Operator Manual

SMARTLYTE®

Electrolyte Analyzer

Na+/K+/Cl-/Ca++/Li+

Digitally signed by Poiata Vitalie
Date: 2024.08.16 12:25:39 EEST
Reason: MoldSign Signature
Location: Moldova

MOLDOVA EUROPEANĂ

DIAMOND®

DIAGNOSTICS

DIAMOND DIAGNOSTICS, INC.
333 Fiske Street
Holliston, MA USA 01746
www.Diamonddiagnostics.com

DIAMOND DIAGNOSTICS Kft
Ezred Street 1-3. C1/07
1044 Budapest Hungary

- Important Information! -

These Instructions for Use contain vital warning and safety information.

This instrument is intended to be used only for the specialized purpose described in the instructions. The most important prerequisites for use, operation, and safety are explained to ensure smooth operation. No warranty or liability claims will be covered if the instrument is used in ways other than those described or if the necessary prerequisites and safety measures are not observed.

The instrument may be operated only by persons whose qualifications enable them to comply with the safety measures that are necessary during operation of the instrument.

Adjustments and maintenance performed with removed covers and connected power may be attempted only by a qualified technician who is aware of the associated dangers.

Instrument repairs are to be performed only by the manufacturer or qualified service personnel.

For a detailed operator training video for your SmartLyte Analyzer, please visit: http://www.diamonddiagnostics.com/video/video_SmartLYTE.htm

Only accessories and supplies either delivered by or approved by Diamond are to be used with the instrument. These items are manufactured especially for use with this instrument and meet the highest quality requirements

Operation of the instrument with solutions whose composition is not consistent with that of the original solutions can negatively affects, above all, the long term measurement accuracy. Deviations in the composition of the solutions can also decrease the service life of the electrodes.

The quality control requirements must be completed at least once daily. Because accurate measurement results depend not only on the proper functioning of the instrument, but also on a number of other factors (such as preanalytics), the results produced by the instrument should be examined by a trained expert before subsequent decisions are reached that are based on the measurement values.

Explanation:

 "Caution, refer to accompanying documents".

- Important Information! -

- Operating safety information -

- The instrument has been constructed and tested according to the protective measures stipulated by EN 61010-1 / IEC 61010-1 / EN 6101010-2-101 for electrical measurement, control, IVD, and laboratory instruments and was delivered from the factory in flawless condition with regards to safety features. In order to preserve this condition and ensure safe operation, the user must respect the notices and warnings that are contained in these Instructions for Use.

- This instrument is classified under the protection class I according to EN 60000-1 / IEC 1010-1.

- The instrument meets the conditions for overvoltage category II.

- The instrument meets the conditions for contamination level 2.

- Do not operate the instrument in an explosive environment or in the vicinity of explosive anesthetic mixtures containing oxygen or nitrous oxide.

- If an object or liquid enters the internal areas of the instrument, remove the instrument from its power supply and allow an expert to check it thoroughly before using it again.

- The instrument is suitable for long-term operation indoors.

CAUTION:

- Plug the power cord into a grounded socket only. When using an extension cord, make sure it is properly grounded.

- Any rupture of the ground lead inside or outside the instrument or a loose ground connection may result in hazardous operating conditions. Intentional disconnection of the grounding is not permitted.

- The instrument is not suitable for operation with a direct current power supply.

  Use only the original mains plug delivered with the instrument.

- Operating safety information –

Table of contents

1 Introduction

The SMARTLYTE Electrolyte Analyzer is designed to quickly, accurately and efficiently conduct basic electrolyte testing in the convenience of the laboratory.

This manual will help guide you through setting up the analyzer and starting sample analysis. As the user becomes familiar with the operation of the unit, the manual is a useful reference for day-to-day routines and as a guide for maintenance and troubleshooting.

Fig. 1-1

1.1 General notes

1.1.1 Symbols

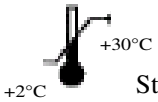
This product fulfills the requirements of the Directive 98/79/EC for in vitro diagnostics medial devices.

Lot number

Expiration date

Electrodes: Install by...
The electrode must be inserted before the indicated date, but can remain in the instrument after the date.

Solutions: Use by...
The solution must be completely consumed by the indicated date.
If a day is not indicated, apply the last day of the respective month.



Storage temperature: The conditions necessary to preserve the product's shelf life.

For in vitro diagnostic use

Manufacturer-according to In Vitro Diagnostic guidelines 98/79/EC

Store upright

Risk of infection (according to the standard DIN EN 61010-2-101)

Reference and/or ordering number

IMPORTANT: read and follow Instructions for Use!

Please read and follow the information on the packaging insert / instructions for use.

Serial number (model plate)

Used in the Instructions for Use

Sections marked with this symbol (see Instructions for Use) contain information that must be observed to avoid potential injuries (to patients, users and third parties)

Risk of infection!

All sections / passages that are marked with this symbol describe procedures and/or indicate conditions or dangers that could damage or lead to a malfunction in the SMARTLYTE Electrolyte Analyzer, and which therefore should never be attempted.

TIP: *All sections / text locations marked with "TIP" describe safe procedures that are intended to provide the user with additional help.*

1.2 Measurement and calibration procedures

1.2.1 Measurement procedure

The SMARTLYTE Electrolyte Analyzer methodology is based on the ion selective electrode (FLUID) measurement to determine the measurement values (see chapter 7, section "The measurement principle").

There are six different electrodes used in the SMARTLYTE Electrolyte Analyzer: sodium, potassium, chloride, ionized calcium, lithium and a reference electrode. At any one time, four electrodes can be installed on the instrument, of which one must be reference. Each analyte electrode has an ion selective membrane that undergoes a specific reaction with the corresponding ions contained in the sample being analyzed. The membrane is an ion exchanger, reacting to the electrical charge of the ion causing a change in the membrane potential, or measuring voltage, which is built up in the film between the sample and the membrane.

A galvanic measuring chain within the electrode determines the difference between the two potential values on either side of the membrane. The galvanic chain is closed through the sample on one side by the reference electrode, reference electrolyte and the "open terminal". The membrane, inner electrolyte and inner electrode close the other side.

A difference in ion concentrations between the inner electrolyte and the sample causes an electro-chemical potential to form across the membrane of the active electrode. The potential is conducted by a highly conductive, inner electrode to an amplifier. The reference electrode is connected to ground as well as to the amplifier.

The ion concentration in the sample is then determined by using a calibration curve determined by measured points of standard solutions with precisly known ion concentrations.

1.2.2 Calibration procedure

A 2-point (non-Li configuration) or a 3-point (Li configurations) calibration is performed automatically every 4 hours in **[H-READY]** mode and a 1-point calibration is automatically performed during each measurement.

An automatic calibration procedure is also performed shortly after power-on or reset. A calibration cycle can also be initiated manually at times when no sample measurements are being performed.

1.2.3 Measurement evaluation

The validity of the test results from the SMARTLYTE Electrolyte Analyzer must be carefully examined by a clinician who will take the patient's clinical condition into consideration before any decisions are reached.

In order to ensure the quality of the measurement results, complete quality control test on 3 levels (low, normal, high) after changing electrodes, test each level at least once daily or more often in accordance with local regulations.

1.2.4 Important safety instructions

For your own safety and the proper operation of your equipment, always follow these precautions when working with the SMARTLYTE Electrolyte Analyzer:

- Keep the analyzer away from sinks and wash basins.

Do not use ammonia-based or alcohol-based cleaners, which can chemically react with plastic, on or around the analyzer.

- Always handle blood samples and collection devices with appropriate precautions.
- Use approved protective gloves to avoid direct contact with sample.
- Aseptic procedures are required when cleaning the sampling probe to avoid contamination.
- Dispose of FLUID PACK according to local regulations.

1.2.5 Sample collection and handling

Universal precautions must be observed when collecting blood samples. It is recommended that all blood be handled as potentially infectious specimens capable of transmitting human immunodeficiency virus (HIV), hepatitis B virus (HBV), and other blood-borne pathogens. Proper blood collection technique must be followed in order to minimize risk to the laboratory staff. Gloves should always be worn when handling blood and other body fluids.

Please refer to NCCLS document M29-A2, "Protection of Laboratory Workers from Occupationally Acquired Infections", Approved Guidelines - Second Edition 2001, for further information on safe handling of these specimens. For further information, see chapter 3: "Measurement".

1.2.6 Disposal of Fluid Pack, electrodes, and instrument

Dispose of used Fluid Pack, electrodes and the instrument according to local regulations for biologically contaminated-hazardous waste!

Disposal of the reference electrode

This *electrode contains mercury. Therefore dispose of it in accordance with the local and/or laboratory regulations for hazardous waste!*

1.3 System description

1.3.1 Analyzer components

Fig 1-2

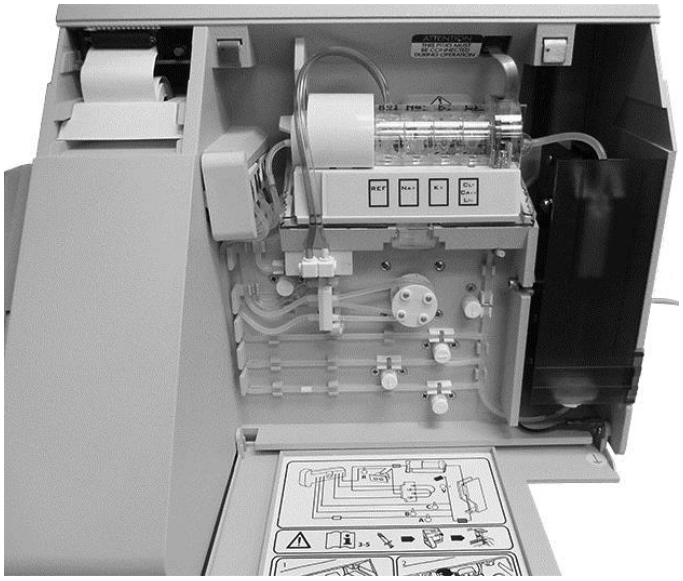


Fig 1-3

Display

The analyzer display has a 160 x 64 pixels graphic display with white backlight. The graphic display shows all characters used in more than 11 international languages.

Note: Refer to the language section for list of supported languages.

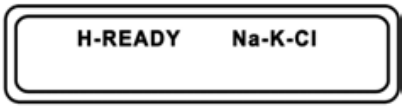


Fig. 1-4

Keypad

With the **YES** and **NO** keys all analyzer functions, including: sample measurement, data input, programming and quality control testing can be performed.

Fig. 1-5

Printer

The graphical printer with 192 pixels/line uses thermal paper to output results and other information. The analyzer will print measured values, calibration values, electrode voltages, and amount of liquid remaining in the Fluid Pack as well as cleaning, maintenance, and error information. The unit allows convenient storage of a second roll of paper in the rear of the paper tray.

The printer supports 3 user selectable printing font sizes that can be set under **[INSTRUMENT SETTING]** then **[PRINTER SETTING].**

Note: Default font size is set to 2.

Fig. 1-6

Measuring chamber

The measuring chamber consists of a movable left locking device, four electrodes, a sample sensor connector, and a measuring chamber base.

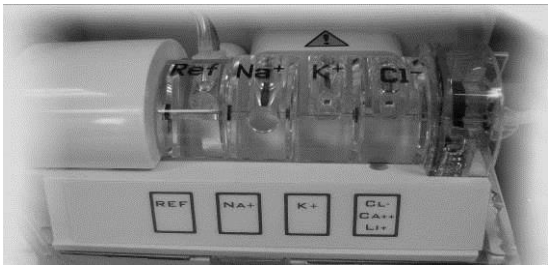


Fig. 1-7

Peristaltic pump

A peristaltic pump transports all samples and operating fluids inside the instrument.

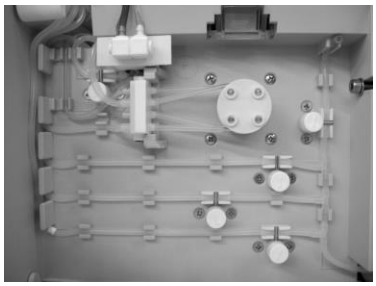


Fig. 1-8

Sample probe and cover

The sample probe mechanism is located behind the sample door at the front of the unit.

