SWEAT•CHEK™

MODEL 3120

Instruction/ Service Manual

SWEAT CONDUCTIVITY ANALYZER

ELITechGroup

BIOMEDICAL SYSTEMS

SWEAT•CHEK™
SWEAT CONDUCTIVITY ANALYZER

Model 3120

Instruction/Service Manual

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INTRODUCTION

1.1 Instrument Description

3120
SWEAT•CHEK
Sweat Conductivity Analyzer

1.1 Instrument Description

The 3120 SWEAT•CHEK Sweat Conductivity Analyzer provides simple and economical sweat analysis for the laboratory diagnosis of cystic fibrosis. Designed specifically for use with the Macroduct® Sweat Collector, it can measure the electrolyte concentration of a sweat specimen as small as 6 to 10 microliters.

The Analyzer's flow-through conductivity cell operates at a precisely controlled temperature for improved stability and accuracy. In keeping with established practice, the readout on the digital display is calibrated in mmol/L (equivalent NaCl). The reading obtained represents the molar concentration of sodium chloride in aqueous solution that would exhibit, at the sample temperature, the observed sample conductivity.

The conductivity cell is located beneath a recessed cover on the front panel of the instrument, just below the digital display. In the recess of this cover, two short 0.76 mm diameter stainless steel nipples serve as inlet and outlet connections to the cell.

For measurement, two short lengths of microbore plastic tubing are slipped over the stainless steel nipples. One of these tubes is from the Macroduct sweat collector and contains the sweat specimen to be analyzed. The other tube serves as the "take-up" tube. During analysis, the sweat specimen is transferred from the Macroduct tube into the take-up tube via the conductivity cell. After the sweat specimen is transferred into the cell, its electrical conductivity is measured, the electrolyte concentration is calculated, and the result appears on the digital display.

Complete instructions for this procedure are found in Section 2.

1.2 Customer Service

ELITechGroup is ready to help you resolve any problems with your SWEAT•CHEK Analyzer. If you cannot solve a problem using the procedures in this manual please contact us.

Customers within the United States and Canada are encouraged to contact us by telephone. Outside the U.S., many of our authorized dealers offer complete customer service and support. Contact ELITechGroup by mail, telephone, fax or e-mail at the address and numbers listed below.

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Sales_EBS@elitechgroup.com (Sales)
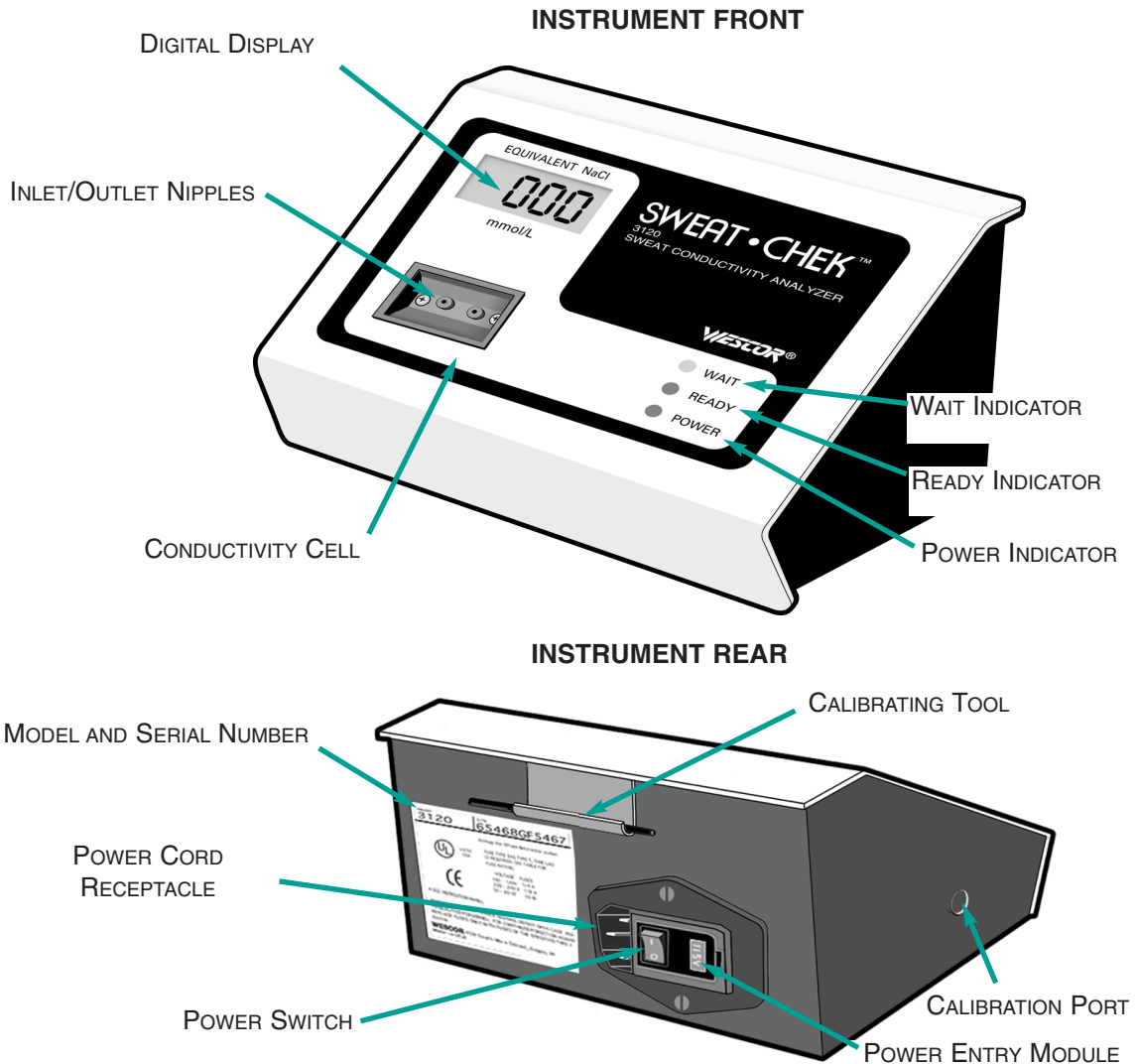
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NOTE:
ELITechGroup's Authorized European Representative for matters relating to the Medical Device Directive is:

