

SM DIAGNOSTICS

SMD ECS™ 2000

OPERATOR'S MANUAL

SM DIAGNOSTICS

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INTENDED USE

ECS 2000 is an Electrolyte Analyzer used for measuring Na^+ and K^+ accurately. Results are displayed in the Alphanumeric Backlight display. The unit of Measurement is mEq/Litre.

Different types of samples that can be used are body fluids such as

- **Whole Blood**
 - **Serum**
 - **Plasma**
 - **Urine (24 Hours / Spot Urine)**
 - **CSF etc**
-



Warning

ECS 2000 is designed to be grounded through power supply lead for proper operation. Make sure that the Instrument is connected to a 3 – Pin socket that has effective earthing.

The normal voltage ratings for ECS 2000

$P \rightarrow N = 230 \text{ V}$

$P \rightarrow E = 230 \text{ V} \pm 5 \text{ V}$

$N \rightarrow E = 0 \rightarrow 5 \text{ V}$

UPS is advisable for avoiding repeated calibration and sampling interruption.

ECS 2000 is free from Electric shocks because purely insulated body.

Instrument is designed for use in environment free from high noise and vibration.

1. INTRODUCTION

1.1 GENERAL SYSTEM DESCRIPTION

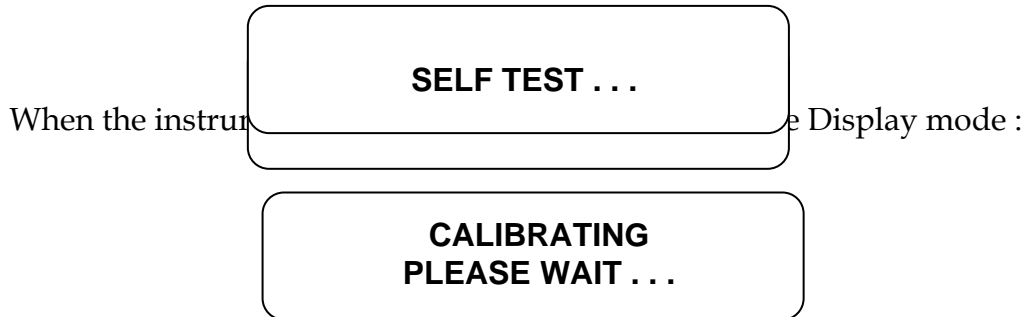
ECS 2000 is an unique product works under the cutting edge technology i.e., Direct Potentiometry (Ion Selective). The principle behind ECS 2000 is Potentiometry. For the purpose of measuring Na⁺ and K⁺ in a single Electrode Assembly is used, which can be replaced if necessary. The Analyzer is controlled by a dedicated Microcontroller which is communicated to the display.

1.2 ANALYSER SPECIFICATION

Size	:	Height : 12 inches (30.5 cm)
		Width : 8.5 inches (21.6 cm)
		Depth : 14.5 inches (36.8 cm)
Weight	:	12 lbs. (5 kg.)
Voltage	:	230 VAC / 115 VAC
Frequency	:	50 Hz / 60 Hz
Power Consumption	:	38 W
Fuse Rating	:	0.5 Amps
Operating Conditions	:	15 to 35 °C (59 to 95 ° F) in
		Less than 85% relative humidity.
		No warm-up time required

1.3 VARIOUS DISPLAY MESSAGES

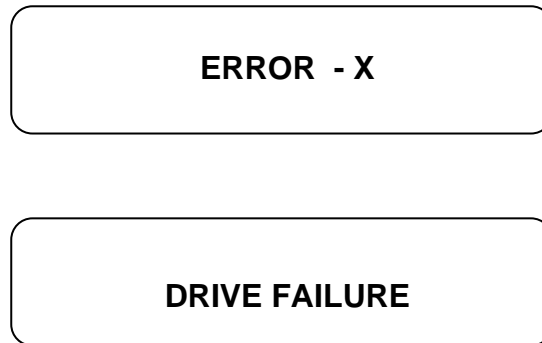
when the instrument is switched ON, the Display reads :



After the successful completion of calibrations and when the Instrument is ready for sampling, the Display reads :



When any errors are encountered, the Display will be



1.5 CONSUMABLES, USAGE AND STORAGE

1.5.1 AUTOCAL Calibrator - order number 33140 (500ml bottle)

The AUTOCAL calibrator is used to rinse the electrode probe and perform one - point calibration each time a sample is run. It is stored at room temperature (15 - 30 °C or 59 to 86 ° F).

