NANODUCT®
Patient Simulator
AC-111

Instruction Manual

PRINT-0175-02A

Wescor and Nanoduct are trademarks of Wescor, Inc.

Other trade names used in this manual may be trademarks of their respective owners, used here for information only.

U.S. Patent Number 6,198,953.

All information in this document is subject to change without prior notice.

section

1 INTRODUCTION

1.1 Customer Service 3
1.2 System Description 4

section

2 OPERATING THE NANODUCT PATIENT SIMULATOR

2.1 Setup 13
2.2 Operation 14
2.3 Cleanup 17
2.4 Battery Replacement 19

section

3 TROUBLESHOOTING

3.1 Troubleshooting 23

APPENDIX A

Specifications 27

APPENDIX B

Supplies 31

SECTION 1

INTRODUCTION

1.1 Customer Service

Wescor is prepared to help you resolve any difficulty with the operation or performance of this device. If you are unable to solve a problem using the procedures described in this manual, please contact us.

Customers should contact Wescor by telephone, fax, or e-mail. Outside the U.S., many of our authorized dealers offer customer service and support.

TELEPHONE

435 752 6011

Extension
- 0 - Operator
- 171 - Orders
- 172 - Service
- 173 - Product Information and Pricing

TOLL FREE (US and Canada)

800 453 2725

Extension
- 0 - Operator
- 171 - Orders
- 172 - Service
- 173 - Product Information and Pricing

FAX
435 752 4127

E-MAIL
service@wescor.com

WEBSITE:
www.wescor.com/biomedical

MAILING ADDRESS:
Wescor, Inc
Biomedical Products Division
459 South Main Street
Logan, Utah 84321-5294
USA

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

EC REP

MT Promedt Consulting GmbH
Altenhofstraße 80
D-66386 St. Ingbert, Germany
Tel. +49 6894 581020
Fax +49 6894 581021
email info@mt-procons.com

1.2 System Description

Intended Use
The Nanoduct Patient Simulator is used as an accessory to the Nanoduct system by hospital or clinical personnel. The simulator allows measurements of prepared electrolyte solutions to be analyzed by the Nanoduct Neonatal Sweat Analysis System with the same degree of accuracy and in a similar manner to the total electrolyte concentration measurements made on the sweat from actual patients for the diagnosis of Cystic Fibrosis.

Nanoduct Inducer/ Analyzer

Patent Simulator

1.2 System Description

Overview

The Patient Simulator is a small DC-powered benchtop accessory with a receptacle where a standard Nanoduct Sensor can be located and locked into position. It is powered by a universal DC adapter, or can be powered by two standard 9 Volt batteries when Mains voltage is not available or convenient. An electronic circuit heats the sensor and holds it at approximately 31.5 degrees Celsius, simulating human body heat. When a liquid sample is introduced through the port on the front of the simulator, it enters the Nanoduct sensor through the apex of the bottom collector surface, just as a sweat sample from a patient would enter. The excess fluid from the sensor exit port runs into the waste collection pad and is easily cleaned using the provided tools.

The Patient Simulator can be used to measure unknown samples as part of a proficiency study or correlative experiments or to verify or validate the function and accuracy of the Nanoduct instrument. It is not intended to be a replacement for or alternative to the stable electronic calibration and control standards provided with the Nanoduct, which are less susceptible to degradation and human error, which can easily be verified to traceable standards, and which provide certainty about the function and accuracy of the Nanoduct electronic circuits. However, the simulator, used in conjunction with the calibration and control standards, allows independent confirmation of the Nanoduct's function, sample testing of the disposable Nanoduct sensors, and easy correlation with other analysis methods.

1.2 System Description

FRONT VIEW

1.2 System Description

INSTRUMENT TOP AND FRONT

Sensor Retaining Arm and Shroud
This is used to hold the Nanoduct sensor in place during simulation. The retaining arm is locked in place using the lever on the right side of the Simulator (see Right Side, below). The shroud helps minimize the effects of ambient air currents.

Sensor Receptacle
The raised round surface is designed to accept the Nanoduct sensor. The round hole at the bottom of the raised area is designed to accept waste collection pads to absorb excess fluid from the sensor output.