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1.3 Controls and Connections

INSTRUMENT FRONT

DIGITAL DISPLAY

INLET/OUTLET NIPPLES

EQUIVALENT NaCl

000

mmol/L

SWEAT•CHEK ™
3120
SWEAT CONDUCTIVITY ANALYZER

WESCOR ®

WAIT — WAIT INDICATOR

READY — READY INDICATOR

POWER — POWER INDICATOR

CONDUCTIVITY CELL

INSTRUMENT REAR

CALIBRATING TOOL

MODEL AND SERIAL NUMBER

3120   6S468GFS467

POWER CORD
RECEPTACLE

CALIBRATION PORT

POWER SWITCH

POWER ENTRY MODULE

The power switch is located on the back of the instrument as part of the Power Entry Module. When connected to the proper line voltage and turned **ON** (I) the power indicator should glow GREEN.

1.4 Important User Information

SPECIFICATION OF SAFE USE:

Using this instrument in a manner not specified by ELITechGroup may impair the safety protection designed into the equipment and may lead to injury.

SAFE USE ENVIRONMENT:

This device has been designed for indoor use only, between 5 and 40 °C, maximum relative humidity 80%, at up to 31 °C. For use at altitudes up to 2000 meters.

FUSES:

All fuses in this equipment are time-lag (Type T).
For use with a Mains Supply voltage of 85 to 264 Volts AC @ 50 to 60 Hz, ±10%.
Transient Overvoltage Category II.
Pollution Degree 2 in accordance with IEC 664.

EXPLANATION OF SYMBOLS FOUND ON EQUIPMENT:

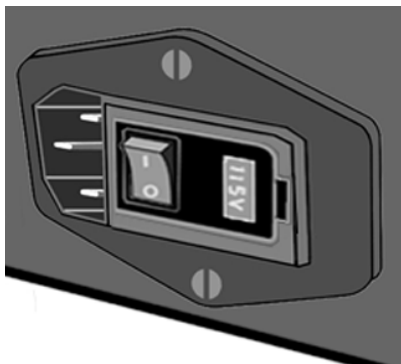$\sim$ Alternating Current (AC)

I Power On

O Power Off

⚠ International Attention Symbol.
Calls attention to important information and instructions in the instruction manual.

OPERATING SWEAT•CHEK

2.1 Instrument Preparation

1 The power switch is located on the back panel in the power entry module. Make certain the switch is OFF (0).

2 Plug the female end of the power cord into the power entry module. Note the voltage indicator window. If the voltage does <u>not</u> match the voltage of your power outlet, refer to Appendix C before proceeding.

NOTE:
We recommend using a grounded power line surge protector to isolate the instrument from spikes and surges.

3 Plug the male end of the power cord into a grounded power outlet.

4 Turn the power switch on (I). The power indicator should glow GREEN. The display will read zero:
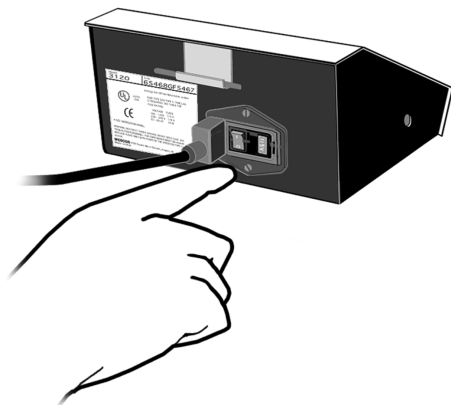
The WAIT indicator glows amber. Within two minutes, it will switch off and the READY indicator will glow green, indicating that the conductivity cell has stabilized at the correct operating temperature. The Analyzer is now ready to accept samples.

2.1 Instrument Preparation

5 Attach a length of clean microbore tubing (SS-044) to serve as the outlet tube to one of the stainless steel nipples. While either nipple can be used, we suggest that the right hand nipple be used as the outlet.

6 Check calibration and run 3 levels of sweat controls before introducing patient specimen, (see Section 2.4). After calibration (if needed), clean and dry the cell before proceeding with analysis, (see Section 2.3).
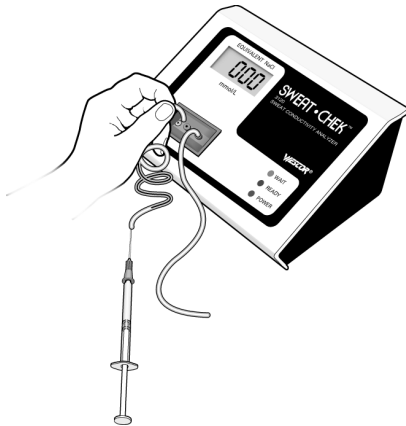
7 Attach the tube containing the specimen for analysis to the opposite (we recommend the left) nipple, which will serve as the inlet. See Section 2.2 for complete instructions.

2.2 Sweat Analysis
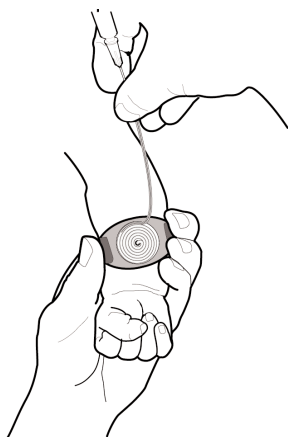
The Macroduct Sweat Collection System manual provides complete instructions for sweat collection. These should be followed rigorously.

Normally, the sweat specimen is introduced directly into the conductivity cell from the Macroduct collection tube. A typical Macroduct sweat collection produces many times the sweat volume needed for analysis. In cases where sweat yield is below average, measurement is possible using 6 to 10 microliters of sweat; but careful and precise technique is mandatory, since positioning of the sample within the cell becomes critical.