1.5.2 CALSET Calibrator - order number 33120 (one 15-ml. vial)

The CALSET calibrator is used to perform the second point of the two-point calibration. It is stored at room temperature (15-30 ° C or 59 to 86 ° F).

1.5.3 SAMPLE CUPS - order number 32110 (Box of 200)

Sample cups are specially designed for use with ECS 2000. Use of any other sample cup could result in damage of the electrode assembly. A sample cup should be used only once and discarded properly. Sample is dispensed into the center well of the sample cup. A minimum of 200 micro litres is required for a test. Sample cups are stored at room temperature.

1.5.4 WASTE CONTAINER - order number 33180 (500ml bottle)

The waste container bottle is used to collect the waste solution . The waste solution collected should be disposed off regularly. The waste container should be cleaned properly.

1.5.5 ELECTRODE CELL ASSEMBLY - order number 33100 (1 assembly)

The Electrode Cell Assembly contains Sodium, Potassium membranes and a Reference within a wash shell which is filled with Autocal solution.

1.6 FUNCTIONS OF CALIBRATORS (Autocal & Calset)

1. ELECTRODES CONDITIONING (Maintenance)
2. CLEANING THE ELECTRODES (Maintenance)
3. TO PERFORM CALIBRATION.

1.6.1 ELECTRODES CONDITIONING

Any new electrode is allowed up to 8 hrs. to soak in the AUTOCAL solution so that the electrodes will reach equilibrium to produce stable readings and measurement. This conditioning of electrodes is highly essential in order to keep the electrodes always ready for measurements.

1.6.2 CLEANING THE ELECTRODES

The membrane tips of the electrodes are washed by means of rinsing while priming, calibration or sampling automatically.

1.6.3 ANALYTICAL FUNCTIONS OF AUTOCAL & CALSET

The AUTOCAL calibrator is involved as standard reference solution for 1 point calibration where as the CALSET for 2 point calibration.

2. INSTALLATION

INSTALLATION PROCEDURE

2.1 UNPACK INSTRUMENT

A. Take care in unpacking so as not to damage any electrical components. Inspect the carton and contents for any shipping damage.

B. Check the following items to verify that you received them :

- SMD ECS 2000 Sodium / Potassium Analyzer
- Dust Cover
- Power Chord
- Plastic waste container
- Electrode Assembly
- Auto Cal bottle with straw
- ECS 2000 Operator's Manual

C. The following supplies will be required to complete installation and initiate operation of your SMD ECS 2000. You should order them from your distributor.

ORDER NUMBER

AUTO CAL Calibrator - 500 ml bottle	33140
CAL SET - 15 ml. Vial	33120
Sample cups - 200 per box	32110
Electrode Cell Assembly	33100

2.2 HANDLING INSTRUMENT

A. Electrode should be soaked in AUTOCAL upto the level marked.

B. Instrument should be kept on the flat surface.

2.4 CRITICAL SPARE LIST

- A. Electrode
- B. Autocal

- C. Calset
- D. Sample Cups

2.5 PROCEDURES TO SWITCH ON THE INSTRUMENT

- A. Check the mains earthing .
- B. Check whether 5amps / 250V 3 pin power socket is being used.
- C. Connect the power chord to the rear side of the unit.
- D. Plug the power chord into a power socket. The system operates on power getting 230 V AC / 115 V AC from the supply.
- E. UPS connection is ideal for continuous sample analysis.

2.6 FIXING OF ELECTRODE ASSEMBLY

- A. Remove the two black knurled thumb screws form the front panel.
- B. Remove the Electrode Cell Assembly from its package carefully by holding the plastic housing. DO NOT TOUCH THE TIP OF THE ELECTRODE . Check and ensure that the black O-rings are present on the back side of the electrode cell assembly.
- C. Push the electrical connector firmly at the top with amplifier connectors and align the guide pins so that the assembly is flat against mounting plate. The electrode probe may be extended to align the assembly with screw holes on the mounting plate, however do not extend the electrode probe any more than necessary to avoid pushing the rubber seal outside the plastic wash cell.
- D. Secure the assembly to the mounting plates on each side with black knurled thumbscrews. Fingers tighten only.
- E. If cleaning the exterior of the Electrode cell Assembly is required use a small amount of water on a damp cloth. Do not use alcohol or other solvents to clean the exterior of the Electrode cell Assembly.