Ready Indicator
This LED indicator glows green when the Simulator has reached the acceptable temperature range (usually within 2 to 5 minutes of power-up when using the AC adapter. When using DC it depends of the state of the batteries).

Power Indicator
This LED indicator glows yellow when power is applied or flashes yellow to indicate that batteries need to be replaced (battery mode only).

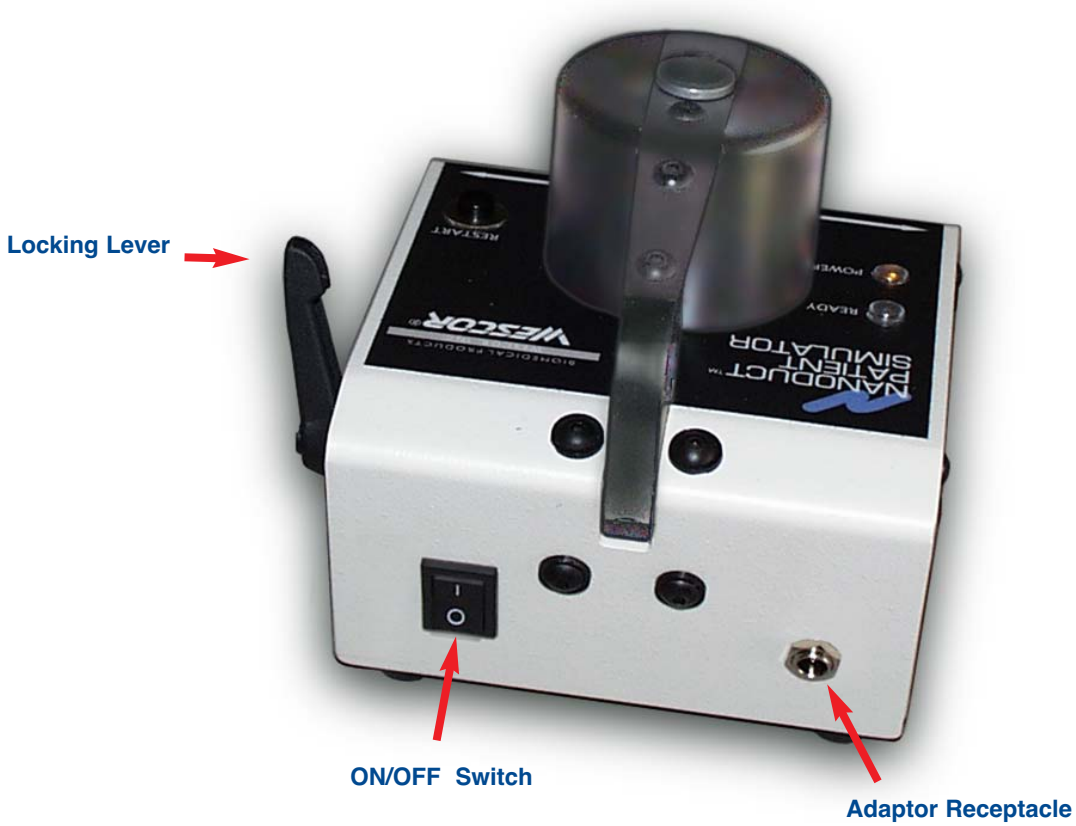
Restart Button
The instrument has an automatic shut-off at about 10 minutes to preserve battery life. Pressing the reset button renews this period and can be used to allow the instrument to reach optimum operating temperature inside the sensor cell.

"Tubing Fill Length" Scale
This graphically indicates the approximate length of tubing that should be filled with sample for optimum simulation results.

INSTRUMENT FRONT (LOWER)

Tubing Input
The input nipple accepts the microbore tubing attached to the syringe for injecting sample solution into the Simulator. **Note: Some Simulators have the rectangular shield shown at left.**

1.2 System Description



1.2 System Description

RIGHT SIDE

Locking Lever

While pressing down on the top of the shroud with fingers on each side of the retainer button (avoid pressing on the retainer button), rotate the lever up and towards the back of the Simulator to lock the mounted sensor assembly into the Simulator.

