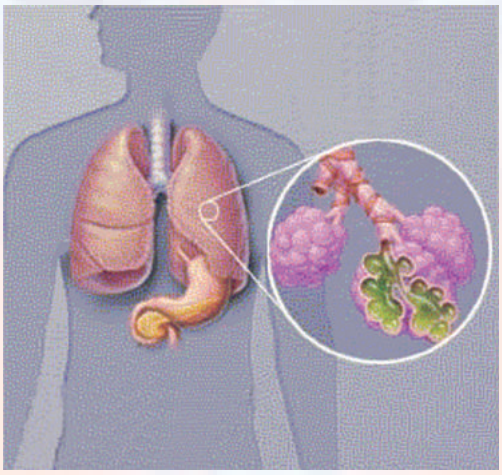
# In the Struggle Against Cystic Fibrosis...

## NEONATE, INFANT, PEDIATRIC AND ADULT



## Sweat Chloride Analysis System

### Coulometric End Point Methode



# CF Δ Collection System

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# GOLDEN STANDARD IN CYSTIC FIBROSIS DIAGNOSIS

This is a quick and easy test used since 1959, in the diagnosis of Cystic Fibrosis for symptomatic patients.

Cystic fibrosis is a hereditary (genetic) disease that passes from the mother or the father through the genes; and which is seen in the lungs, pancreas, intestines, sweat glands, external excretion glands

Cystic Fibrosis can affect multiple systems or organs such as the respiratory system or the digestive system at the same time. Fibrosis, which is seen with birth, can cause functional disorders due to the result of this interaction.

In cystic fibrosis patients, the thin and viscous fluid from the excretory glands, which allows for lungs to stay clean, will become denser and its fluidity will decrease. This situation, which makes the discharge of mucus difficult, will cause the small air pathways to become clogged. The clogging of these channels will cause ailments such as bronchitis, pneumonia, cough and wheezing. Cystic fibrosis, which causes children to be underdeveloped and their growth to be halted, will also cause problems in the sweat glands, which will induce dehydration in the body.

The purpose of the sweat test is to diagnose the presence of the cystic fibrosis disease in the patient. The sweat test method is an exceptionally simple as well as a very safe method. For the diagnosis of cystic fibrosis, the application of the sweat test is sufficient. The definite diagnosis is made by identifying high levels of chlorine in the sweat test.

## Sweat Test Application Area

Sweat test is usually applied in the arm, above the wrist; but with neonatal babies and with weak children, it can also be applied at the lower calf area.

## How to do the Sweat Test

The test includes the stages of accumulating the sweat by sufficiently sweating a certain portion of the skin and then quantitative measuring chloride concentration in the sweat. The duration of sweat accumulation period will change according to the patient.


*Pilocarpine gel will stimulate the sweat glands to induce sweating.*

## UCF 2010 Iontophoresis Unit:

The unit has been manufactured; keeping patient safety and usage comfort foremost with the principle of microcontroller managed working system.

### Error, Warning and Alarm Messages on the LCD Screen

✓ **Open Circuit:** It shows that the electrodes do not have a proper contact with the skin and that there is a disconnection in the cables. The unit will stop working.

✓ **Short Circuit:** It is understood that the electrodes are in contact with each other. Since the unit is protected against short circuit, it will automatically protect itself by turning off.

✓ **Low Battery:** Battery value is below 6 volts. It requires changing.

✓ **Dirty Contact:** It shows that the contact surfaces of the electrodes are dirty. In this situation, the skin needs to be cleaned thoroughly.

✓ **High Current:** It shows that the unit had a technical problem. If the same message is repeated, then you must contact technical service.

When the unit starts working, the UCF 2010 Iontophoresis unit's microprocessor will do a self test of the power source to start the system.

The system will automatically perform a checking of normal resistance mode and high resistance mode; and it will start up according to the mode selected as based upon the self check.

While minor skin reddening is an unpleasant side effect of Pilocarpine Iontophoresis; these types of burns and chafes have been placed under control by the microcontroller and the software inside, to eliminate any risk of burn.

