NEONATAL CYSTIC FIBROSIS DIAGNOSIS
Announcing Our New Arrival!!
It has become widely recognized that early diagnosis and treatment can significantly improve the quality of life and increase the lifespan of children born with cystic fibrosis. The proven diagnostic effectiveness of analyzing the concentration of electrolytes in sweat makes it vital to perform this test as soon as possible after birth. Unfortunately, this critical need has in the past been severely hampered by the tiny limbs and small sweat yields typical of neonates, resulting in frequent test failures. This combination of factors has often frustrated attempts to positively diagnose the disease at a very early age, and led many to avoid sweat testing of very young babies.

Wescor has been the leading innovator in the laboratory diagnosis of cystic fibrosis for nearly a quarter-century. The novel Macroduct® Sweat collector and its companion Sweat-Check® Sweat Conductivity Analyzer have revolutionized the sweat test and brought simplicity and reliability to a much maligned and controversial laboratory procedure due to frequent false diagnostic results. The Macroduct system is accepted worldwide as the method of choice for sweat testing in contemporary diagnostic laboratories.

The only limitation of the Macroduct Sweat Collector is that its physical size precludes use with very small neonates until their limbs have grown sufficiently to properly interface with the collecting surface. In such cases, as stated earlier, diagnosis and appropriate intervention may have been delayed, with negative consequences for the child.

Nanoduct provides an additional benefit by further simplifying the sweat test procedure. It is a complete integrated diagnostic system that induces and analyzes sweat in situ—while attached to the patient. No more worries about lost or compromised samples between collection and analysis phases, and the entire procedure can be completed in minutes with minimal disturbance to the patient.

Other innovative features of the Nanoduct system include the special electrode/sensor holders that are positioned on the patient’s limb before iontophoresis. The holders make electrode placement simple and secure. They also guarantee that the sensor collecting surface will be perfectly registered with the stimulated skin area and that the attachment pressure will be optimal when the positive electrode is replaced by the sensor.

Nanoduct incorporates the classic method of inducing sweat by pilocarpine iontophoresis. The pilocarpine is carried into the dermis of the patient from improved Pilogel® Iontophoretic discs by a controlled DC electric current supplied by the Nanoduct Inducer/Analyzer. This is followed by continuous-flow analysis of sweat electrolyte concentration using the unique conductivity sensor. Electrodes and the sensor are connected to the Inducer/Analyzer via a single control cable.
Nanoduct Neonatal Sweat Analysis System further simplifies the sweat test and for the first time makes possible reliable CF diagnosis in the first days of life.

IMPROVED PILOGEL® DISCS

- Increased pilocarpine concentration
- Iontophoresis time reduced to only 2.5 minutes
- Buffered to prevent pH changes
- Increased protection against freezing
CONTINUOUS-FLOW ANALYSIS OF ELECTROLYTE CONTENT

When the sensor is attached to the patient, the stimulated sweat emerging from the sweat glands is anaerobically directed by the conical collecting surface into a microconductivity cell within the sensor. This provides a continuous display of the electrical conductivity in the freshly emerged sweat. Conductivity has been shown to be the equal of chloride in its ability to discriminate diagnostically between CF and non-CF subjects.4,5,6,7

SEPARATE COLLECTION PHASE IS ELIMINATED

Continuous-flow analysis, while the sensor is on the limb, combines the separate collection and analytical phases and thus ends the need to handle or transport the sweat specimen. This method ensures that the conductivity result is constantly updated to represent the freshly excreted sweat arriving at the measuring cell. This has the advantage of eliminating potential handling errors, saves laboratory time, and ensures accuracy by providing virtually infinite replications of the analysis on freshly excreted sweat. A further benefit is that any inadvertent contamination of the sensor collecting surface will be dissipated before the final reading is displayed.

INITIAL SWEATING RATE DISPLAYED AUTOMATICALLY

The continuous-flow principle allows the initial sweating rate to be displayed in grams per square meter of skin surface per minute. This new feature avoids one of the major limiting factors in accepting sweat test results: the frequently-used arbitrary assignment of minimum sweat yield. As soon as sweat enters the microconductivity cell, the display alerts the operator to the presence of sweat. After a very short interval, the display reads out the initial sweating rate and gives continuous readings of real-time conductivity.