INSTRUMENT REAR

ON/OFF Switch

I = ON

0 = OFF

Universal DC Adapter Connector

Used to connect the Simulator to a universal DC power adapter.

Other Equipment and Supplies

Sensor (standard Nanoduct supply item)

The base of the sensor is a shallow concavity leading at its center to an entry port, and from there to an internal fine channel passing by two analyzer micro-electrodes, forming a microconductivity cell.

Sensor Socket (part of the Nanoduct System)

The socket on the cable connects the electrode/sensor cable assembly to provide electrical current for sweat stimulation and to receive sensor signals to the analyzer module during the analysis phase.

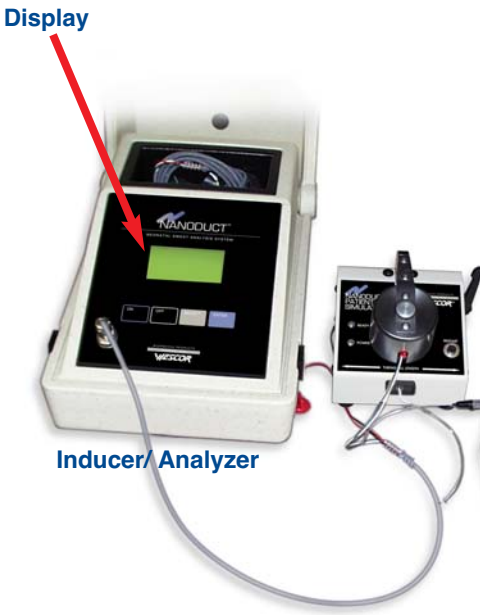
Cleaning Adapter

The adapter is clamped into the Simulator in place of the sensor to allow the Simulator to be cleaned.

Note:

To preserve battery power when operating in battery mode, leave power off except while performing a test, (after the Average Conductivity is displayed and recorded). In addition, the Simulator shuts own automatically after approximately 10 minutes and must be turned on again to complete testing or retrieve a result.

1.2 System Description



Note:
The following are features of the Nanoduct Inducer Analyzer and not the Patient Simulator and are presented to allow effective use of the Simulator. Refer to the Nanoduct Neonatal Sweat Testing System User's Manual for more information.

DISPLAY (Nanoduct Inducer/Analyzer)
The LCD alphanumeric read-out displays all functions and results as they occur, including iontophoresis status and analysis results. The user responds to prompts on the display to activate various functions. The instrument emits a short beep once iontophoresis is complete.

The instrument displays concentration measurements in mmol/L (equivalent NaCl) during analysis. The concentration display is factory calibrated for a standard NaCl solution at 31.5 °C which has been established as the average temperature reached by the sensor microconductivity cell after 3 to 4 minutes in place on the patient's arm, calibrated to equivalent resistance.

LOW BATTERY Indicator (Nanoduct Inducer/Analyzer)
If the battery voltage drops below a preset level as the instrument is turned on, the Low Battery indicator appears on the display accompanied by a warning tone. When this indicator first sounds you can usually complete 1 to 2 tests before a dead battery is indicated. If the battery is too low to complete a test, the module will automatically shut off and iontophoresis cannot be started. You must replace the battery to continue. See Section 4.3 for information.

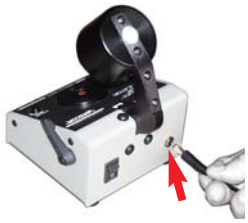
Note:
The inducer/analyzer is powered by one 9 Volt cell, which should provide a minimum of 150 tests with a standard alkaline battery or 300 tests with a lithium battery.

SECTION 2

OPERATING THE PATIENT SIMULATOR

2.1 Setup

1 Place the Simulator and the Nanoduct Inducer/Analyzer on a suitable lab bench, cart, or table. Place the units away from strong drafts in a room with normal ambient temperatures.