Fig. 1-9

Valves

Valves control the movement of the liquid within the analyzer.

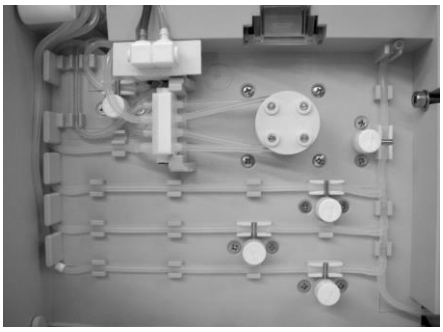


Fig. 1-10

FLUID PACK

The self-contained FLUID PACK is constructed to ensure that waste cannot spill out of the package.

Fig. 1-11

Rear panel

The rear panel of the unit contains a serial number plate, two USB connectors, an RS232 interface port, and a power switch/power receptacle module.

Fig. 1-12

Electronics

The following accessories are available for use with the SMARTLYTE Electrolyte Analyzer. The mini-keyboard is provided with the instrument. The barcode scanner is not and can be purchased separately.

Fig. 1-13

1.4 Installation

1.4.1 Location

Location is important for trouble-free operation of your analyzer. Before you begin setup, choose a site that is convenient for your sampling needs and meets the following physical requirements of the unit:

- Ambient temperature + 15°C to + 32°C
- Avoid exposure to direct sunlight, vibration and strong electromagnetic fields (electric motors, transformers, X-ray equipment, cellular phones, etc).
- Use a stable and level work surface.
- Maximum relative humidity of 85% (15 % - 85 %)
- Ample room to allow air to circulate freely around the unit sees Fig. 1-14.
- Avoid exposure to explosive gases or vapors.
- Check for correct voltage: 100 to 240 VAC, 50/60 Hz.

Fig. 1-14

After setting up the SMARTLYTE Electrolyte Analyzer in a location that meets the above requirements, perform the following steps to ensure the instrument is ready for operation:

- Refer to the packing slip to check for the completeness of the shipment.
- If the shipment is incomplete, please inform your Diamond representative immediately.

If the instrument has been damaged during shipment, immediately inform the company that made the delivery. Retain all packaging materials and products as this may be needed as evidence in the event of a damage claim.

Do not remove the analyzer from the shipping carton by pulling upward on the packing materials. These packaging materials do not provide strength to support the analyzer.

Accessories

The following parts are delivered as standard accessories with the SMARTLYTE Electrolyte Analyzer:

- AV-BP5194D – Startup Kit
- AV-BP5014D – Shutdown Kit
- DD-0201 – Keyboard

You will also need a supply of lint-free tissues and disposable sample cups, which should be kept in a location convenient to the analyzer.

Optional Accessory

The following part is an optional accessory for the SMARTLYTE Electrolyte Analyzer (see Section 1.5.1 for further information):

- Barcode Reader

1.4.2 Setting up

Prior to beginning the actual installation, it is recommended that the operator read through this section thoroughly to develop an understanding of the procedures that are required.

Begin by placing the analyzer on a secure table top that allows plenty of working space and is convenient to a power connection.

Open the analyzer main door. Locate and carefully remove the five red relief clamps.

TIP: *Save the clamps for reuse to prevent damaging the tubes if the analyzer is later shut down for any reason. ("See Shutdown")*

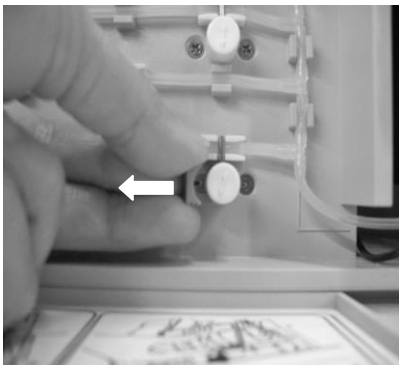


Fig.1-15

Fig. 1-16

Slip the two pump windings around the analyzer pump rollers, making sure not to over stretch the tubing.

1.4.3 Electrodes and measurement chamber

The next procedure involves preparing and installing the electrodes in the measurement chamber.

- Remove all electrodes from their protective boxes and place on clean surface.
- Verify that all measurement electrodes, Na, K, Cl, Ca, and/or Li have sufficient fill solution. Each should be 3/4 full.
- Check for air bubbles in the fill chamber near sample path. If there are any, tap the electrode body to dislodge air bubbles.
- Check that all measurement electrodes and reference housing have o-rings properly seated on the left side of the electrode as shown in Fig 1-17.

Fig.1-17

- Unscrew the transport housing from the reference electrode and check that the o-ring on the electrode is properly seated. Rinse, dry and save the transport housing for storage of the reference electrode in the event the analyzer is turned off or taken out of service.

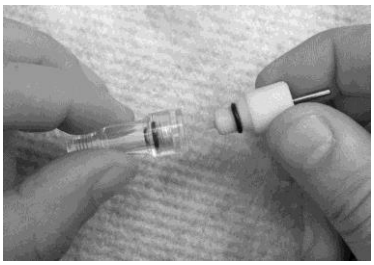


Fig.1-18

- Carefully screw the reference electrode into the reference electrode housing as shown in Fig 1-19.

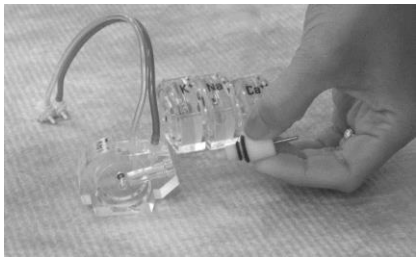


Fig.1-19

- Slide the measurement chamber forward until it locks in the front position. (Fig 1-20)

- Unclamp the left electrode holder of the electrode tray by moving the clamp forward. (Fig 1-21)

Fig.1-20

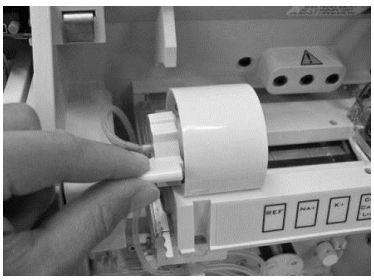


Fig.1-21

- Locate the sample sensor on far right of the electrode tray. Check that the cable is connected correctly to the instrument.

- Check that an o-ring is present on the left side of the sample sensor.

Fig.1-22

- Now install the electrodes in the measurement chamber, beginning on the right and working to the left (the reference electrode will be installed last).

TIP: *The electrode on the right may be one of the following: chloride, ionized calcium, lithium or a dummy electrode. If sodium and lithium are selected, the K+ electrode is replaced by a dummy electrode. . (See Fig. 1-27 for possible configurations of electrodes.)*

- Check to make sure that the lettering on the electrode corresponds with the correct electrode position on the label. Also, note that all electrodes have a lip on the bottom that rests on the flat edge of the measurement chamber to aid in proper positioning.

Fig.1-23

- After all electrodes have been installed, close the clamp on the left electrode holder by lifting it upward until it locks in the back position. Ensure that the electrodes are properly seated by checking position of each. (Fig 1-24)

Fig.1-24

- Slide the measurement chamber back until it snaps into position.

Tip: *Electrode tray may need to be slid upwards towards the back for proper fit into electrode receptacle. Check that sample sensor is connected, connect if it is not.*

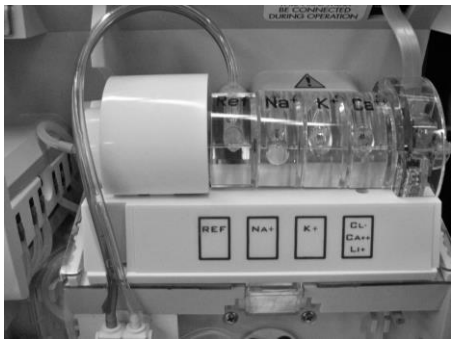


Fig.1-25

- Plug the tubing connector of the reference housing assembly in the receptacle below the left side of the measurement chamber.

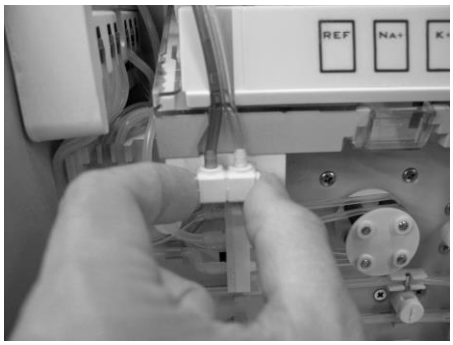


Fig.1-26

Possible parameter configurations are the following:

		Electrode Position		
		Na	**K**	**Ca/Cl/Li**
Configuration	**1**	Na	K	Dummy
	2	Na	K	Cl
	3	Na	Dummy	Cl
	4	Na	K	Ca
	5	Na	Dummy	Ca
	6	Na	K	Li
	7	Na	Dummy	Li
	8	[Na]	Dummy	Li
	9	Na	Ca	Li

Fig.1-27

For details to access menu to select parameters, see section "7 Selecting parameter configuration" which is under Operator Settings.

1.5 Preparing the Analyzer for Operation

1.5.1 Installing accessories

The keyboard and barcode scanner must be plugged in prior to start-up. If the instrument is powered on before installing these items, the user must shut the analyzer off before connecting these accessories to prevent hardware failures that can occur if parts are plugged in while the unit is on.

Connectors for these items are located on the back of the instrument as shown in Fig.1-12.

The function keys on the mini-keyboard have been programmed to correspond to the SMARTLYTE menu options. The table below indicates the menu selection for each function key. In addition, menu can be navigated using the arrow keys on the lower right side of the keyboard. All functions can be accessed using the keyboard.

FUNCTION KEY	**DESCRIPTION**
F1	ANALYZE BLOOD
F2	SEE RESULTS
F3	URINE/QC/STD
F4	MAINTENANCE
F5	OPERATOR SETTINGS
F6	INSTRUMENT SETTINGS
F7	DIAGNOSTICS
F8	PERFORM CALIBRATION
F9	STANDBY
F10	SERVICE LOGIN
NAVIGATION KEYS (Lower right side)	
RIGHT ARROW	NEXT/NO
LEFT ARROW	PREVIOUS
DOWN	YES

The barcode scanner is an optional device convenient for entering barcodes from Fluid Packs and Patient samples.

Fig. 1-28

1.5.2 Start-up

- Locate the power switch on the back of the unit and make sure that it is in the OFF (0) position.

- Plug the power cord into the power receptacle module on the back of the unit, and then plug the cord into a grounded electrical outlet (100 - 240 V, 50/60 Hz).

Fig.1-29

- Push the power switch to the ON (I) position. The unit will automatically begin to operate.

Fig.1-30

Now that the SMARTLYTE Electrolyte Analyzer is functioning, begin using the keypad interface to communicate with the instrument. Use the NO key to make changes, the YES key to accept the displayed values or information.

TIP: *After start-up, change the language, set date and time and insert printer paper.*

1.5.3 Selecting language

The factory-set language is English. However, to change the language:

- Press the **NO** key until **[INSTRUMENT SETTING?]** is displayed
- Select **YES**.
- Press **NO** to scroll through the menu until **[LANGUAGE SETTING?]** is shown
- Press **YES**. Upon entering this menu the languages will be displayed.

ENGLISH
GERMAN
FRENCH
SPANISH
ITALIAN
PORTUGUESE
CHINESE
JAPANESE
RUSSIAN
KOREAN

- Select **YES** when the desired language is displayed on the screen.

1.5.4 Setting date and time

The analyzer will display a default date and time and will allow you to input the correct date and time:

DATE: 01-JUN-11
TIME: 00:00

To enter the correct date and time:

- Press **NO**, until the actual day is displayed. To accept this value, press **YES** and the cursor will move to the month.
- By keeping the **NO** key depressed, the analyzer will automatically scroll through the numbers, first slowly, then faster.
- Press **NO**, until the actual month is displayed. To accept this value, press **YES**.
- Press **NO**, until the actual year is displayed. To accept this value, press **YES**. Now the actual date will be displayed.
- Follow the same procedure to enter the current time.
- After entering the time, the analyzer will prompt **[ok?].** Press **YES** if the date and time entered are correct, or press **NO** to make a change.
- After pressing **YES** at the last prompt, the analyzer will prompt: [**STATUS: NO PACK INSTALLED**].