If the sample volume is insufficient to establish continuity between the electrodes in the conductivity cell (approximately 6 microliters), no measurement will be possible. However, any reading sustained on the digital display for at least a few seconds will be valid.
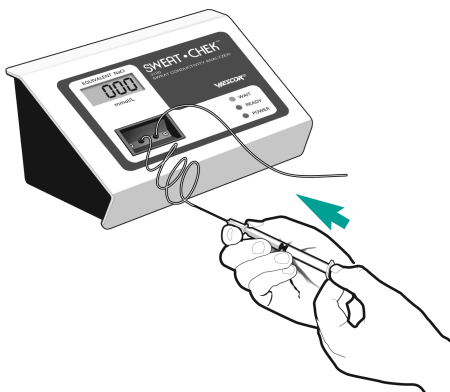
PREVIOUSLY COLLECTED SWEAT OR SWEAT CONTROLS

If the sweat specimen has been transferred to a storage cup, or if you wish to inject Calibrator solution (SS-140), sweat control solutions (SS-150), or water into the Analyzer, simply attach a spare take-up tube to the syringe. Position the syringe plunger near mid-point, and carefully withdraw the plunger to bring the specimen into the tube. Use only new, clean tubing that is certified solute-free to avoid measurement errors (tubing supplied by ELITechGroup meets this requirement). **<u>Do not</u> aspirate liquid into the syringe body.**

NOTE:

Handle the sweat specimen with care before analysis to avoid introducing air bubbles into the sweat column. An air bubble in the conductivity cell will prevent measurement.

1 Connect the end of the specimen tube to the inlet nipple of the conductivity cell (we suggest the left hand nipple). Push tubing "straight on" the nipple.

2.2 Sweat Analysis

CAUTION!

Push the tubing STRAIGHT ON to the stainless steel nipples without bending them. Repeated bending will eventually cause the nipple to fracture, requiring replacement of the conductivity cell.
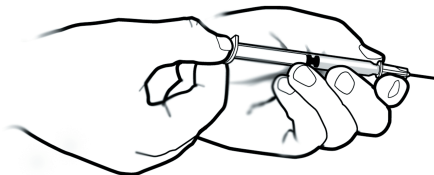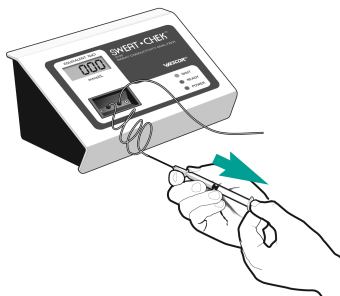
2 Transfer the specimen into the cell by gently moving the syringe plunger into its barrel. When the liquid column of the specimen makes contact with the cell electrodes, the digital display will rise quickly from its zero reading. Stop injecting the sample at this point, and the sample will rapidly equilibrate to the cell temperature.

Moving the liquid column brings cooler liquid into the conductivity cell, briefly producing a lower reading, but the reading quickly stabilizes when motion ceases. In large samples, a slight beginning-to-end conductivity variation is normal. See Section 3.2 to interpret readings.

3 When the liquid column of the specimen loses contact with the first cell electrode, the reading will fall to zero.

4 If desired, the specimen can be drawn back into the cell to repeat the measurement. If the plunger is moved smoothly and gently, the specimen can be transferred in and out of the conductivity cell for as many measurements as desired. Abrupt, jerky movements of the plunger can separate the liquid column, and the resulting air bubbles will interrupt readings as they pass through the cell.

5 Thoroughly clean and dry the conductivity cell using the instructions in Section 2.3.

2.3 Cleaning the Conductivity Cell
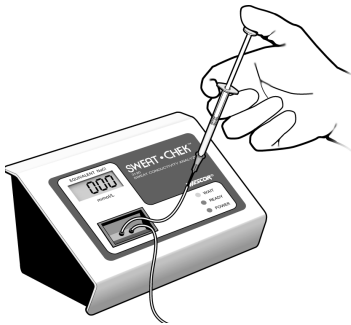
1 After testing each specimen, rinse the conductivity cell with at least one full take-up tube of deionized water.

2 When all residual salt has been flushed from the cell, the reading on the display reads "000" (with pure water in the cell).

3 Remove water by using the syringe to push air through the cell. After all discernible liquid has been flushed, remove the take-up tube and "pump" the syringe to blow out any remaining micro droplets and dry the cell. Finally, push the syringe plunger completely down to purge remaining droplets of water from the cell. This procedure is necessary to ensure accuracy of any subsequent measurement.
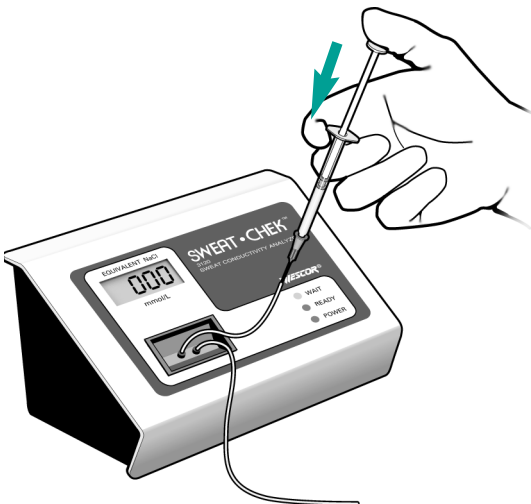
CAUTION!

Never allow any liquid to remain in the conductivity cell after measurements are complete. Besides risking a measurement artifact in the next procedure, the instrument can be damaged if it is inadvertently exposed to freezing temperatures such as could occur during transport to a testing site in cold weather. To avoid damage to the cell or other sensitive electronic components, do not expose the instrument to extremes of heat or cold.

2.4 System Operating Checks

SWEAT•CHEK is factory-calibrated and under normal conditions should not require further adjustment. IF THE CELL IS CLEAN AND FREE OF RESIDUAL SALT OR WATER, calibration of the instrument can be checked using a freshly opened NaCl standard solution such as that initially supplied with the instrument. The reading given by the Analyzer should agree with the specified molarity of the standard solution within ± 2 mmol/L. If recalibration becomes necessary refer to Section 4.2.