2.7 PLACING AUTOCAL CALIBRATOR BOTTLE

- A. Remove the outer and inner cap of the Autocal bottle.

- B. Place the AUTOCAL bottle in space provided on the right side of the analyser .
- C. Replace the cap on the AUTOCAL bottle with the cap/straw assembly supplied with the analyser. Tighten the cap on the bottle by rotating the bottle.

2.8 PLACING WASTE CONTAINER

- A. Remove the cap from the waste container and place it in the space provided in the left side of the analyser.
- B. Place the cap with tubing attached on the waste container.

NOTE: Both the AUTO CAL calibrator bottle and waste container tubing lines attach to plastic housing called the Manifold. The Manifold attaches to the Pump tubing which is a special black elastic tubing set consisting of three lines molded in a single unit.

2.9 TURN SYSTEM ON

- A. Push the ON/OFF switch at the back of the unit to ON position.
- B. After a few seconds, the message on the display . . . SM DIAGNOSTICS, CHENNAI -94 with version 3.x.
- C. The instrument will then perform Self-test . . . before going in for priming and calibration.

3. BASIC MENU FUNCTIONS

3.1 SELF - TEST

When the instrument is powered on it sets the electrode to probe to be in the home position. For that the electrode moves down and up performing one prime operation with a message,

SELF TEST

on the display.

3.2 PRIMING

After the self-test is over, the message

PRIME . . . Y/N

will be on the display. If the key 'YES' is activated SMD ECS 2000 performs a PRIME, where the electrode moves down and up rinsing the membranes with AUTOCAL solution, if the wash cell of electrode is not completely filled upto the level of black knurl screws with AUTOCAL, an additional PRIME is required.

3.3 CALIBRATION

If 'NO' is activated when the message on the display is

PRIME . . . Y/N

the menu

CALIBRATION Y/N

is read by the display.

NOTE: Detailed procedure to calibrate SMD ECS 2000 is explained in section 5.3

3.4 SAMPLING

After successful calibration SMD ECS 2000 is ready for measurement of unknown samples with a message

**READY FOR SAMPLE
SAMPLE # 001**

when the YES key is activated SMD ECS 2000 measures, calculates and displays the Sodium and Potassium values of the sample. After successful measurement of the sample the SAMPLE count is incremented by one.

3.5 PREVIOUS SAMPLE VALUES

ECS 2000 has the facility to store up to One Hundred patient samples in its permanent memory. After each sample when 'No' key is activated the display reads the menu

PRE-VALUE Y/N

By activating YES key continuously we can see the last 100 sample values one by one, cyclically.

To come back to sample mode or to view the calibrated slope values.

- Press NO key to enter PRIME . . . Y/N
- Press NO key to enter CALIBRATION . . . Y/N
- Press again NO to display slope values of calibration and then SMD ECS 2000 comes

back to

**READY FOR SAMPLE
SAMPLE # XXX**

4. DAILY START - UP PROCEDURE

4.1 Check the following :

- A. Make sure the AUTOCAL Calibrator is sufficient to perform the required number of tests for the day. Tighten the cap on the AUTOCAL container.
- B. Check the waste container fluid level and replace if necessary. Dispose of waste according to proper laboratory practice.
- C. Check for any evidence of leakage of AUTOCAL Calibrator (pink fluid) at tubing connections, around the Electrode Cell Assembly, and on the sample platform.
- D. Check that CAL SET has not expired.
- E. If the display reads "NEED CALIBRATION", proceed to Section 5.3
- F. If the display reads "Ready for Sampling Sample #", proceed sampling.

5. CALIBRATION

5.1 REASONS FOR CALIBRATION

- A. To ensure the accuracy of the patient or control results.
- B. Compensate for changes in electrode response and in new lots of AUTOCAL calibrator.