1.5.5 Installing the printer paper

TIP: *The printer paper is heat sensitive on one side only. Please make sure that you insert the paper roll correctly.*

The thermal printer paper supplied by DIAMOND DIAGNOSTICS, INC. contains an indicator strip to alert you when the paper roll should be changed.

- Place a new paper roll in the paper tray
- Fold the printer paper as shown below

Fig. 1-31

- Press the paper feed button to completely feed the paper through the printer.

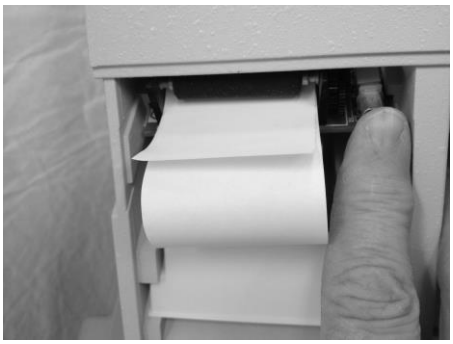


Fig 1-32

TIP: *By pressing the paper advance button once, the paper will automatically advance 10 lines.*

To avoid damage to the printer, do not pull the paper out of the printer. Use the paper feed button to advance the paper through the printer.

1.5.6 Installing the FLUID PACK

- Record the installation date of the Fluid Pack on the label on the Fluid Pack.
- Remove the protective strip and slide the Fluid Pack into position on the left side of the analyzer. Save the protective strip for disposal.

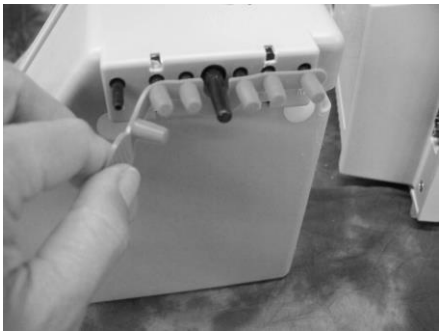


Fig. 1-33

Fig. 1-34

Once the protective strip is removed, be sure to keep the Fluid Pack upright to avoid spillage.

- If a new pack is installed, instrument will prompt **[PACK BARCODE:].** Using the Keyboard or barcode scanner, input the pack barcode number from side label as shown in figure 1-13.
- If barcode is valid, instrument will perform initial maintenance. Please refer to error messages [Chapter 6] in case input barcode label is not accepted.

1.5.7 Selecting parameter configuration

After completion of the daily maintenance procedure, the analyzer starts an automatic calibration for sodium and potassium.

To select a different parameter configuration, interrupt the calibration by pressing **NO** shortly after it starts.

- Continue pressing **NO**, until **[OPERATOR SETTINGS?]** is displayed. Enter **YES**.
- Press **NO**, until the prompt **[CHOOSE PARAMETERS?]** is displayed.
- Enter **YES** and the current configuration will be displayed. The default configuration is the following:
- SEL. PARAMETER:
- [Na] [K] [ ] ok?
- Press **NO** until the desired configuration is displayed. Enter **YES** to accept this selection.

TIP: *If [(Na)] [ ] [Li] is selected, only lithium results are reported. A working sodium electrode is required lithium measurements. Install the sodium electrode and calibrate for lithium.*

- Press **NO** to [**CLEAN?]** And [**CONDITION?]** The SMARTLYTE will automatically start a calibration.

The SMARTLYTE Electrolyte Analyzer is now ready to operate.

1.5.8 Maintenance (Manual)

Prior to performing the first calibration or running the first sample, the SMARTLYTE Electrolyte Analyzer needs to undergo a simple cleaning and conditioning procedure that helps ensure that the analyzer will perform properly. This procedure is called Maintenance. It should be performed each day the analyzer is used.

The process involves cleaning the sample path and conditioning electrodes. The bottles containing Cleaning Solution A and Electrode Conditioning Solution should be ready, along with a package of lint-free tissues that will be used to dry the probe.

Check expiration date on the bottles of the Cleaning Solution A and the Electrode Conditioning Solution.

In some cases, when the analyzer prompts you for an action and you do not respond within a set period of time, an alarm will sound and the unit will discontinue its current operation.

To start the daily maintenance:

- Pour a small amount of Cleaning Solution A into a clean container or sample cup

- Press the **NO** key, until **[MAINTENANCE?]** is displayed, and YES to select. Select **[CLEAN?]** by pressing **YES**.

- At the prompt **[LIFT DOOR LOAD SAMPLE],** lift the sample door and the pump will begin to turn.

Fig. 1-35

- Dip the probe into the Cleaning Solution A until **[WIPE PROBE_SHUT SAMPLE DOOR]** is displayed. Use a lint-free tissue to remove the cleaning solution from the probe. Close the sample door.

Fig. 1-36

- While the analyzer displays **[THANK YOU]** and a brief countdown, pour a small amount of conditioning solution into a clean container sample cup.

- Answer the prompt **[CONDITION?]** by pressing **YES**.

- At the prompt **[LIFT DOOR LOAD SAMPLE],** lift the sample door and the pump will begin to aspirate.

Fig. 1-37

- Hold cup of Electrode Conditioning Solution under the probe, until **[WIPE PROBE_SHUT SAMPLE DOOR]** is displayed. Use a lint-free tissue to wipe the probe to remove conditioning solution.

- Close the sample door.

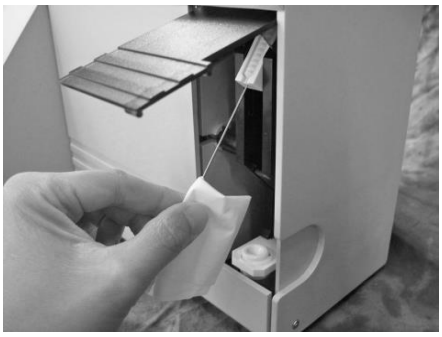


Fig. 1-38

- After the analyzer has displayed **[THANK YOU**], there is a brief countdown. The prompt **[CONTINUE MAINTENANCE?]** can be answered with NO, and an automatic calibration will begin.

TIP: *If the instrument is not configured as Na-K, press NO to stop the calibration and proceed to 1.6.8.*

It is very important that the main door is closed during calibration, since it provides shielding from sources of electromagnetic interference.

Calibration is an automatic process. During this time, the analyzer is conducting measurement operations to ensure the accuracy of the instrument. Occasionally additional time is required, and the analyzer displays an asterisk.

- After finishing the calibration, the analyzer displays **[H - READY]** and is now ready for sample analysis.

1.6 Shutdown

A complete shutdown of the analyzer may be necessary to prepare the analyzer for shipping or in case the analyzer is not being used for an extended period of time. For this procedure, you will need a special shutdown kit.

Never attempt to turn the power off for an extended period of time without performing a complete shutdown of the analyzer.
In case the analyzer is not being used for several days only, it is not recommended to perform a complete shutdown, but to put the analyzer in Standby Mode.

To perform the shutdown, you will need the following items:

- One shutdown plug (supplied with shutdown kit).
- Five solenoid relief clamps (supplied with analyzer and shutdown kit).
- One reference electrode transport housing (supplied with shutdown kit).
- Two containers, one filled with at least 100 mL of water, the other one empty.
- Protective strip for Fluid Pack (supplied with shutdown kit).

Starting at the **[H - READY]** display, do the following:

- Press **NO** until **[OPERATOR FUNCTIONS?]** is displayed. Enter **YES**.
- Select **[ACTIVATE SHUTDOWN?]** and enter **YES.**
- Confirm **[ARE YOU SURE?]** by entering **YES.**

1.6.1 Installing shutdown plug

The analyzer prompts **[WATER & PLUG INSTALLED?].**

- Remove the Fluid Pack and push the protective strip firmly onto the Fluid Pack connector.
- Fill one container of the shutdown kit about halfway with distilled water.
- Insert the shutdown plug carefully into the Fluid Pack receptacle.
- Place the blue marked line into the disposable container filled with water
- Place the red marked line into the empty container.
- Begin the tubing wash procedure by pressing YES.

Fig. 1-39

1.6.2 Installing the transport housing

The analyzer will prompt [**REF PROTECTIVE HSG INSTALLED?**].

- Pull the electrode holder forward and remove the reference electrode assembly.
- Carefully unscrew the reference electrode from the reference electrode housing.
- Temporarily place the reference electrode on a clean, soft cloth.
- Pour the remaining reference solution in the reference housing into transport housing.
- Carefully screw the reference electrode into the filled transport housing.
- The second transport housing is screwed into the reference housing.
- Place the reference housing back into the electrode holder and move the lever backwards, making sure all electrodes are seated properly. The electrode holder remains in the forward position.

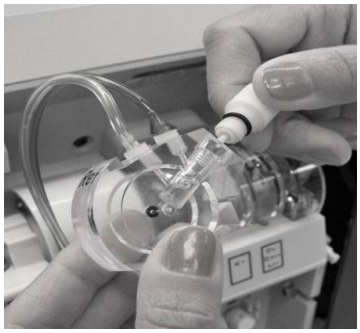


Fig. 1-40

Fig. 1-41

- Press **YES**.

1.6.3 Washing the lines

The analyzer will take approximately one minute to flush all lines with water. Upon completion, you will receive the prompt **[WITHDRAW WATER PRESS YES].**

- Remove the line with the blue mark from the water and place it on a cloth.
- Press **YES**. During this cycle, all lines are purged of water.
- Upon completion, **[ALL ELECTRODES REMOVED?]** will be displayed.

Fig. 1-42

1.6.4 Removing the electrodes and the shutdown plug

- Remove the shutdown plug from the Fluid Pack receptacle.
- Unplug the reference connector below the left side of the electrode holder.
- Move the lever on the left side forward and remove all electrodes, placing them on a soft cloth.
- Move the lever back and push the empty electrode holder into its back position. Unscrew the transport housing from the reference housing.
- Empty the reference housing and place all electrodes into their protective boxes.
- Press **YES.**

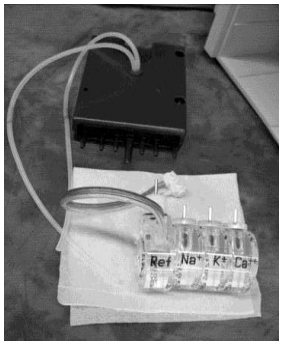


Fig. 1-43

1.6.5 Installing the relief clamps and removing the pump windings

The display will prompt **[VALVE CLAMPS INSTALLED?].**

- Install the red relief clamps making sure that they are snapped securely into position.

Fig. 1-44

- Press **YES.**

Never insert the solenoid relief clamps with the Fluid Pack in place.

- The prompt **[PUMP TUBING RELIEVED?]** appears.
- Grasp the front winding close to the pump roller and gently pull it off the roller.
- Repeat the same procedure for the rear pump winding.

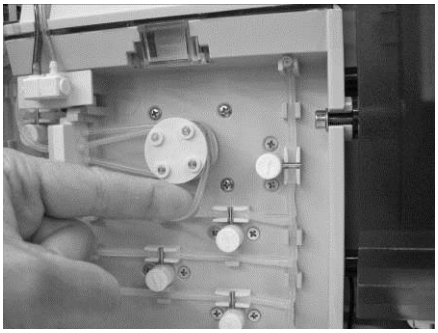


Fig. 1-45

- Press **YES**. The prompt **[RESET ALL DATA?]** will appear.
- By pressing **YES**, all QC values and statistics will be deleted and the sample number is reset to 0. QC and normal ranges as well as correlation factors, printer settings, date/time and Fluid Pack volume are reset to default. Also, all service codes are deactivated. A deletion of all data is recommended in case the analyzer is operated by different personnel later on.
- Press **NO** to retain all data.

1.6.6 Turning the analyzer "off"

- The prompt **[ACTIVATE SHUTDOWN]** will appear.
- Turn the analyzer off.
- Unplug the power cord from the receptacle.
- Close the front door.
- Clean all external surfaces of the analyzer as well as the areas accessible through the main door and sample door (see chapter 5: "Maintenance", section "Clean sample probe and fill port").
- Shutdown is complete.
- Use the original packaging when transporting the analyzer.