SWEAT•CHEK has an extremely stable response characteristic that is virtually linear through the critical range from 75 to 110 mmol/L. At extremely low ranges, there will be a slight positive error in the reading, and at extremely high ranges, a slight negative error. These errors will not invalidate the diagnostic result. See Section 3.5.

Check calibration to ascertain that the temperature of the cell is within the correct range and that the electronics are otherwise functioning normally. A reading that agrees with the labeled value of the standard solution indicates correct overall performance to a very high level of confidence. Further testing is not normally necessary.

Sweat Controls

If you require a CF-positive and/or CF-negative control value, Elitechgroup Sweat Controls (SS-150) provide three levels of control for validating measurements of electrolyte concentration as shown at left: **We strongly recommend that you calibrate the instrument and run three levels of sweat controls each day before running patient specimens.**

Normal
Appr. 40 mmol/L

High Normal/Equivocal
Appr. 70 mmol/L

Abnormal
Appr. 130 mmol/L

CAUTION!
Push the tubing STRAIGHT ON to the stainless steel nipples without bending them. Repeated bending will eventually cause the nipple to fracture, requiring replacement of the conductivity cell.

INTERPRETATION OF RESULTS

3.1 Background

Children afflicted with cystic fibrosis (CF) clearly show elevated electrolyte concentrations in their sweat, compared with the sweat of children unaffected by this disease.[1,2] With increasing age, however, the difference between normal and abnormal sweat electrolyte levels becomes less distinct; thus, the borderline and low abnormal results commonly encountered in adults are not indicative of disease. A diagnosis of CF will always be based upon clinical findings and observations, but the "laboratory diagnosis" or "sweat test," performed properly, provides valuable quantitative corroboration of the physician's clinical diagnosis.

Historically, the "sweat test" was performed without Macroduct and SWEAT•CHEK and has shown a high incidence of both false positive and false negative results, with false positives predominating. The professional literature[3,4,5] has been highly critical of various commercial systems that purport to simplify one or more of the three steps in the procedure, i.e. SWEAT INDUCTION, SWEAT COLLECTION and SWEAT ANALYSIS. Most of the errors involved the collection phase of the test. Webster's comprehensive review of quantitative sweat testing, from the early 1950's through 1983, identified error factors associated with each of these methods.[6]

Although numerous sweat testing systems have been marketed, the Cystic Fibrosis Foundation of America has approved only two methods of sweat collection. They are the original pad absorption method of Gibson and Cooke[7] and the Elitechgroup Macroduct Sweat Collection System.[8,9]

The sweat test's analytical phase was limited to chloride ion assay in laboratories of the early 1950's. Today, laboratory technologists can choose from a number of alternative analytical methods, including anion assay, cation assay, osmolality, or electrical conductivity. The SWEAT•CHEK Sweat Conductivity Analyzer measures the electrolyte concentration of the specimen by electrical conductivity.

3.1 Background

Licht,[10] Gibson,[11] Phillips,[12] Shwachman,[13] and others extensively investigated conductivity as an alternative method of sweat analysis. They concluded that conductivity can be a reliable laboratory indicator to either rule out or confirm the clinical diagnosis of cystic fibrosis. See Section 3.4 for more information on the status of conductivity.

The designs of earlier sweat conductivity measuring instruments were lacking in terms of specimen handling, calibration stability, and measurement resolution. The SWEAT•CHEK Sweat Conductivity Analyzer, with its temperature-controlled measurement cell, flow-through operation, and wide-range digital readout, is a modern adaptation of a proven analytical method. One of the world's leading authorities on sweat testing, commenting on SWEAT•CHEK stated, "If this machine is kept clean, it gives results that are every bit as reliable as an analysis for sodium or chloride."[14]

3.2 Units of Measurement and Clinical Ranges

In addition to sodium and chloride ions, sweat also contains significant concentrations of potassium, bicarbonate, and lactate ions. This poses a problem when selecting a reference or calibration solution, but sodium chloride solutions serve well if allowance is made for the other electrolytes. Thus, the reference ranges for electrolyte concentration in normal and abnormal groups, in terms of sodium chloride standards, will differ from those established for specific assay of chloride ions.

SWEAT•CHEK was evaluated at three separate medical centers in studies of 514 patients, among whom were 43 clinically confirmed cases of cystic fibrosis.[15] Analysis of the combined data is shown on the following page (Table 3-1).

The normal, borderline and abnormal electrolyte concentration ranges were established by reference to the data published by Hammond et.al.[15], using their equation relating electrolyte concentration to chloride:

Bias = Electrolyte Concentration (conductivity) - Chloride

The bias (unmeasured anions) was observed to be a function of the conductivity value, and this enabled converting chloride range-limiting levels of 40 to 60 mmol/L to their electrolyte conductivity equivalents shown in the accompanying table.

Carefully assess any result in the "borderline" region between 60 and 80 mmol/L. Factors such as age, state of hydration, family history of CF, etc., must be assessed by the attending physician, together with the sweat analytical data. Retesting, along with alternative methods of analysis, such as chloride or sodium ion assay, may help resolve an equivocal sweat test result.

It has been shown that the concentration of electrolytes decreases as sweating continues in time.[11] If the sweat yield during collection is 30 microliters or more (typical yield is 50 to 60 microliters in 30 minutes using Macroduct), then an increase in the reading may be observed as the sweat column passes from the Macroduct collection tube through the conductivity cell into the "take-up" tube. The variation will be small in comparison with the difference between normal and abnormal sweat, and thus will not confound the diagnosis.

ELECTROLYTE CONCENTRATION (USING SWEAT-CHEK)			
Normal	Borderline	Abnormal	
0-60	60-80	80+	(mmol/L)
CHLORIDE			
Normal	Borderline	Abnormal	
0-40	40-60	60+	(mmol/L)

Readings on Sweat-Chek classified and compared to chloride analysis.