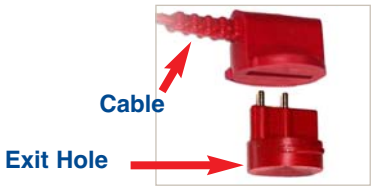


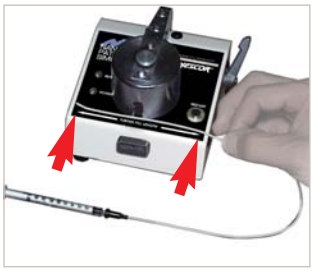
2 If using the DC adapter, plug the adapter into the Simulator using the receptacle on the back of the unit. Plug the adapter into a suitable AC outlet. (90 to 240 V).

3 Turn the Simulator ON using the rocker switch on the back. The yellow POWER LED on the front panel indicates that power is on and the green LED ready light indicates when the acceptable temperature range has been achieved (usually within 2 to 5 minutes when using the AC power adapter, DC power will vary according to battery life). A flashing POWER light indicates a low battery condition and will require replacement within a few more tests.

4 Place a waste collection pad in the hole on the lower part of the sensor mounting ring.

2.2 *Operation*





1 Snap a standard Nanoduct sensor into the sweat analysis connector of the Nanoduct with the exit hole on the same side as the cable.

2 Attach a #22 blunt needle to the 1 mL syringe. Attach the provided length of microbore tubing to the blunt needle.

NOTE
An ampule organizer (AC-071) is available for holding sweat control ampules. See Appendix B.

3 Open the sample to be measured and immerse the end of the microbore tubing in the sample fluid.

4 Draw the sample fluid into the microbore tubing about 3.5 to 4.5 inches (about 90 to 115 mm). Sample volume should be about 35 microliters. The suggested tubing fill length is represented at the bottom of the front panel of the instrument to allow you to gauge the needed sample volume. If necessary, smaller volumes can be used.

5 Inspect the sample in the tubing for bubbles. Bubbles in the sample tubing will cause erratic readings. There must be at least 1 inch of bubble free sample near the free end of the tubing. If there is not a sufficient length of bubble-free sample, you must carefully repeat the process of drawing sample into the tubing until you achieve a sufficient length of bubble-free sample.

2.2 Operation

6 Draw a few millimeters of air into the end of the tubing, then attach the free end of the tubing to the simulator input nipple on the front of the device.

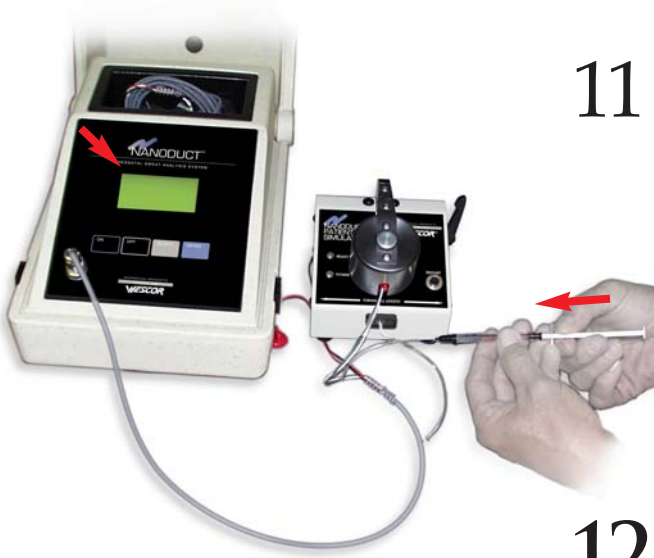
7 Turn the Nanoduct Inducer/Analyzer ON. Move the cursor to “Sweat Testing” on the display and select it by pressing ENTER. Select “Display Results” by pressing ENTER.

8 Check that the green READY light is on. If it is not on, wait until it is lit. Then press RESTART to extend the warming time for approximately 10 minutes.

9 Place the mated sensor and and connector into the receptacle of the Simulator with the cable and exit hole on the bottom side of the sloped platform.

10 Press the sensor retainer and shroud down firmly over the sensor assembly (avoid pressing on the center button by placing a finger on each side of the but ton) while locking the cup with the locking lever on the side of the Simulator (move lever clockwise to lock).The center button will be raised above the body of the cup when it is correctly locked.