1.7 Standby mode

The SMARTLYTE Electrolyte Analyzer is designed to calibrate automatically every four hours during normal operation. If sampling will be delayed for an extended period of time, such as evenings and weekends, you may place the analyzer into Standby mode to suspend automatic calibration and conserve reagents.

TIP: *The analyzer can be programmed to automatically enter Standby mode. For instructions see chapter 6, section "Service codes".*

To enter standby mode:

- Press **NO** until **[OPERATOR SETTINGS?]** appears.
- Press **YES**, then **NO**, until **[ACTIVATE STANDBY?]** appears. Press **YES**.
- The analyzer shows a Standby mode status on the display**. [*STANDBY ON* YES → READY]**
- To exit from Standby mode:
- Press **YES**; **[DEACTIVATE STANDBY?]** will be displayed.
- Press **YES** again.

Depending on the duration of the standby mode, an automatic calibration may be performed.

After that, the analyzer returns to **[H-READY].**

1.8 Daily auto calibration

When the instrument is in Standby, it can be set to do an automatic daily calibration at any time of the day. This allows the instrument to be ready when the operator requires it at a specific time each day.

To enable this function and to set the time for Auto Cal:

- Enter **[INSTRUMENT SETTING]** menu.
- Select **[AUTO CAL SETTINGS?]** by pressing **YES.**
- To set or change the time of the automatic calibration, press **YES** when **[CHANGE HOUR?]** is displayed.
- The time can be adjusted by selecting **NO** to scroll through the numbers.
- Then press **Y**ES when the correct number is displayed.

To disable this function:

- Enter **[INSTRUMENT SETTING]** menu.
- Select **[AUTO CAL SETTINGS?]** by pressing **YES**.
- At **[CHANGE HOUR?],** press **NO**.
- At **[DISABLE AUTOCAL]**, press **YES** which will disable **[DAILY AUTO CAL].**

Auto Cal will occur when instrument is in Standby Mode.

(Page intentionally left blank)

2 Specifications

2.1 Measurement parameters

	Matrix	Specified range
Na^+	B/P/S/Q/D	40 - 200 mmol/L
	U/D	3 - 300 mmol/L
K^+	B/P/S/Q/D	1.7 - 15 mmol/L
	U	5 - 120 mmol/L
CI-	B/P/S/Q/D	50 - 200 mmol/L
	U	15 - 300 mmol/L
iCa2+	B/P/S/Q/D	0.3 - 5 mmol/L
Li+	B/P/S/Q	0.2 - 5.5 mmol/L

B = Whole blood P = Plasma S = Serum

Q = Aqueous QC U = Urine D = Dialysate

	(Normal)		(High)
Display Resolution:	Na^+: 1 mmol/L	or	0.1 mmol/L
	K^+: 0.1 mmol/L	or	0.01 mmol/L
	Cl^-: 1 mmol/L	or	0.1 mmol/L
	iCa^{2+}: 0.01 mmol/L	or	0.001 mmol/L
	Li^+: 0.01 mmol/L	or	0.001 mmol/L

2.2 Performance parameters

2.2.1 Reproducibility

Typical Within-Run Precision is determined from 20 samples run between calibrations.

	BLOOD/SERUM/PLASMA		
Reproducibility Within Run (n=20)	**Na^+**	C.V. ≤ 1%	(120 – 160 mEq/L)
	K^+	C.V. ≤ 1.5%	(2.5 – 6 mEq/L)
	Cl^-	C.V. ≤ 2%	(85 – 130 mEq/L)
	Ca^{2+}	S.D. ≤ 0.02 mmol/L	(0.8 – 1.5 mmol/L)
	Li^+	S.D. ≤ 0.03 mEq/L	(0.4 – 1.3 mEq/L)

	URINE		
Reproducibility Within Run (n=20)	**Na^+**	C.V. ≤ 5%	(100 – 250 mEq/L)
	K^+	C.V. ≤ 5%	(10 – 60 mEq/L)
	Cl^-	C.V. ≤ 5%	(100 – 250 mEq/L)
	(Calcium and Lithium are not measured in urine sampled)		

	DIALYSIS FLUID		
Reproducibility Within Run (n=20)	**Na^+**	C.V. ≤ 1%	(120 – 160 mEq/L)
	K^+	C.V. ≤ 1.5%	(2.7 – 7 mEq/L)
	Cl^-	C.V. ≤ 2%	(85 – 120 mEq/L)
	Ca^{2+}	S.D. ≤ 0.02 mmol/L	(0.8 – 1.7 mmol/L)
	(Lithium is not measured in Dialysis Fluid)		

2.2.2 Linearity

Whole blood, Plasma, Serum and Urine are linear across the claimed performance range. A minimum of 5 levels were tested for each type of sample. Dilutions were made from starting stock solutions and regression analysis done. Correlation coefficients were all greater than 0.99. Slopes were in the range of 0.97 to 1.02.

2.2.3 Correlation Studies

Studies were conducted comparing the Diamond SMARTLYTE to the Roche 9180 with whole blood, plasma, serum and spot urine samples

Whole Blood in mmol/L

Parameter	Slope	Intercept	R^2	Range	n	Ste_{yx}
Sodium	0.988	1.04	0.9962	42.3 – 188.1	128	1.13
Potassium	0.972	0.223	0.9957	1.51 – 14.46	112	0.166
Chloride	1.011	-0.49	0.9882	54.0 – 191.4	123	1.76
Calcium	0.994	0.019	0.9885	0.304 – 4.514	124	0.076
Lithium	0.983	-0.049	0.9919	0.255 – 5.410	123	0.079

Plasma in mmol/L

Parameter	Slope	Intercept	R^2	Range	n	Ste_{yx}
Sodium	0.987	0.87	0.9977	43.5 – 194.4	105	1.06
Potassium	1.006	-0.014	0.9973	1.55 – 13.97	107	0.178
Chloride	1.022	-3.23	0.9879	55.2 – 193.2	115	2.58
Calcium	0.971	0.042	0.9915	0.363 – 4.386	123	0.059
Lithium	0.993	0.002	0.9878	0.298 – 5.071	115	0.092

Serum in mmol/L

Parameter	Slope	Intercept	R^2	Range	n	Ste_{yx}
Sodium	0.99	0.03	0.9964	44.6 – 196.9	122	1.37
Potassium	0.981	0.085	0.9979	1.58 – 14.64	127	0.118
Chloride	1.021	-2.57	0.9687	50.7 – 185.7	125	3.79
Calcium	0.970	0.036	0.9842	0.655 – 4.309	120	0.082
Lithium	1.004	0.092	0.9876	0.213 – 5.149	131	0.122

Urine (Spot) in mmol/L

Parameter	Slope	Intercept	R^2	Range	n	Ste_{yx}
Sodium	0.983	-2.57	0.9843	8– 296	118	8.42
Potassium	0.965	0.34	0.9934	5.3 – 118.2	108	2.22
Chloride	0.976	-1.86	0.9807	15 – 272	118	8.99

Spent Dialysate, mmol/L

Parameter	Slope	Intercept	R^2	Range	n	St_{yx}
Sodium	1.0183	-2.52	0.9989	49 – 179	43	1.31
Potassium	0.9882	0.04	0.9996	1.5 - 14	56	0.08
Chloride	0.9825	2.86	0.9966	52 - 199	51	2.25
Calcium	1.0021	0.03	0.9956	0.25 – 4.5	43	0.08

2.3 Interferences

Negatively charged ions are known to interfere with the chloride electrode causing a positive bias. Salicylate is a common interferent and in its clinical range causes a positive bias of approximately 1 mmol/L which is clinically insignificant. Other ions such as Thiocyanate and Bromide can also cause a positive bias in the chloride ion.

Interferent	**Interferent**	**Concentration Effect**
Bromide	1 mmol/L	increases chloride results by 13 mmol/L
Thiocyanate	2 mmol/L	increases chloride results by 2 mmol/L
Albumin	20 g/L	decreases chloride results by 4 mmol/L
Bicarbonate	10 mmol/L	decreases chloride results by 1 mmol/L

Use only lithium-free sampling containers for the determination of lithium measurement values! If sample containers are used which contain lithium as anticoagulant, this may lead to incorrect patient measurements, which may result in incorrect clinical decisions, possibly endangering the patient's health.

For dialysis solutions, small organic molecules such as lactate can affect ionized calcium concentrations. At 12 mmol/L Lactate, a 0.1 mmol/L decrease in ionized calcium may be observed.

2.4 Limitations

A number of substances have been reported to cause physiological changes in blood, serum and plasma analyte concentrations. These substances can also alter dialysates. Medications and endogenous substances can affect results and clinicians must evaluate results based on the patient's entire clinical situation.

A comprehensive discussion concerning these and other interfering substances, their blood, serum, plasma or dialysate concentrations, and their possible physiological involvement is outside the scope of this Operators Manual.

Opening and closing the fist with a tourniquet in place can result in an increase in potassium levels. It is recommended that the blood sample is obtained without a tourniquet, or that the tourniquet be released after the needle has entered the vein. Difficulty in obtaining blood and/or slow flow through the needle may result in hemolysis.

Since the concentration of potassium inside erythrocytes is much greater than that in extra cellular Fluid, hemolysis should be avoided. Serum and plasma should be separated from the cells as soon as possible after collection. Potassium levels may also be falsely elevated in patients with severely elevated white blood cell (leukocytosis) levels.

The lithium electrode response is dependent on the actual sodium concentration of the sample. Sodium concentrations between 95 and 180 mmol/L (89.6 -169.5 mmol/L for blood/serum) are required for lithium values to be reported.

Pease refer to the Bibliography Section of this manual for the references regarding to the potential interference substances and their effects on the individual analyte.

2.5 Relationship of ionized calcium to total calcium

The ratio of ionized calcium to total calcium in a healthy population is around 0.50 or 50%. These relationships may be altered when using citrate in blood, or when the acid base metabolism is disturbed.

2.6 Bibliography

Bishop ML, Duben-Engelkirk JL, Fody EP. Clinical Chemistry Principles Procedures Correlations, 2nd Ed., (Philadelphia: J.B.Lippincott Co.),1992,p.281.

Burritt MF, Pierides AM, Offord KP: Comparative studies of total and ionized serum calcium values in normal subjects and in patients with renal disorders. Mayo Clinic Proc. 55:606, 1980.

Burtis C, Ashwood E (Eds.), Tietz Textbook of Clinical Chemistry, 2nd Ed., (Philadelphia: W.B. Saunders, Co.,1994) pp.1354-1360,2180-2206.

Calbreath, Donald F., Clinical Chemistry A Fundamental Textbook, (Philadelphia: W.B. Saunders Co., 1992) pp.371, 376, 390-395.

Leypoldt, J.K. Solute Fluxes in Different Treatment Modalities. Nephrology Dialysis Transplantation (2000) 15 [Suppl 1]: 3-9.

National Committee for Clinical Laboratory Standards. Protection of Laboratory Workers from Occupationally Acquired Infections, Second Edition; Approved Guidelines; NCCLS Document M29-A2, (2001).

National Committee for Clinical Laboratory Standards. Additives for Blood Collection Devices: Heparin; Tentative Standard; NCCLS Document H24-T, (1988).

National Committee for Clinical Laboratory Standards. Evaluation of Precision Performance of Clinical Chemistry Devices, Second Edition; Tentative Guideline. NCCLS Document EP5-T2, (1992).

Tietz, Norbert W.,Ed., Textbook of Clinical Chemistry, 2nd Ed., (Philadelphia: W.B. Saunders, Co.,1986), pp.1816, 1837, 1840-1842, 1845.

Toffaletti J, Gitelman JH, Savory J: Separation and quantification of serum constituents associated with calcium by gel filtration. Clin Chem 22: 1968-72, 1976.