Hardware managed flow control is handled through the microcontroller in the UCF 2010 unit.

Any skin burns related to current have been eliminated and it has been kept at a level of Pilocarpine induced temporary reddening.


## CF Δ Collection System

# Sweat Test

## SWEAT COLLECTION SYSTEM

A disposable CFΔ collector sweat collection apparatus with a concave surface will be placed on the region, which has been stimulated by the Pilocarpine Iontophoresis method (Figure 1).

Figure 1

Figure 2

The pure sweat shows its presence by becoming colorful in the capillary tube (Figure 2). Once the sufficient amount is collected (at least 2-3 spirals /17-29 uL / must have color), it will be transferred to the sweat analysis unit for measurement. The sodium and the chlorine concentration in the collected sweat are used for the diagnosis of cystic fibrosis.

## UCF 2011 SWEAT ANALYSIS UNIT

The processes which are conducted through the menu can be followed up from the microprocessor controlled digital screen.

Once the patient is given an ID number through the unit, the sweat sample is automatically carried (absorbed) with the peristaltic pump mechanism and the measurement takes place in the measurement compartment. The cleaning and the resetting functions after the measurement process are performed automatically through the menu system.

The memory of the unit has a capacity of 1000 patients and it can be integrated into the hospital information

System (HIS) via USB.

From the menu, three levels of linearization and calibration validation will be performed.

## CF Δ Collection System

# CF Δ Collection System

## TECHNICAL SPECIFICATIONS

### UCF 2010 Iontophoresis Unit

| | |
|---|---|
| **Power** | 1 x 9V Alkaline Battery, EDA/ANSI Duracell 1604A |
| **Iontophoresis Current/Duration** | Automatic microprocessor control;<br>a) at normal resistance mode 1.5 mA - 5 minutes<br>b) at high resistance mode 1.0 mA - 7.5 minutes |
| **Current control** | a) Current characteristics, first 20 seconds increasing, last 10 seconds decreasing<br>b) 0-150 Kohm working interval<br>c) Microcontroller based continuous safety control |
| **Error display** | Audible and visual warning |
| **Current Display** | Current and timing duration observation on the LCD |
| **Low Battery Warning** | Text alert and warning with an alarm sound on the LCD |
| **Electrode Kit** | Passed through a biocompatibility test with stainless steel electrode surfaces and cables (color coded),with lockable micro jack socket connector to the device |
| **LCD Screen** | 2x8 characters (Language options: Turkish, English) |
| **Device / Box** | ABS |
| **Dimensions** | 85 x 155 x 30 mm |
| **Weight** | 228 gr |

### UCF 2011 Sweat Analysis Unit

| | |
|---|---|
| **Power** | 85-264 VAC, 50 - 60 Hz, 10W, M-1A |
| **Minimum Sample Volume** | 4.1 - 6 microliters |
| **Measurement Interval** | 0-220 mmol/L sweat $Cl^-$ + 0 - 250 mmol/L (equivalent NaCl) |
| **Measurement Methode** | Coulometric end point |
| **Precision** | CV < 0.01 |
| **Linearization error** | ± 0.1 mmol/L |
| **Measurement Temperature** | 39.5 °C ( ± 0.1°C) |
| **Reference Calibration** | Standard NaCl solution |
| **Measurement Cell Heating Duration** | 2 minutes after the device swicht on (at 25°C) |
| **Calibration Validation** | Single point 90mmol/L (equivalent NaCl) |
| **Linearization Validation** | Three points 40mmol/L, 70mmol/L and 130mmol/L (equivalent NaCl) |
| **Error display** | Audible and text based warning on the LCD screen |
| **Port Exit** | USB 2.0 device, Type B receptacle |
| **Keyboard** | 16 key options, numerical /alphanumerical |
| **LCD Screen** | 128x64 pixel BLUE NEGATIVE graphics (Language options; Turkish, English) |
| **Device / Box** | ABS |
| **Dimensions** | 228 x 220 x 105 mm |
| **Carrying Case** | 405 x 300 x 140 mm |
| **Weight** | 1150 gr |

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