5.2 WHEN TO CALIBRATE

- A. Once in 24 hours when patient samples are to be tested.
- B. While changing new AUTOCAL calibrator.
- C. If quality control results are outside acceptable range.
- D. Whenever "NEED CALIBRATION" is prompted by the SMD ECS 2000 Analyser.
- E. Whenever any Error message is displayed.
- F. When Electrode is replaced.

5.3 HOW TO PERFORM A CALIBRATION

- A. Fill inner well of sample cup with CALSET calibrator.

Note: Be sure to replace the cap on the CALSET bottle after use to prevent evaporation. If re - calibration is required, always use a new sample cup with fresh CALSET calibrator.

- B. Place the sample cup on the sample platform and slide it smoothly until it stops and is securely held within the slot.
- C. When the display reads "CALIBRATION Y/N", pressing the key Yes the instrument starts calibrating.
- D. After about 60 seconds, the calibration slope values are displayed for each analyte. These slope values are indicative of the performance of the Electrode Cell Assembly and will vary from calibration to calibration.
- E. Acceptable slope values are as follows: Na = 50 - 70 mv, K = 50 - 70 mv
- G. Slope values can be reviewed at any time (Section 3.5)

6. QUALITY CONTROL TESTING

6.1 WHEN TO RUN QULITY CONTROL

- A. It is recommended that a quality control program be established according to the guidelines of approved laboratory practice and in accordance to Government regulations.
- B. As a general rule, quality control tests of at least levels (normal and abnormal) should be run each day before analyzing the patient samples.

6.2 HOW TO RUN QUALITY CONTROL TESTS

- A. Use only ISE Quality controls.
- B. Make sure controls are at room temperature. Allow at least 10 minutes to reach room temperature before using.

- C. Fill inner level of sample cup with control material. Be sure to replace the cap securely on the control bottle to prevent contamination.

Note: If a duplicate control level reading is to be run, always use a new sample cup and fresh sample of control.

- D. Place the sample cup on the sample platform and slide it smoothly until it stops and it securely held within the slot.
- E. Press 'YES' for sampling.
- F. When the results are displayed, compare the values with the ranges on the package insert to verify that the results are within the acceptable ranges.
- G. If the values are within the range, record the values for each analyte and level.
- H. If the results are not within the ranges
 - Verify that the control material has not expired and is at room temperature.
 - Repeat the analysis, if still outside the acceptable range, recalibrate the analyzer and repeat the control analysis.
- I. Never run the CALSET as control.

7. RUNNING PATIENT SAMPLES

7.1 SAMPLE COLLECTION AND HANDLING

- A. Analysis should be performed on the serum or heparinised whole blood or plasma. Heparin is the anticoagulant of choice for plasma specimen. EDTA or CITRATED ANTICOAGULANTS MAY INTERFERE WITH SODIUM AND POTASSIUM RESULTS AND HENCE SHOULD NOT BE USED. WHOLE BLOOD SAMPLES SHOULD NOT BE ANALYSED WITHOUT ANTICOAGULANT.
- B. Samples should be maintained in containers with stoppers to avoid contamination or evaporation. If testing is to be delayed, samples should be capped, refrigerated and returned to room temperature before analysis. Serum or Plasma samples must be separated from the red blood cells if not tested immediately to avoid false high potassium values.

- C. Whole blood samples should be run within one hour to avoid haemolysis, which will cause erroneous test results.
- D. Because of the small volume of sample in the Sample cup, evaporation can occur causing erroneous results, if the sample is not run within few minutes. For this reason, do not dispense the sample into sample cup until you are ready for analysis.

8. CLEANING AND MAINTENANCE

- 8.1 Clean sample cup platform if necessary using cotton swab or soft cloth moistened with water [Figure A]. It may be necessary to remove the platform for cleaning. To reinstall, slide the top of the platform under the mounting plate protrusions to lock into location [Figure C]. Then with the platform against the mounting plate, press on the snap fastener to secure it. [Figure D].

Spills on the analyser should be cleaned as soon possible after they occur. DO NOT USE ALCOHOL OR OTHER ORGANIC SOLVENTS TO CLEAN THE ANALYSER. A MILD MIXER OF SOAP AND WATER MAY BE USED. HOWEVER, THE ELECTRODE ASSEMBLY SHOULD BE REMOVED PRIOR TO CLEANING. NEVER PUMP SOAP THROUGH ANY OF THE TUBING LINES OR PUMP TUBING.