2.7 Sample throughput

48 per hour with printout

60 per hour without printout

2.8 Sample volumes

95 µL typical

2.9 Sample types

Whole blood, serum, plasma, urine, dialysate and QC material

2.10 Calibrations

1-point calibration after each sample

2-point or 3-point calibration every 4 hours

2.11 Environmental parameters

Temperature / humidity / stability

Instrument

Operating conditions:

Ambient temperature ……..…..5 - 32°C

Relative humidity ……...……..< 85% (not condensing)

Storage and transportation conditions:

Temperature ……...…...-20 - 40°C

Humidity …….……< 85% (not condensing)

Electrodes

Operating conditions:

Operating temperature ……..…….15 - 33°C

Relative humidity ……..…..……20 - 95%, if T ≥ 15 to ≤ 31 °C
20 - 90%, if T > 31 to ≤ 33 °C

Storage conditions in original package:

Temperature…….18 – 25°C (dry)

Humidity ……15 - 85% (not condensing)

2.12 Reagents

Fluid Pack (PN AV-BP5186D)

Contains the following reagents:

Standard A

For calibration of sodium, potassium, chloride, ionized calcium and lithium in the SMARTLYTE Electrolyte Analyzer.

Contents: 350 mL

Active ingredients: Na^+ 150 mmol/L
K^+ 5.0 mmol/L
Cl^- 115 mmol/L
Ca^{2+} 0.9 mmol/L
Li^+ 0.3 mmol/L

Additives: Germicides

Storage temperature: 18 – 25 ° C

Stability: Expiration date and lot number are printed on each container label

On-board stability: 14 weeks

Standard B

For calibration of sodium, potassium, chloride, ionized calcium and lithium in the SMARTLYTE Electrolyte Analyzer.

Contents: 85 mL

Active ingredients: Na+ 100 mmol/L
K+ 1.8 mmol/L
Cl- 72 mmol/L
Ca^{2+} 1.5 mmol/L
Li+ 0.3 mmol/L

Additives: Germicides

Storage temperature: 18 - 25 °C

Stability: Expiration date and lot number are printed on each container label

On-board stability: 14 weeks

Standard C

For calibration of sodium, potassium, ionized calcium and lithium in the SMARTLYTE Electrolyte Analyzer.

Contents: 85 mL

Active ingredients: Na+ 150 mmol/L
K+ 5.0 mmol/L
Cl- 115 mmol/L
Ca2+0.9 mmol/L
Li+ 1.4 mmol/L

Additives: Germicides

Storage temperature: 18 - 25 °C

Stability: Expiration date and lot number are printed on each container label

On-board stability: 14 weeks

Reference Solution

A salt bridge for calibration and measurement in the SMARTLYTE Electrolyte Analyzer.

Contents: 85 mL

Active ingredients: Potassium, chloride 1.2 mmol/L

Additives: Germicides

Storage temperature: 18 - 25 °C

Stability: Expiration date and lot number are printed on each container label

On-board stability: 14 weeks

On-board stability refers to the Fluid Pack installed in the analyzer. The Fluid Pack has to be exchanged at the latest after 14 weeks.

Dispose of the Fluid Pack according to local regulations for hazardous waste material. A waste container is provided with the Fluid Pack which holds all waste Fluids used, therefore, all sample types, calibrators, cleaning solution, and conditioning solution. This must be handled with appropriate care due to its infectious potential. Avoid skin contact or ingestion.

Urine Diluent (PN AV-BP0344D)

Use as a diluent for the measurement of urine samples in the SMARTLYTE Electrolyte Analyzer.

Contents: 500 ml of solution

Active ingredients: 120 mmol/L Sodium Chloride

Additives: Germicide

Storage temperature: 18-25°C

Stability: Expiration date and lot number are printed on each container label

QC Material (PN DD-92001, DD-92002, and DD-92003, or DD-92123)

Mission Controls Single Level 1, 2, and 3 (DD-92001, DD-92002, and DD-92003) Tri-level, 10 ampules of each level (DD-92123)

Contents: 30 ampules total

Storage Temperature: 18 - 25 °C

2.13 Product data

2.13.1 Electrical data

Mains voltage range……100 to 240 VAC

Frequency……50/60 Hz

Required power……50 W

2.13.2 Classification

Safety Category……I

Overvoltage category……II

Contamination level……..2

2.13.3 Dimensions

Height……33.5 cm

Width……31.5 cm

Depth……29.5cm

Weight……...< 6 kg

2.14 Printer

Type……..Graphical Thermal Printer
Resolution……..192 pixels per row
Printing speed…….28 mm / sec
Paper width…….38 mm
Paper length……about 30 m

2.15 Display

Type……Graphical Display
Resolution……...160 x 64 pixels
Backlight……White

2.16 Interface Settings (Hyper Terminal)

Bits per second……...115200
Data Bits…….8
Parity……..None
Stop Bits……1
Flow Control……..None
Serial Connector……9-pin male DB-9
Recommended cable length…...< 40 feet
Interface setting ……ON

3 Measurement

3.1 Preanalytics

3.1.1 Sample collection

Safety

Follow the usual applicable safety precautions when drawing blood samples. When handling blood samples, there always exists the danger of transmission of HIV, hepatitis B and C viruses or other pathogens transmissible by blood. Employ suitable blood sampling techniques in order to reduce risk to personnel. Always wear protective gloves and suitable protective clothing.

Please refer to NCCLS document M29-A2, "Protection of Laboratory Workers from Occupationally Acquired Infections", Approved Guidelines - Second Edition 2001, for further information on safe handling of these specimens.

Sample requirements

Only qualified personnel may perform the collection of blood needed for analytical purposes.

The puncture site may never be squeezed! Mixing the blood sample with tissue Fluid may lead to the premature onset of clotting despite sufficient heparinization of the sample collection containers! Incorrect sample collection or the use of an unsuitable sample collection container may lead to errors and discrepancies in the measurement values.

See, for example, NCCLS document H11-A3, "Procedures for the collection of arterial blood specimens - Third Edition", Approved Standard, 1999, for detailed information about blood sampling, storage, and handling.

Hemolyzed samples and icteric samples should not be used since their interferent effect on the SMARTLYTE has not been tested.

Acceptable anticoagulants

The only clot inhibitors that may be used for analyses in the SMARTLYTE Electrolyte Analyzer are heparin salts. Other clot inhibitors, such as EDTA, citrate, oxalate, fluoride, and ammonium-based materials have significant influence on parameters and may not be used for this reason.

Use only lithium-free sampling containers for the determination of lithium measurement values! If sample containers are used which contain lithium as anticoagulant, this may lead to incorrect patient measurements, which may result in incorrect clinical decisions, possibly endangering the patient's health.

Sample collection containers

The SMARTLYTE Electrolyte Analyzer will accept samples directly from syringes, collection tubes, and sample cups.

3.1.2 Sample handling

For ionized calcium values, anaerobic conditions must be followed for all sample types. Contact with ambient air will cause a loss of CO_2 in the sample and the subsequent rise in pH will cause a reduction in ionized calcium.

Hemolyzed samples and icteric samples should not be used since their interferent effect on the SMARTLYTE has not been tested.

Whole blood

Withdraw whole blood samples using heparinized syringes, capillaries, or the microsampler.

Analyze the samples as soon as possible after sampling. Remove air bubbles from the sample collection container immediately after the sampling procedure.

Serum

After the appearance of spontaneous clotting, process the sample in a centrifuge to separate the cellular, solid components and the fibrin from the watery serum. Transfer the serum to a suitable sample container and seal.

If it is necessary to store the sample, close the sample container tightly and store between 4 - 8 °C. If a sample is cold, warm it to room temperature (15 - 33 °C) before analysis.

Plasma

Plasma samples are obtained by centrifuging heparinized whole blood, during which the cellular components of the blood are removed from plasma.

Complete the analysis as quickly as possible.

If it is necessary to store the sample, close the sample container tightly and store between 4 -8 °C. If a sample is cold, warm it to room temperature (15 - 33 °C) before analysis.

Plasma samples older than 1 hour must be re-centrifuged in order to remove fibrin clumps that may have formed.

Each laboratory should determine the acceptability of its own blood collection syringes, and tubes and the serum or plasma separation products. Variations in these products exist between manufacturers, and at times, from lot to lot.

Dialysis Fluid

Bicarbonate based dialysis fluid should be analyzed in the Bicarbonate mode. Analysis should be carried out as quickly as possible after collection of the sample into an air tight container to prevent changes in Bicarbonate concentration.

Aqueous solutions

Aqueous samples, such as Standard A, have to be measured in the Standard Mode.

The Standard Mode ALWAYS reports direct FLUID values and is not affected by correlation factors or the setting of QCF (see 'Service Codes').

3.1.3 Limitations of clinical analysis

The determined performance data can be influenced by known and unknown factors as described below.

3.1.4 General

The literature lists various substances which may negatively affect the measurement result of the blood and plasma/serum sample material. A detailed discussion of these phenomena can be found at different places in the technical literature. With respect to the SMARTLYTE Electrolyte Analyzer, an attempt was made to identify or evaluate these possible influences. But since it is not possible to check all medication or substances, the user should be immediately informed with abnormal deviations of the measurement results as with every clinical analysis and evaluate the complete picture of the patient or perform expanded measurements in his own laboratory, if necessary.

3.1.5 Electrolytes

It is well-known, for example that the potassium value of a patient can vary by up to 20% from the normal state, simply because of the presence of a pressure bandage. Hence, taking a blood sample while a pressure bandage is present should be avoided. In general, a local hemolysis caused by pressure should be avoided prior to taking a blood sample.

3.2 Measuring procedure

QC measurements must be performed in their entirety (i.e., all three QC levels must be measured). Omitting QC measurements or ignoring QC measurement result may lead to incorrect patient measurements, which may result in incorrect clinical decisions, possibly endangering the patient's health.

In order to ensure the quality of the measurement results, complete a quality control test on 3 levels (low, normal, high) after each electrode change and after startup of the instrument. Diamond recommends this be done at least once daily or more often in accordance with local regulations.

3.2.1 Sample measurement

The SMARTLYTE Electrolyte Analyzer provides fast and easy operation. Whenever [**H-READY**] appears, the analyzer is ready to accomplish sample measurements.

It is very important that the main door is closed during sampling to provide shielding from sources of electromagnetic interference.

Urine samples require dilution, and must be analyzed in the urine mode. Instructions for analyzing urine samples: see "Urine samples".

*The SMARTLYTE provides the ability to enter the patient name and ID associated with the sample being tested. To enable this feature, press **YES** at **[OPERATOR SETTINGS?]**. Select **NO** until **[PATIENT DATA ENTRY?]** is displayed and then press **YES**. This enables patient data entry.*

TIP: *If **YES** is pressed, the SMARTLYTE will ask for ID# and name if enabled. Opening the door will not allow the operator to enter a name or ID#. No name or ID# will be assigned to the sample.*

To take a sample measurement, follow procedure below.

- Open the sample door when **[H-READY]** is displayed or press **YES**. The prompt **[LIFT DOOR LOAD SAMPLE]** will be displayed and the pump will start to aspirate.

Fig. 3-1

- Hold the ampule under the probe until **[WIPE PROBE SHUT SAMPLE DOOR]** is displayed.
- Use a lint-free tissue to wipe the probe. Then close the sample door when prompted.

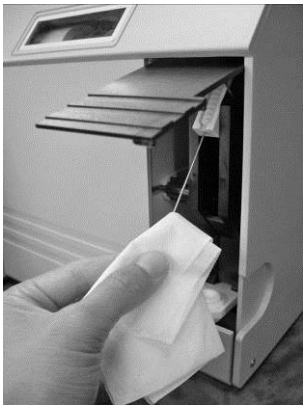
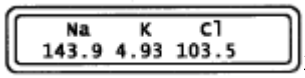


Fig. 3-2

It is very important that the sample probe is carefully cleaned each time following a sample introduction.

The analyzer will display **[THANK YOU]** and a brief countdown will begin. At completion of analysis, the test results will be displayed and printed.

ISE ANALYZER
H-SMARTLYTE
NA-K-Cl



JM

12-JUN-11 14:58
HOSPITAL EAST (optional)
NAME: _ _ _ _ _ _ _ optional)
ID: _ _ _ _ _ _ _ _ _ _
_ _ _ _ _ _ _ _ _ _ _ _

TEST #: 72
Na=143.9 mmol/L
K = 4.93 mmol/L
Cl = 103.5 mmol/L

Fig. 3-3 Fig. 3-4

Values that are higher or lower than the programmed normal range will be indicated by an arrow pointing up or down.

If the Na+ result is above 169.5 mmol/L or below 89.6 mmol/L for blood/serum, the Li+ value cannot be calculated.