3.2 Units of Measurement and Clinical Ranges

Among the patient populations mentioned above, data on chloride ion assay and sodium plus potassium ion assay, determined simultaneously with the conductivity data, enables linear regression analysis:

Chloride Ion Concentration
vs.
Sweat Conductivity

n = 514   r = 0.974

$Cl^- = 0.96 (C) -15.21$

Sodium + Potassium Ion Concentration
vs.
Sweat Conductivity

n = 514   r = 0.987

$Na^+ + K^+ = 0.974 (C) - 1.49$

C = (electrolyte concentration equivalent NaCl mmol/L)

Table 3-1

CLINICAL RANGES
SWEAT CONDUCTIVITY AS EQUIVALENT NaCl (mmol/L)

	Non CF	CF
Number of Patients	471	43
Mean Value	33.4	113.1
Standard Deviation	11.2	9.9
Observed Range	13-87	90-136

3.3 Conductivity and the CAP Survey Program

The readout in mmol/L (equivalent NaCl) means that the sweat sample has a conductivity equivalent to that of a NaCl solution of the displayed mmol/L concentration (at the same temperature).

This reading DOES NOT represent the actual concentration of either sodium or chloride in the sweat.

The level of electrical conductivity is a direct function of the concentration of ionized molecules in a solution. Sweat samples are made up of sodium, potassium, and a small amount of ammonium, as the cation contribution. The anions balancing these are mainly chloride, with lactate and bicarbonate. Thus, the conductivity can be seen as a measure of the total electrolyte concentration in mmol/L. The electrolyte selected for calibration reference is sodium chloride but it could be any other salt. The chemical nature of the calibration solution is immaterial, because the reference ranges for sweat conductivity will be based upon comparison with the calibration value, and will be valid whatever electrolyte is used as a reference.

Conductivity in the CAP Sweat Survey Program

Regrettably, in the CAP Survey Program, some Sweat-Chek users continue to present their sweat **conductivity** results in the survey section meant for those labs that specifically measure **chloride** by one method or another.

Prior to 1997, when the CAP samples were pure NaCl solutions, this practice did not lead to a problem in terms of numerical value of conductivity as compared with the chloride value because the sample only contained NaCl. However, when laboratories were asked to make diagnostic judgments on the basis of their results, it did create a serious problem for those mistakenly submitting conductivity as chloride. These laboratories did not appear to recognize that by submitting their data to the **chloride section** their results would be assessed in terms of the accepted diagnostic ranges for **chloride**. Since conductivity ranges are different from chloride ranges due to the presence of significant amounts of non-chloride ions in sweat, this usually resulted in an apparent misdiagnosis as far as the CAP Survey was concerned.

3.3 Conductivity and the CAP Survey Program

For example, a laboratory finding a conductivity result of 70 mmol/L (equiv. NaCl) would judge this as an **equivocal** result in terms of the recommended diagnostic ranges for conductivity based on clinical trials. If it had been properly presented to the **conductivity** section of the Survey, it would be correctly judged by its peer group (conductivity users) as **equivocal**. However, if it were placed in the CAP section meant specifically for **chloride** measurers, it would be viewed as a false diagnosis, because a level of 70 mmol/L is a **positive** result for chloride.

In 1997 the CAP replaced pure NaCl solutions with simulated sweat samples for analysis in the assessment of laboratory competence. This was accomplished by the addition, to the basic NaCl, of a representative quantity of other salts to produce a total electrolyte content similar to sweat in each of the three diagnostic categories. This was a long awaited and much welcomed move. However, it must be understood that in all three simulated sample groups, low, medium, and high in electrolyte content, the chloride content will be, as in sweat, lower than the total anion content and therefore lower than the conductivity value. For this reason, all conductivity results that are included in and compared with the data of the chloride-analyzing group of laboratories will apparently be significantly in error.

Consequently, it remains extremely important that those laboratories that wrongly present conductivity results to the chloride section must desist from this practice. When properly included in the conductivity section, the results will be seen in relation to and compared with those of peer laboratories.

3.4 Conductivity in the Diagnostic Analysis of Sweat

Recently much confusion has arisen in laboratory departments after the publication of the recommendations of the National Committee for Clinical Laboratory Standards, (Sweat Testing Guideline C34-A) that have been adopted by the Cystic Fibrosis Foundation of America.

The Foundation did not recognize electrical conductivity as a *diagnostic* analytical procedure in sweat testing. Rather, conductivity is relegated to a *screening* procedure only. Accordingly, Sweat-Chek is not accepted for use in the Care Centers under its control.

Until 2000, NCCLS also advised that a patient with a sweat conductivity result of 50 mmol/L or higher should be referred to an accredited CF care center for a sweat chloride analysis, and on page 21 of Guideline C34-A (1994) one found the following statement: "Any sweat conductivity result greater than or equal to 50 mmol/L (equivalent sodium chloride, NaCl) is considered positive." Reference to the Hammond, et. al. sweat data[15] shows that **50 mmol/L** conductivity is in fact equivalent to **28 mmol/L** chloride, a value that does not fall into either the positive or equivocal compass, but is **well within the normal range** for chloride. Elitechgroup brought this to the attention of the Foundation and in the Revised NCCLS Guideline C34-A2 (2000) the referenced statement had been removed.

The rationale for the Foundation's position is not readily apparent. If, as it would seem, it stems from their statement that conductivity is to be regarded as only a *screening* test, there is no support for this premise in the scientific literature. A thorough perusal of the Hammond paper fails to reveal any basis for such an interpretation[15, 16]. On the contrary, we submit the following quotation from Shwachman and Mahmoodian in the paper published in 1967:

"The standard conductivity measurement is made immediately after the collection of sweat and provides an instant answer... The correlation between this measurement and the electrolyte concentration is excellent and every patient with cystic fibrosis tested was properly identified. No individuals were falsely diagnosed. The rarely encountered borderline case by one method gives the same borderline value by the other method."[17]

3.4 Conductivity in the Diagnostic Analysis of Sweat

Further, a comparative statistical analysis of the extensive chloride data of Shwachman,[17] the Macroduct trial results of various electrolytes versus conductivity by Hammond, and osmolality results from Webster clearly shows that conductivity, chloride, and osmolality are equivalent in their ability to discriminate between non-CF and CF groups. These statistics were presented in a poster at the 5th International Conference on Neonatal Screening for Cystic Fibrosis, Caen (France), 1998.[18]

Finally, a recent large scale study (3834 subjects) has shown convincing correlation between conductivity and chloride concentration. This study identified conductivity values associated with normal and CF positive with the normal cutoff being <75 mmol/L and CF diagnosis confirmed at ≥ 90 mmol/L.[19]

ELITechGroup makes no pretense of authority in setting, determining, or influencing reference ranges, being content to defer to the collected research of the medical community. However, an objective reading of the extant studies on the subject seem to agree, with some slight variations from study to study, that it is quite reasonable to assume that the upper limit of normal would be >70 mmol/L, and that >90mmol/L would be a positive indication for CF. Further, we are confident that the Sweat Chek Analyzer can accurately indicate a patient's true sweat conductivity values whatever the accepted and established ranges might be.