AUTOMATIC AVERAGING OF CONDUCTIVITY

For the first minute or two after stimulation, the sweat electrolyte concentration drops rapidly, then slows to a steady slow decrease. To standardize the result with commonly used reference ranges, the instrument automatically waits 3 minutes after the first display of conductivity, then commences a 5 minute averaging period, and displays the resultant average value as the reportable diagnostic result.

REQUIRED 0NL Y 3 MICROLITERS OF SWEAT!

The miniscule dimensions of the conductivity sensor allow a reading to be obtained at a minimum production of only 3 microliters of sweat, which, for reasonably mature glands usually happens within 6 minutes after applying the sensor.

SHORTER STIMULATION TIME

Pilogel iontophoretic discs have been improved to allow maximal gland stimulation after 2.5 minutes of iontophoresis at 0.5 mA total current, which is desirable both in safety and time of involvement for neonates.

NEONATE-TO-ADULT CAPABILITY

While Nanoduct is designed for neonates, it works equally well on patients of any age.
Holders attach easily to limbs

Ring-shaped holders attach firmly to the limb with easy-to-use synthetic rubber straps, and provide stable electrode and sensor cell contact with the skin. These holders accept Pilogel electrodes and the conductivity sensor at the positive electrode site. Components are easy to install and remove and the design ensures perfect registration of the conductivity sensor with the stimulated site.

Simple to use on neonates

Infant sized electrodes slip easily into the holders, thus greatly simplifying electrode and sensor attachment, as attested by clinical trials.
REFERENCES


# Nanoduct™ Specifications

## Neonatal Sweat Analysis System

### Sweat Induction Control
Current profiled for patient comfort. For use with Pilogel Iontophoretic discs and with multiple fail-safe features to limit current even in failure mode. Nominal current is 0.5 mA for 2.5 minutes.

<table>
<thead>
<tr>
<th>Current Limit (Failure Mode)</th>
<th>Maximum failure mode current limited to 5 mA with fresh battery.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Range</td>
<td>0 to 200 mmol/L (equivalent NaCl).</td>
</tr>
<tr>
<td>Initial Sweating Rate Reading</td>
<td>0.1 to 10 g/m²/min.</td>
</tr>
<tr>
<td>Calibration</td>
<td>Single point automatic calibration at 80 mmol/L (equivalent NaCl).</td>
</tr>
<tr>
<td>Power Supply</td>
<td>One 9.0 volt Lithium battery (Alkaline battery can be used). 100 milliwatt power use during operation. Lithium batteries are good for approximately 300 tests.</td>
</tr>
<tr>
<td>Readout</td>
<td>128 x 64 dot graphic display with multi-lingual support.</td>
</tr>
<tr>
<td>Audio Signals</td>
<td>ALERT and ALARM audible signals.</td>
</tr>
<tr>
<td>Keyboard</td>
<td>ON, OFF, SELECT, and ENTER keys.</td>
</tr>
<tr>
<td>Connection</td>
<td>5 pin connector to mate with induction/conductivity cell cable.</td>
</tr>
<tr>
<td>Operating Temperature</td>
<td>13 to 30 °C.</td>
</tr>
<tr>
<td>Storage Temperature</td>
<td>0 to 60 °C.</td>
</tr>
<tr>
<td>Physical</td>
<td>Housed in a portable carrying case with storage compartment for supplies. and handle for ease of carrying.</td>
</tr>
<tr>
<td>Height X Width X Depth:</td>
<td>16 cm x 23 cm x 33 cm.</td>
</tr>
<tr>
<td>Weight</td>
<td>Less than 2.25 kg.</td>
</tr>
</tbody>
</table>

## Buyer’s Specifications
The neonatal analyzer shall be a Wescor Nanoduct™ Neonatal Sweat Analysis System and shall use pilocarpine iontophoresis for sweat induction and employ continuous-flow analysis of sweat conductivity to produce a diagnostic result.