If an additional sample report is desired or the automatic sample report is turned off, the results may be printed from memory. The SMARTLYTE can store up to 1000 test results. To print stored results follow these steps:

- Press **NO**.
- The prompt appears. **[PRINT SAMPLE REPORTS?]**
- **E**nter **YES**.
- The prompt is displayed. **[PRINT LAST SAMPLE REPORT?]**
- Enter **YES.**
- The measurement results will be displayed, and the report will print.
- The prompt appears. **[PRINT BY SAMPLE ID?]**
- Enter **YES.**
- The prompt is displayed**. [ENTER ID TEXT:]**
- Enter **NO** to scroll through the numbers and select **YES** when the correct number is shown or use keyboard or barcode scanner.
- The SMARTLYTE will begin printing.
- The prompt **[FIND MORE?]** is displayed which allows the user to find more results for the same sample ID performed at another day or time. Press **YES** to continue or **NO** to move to the next menu option.
- If **NO** is selected, the prompt **[PRINT BY NAME?]** is shown.
- Enter **YES**.
- Enter **NO** to scroll through the letters and select **YES** when the name is displayed or use keyboard or barcode scanner.
- The SMARTLYTE will begin printing.
- The prompt **[FIND MORE?]** is displayed which allows the user to print more results from another test for the same patient name. Press **YES** to continue or **NO** to move to the next menu option.
- The prompt is displayed. **[PRINT BY TEST#?]**
- Enter **YES**
- At the prompt, **[ENTER TEST #:]** enter **NO** to scroll through the numbers and select **YES** when the correct number is shown or use keyboard or barcode scanner.
- The SMARTLYTE will begin printing.
- The prompt **[FIND MORE?]** is displayed which allows the user to print results with the same test number. Press **YES** to continue or **NO** to move to the next menu option.
- The prompt appears. **[PRINT BY DATE?].** This will print all results for a specific day.
- **[PRINT DAILY SUMMARY]** will print the last day's results.
- **[PRINT WEEKLY SUMMARY?]** prints the results from the previous 5 days.
- **[PRINT ALL?]** will print all data stored. This function can be interrupted by selecting NO.

Stored results can also be deleted.

3.2.2 Direct ISE

- Press **NO** until **[QC/STD/URINE SAMPLE?]** appears; press **YES** and then **NO**, until [**STANDARD SAMPLE?**] is displayed. Press **YES** to confirm.

The Standard Mode ALWAYS reports direct ISE values and is not affected by correlation factors or the setting of QCF (see 'Service Codes').

3.2.3 Dialysate Analysis

- Press **NO** until [**QC/STD/DIALYSATE URINE SAMPLE?**] appears; press **YES** and then **NO**, until [**BICARBONATE?**] or [**ACETATE?**] is displayed. Press **YES** to perform the desired test(s).

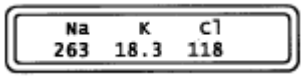
***NOTE**: By default dialysate mode is **OFF**. Please contact your customer support to activate the dialysate mode.*

3.2.4 Urine samples

Before measuring urine, accurately dilute the sample with Urine Diluent in the ratio of 1 part urine to 2 parts diluent (e.g., 1 mL urine and 2 mL urine diluent). Thoroughly mix the sample and analyze in the urine mode.

As soon as [**H-READY**] is displayed, the analyzer is ready for measurements. Urine samples, diluted with urine diluent, are analyzed in the urine mode. To enter this mode:

- Press **NO**, until **[QC/STD/DIALYSATE/URINE SAMPLE?]** is displayed. Enter **YES.**
- Press **NO**, until **[URINE SAMPLE?]** is displayed. Enter **YES** and follow the instructions.
- Upon completion of measurement, the analyzer will display and print out the results.



ER ISE ANALYZER
IE H-SMARTLYTE
Na-K-Li

12-JUN-11 15:06

_ _ _ _ _ _ _ _ _ _ _

Fig. 3-4

12-JUN-11 15:06

HOSPITAL EAST
ID: _ _ _ _ _ _ _ _ _

_ _ _ _ _ _ _ _ _ _

TEST: URINE
TEST#: 29
Na=263 mmol/L
K =18.3 mmol/L
Cl =118 mmol/L

HOSPITAL EAST
ID: _ _ _ _ _ _ _ _

TEST: URINE
TEST#: 30
Na=142 mmol/L
K = ↑ ↑ ↑ mmol/L

Fig. 3-5

Ca^{2+} and Li^{+} are not measured in urine.

If the K^{+} urine sample result is ↑↑↑, then the sample value is higher than 45 mmol/L. The measurement must be repeated using the following procedure:

- Record the Na^{+} value (as well as Cl^{-}, if activated) of the first urine measurement.
- Dilute the diluted urine (already diluted 1:2 with urine diluent) with distilled water in the ratio of 1:2 (e.g., 1 mL of diluted urine and 2 mL distilled water).
- Thoroughly mix the sample.
- Run a second urine measurement with the twice-diluted urine sample.
- Ignore the Na^{+} value (and Cl^{-}, if activated).
- Multiply the K^{+} value by 3 and record.

3.3 Normal ranges

The instrument has preset normal ranges for whole blood, plasma and serum samples which are:

Na^+	136	-	145 mmol/L
K^+	3.5	-	5.1 mmol/L
Cl^-	97	-	111 mmol/L
iCa^{2+}	1.0	-	1.30 mmol/L
Li^+	0.6	-	1.2 mmol/L

The normal ranges can be adapted to the respective laboratory-specific requirements[2].

Values that are higher or lower than the programmed normal range will be indicated by an arrow pointing up or down.

The normal ranges can be changed through the programming menu. Follow the instructions for [**INSTRUMENT SETTINGS?**] in chapter 4.2 and enter 3-digit password.

- Press **NO** until [**SETUP NORMAL RANGES**?] is displayed. Press **YES**.
- The analyzer will display the normal ranges of the current parameter configuration:

  Na LOW=xxx
  Na HIGH=xxx ok?

Normal ranges can be entered by pressing **NO**

- Press **NO** until the desired number is displayed, and press **YES** to advance to the next position. Repeat this for all numbers of the normal range.
- After entering the normal ranges, the new values will be displayed. Verify correctness of the ranges:

  Na LOW=xxx
  Na HIGH=xxx ok?

TIP: *If an incorrect number was entered inadvertently, press **NO**, and the analyzer allows for retyping the normal range.*

- Press **YES** and the display will advance to the next parameter.

Repeat the above procedure for all parameters. After all activated parameters have been programmed; the display prompts **[SETUP CORREL. FACTORS?].** This allows programming of the correlation factors.

The expected normal urine values are given in the table below2. It should be used only as a guide. Each laboratory or testing site should establish its own range of normal values, taking into account factors such as age, sex, diet, and other determinants of electrolyte levels.

Urine Expected Values

Na^+	40	-	220 mmol/day
K^+	25	-	120 mmol/day
Cl^-	110	-	250 mmol/day

3.4 Correlation factors

The correlation factor allows for the correlation of SMARTLYTE measurement results to other electrolyte analyzers. Activated correlation values are taken into consideration when sampling whole blood, serum, plasma and QC samples. They are not used for standard samples analyzed in the [**QC/STD/URINE SAMPLE**] mode. A separate set of correlation factors is available for urine and dialysate samples.

In case the QC samples were switched to report direct ISE values (Code QCF, see 'Service *Codes'), the values are NOT affected by correlation factors.*

The measurement range as well as normal and QC ranges are ALWAYS checked against the DISPLAYED values. Therefore, you may have to adjust the QC and normal ranges to your correlation factors.

The correlation factors can be changed through the programming menu. Follow the instructions for **[INSTRUMENT SETTINGS?]** in chapter 4.2 and enter the password.

- Press **NO**, until **[SETUP CORREL. FACTORS?].**
- Enter **YES**, the analyzer prompts **[RESET CORREL. FACTORS?].**
- Entering **YES** deletes all current correlation factors. The analyzer will then advance to the other correlation programming functions.
- Entering **NO** shows the prompt **[ENTER/CHECK CORREL. FCTR?]** and allows to input or to verify correlation factors for each parameter.
- Entering **YES** to the prompt **[ENTER/CHECK CORREL. FCTR]** will allow to change the correlation factors or to verify correlation factors already programmed.

The current values will be displayed, such as:

Na(b) = +00.0
Na(m) = 1.000ok?

If the Na^+ intercept (b) and the slope (m) are correct, press **YES**.

- To change these values, press **NO.**
- The intercept and slope values may be adjusted by pressing **NO** to change the number, and by pressing **YES** to accept the number.
- The programmed factors are automatically applied to blood/serum and QC samples.

Follow the same procedure for the intercept (b) and slope (m) for K^+, Cl^-, iCa^{2+} and Li^+.

Only activated parameters can be programmed.

A separate set of correlation factors is available for urine samples.

- At the prompt **[ENTER URINE CORREL. FACTORS?],** press **YES**.
- Program the factors as described above.

Note that there are no urine correlation factors available for iCa^{2+} and Li^+, since these parameters are not measured in urine mode.

A separate set of correlation factors is available for Dialysate samples.

- At the prompt [**ENTER (DIALYSATE) CORREL. FACTORS?**], press **YES**.
- Program the factors as described above.

Note that there are no urine correlation factors available for Li^+, since this Parameter is not measured in Bicarbonate mode.

*Correlation factors can be printed from the **[PRINT REPORTS?]** menu. To do this, press **NO** until **[PRINT CORRELATION FACTORS?]** is displayed. Then press **YES**.*

3.4.1 Determination of the correlation factors

If the analyzer to correlate with does not compare to flame photometer values, the correlation factors need to be determined. This may be done using one of the following two methods:

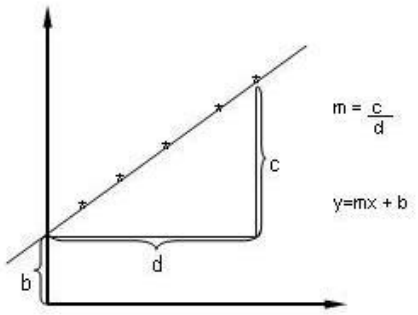


Fig 3-7

a) Worksheet for the correlation factors

1) Measure MISSION CONTROLS Level 1 and Level 3, three times each on the SMARTLYTE Electrolyte Analyzer and the reference analyzer.
2) Fill out a Correlation Factor Worksheet for each parameter. Follow the arrows and calculations to determine the intercept (b) and slope (m). (See appendix for blank worksheets).

b) Sample Analysis Regression function

1) Analyze at least 20 lipid-free serum samples or samples with normal lipids on the SMARTLYTE Electrolyte Analyzer and on the reference analyzer. Select samples with different concentrations in order to provide determination points from the lowest point to the highest point of the measurement range.
2) Use a calculator with a linear regression function to determine the intercept (b) and slope(m).

3.5 Selecting Vet Mode

Vet Mode can be selected from the Operator Settings menu. Contact your local distributor to obtain the password. See Section 8.8 for flow charts, instructions and normal ranges.

Once changed over to Vet Mode, verify that the display is [**V-READY]** after calibration**.**

4 Quality Control

QC measurements must be performed in their entirety (i.e., all three QC levels must be measured).Omitting QC measurements or ignoring QC measurement results may lead to incorrect patient measurements, which may result in incorrect clinical decisions, possibly endangering the patient's health.

4.1 General QC concept

DIAMOND DIAGNOSTICS, INC. always strives to ensure the highest quality standards for its products. This quality awareness is the result of a sense of responsibility toward the customer and the well-being of the patient.

Quality control is an important element of this claim. Diamond offers an aqueous QC material called MISSION CONTROLS that should be used to ensure that the SMARTLYTE Electrolyte Analyzer provides measurements of high quality in order to protect patients.

In order to ensure the quality of the measurement results, complete quality control tests on 3 levels (low, normal, high) after each electrode change and startup of the instrument. A quality control program for electrolytes includes the analysis of sample materials with known ranges of expected values and the comparison of these values with analyzer results.

The following control material is recommended:

- MISSION CONTROLS (REF: DD-92001, DD-92002, DD-92003, DD-92123)

The target values listed in the package insert sheet should be taken as 2 SD values (SD = standard deviation).
The QC measurement results within the target value range ± 2SD are acceptable.