- 8.2 Check for leaks around the sample cup area, the AUTOCAL calibrator and waste container tubing connections and the tubing connections on the manifold once in a week.
- 8.3 Make sure that the wash cell is always filled with AUTOCAL allowing the electrode to soak in the solution.

9. PERFORMANCE DATA

9.1 ANALYZER PERFORMANCE SPECIFICATIONS

A. Usable Range (mMol/L)	Sodium 10-999	Potassium 0.2-300.0
B. Resolution (mMol/L)	Sodium 0	Potassium 0.1
C. Calibration points	Sodium 120-180	Potassium 4.0 - 8.0

9.2 ANALYZER PRECISION

A. Within - Run C.V (%)

Sodium			Potassium		
Low	Normal	High	Low	Normal	High
0.3	0.8	0.4	1.2	1.5	0.8

B. Day-to-Day C.V. (%) Multiple testing over 15 days period

Sodium			Potassium		
Low	Normal	High	Low	Normal	High
0.7	0.5	0.5	0.4	0.6	1.1

9.3 CORRELATION (ACCURACY COMPARED WITH FLAME PHOTOMETER)

A Correlation coefficient of 0.99 for both Sodium and Potassium was obtained on both whole blood and plasma samples when the ECS 2000 was compared with a flame photometer.

10. PRECAUTIONS

- A. 1. Should not use the Instrument in the room having X-Ray or Radiation equipments.
- 2. Patients having implant devices should not handle the instrument

- B. Non- Usage of Instrument for a long period
 - 1. Switch on the Instrument and check the display
 - 2. Check fluidics
 - 3. Check for calibration.
 - 4. In case of any errors / problem contact our ECS Representative.

11. TROUBLE SHOOTING

ERROR - 1

CAUSES:

- Continuous Drift in measurement.
- Improper mains earthing.

ACTIONS:

- Change mains cord to plugpoint with proper earthing.
- If the problem is not solved, call your service engineer.

ERROR - 2

CAUSES:

- Potential difference generated by the Electrode for both standards.
- Instability of Calibrator due to improper closing of the vial.
- Insufficient Autocal and Calset used during Calibration.

ACTIONS:

- Change the Calset.
- If the problem persists, call your Service Engineer.

ERROR - 3

CAUSES:

- Drift in Calibration.
- Insufficient of Autocal and Calset.
- Improperly connected Power Supply Unit.
- Electrode Instability.

ACTIONS:

- Switch on the Power Supply unit.
- Calibrate again.
- If still the problem persists, call your service engineer.

ERROR - 4

CAUSES:

- Sample Value out of Instrument's Measuring Range,

ACTIONS:

- No need to Calibrate.
- Abnormal Sample Value (either low or high).

ERROR - 5

CAUSES:

- Potential Drift is out of the slope tolerance level.
- Insufficient Sample Volume.

ACTIONS:

- Calibrate Again.
- Take sufficient volume of Sample.
- If still the problem persists, call your Service Engineer.

DRIVE FAILURE

CAUSES:

- Misalignment of Electrode Assembly.

ACTIONS:

- Restart the equipment by switching it off.
- Remove the Electrode Assembly & check for the Free movement of Electrode and reinstall.

12. SYSTEM SHIPMENT OR STORAGE PROCEDURE.

12.1 FOLLOW THE BELOW PROCEDURE FOR PREPARATION OF THE ECS 2000 FOR SHIPMENT OR EXTENDED STORAGE.

- A. Remove the AUTOCAL Calibrator and straw assembly from the bottle.
- B. Remove and re-cap the AUTO CAL Calibration bottle from the Analyser.
- C. Remove cap and properly dispose of the Waste Container.
- D. Remove the Electrode Cell Assembly and store in a container with sufficient volume of AUTOCAL Calibrator to submerge the Electrode bands within the Wash Cell. The AUTO CAL Calibration solution should be kept above the Electrode bands by additon solution to compensate for evaporation.
- E. Turn the on/off switch in the rear of the instrument to the "off" position.
- F. If possible, store or ship Analyzer in the original box in which it was shipped.

**IN THE EVENT OF WRONG RESULTS OR NON FUNCTION OF EQUIPMENT, IT
SHOULD BE REPORTED TO ECS REPRESENTATIVE.**

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