are packaged in quantities for six (6) sweat tests. Each package contains 12 Pilogel discs, 6 Macroduct collectors and 6 sealable micro cups. Order catalog number SS-032.

Sweat-Chek Analyzer Model 3120

Minimum Sample Volume	6 to 10 microliters
Useful Range	0 to 150 mmol/L (equivalent NaCl)
Precision	2 mmol/L (equivalent NaCl) (1 S.D.)
Critical Range Linear Error	Less than 2 percent from 75 to 110 mmol/L
Warm-up Time	Approximately 2 minutes after power-up
Readout	3-digit LCD
Cell Operation Temperature	Approximately 39.5°C to ± 0.5 °C
Specimen Temperature Equilibration Time	10 seconds typical
Line Voltage (User Selectable)	115 V (100 to 120 V nominal) or 230 V(220 to 240 V nominal), 50/60 Hz
Power	Less than 10 W
Fuse	1/4 A time-delay type for 100/120 volts (2 required) 1/8 A time-delay type for 220/240 volts (2 required)
Size and Weight	10 cm x 20 cm x 16 cm, 1.0 kg

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