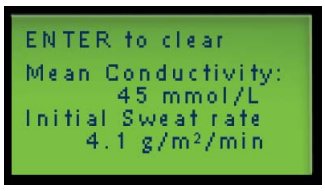
2.2 Operation



11 Use the syringe plunger to push the sample fluid slowly into the Simulator while observing the display on the Nanoduct. Continue moving the sample column until the Nanoduct reading is relatively stable.

NOTE
The reading will “drift“ by a few mmol/L as the the sample equilibrates to temperature, but should not jump between 0 and a much higher reading.

12 Use a hemostat to clamp off a portion of the microbore tubing containing the liquid sample. This prevents thermal changes in the air of the empty syringe from drawing back from or pushing the sample completely through the sensor.



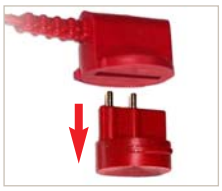
13 Wait for the Nanoduct to complete the sweat test (approximately 8 minutes). Record the reading.

NOTE
To perform additional measurements, remove used sensor cell (press down on holder as in Step10 and release the locking lever), remove the hemostat and install a new take-up tube. Perform cleaning procedure (Section 2.3) then repeat steps 1-13 of this section.

14 When the last measurement is complete, turn the Simulator OFF.

NOTE
The Simulator turns itself off automatically after about 10 minutes unless the restart button is pushed.

2.3 Cleanup

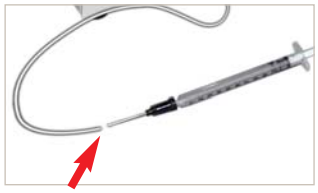


1 Remove the used sensor assembly from the Simulator by pressing down on the holder assembly as explained in Section 2.2 (Step 10) and moving the locking lever counter-clockwise to release the retainer cup.

2 Remove the used sensor from the Simulator by unsnapping it from the connector. Then discard the used sensor.

3 Remove and discard the small round waste collection pad.

4 Wipe the seat of the Simulator clean with deionized water, then dry it using a cotton swab.



5 Remove the blunt needle from the microbore tubing (leaving it connected to the Simulator). **Make sure the hemostat clamp has been removed from the attached tubing.** Attach a new length of tubing to the needle.

6 Make sure that the 1 mL syringe is still dry and uncontaminated, then retract the plunger at least halfway. Draw up about 7 inches (180 mm) of deionized water into the new tubing.

2.3 *Cleanup*

7 Attach the free end of the new tubing to the nipple of the cleaning adapter.

8 Place the cleaning adapter in the receptacle of the Simulator in the sensor position. Lock the retainer cup in place.

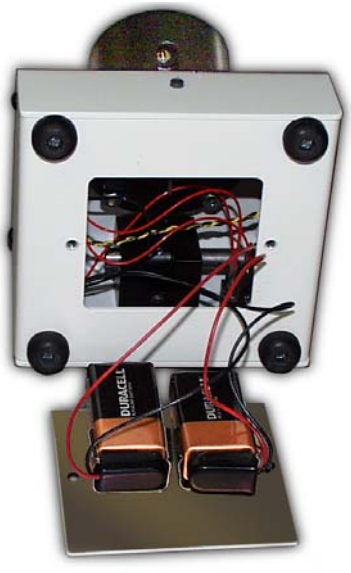
9 Push the deionized water through the system until the air in the tubing reaches the Simulator retaining cup. Work the water back and forth a few times with the plunger. Then push the plunger completely down to expel all the remaining water with a burst of air.

10 Replace the 1 mL syringe with the 10 mL syringe and purge the Simulator with air. Fill the 10 mL syringe with air and push the air through the Simulator. Repeat at least 3 times. Remove the blunt needle from the 10 mL syringe after each purging in order to refill the 10 mL syringe with air.