If QC measurement results fall outside the target value range ± 3SD, the parameter must not be used for further measurements!

QC measurement results that are greater than the target value ± 2SD, but less than the target value ± 3SD, should be investigated.

Refer to Chapter 6 for Troubleshooting tips.

4.2 Material setup

The QC material must be defined prior to the QC measurement.

- Starting from the [**H-READY**] screen, press **NO**, until the prompt **[INSTRUMENT SETTINGS?**] appears, and select with **YES**.

For safety and security, the analyzer can only be programmed or have existing parameters changed by entering the correct password.

The analyzer prompts [**ENTER PASSWORD**]. The code "**DDI**" can be entered using the keyboard or as follows:

- Press **NO**, until the character D appears.
- Press **YES** and the cursor will advance to the second position.
- Press **NO**, until the character D appears.
- Press **YES** and the cursor will advance to the last position.
- Press **NO**, until I appears.

***TIP**: If the desired character was missed, keep pressing the* **NO** *key until the correct character appears.*

***TIP**: If an incorrect code was entered inadvertently, the analyzer will display* [**INVALID PASSWORD RETRY?**]. *Enter* **YES**; *the* [**ENTER PASSWORD**] *prompt is displayed. To exit this menu, press* **NO**.

If the code was entered correctly, press the **YES** key. The analyzer is now prepared for programming and will display [**SETUP CONTROL LEVEL 1 RANGES?**].

- To enter a new lot number, press **YES**.
- The analyzer prompts **[LOT: xxxxx CHANGE LOT#?].**
- Enter **YES**, the analyzer shows **[PRINT OLD VALUES AND STATISTICS?].**
- Enter **YES** to receive a printout that contains information including the mean, standard deviation (SD) and coefficient of variation (CV) of stored data.
- Enter **NO**, the analyzer shows **[NEW CONTROL LOT RESET DATA?].**

At confirming this prompt, all statistical data for current lot will be deleted.

Enter **YES** to display [**ENTER CONTROL LOT #**]. Enter the new lot number by pressing the **NO** key until the desired number is displayed, and press **YES** to advance to the next position.

***TIP**: The first time* QC *lot number information is entered, the SMARTLYTE Electrolyte Analyzer will display a default lot number. Thereafter, the current lot number will appear. If the current lot information does not need to be changed, but the current programmed QC ranges need to be verified, press* **NO**.

TIP**: If an incorrect lot number was entered inadvertently, press* ***NO*, and the analyzer returns to* [**ENTER CONTROL LOT #**].

- The analyzer will now sequentially display high and low ranges for the electrolytes that correspond with the QC level and lot number, such as:

  Na LOW = 040
  Na HIGH = 205

- Press **YES** to display the next parameter range.
- After all activated parameters have been programmed, the display prompts [**ADDITIONAL PARAMETERS?**]. Select this option to program deactivated parameters.
- After each range has been displayed, QC level 1 programming will be completed.

To continue programming, repeat the above procedure for QC Level 2 and QC Level 3.

At the completion of QC Level 3 programming, the analyzer will prompt [**SETUP NORMAL RANGES?**]. This programming feature allows you to customize the normal ranges that the SMARTLYTE Electrolyte Analyzer will use to flag abnormal patient measurement values on both the display and printed report (see chapter 8.1.2: "QC report").

4.3 Performing a QC measurement

In order to ensure the quality of the measurement results, perform a quality control test using all 3 levels (low, normal, high) after each electrode exchange and after startup of the instrument. Local regulations or your operating procedure may require quality control tests daily or more often.

TIP: *Up to 500* QC *measurements can be stored per level. The values can be stored and the statistics printed at any time.*

MI *CONTROLS should be stored at 18 - 25°C before use.*

It is very important that the main door is closed during sampling, since it provides shielding from sources of electromagnetic interference.

Starting from the [**H-READY**] screen, press **NO** until [**QC/STD/URINE SAMPLE?**] appears.

- Press **YES**, [**CONTROL LEVEL 1?**] will be displayed. Press **YES** or lift door.

The prompt [**LIFT DOOR LOAD SAMPLE**] will be displayed.

- Take a Level 1 ampule from the MISSION CONTROLS box and mix it carefully.
- Gently tap the head of the ampule with the fingernail to remove any liquid.
- Carefully open the ampule by breaking off the top.

Pro *ers by using gloves or tissue while breaking ampule.*

- Open the sample door: The prompt **[LOAD SAMPLE]** appears.

TIP: *Introduce the QC material directly from the ampule!*

Hold the ampule under the probe until **[WIPE PROBE SHUT SAMPLE DOOR]** is displayed. Use a lint-free tissue to clean the probe, and then close the sample door.

It is very important that the sample probe is carefully cleaned each time following a sample introduction.

The instrument will display **[CONTROL LEVEL 1 TESTING…]** and a countdown will begin, during which the QC will be analyzed. Upon completion, the results will be briefly displayed, such as:

Na	**K**	**Cl**
125.1	**3.05**	**77.8**

The SMARTLYTE Electrolyte Analyzer "flags" values that are above or below the programmed target ranges by using an "up" or "down" arrow.

- The prompt **[SAVE QC VALUES?]** appears.
- To save the values in memory, press YES. To reject the values, press **NO**. If the values are rejected, the analyzer will return to the **[CONTROL LEVEL 1?]** display, allowing to repeat the QC Level 1 measurement by pressing **YES**, or to skip to QC Level 2 by pressing **NO**.

If the value is outside the measurement range (↑↑↑↑,↓↓↓↓ *or* **ERR**), *it will automatically be rejected.*

TIP: ***YES*** *must be pressed to save QC values.*

If the values have been saved, [**VALUES ACCEPTED!**] will be displayed shortly, followed by the prompt [**CONTROL LEVEL 2?**].

For further QC measurements (Level 2 and Level 3), follow the outlined instructions for

Level 1, being sure to use Level 2 or Level 3 MISSION CONTROLS.

TIP*: To discontinue QC measurement, press the* **NO** key, *until* [**H-READY**] *is displayed.*

At completion of QC Level 3 measurement, the analyzer prompts [**CONTINUE QC/STD/URINE SAMPLE?**]. If measurements for all Levels have been completed, press **NO** and the analyzer returns to the [**H-READY**] display.

TIP*: Responding* ***YES*** *to the* [**CONTINUE QC/STD/URINE SAMPLE?**] *prompt, the analyzer returns to* [**CONTROL LEVEL 1?**].

4.4 Printing a QC report

The SMARTLYTE Electrolyte Analyzer will store in memory the last 500 QC measurement values for each of the three QC levels.

To print the last QC value stored:

- Press **NO** until **[PRINT REPORTS?]** is displayed. Press **YES.**
- **[PRINT QC AND STATS]** press **YES**.
- At **[PRINT LAST CONTROL?]** press **YES**.
- Select the last stored results by pressing **YES** and **NO.**

To print statistical report:

- Press **NO** until **[PRINT REPORTS?]** appears. Press YES.
- Press **NO** until **[PRINT QC AND STATS?]** appears. Press YES.
- Press **NO** until **[PRINT QC STATISTICS?]** appears. Press YES.
- Press **YES**, and select the QC statistics desired by level.

If correlation factors are changed or QC values switched to direct ISE, ALL values in memory are recalculated and printed in the new setting.

(Page intentionally left blank)

5 Maintenance

After use, components of the SMARTLYTE Electrolyte Analyzer, including tubing, fill port, Fluid Pack etc., contain biological Fluids and therefore represents a possible infectious risk.

Handle these components with care and according to regulations surrounding potentially infectious materials.

Avoid contact with skin! Always wear gloves! Danger of infection!

5.1 Decontamination

5.1.1 Decontamination Procedure

The purpose of this procedure is to minimize the risk of infections when replacing items that were in contact with blood.

Perform these decontamination procedures regularly.

Diamond recommends following a decontamination procedure in addition to regulations specific to the laboratory.

Never use alcohol based disinfectants!
Never use disinfectant sprays.

IMPORTANT: Do not attempt to decontaminate any part of the instrument before shutting it down and unplugging it from the power source.

Before plugging the instrument back in and turning it on, always wait 15 minutes to allow the disinfectant to evaporate.

Regularly decontaminate the following parts of the instrument:

- Sample probe mechanism consisting of sample probe and fill port
- Surfaces of the instrument

Sample probe mechanism

See "Clean sample probe and fill port" on page 65.

Surfaces of the Instrument

See "Cleaning analyzer surfaces" on page 65.

5.1.2 Recommended disinfectant

Surfaces

Protein remover (*PN AV-BP0521*)

- Potential dangers

Due to the alkaline and oxidizing character of this preparation, we cannot rule out local irritation to the skin, eyes, and mucous membranes.

- First Aid measures

After inhalation: breathe fresh air.

After skin contact: wash with generous amounts of water, remove contaminated clothing.

After eye contact: rinse eyes with-generous amounts of water, contact an eye doctor.
After drinking: drink large amounts of water, avoid vomiting, contact a doctor.

5.2 Daily maintenance

Prior to running the first sample of the day, the SMARTLYTE Electrolyte Analyzer needs to undergo a simple cleaning and conditioning procedure that helps ensure the unit will perform properly. This procedure is called “maintenance” because it must be performed once each day the analyzer is used to conduct sampling.

In case cleaning and/or conditioning has not been performed within the last 24 hours, the analyzer will automatically print on each sample report [**EXECUTE MAINTENANCE!].**

TIP: *If fewer than 5 samples are analyzed each day, cleaning should be performed once a week instead of daily (see Weekly maintenance").*

- Press the **NO** key, until [**MAINTENANCE?**] is displayed, and **YES** to select.
- Select [**CLEAN?**] by pressing **YES**.
- At the prompt [**LIFT DOOR LOAD SAMPLE**], pour a small amount of Cleaning Solution A into a clean container. Lift the sample door and the pump will begin to aspirate.
- Hold the Cleaning Solution A under the probe, until analyzer beeps and the message [**WIPE PROBE_SHUT SAMPLE DOOR**] is displayed, and use a lint-free tissue to remove the cleaning solution from the probe. Close the sample door.

Fig. 5-1

Fig. 5-2

- While the analyzer displays **[THANK YOU]** and a brief countdown, pour a small amount of conditioning solution into a clean container.
- At the prompt **[CONDITION?]**, press **YES**.
- At the prompt **[LIFT DOOR LOAD SAMPLE]**, lift the sample door and the pump will begin to aspirate.
- Hold the Electrode Conditioning Solution under the probe, until analyzer beeps and the message **[WIPE PROBE_SHUT SAMPLE DOOR];** use a lint-free tissue to remove the conditioning solution from the probe. Close the sample door.
- After the analyzer displayed **[THANK YOU]** and a brief countdown, press **NO** at the prompt **[CONTINUE MAINTENANCE?].** An automatic calibration will be started.

It is very important that the main door is closed during calibration, since it provides shielding from sources of electromagnetic interference.

5.3 Weekly maintenance

On a weekly basis, or whenever necessary, you should clean the sample fill port and sample probe as well as the exterior analyzer surfaces.

5.3.1 Clean sample probe and fill port

Starting from the **[H-READY]** screen, perform the following actions:

- Open the sample door.
- Clean the fill port, probe and surrounding area with a damp cotton swab.
- If the analyzer attempts to perform sample analysis, **[SAMPLE NOT FOUND]** will be briefly display, and it will return to the **[H-READY]** screen.
- The exterior surfaces should be wiped clean with a soft, damp cloth.

Never use strong or abrasive cleaners. Do not use cleaners containing alcohol on the SMARTLYTE Electrolyte Analyzer. Use a slightly damp cloth to avoid getting Fluid inside the analyzer.

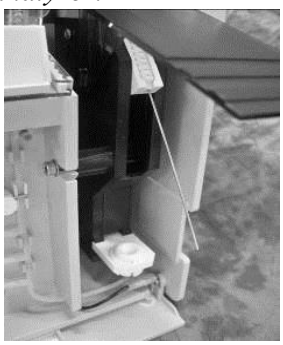


Fig 5-3

5.3.2 Cleaning analyzer surfaces

Never use alcohol based disinfectants!
Never use disinfectant sprays.

IMPORTANT: Do not attempt to decontaminate any part of the instrument before shutting it down and unplugging it from the power source.