3.5 Reportable Range and its Justification

The following information is provided to help you meet regulatory and quality requirements:

1. Reportable Range

The reportable range with Sweat-Chek conductivity measurement is 0 to 150 mmol/L, defined as the range of values that have been established as providing acceptably accurate laboratory results for the intended clinical use.

2. Linearity of Conductivity Versus Electrolyte Concentration

Data produced by ELITechGroup using the Sweat-Chek analyzer is based upon the calibration of the instrument at one point only: 90 mmol/L (equivalent NaCl), then recording the readings given by standard NaCl solutions ranging from 0 to 150 mmol/L. The calibration point of 90 mmol/L was selected since it coincides approximately with the middle point of the complete range and with the lowest published values for CF subjects. The results show that the response is reasonably linear from 20 to 90 mmol/L. The error in this range is relatively constant and represents an **overestimate** of the true value by about 2 mmol/L reducing to zero at 90 mmol/L. In the range 90 to 140 mmol/L the error becomes an **underestimate** that increases regularly from zero at 90 mmol/L to 6 mmol/L below the true value at 140 mmol/L, (a range that corresponds with the clinically recorded span of CF values).

3. Justification for Reportable Range

The designation *acceptably accurate* referred to above is applied for the following reasons:

For **control** patients in the normal range (0 to 60 mmol/L) the constant **overestimate** (+2 mmol/L) is too small to convert a normal result into a frankly borderline result.

For **borderline** patients (60 to 80 mmol/L), the measured value is a constant **overestimate**, at about 1 to 2 mmol/L and is again much too small to convert a borderline into a positive result.

For **positive** (greater than 80 mmol/L), CF subjects, the error is an **underestimate** and variable, negligible in the critical range of 80 to 110 mmol/L, and maximal in the upper part of the abnormal range (140 mmol/L) where it cannot in any way effect the diagnosis.

3.6 References

References

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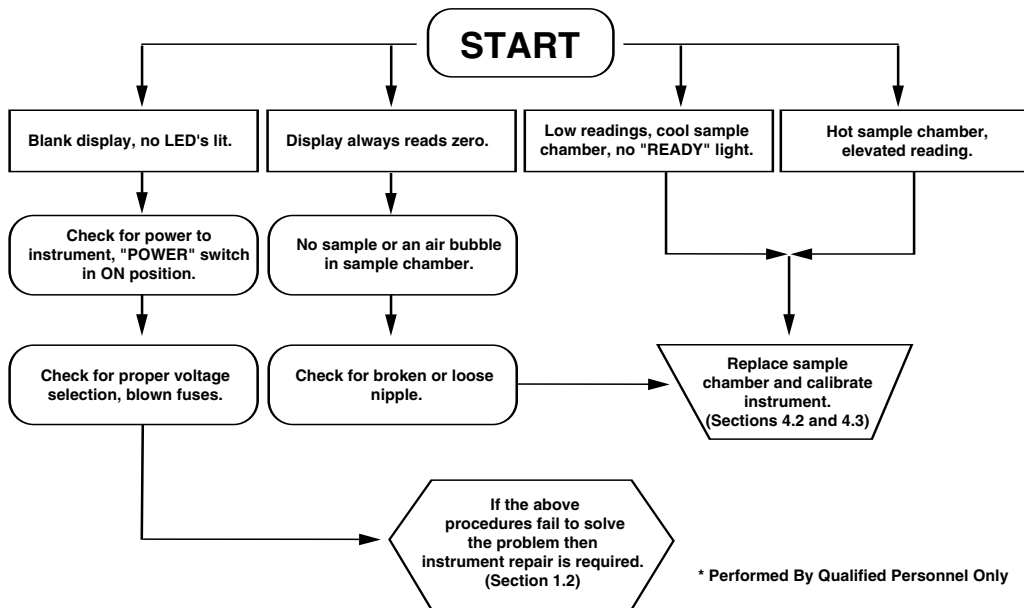
TROUBLESHOOTING AND SERVICE
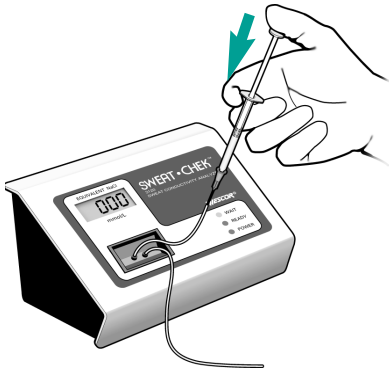
4.1 Troubleshooting and Service Overview

The SWEAT•CHEK analyzer is designed to be simple to operate and easy to maintain. The following troubleshooting chart provides suggestions to help you quickly solve routine problems that might be encountered using the SWEAT•CHEK Analyzer. These solutions are indexed to additional information found in this section.

Aside from replacing the conductivity cell, there are no user-serviceable parts inside the instrument case. The analyzer case should never be opened except by qualified service personnel.

More difficult problems may require detailed technical service. Contact your dealer or ELITechGroup for assistance. Refer to Section 1.2 for Customer Service information.

START

| Blank display, no LED's lit. | Display always reads zero. | Low readings, cool sample chamber, no "READY" light. | Hot sample chamber, elevated reading. |

Check for power to instrument, "POWER" switch in ON position.

No sample or an air bubble in sample chamber.

Check for proper voltage selection, blown fuses.

Check for broken or loose nipple.