11 Place a new waste collection pad in its holder below the sensor receptacle.

2.4 Battery Replacement

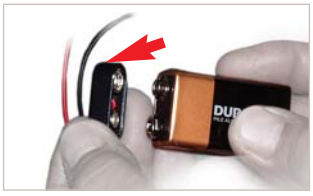
When used in battery mode, the Patient Simulator is powered by two 9 volt batteries. The batteries are mounted internally on a removable plate under the unit. To replace the batteries:



1 Completely loosen the two captive screws from the bottom plate.

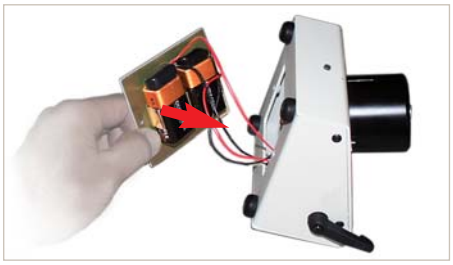
2 Remove the bottom plate with the batteries attached.

3 Remove and discard (see following page) both spent batteries.

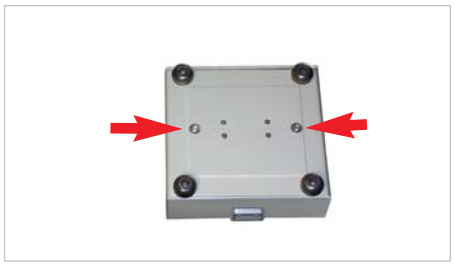


4 Insert 2 new 9 volt batteries (type NEDA/ANSI 1604A). Be sure the batteries are correctly aligned and seated in the connectors.

2.4 *Battery Replacement*



5 Replace the bottom plate, taking care to place batteries and all wires inside the simulator.



6 Tighten the bottom plate screws.

NOTE:
If the instrument will be unused for an extended time, remove the batteries. Batteries can leak and damage terminals.

Battery Care and Disposal

WARNING!

Do not connect improperly, charge, or dispose in fire. Batteries may explode or leak. To prevent burn injury, do not carry batteries loose in your pocket.

Dispose of batteries in accordance with applicable laws and ordinances.

SECTION 3

TROUBLESHOOTING

3.1 Troubleshooting

The Patient Simulator requires no routine maintenance except for cleaning as described in Section 2 and/or replacement of batteries when necessary. There are no user-serviceable parts.

SYMPTOMS	PROBLEM/SOLUTION
Temperature “ready”light does not come on.	AC adapter not properly plugged in. Dead batteries (without AC adapter). Possible calibration change. Contact your dealer or Wescor Service for calibration information.
Change in performance.	Check for stable ambient temperature: no cold drafts or excessive heat from other equipment.
Unexpected high reading when using control solutions.	Alternate conductivity path/damage to Simulator’s sensor receptacle. Contact Wescor Service.

APPENDIX A

SPECIFICATIONS

Power	7.5 to 14 Volts. 
	Current less than .4 Amps during peak heating. Jack for external power supply: 12 V AC/DC adapter provided.
	Internal connections for two standard 9 Volt batteries (NEDA/ANSI 1604A). Auto shut off after 10 minutes. Can be extended by Restart push button.
Temperature	Holds liquid sample at 31.5 °C ± 1 °C.
Keyboard	ON, OFF switch and RESTART button..
Regulatory	Meets EN 61326 Standards for EMC compatibility. Meets IEC 60601 standards for safety. Manufactured under Wescor's quality system (ISO 13485). Bears the CE mark as a Class IIa medical device. Certificate issued by BSI 0086.
Size	Approximately 11.43 cm W x 10.92 cm D x 11.43 cm H. (4.5" x 4.3" x 4.5")
Weight	Approximately 0.7 kg (1.5 lbs.)

APPENDIX B

SUPPLIES

SUPPLIES

Nanoduct Sensor Cells	310565-01
Ampule Organizer	AC-071
DC Power Adapter	AC-113
Cleaning Adapter	310898-01
1 mL Tuberculin Syringe w/ #22 blunt needle	SS-045
10 mL Tuberculin Syringe	14-0175
Microbore Tubing lengths (14”)	SS-044
Cotton Swabs	14-0290
Waste Collection Pads	SS-220
Deionized Water	SS-006
Hemostat Clamp	42-0126
Plastic Tweezers	42-0125