

IMPROVING LIVES THROUGH EARLY DIAGNOSIS

NANODUCT® NEONATAL SWEAT ANALYSIS SYSTEM

For clinical laboratory use for stimulation, collection and analysis of sweat from humans for the diagnosis of cystic fibrosis.

NANODUCT NEONATAL SWEAT ANALYSIS SYSTEM

Nanoduct is a complete, integrated system for inducing and analyzing sweat for cystic fibrosis (CF) diagnosis—all while attached to the patient. This enables pristine samples to be obtained from neonates and analyzed in situ.

AUTOMATIC AVERAGING OF CONDUCTIVITY

As sweat enters the microconductivity cell, the initial sweating rate is displayed, followed by a continuous reading of real time conductivity. After three minutes, the Nanoduct commences a 5 minute averaging period, then displays the resultant average value as the reportable diagnostic result.

SMALL SAMPLE SIZE AND SHORTER STIMULATION TIME

The miniscule conductivity sensor provides a reading using only 3 microliters of sweat. Pilogel iontophoretic discs yield 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.

COMPACT HAND-HELD UNIT

Nanoduct's trim, hand-held case simplifies handling, set-up, and operation.

NEONATE-TO-ADULT CAPABILITY

While the Nanoduct is designed for neonates, it works equally well on patients of any age.



It is vital to perform a sweat test as soon as possible after birth. With Nanoduct it becomes extremely simple and reliable.

Early diagnosis and treatment can significantly improve both the quality of life and the lifespan of children born with cystic fibrosis.

The proven diagnostic effectiveness of analyzing electrolyte concentration in sweat makes it vital to perform this test as soon as possible after birth.

GROUND BREAKING INNOVATION BASED ON PROVENTECHNOLOGY

The Nanoduct Neonatal Sweat Analysis System combines and miniaturizes the proven collection and analysis technologies of legacy ELITechGroup systems to accommodate the tiny limbs of newborn infants, and provides reliable laboratory diagnosis of CF as soon as a newborn's sweat glands are capable of producing sweat.

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 is perfectly registered with the stimulated skin area and attachment pressure is optimal when the sensor is attached.

Nanoduct incorporates the classic method of inducing sweat by pilocarpine iontophoresis. The pilocarpine is carried into the dermis of the patient from Pilogel® lontophoretic Discs by a controlled DC electric current supplied by the Nanoduct System.

This is followed by continuous flow analysis of sweat electrolyte concentration using the unique conductivity sensor.

Electrodes and the sensor are connected to the Nanoduct System via a single control cable.

The Nanoduct Neonatal Sweat Analysis System simplifies the sweat test and for the first time makes possible reliable laboratory diagnosis of CF in the first days of life.

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 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.

SEPARATE COLLECTION PHASE IS ELIMINATED

Continuous-flow analysis while the sensor is on the limb eliminates potential handling errors, saves laboratory time, and ensures accuracy by providing virtually infinite replications of the analysis on freshly excreted sweat. A further benefit: any inadvertent contamination of the sensor collecting surface will be dissipated before the final reading is displayed.

PILOGEL® DISCS

- Increased pilocarpine concentration
- Iontophoresis time reduced to only 2.5 minutes
- Buffered to prevent pH changes, enhancing safety

Nanoduct® Neonatal Sweat Analysis System Model 1030

| Readout | 128 x 64 LCD graphic display (non-backlit); Supports up to 8 lines of 18 characters or numerals, with multi-lingual support (English, French, German, and Spanish) |
|-------------------------------------|--|
| Sound | Alert and alarm signals |
| Keyboard | ON, OFF, SELECT and ENTER keys |
| Electrode Connection | 6-pin locking medical connector to mate with induction/conductivity cell cable |
| Serial Outputs | RS-232 (ASCII format) 9-pin D-sub male connector; USB – device Type B receptacle |
| Electrical | Four AA Alkaline batteries (NEDA 15A, IEC LR6); Typical solid- state, over-current circuit protection; 3.0 VDC lithium coin cell for the real-time clock |
| Sweat Induction Control | Current profile controlled for use with Pilogel Iontophoretic Discs with multiple fail-safe circuits to limit current; Nominal current is 0.5 (± 0.02) mA for 2.5 minutes (± 0.2 Sec.); Maximum fail-safe current limited to 5 mA. |
| Real-Time Clock | ± 2 minutes per year (battery backed) |
| Operating Temperature | 15 to 30 °C (59 to 86 °F) |
| Storage Temperature | 0 to 60 °C (32 to 140 °F) |
| Instrument (H x W x D) | 7.5 x 5 x 2 in (19.1 x 12.7 x 5.1 cm) |
| Weight | 1.2 lb (0.5 kg) |
| Carrying Case | 13.5 x 10.5 x 4 in (34.3 x 26.7 x 10.2 cm) |
| Sweat Analysis Conductivity Readout | mmol/L (equivalent NaCl) |
| Conductivity Range | 3 to 200 mmol/L |
| Precision | CV ≤ 1% from 25 to 150 mmol/L (equivalent NaCl) |
| Initial Sweat Rate | 0 to 50 g/m²/min |
| Calibration | Single-point automatic calibration at 80 mmol/L (equivalent NaCl) using the AC-081 Calibration Plate |

| Catalog Number | Description |
|----------------|--|
| SS-043 | Nandoduct® Supply Kit, Qty 6 |
| SS-231 | Nandoduct® Conductivity Sensor Cell, Qty 1 |

Not available for sale in the European Union



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