Replace sample chamber and calibrate instrument. (Sections 4.2 and 4.3)

If the above procedures fail to solve the problem then instrument repair is required. (Section 1.2)

* Performed By Qualified Personnel Only

4.2 Instrument Calibration

The instrument must be calibrated if the conductivity cell has been replaced or if you determine that recalibration is needed (see System Operating Checks, Section 2.4). Two common factors can influence the reading, so before performing recalibration, be sure to check the following:

A. RESIDUAL SALT OR WATER IN THE CONDUCTIVITY CELL.

If the cell is not rinsed thoroughly after testing sweat or saline solutions, residual salt may be left in the cell. This tends to increase the reading on a subsequent specimen. Rinse water must be purged from the cell after rinsing, or it may dilute a subsequent specimen, causing a decreased reading. Make certain the cell is clean and dry before calibrating or processing samples.

B. CONCENTRATED CHECK SOLUTION

NaCl standard solutions tend to concentrate whenever the contents are exposed to the atmosphere. If you doubt the validity of the Calibrator solution, use a freshly-opened ampule before proceeding.

4.2 *Instrument Calibration*

If you have eliminated the possibility of error from other sources, and recalibration is indicated, the procedure is as follows:
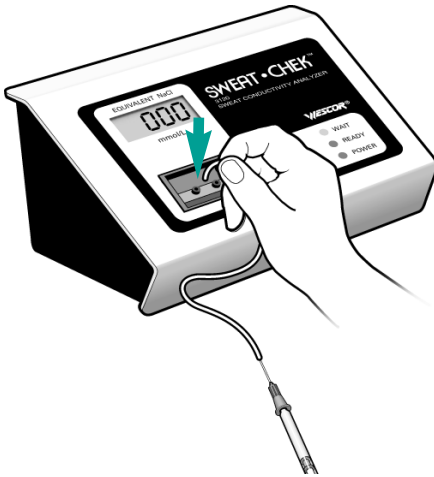
1 INJECT CALIBRATOR SOLUTION INTO THE CON-DUCTIVITY CELL.

a. Connect a new tube (SS-044) to the outlet (right) nipple of the cell.

b. Attach a second new tube to the blunt-end needle of the syringe, and draw a specimen directly from the calibrator ampule into the tube (do not draw solution into the syringe).

c. Connect the syringe tube to the inlet (left) nipple of the cell.

d. Gently move the syringe plunger to transfer the Calibrator solution into the conductivity cell. The reading will stabilize in approximately 10 seconds.
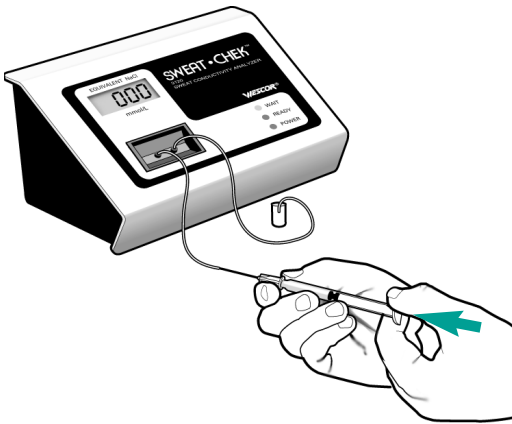
4.2 Instrument Calibration
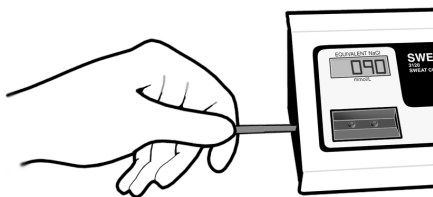
2 ADJUST CALIBRATION

Insert the small end of the calibration tool into the small calibration port on the left side of the analyzer. With the tool seated in the small slot in the bottom of the port, observe the display while rotating the tool in either direction until the display agrees with the assayed molarity of the Calibrator solution.

3 RE-CHECK CALIBRATION

To double check calibration you should repeat steps a though d.
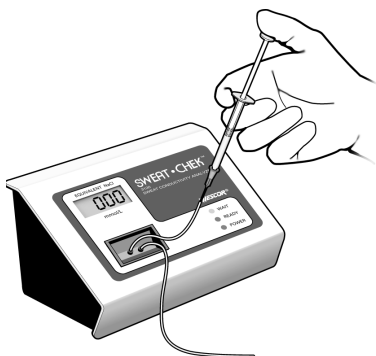
4 CLEAN THE CONDUCTIVITY CELL

Flush the conductivity cell with deionized water, followed by bursts of air to purge any remaining droplets (see Cleaning the Conductivity Cell, Section 2.3).

4.3 *Replacing the Conductivity Cell*
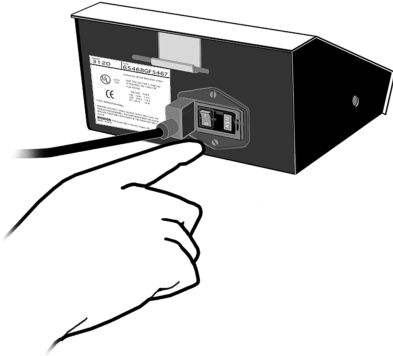
If one of the stainless steel nipples of the conductivity cell breaks, you must replace the cell assembly (see Appendix C for details). Use the following procedure:

1   Switch the instrument off and disconnect line power.

2   Remove the cell cover.

   a. Remove the small Phillips-head screws located in the recess of the cover on each side of the nipples.

   b. Check to see that the nipples are parallel with each other and perpendicular to the cover.

   c. Carefully lift the cover away from the front panel, sliding it off the nipples as it comes forward.

3   Remove the conductivity cell.
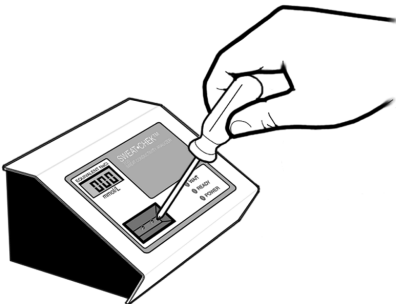
NOTE:
Do not remove the two small screws that are located near the nipples on the printed circuit board of the cell assembly.

The cell is held in place by a circuit board connector. Carefully insert needle-nose pliers in the holes provided in the circuit board. Disconnect the circuit board from the connector by gently gripping the pliers and pulling the circuit board straight out. Do this carefully to avoid damage to the circuit board or the connector.

4.3 *Replacing the Conductivity Cell*

4 INSTALL THE NEW CONDUCTIVITY CELL

Make certain that the nipples of the new cell assembly align precisely with the holes in the cover before installing the cell in the instrument. Hold the circuit board with needle-nose pliers. Then, position the cell so that its connector engages properly with the pins protruding from the circuit board connector inside the instrument. Gently press the cell down until it seats against the connector.

5 REPLACE THE CELL COVER

Make sure both cell cover mounting screws pass completely through the holes in the cell to engage the threaded stand offs.

6 CALIBRATE THE NEW CONDUCTIVITY CELL

Follow the procedure under "Instrument Calibration" (Section 4.2).

INSTRUMENT SPECIFICATIONS

Instrument Specifications

Minimum Sample Volume	6-10 microliters
Accuracy	2 mmol/L (1 S.D.)
Useful Range	0 to 150 mmol/L
Critical Range/Linear Error	Less than 2%
	(in the range from 75 to 110 mmol/L)
Sample Stabilization Time	Approximately 10 seconds
Cell Warm-up Time	Approximately 1 minute after power-up
Readout	3 1/2 digit liquid crystal display
Calibration Reference	Standard NaCl solution
Cell Set Temperature	39.5 °C ± 0.2 °C
Line Voltage Options*	100 to 120 V, or 220 to 240 V nominal,
	(Set at factory, user-selectable with
	fuse change) 50-60 Hz Transient
	Overvoltage Category II
Power	Less than 10 Watts
Fuse	1/4 Amp time-lag 3AG (Type T)
	(100 to 120 V) (2 required)
	1/8 Amp* time-lag 3AG (Type T)
	(220 to 240 V) (2 required)
Dimensions	10 cm x 20 cm x 16 cm
Weight	1.0 kg

* Make sure that the voltage specification on the rear panel of the Analyzer
  matches the local line voltage before connecting to electrical power.

This device is designed for indoor use only between 4 and 40 °C, Maximum rel-
ative humidity of 80% at up to 31 °C. For use at altitudes up to 2000 meters.

ACCESSORIES, SUPPLIES, AND REPLACEMENT PARTS

Accessories, Supplies, and Replacement Parts

Contact ELITechGroup for a complete list of replacement parts.

ACCESSORIES

Ampule Organizer for Calibrator and Sweat Controls	AC-071

SUPPLIES

Deionized water, 60 mL dropper bottle	SS-006
Take-Up Tube microbore plastic tubing (package of 100)	SS-044
Syringe/Needle Set (package of three 1 mL syringes with #22 blunt end needles)	SS-045
Calibrator for SWEAT•CHEK Conductivity Analyzer (package of 60 ampules) Molarity 90 mmol/L	SS-140

Sweat Controls: SS-150
   Sweat Controls 1, 2, 3, 0.75 mL vial (package of 36,
     12 each of Control 1, 2, 3)
   Sweat Control 1 molarity is approximately 40 mmol/L.
   Sweat Control 2 molarity is approximately 70 mmol/L.
   Sweat Control 3 molarity is approximately 130 mmol/L.
   Each Sweat Control lot has a specific control value and range.

REPLACEMENT PARTS

Conductivity Cell, Model 3120	RP-190
Conductivity Cell Cover, Model 3120	RP-373
Main Printed Circuit Board Assembly, Model 3120	330947-03

MANUAL

3120 SWEAT•CHEK Conductivity Analyzer Instruction/Service Manual	RP-377

CHANGING THE VOLTAGE SELECTOR

Changing the Voltage Selector

The voltage setting is designated at the factory before shipping. If the voltage shown does not match your power outlet, you must change the voltage selector before plugging the instrument into the outlet. To change the voltage selector:
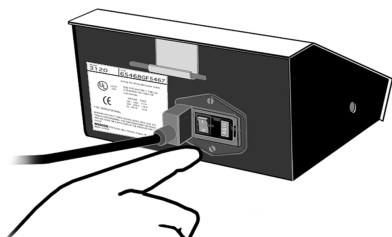
1 Switch the power off and remove the power cord from the power entry module.
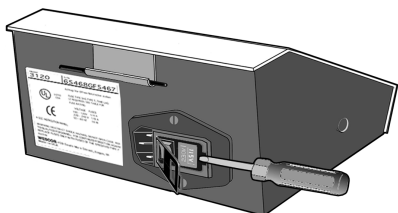
2 Use a screwdriver to open the fuse access door from the right end of the power entry module.

3 Use the screwdriver to pry the red voltage indicator (also from the right side) from the power entry module.
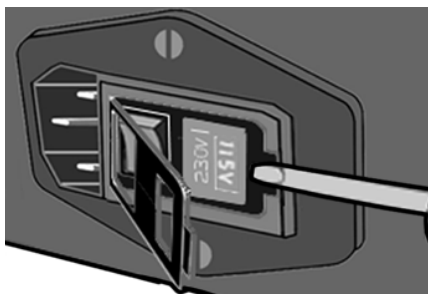
4 Rotate the indicator until the correct voltage appears in the indicator window, then press it back into the module until it clicks into place.

NOTE:

If necessary, change the fuses to match the new voltage setting. 100 or 120 V Setting: 1/4 Amp time-lag type (Type T) fuses (2 required). 220 or 240 V Setting: 1/8 Amp time-lag type (Type T) fuses (2 required).
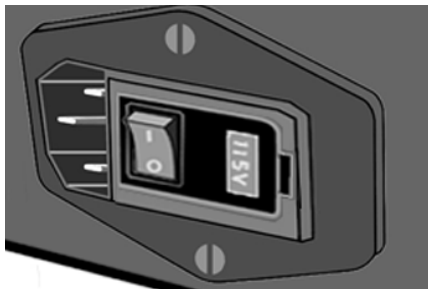
5 Close the module door and check to ensure the correct voltage appears in the indicator window.

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