Before plugging the instrument back in and turning it on, always wait 15 minutes to allow the disinfectant to evaporate.

Regularly, decontaminate the surfaces of the analyzer including the front door with an undiluted disinfectant (Deproteinizer). Use swabs or sponge that has been soaked with Deproteinizer. The minimum deproteinizing disinfection contact time of 15 minutes is to be strictly followed.

Very dirty surfaces (e.g., contaminated with blood) should first be cleaned with swabs or a sponge that have been soaked with Deproteinizer disinfectant. If the grooves in the front door or the areas around the measuring chamber window require more cleaning, use a small commercial plastic brush to clean them. Remove all visible impurities. The deproteinizing disinfection procedure should be followed as described above.

5.4 Monthly maintenance

5.4.1 Cleaning the reference electrode housing

Monthly maintenance involves cleaning the reference electrode housing, and should be performed prior to daily maintenance. To complete this procedure, a small amount of deproteinizer is needed.

- From the **[H-READY]** screen, press NO to access **[MAINTENANCE?].**
- Press YES, the prompt **[CLEAN?]** appears.
- Do not press any keys.
- Open the front cover of the analyzer.
- Unplug the tubing of the reference electrode from the receptacle below the left side of the measuring chamber.

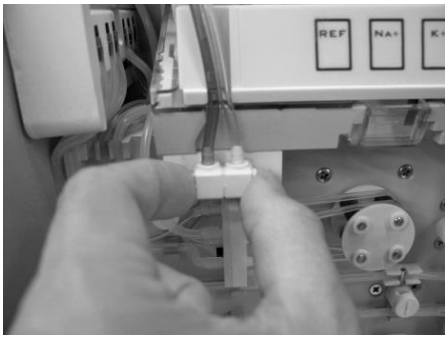


Fig. 5–4

- Slide the measuring chamber forward until it locks in the front position.
- Unclamp the left electrode holder by moving the clamp forward.

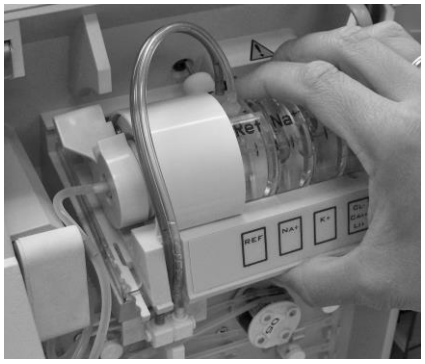


Fig. 5-5

Fig. 5-6

- Open the reference electrode assembly from the analyzer
- Unscrew the reference electrode from the reference housing. Store the reference electrode in the transport housing filled with reference solution.

Fig. 5-7

TIP: *The reference solution can be taken from the reference electrode housing.*

It is very important that the reference electrode always be stored in reference solution and never allowed to become dry.

- Pour deproteinizer solution into a small container and submerge the reference housing into it, ensuring that no air bubbles remain in the housing.

Do not submerge the reference connector and tubing.

- After 15 minutes, remove the reference housing from the deproteinizer. Thoroughly rinse the housing with tap water and dry.
- Unscrew the transport housing from the reference electrode. Check that the O-ring on the electrode is properly seated. Rinse the transport housing with water and save for later use.
- Carefully screw the reference electrode into the reference electrode housing. Install the assembly into the left side of the measuring chamber.
- Close the clamp on the left electrode holder by lifting it upward until it locks in the back position. Ensure the electrodes are seated properly.

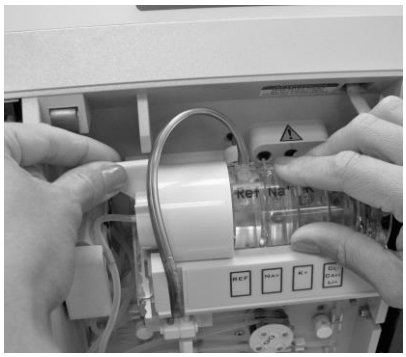


Fig.5-8

- Plug the tubing of the reference electrode into the receptacle below the left side of the measuring chamber.
- Slide the measuring chamber back until it snaps into position, and close the front cover of the analyzer.

Tip: *Measuring chamber may need to be tipped upwards to slide electrodes into this receptacle*

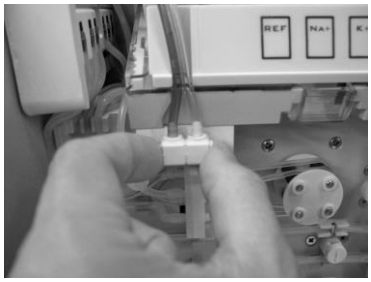


Fig 5-9

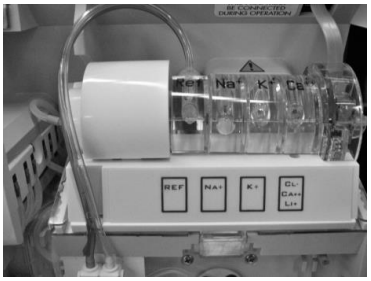


Fig.5-10

- At this time, you may perform daily maintenance by pressing **YES**.
- If daily maintenance is not needed, press **NO** until **[PERFORM CALIBRATION?]** is displayed. Press **YES** and a complete calibration cycle will be performed.

5.5 Semi annual maintenance

5.5.1 Exchanging the pump tubing set

To make sure that the pump does not turn on during this procedure, press **NO** until [**MAINTENANCE?**] is displayed. Press **YES** and [**CLEAN?**] will appear. Then, do not press any keys.

When changing the pump tubing set, proceed as follows:

- Remove the front cover and slip the two pump windings from the pump rollers.
- Next, disconnect one tube at a time from the old pump winding plate and reconnect to the same place on the new pump winding plate.

Tip: *Have the new pump tubing set ready to replace the old one*

Fig.5-11

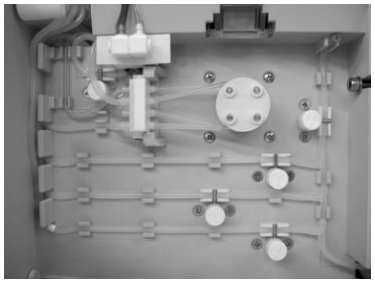


Fig.5-12

- Install the new pump winding plate and slip the new pump windings over the pump rollers, being careful not to cross the tubes.

- Press **NO** until [**PERFORM CALIBRATION**?] is displayed. Press **YES** to initiate a calibration cycle.

Dispose of the pump tubing set according to local regulations for hazardous waste!

5.6 Annual maintenance

5.6.1 Exchanging main tubing harness

Once a year or as needed, the main tubing harness should be replaced.

Always wear gloves! Danger of infection!

- At the **[H-READY**] screen press **NO**, until **[SERVICE MENU?]** appears, and press **YES.**
- Press **NO,** until **[CHECK PINCH VALVES?]** appears. Press **YES**.
- Remove the valve caps, sliding them in the direction of the arrow.
- Then remove the pinch bars.
- Disconnect the reference electrode and pull out the white reference electrode receptacle.
- Disconnect the tubing with the green band from the left side electrode holder.
- Open the sample flap and pull out the fill port.
- Remove the Fluid Pack and slide out the white Fluid Pack receptacle. Disconnect the tubes from the pump winding plate and pull out the tubing harness.
- Re-install the new main harness in reverse order; use the tubing diagram in the front door as a guide for installation. Take special care to reconnect the tubes to the correct nipples of the pump winding.
- Activate each solenoid by pressing **YES**, then slide the pinch bar on and snap on the valve cap in the direction of the arrow.
- To activate the next solenoid, press **NO** twice. Notice the display text.

***TIP**: It may be necessary to pull on the metal tip of the valve in order to put the valve cap into position.*

Dispose of the main tubing harness according to local regulations (hazardous waste!).

***TIP**: It is recommended to replace the sample probe and the fill port at the same time as the main tubing harness is replaced (see section 5.7.3: Replacing sample probe and fill port).*

- Press **NO** until **[PERFORM CALIBRATION?]** is displayed.
- Press **YES** to start a calibration.

5.6.2 Replacing Sample Probe

Once a year, the sample probe should be replaced.

- Disconnect tubing of Sample Probe from Sample Detector
- Open Sample Door
- Lift and remove Sample Probe from holder
- Place and secure new Sample Probe into holder
- Connect tubing of Sample Probe to the Sample Detector

5.7 Unscheduled maintenance

5.7.1 Replacing electrodes

- Slide the measuring chamber forward until it locks in the front position.
- Unclamp the left electrode holder by moving the clamp forward.

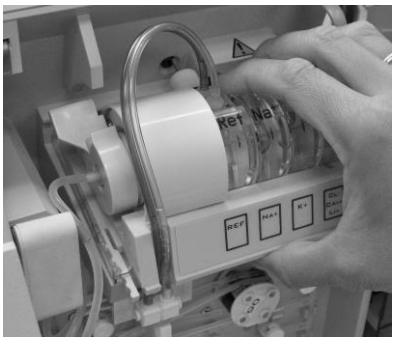


Fig. 5-13

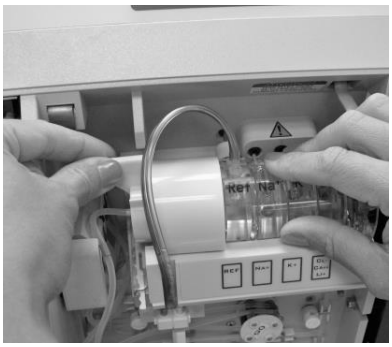


Fig.5-14

- Remove the used electrode from the measuring chamber.

Fig. 5-15

- Remove the new electrode from its protective box and check for the presence of an o-ring in the left side of the electrode.

- Check for fill solution in the electrode according to the instructions enclosed with the electrode

- Install electrode in its labeled position in the measuring chamber. Note that the electrode has a lip on the bottom that rests on the flat edge of the measuring chamber to aid in proper positioning.

Fig. 5-16

Fig. 5-17

- Close the clamp on the left electrode holder by lifting it upward until it locks in the back position. Ensure that the electrodes are seated properly.
- Slide the measuring chamber back until it snaps into position.

Tip: *The measuring chamber may need to be pushed upwards to position the electrode pins in the instrument receptacle*

Fig.5-18

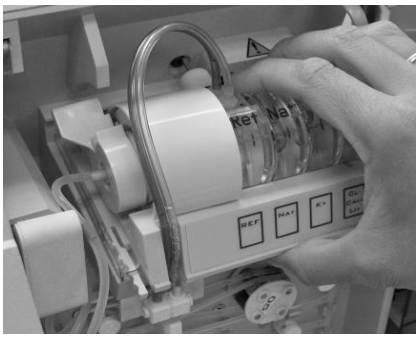


Fig. 5-19

After installing a new electrode, the SMARTLYTE Electrolyte Analyzer needs to undergo Daily Maintenance, Calibration and QC Measurement to verify the performance of the electrode.

Dispose of the electrodes according to local regulations hazardous waste!

In order to ensure the quality of the measurement results, complete a quality control test on 3 levels (low, normal, high) after installation each electrode exchange

5.7.2 Checking reagent fluid level and changing the Fluid Pack

The SMARTLYTE Electrolyte Analyzer monitors the level of solutions in the Fluid Pack and displays the amount remaining. To check the status of Fluid remaining in the Fluid Pack:

- In the **[H-READY]** screen, press the **NO** key, until **[OPERATOR SETTINGS?]** is displayed. Press **YES.**
- The prompt **[VERIFY FLUID PACK?]** will be displayed. Press **YES.**
- The analyzer will display the amount of Fluid remaining.

Always wear gloves! Danger of infection!

- To change the Fluid Pack, just grasp the extended portion and slide it out.

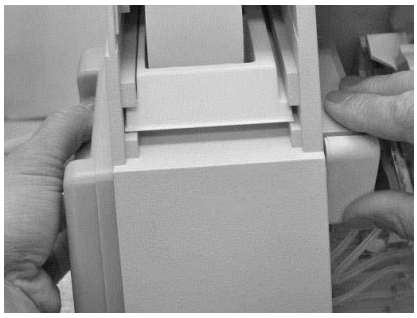


Fig. 5-20

As soon as the analyzer detects that the Fluid Pack has been removed, the display prompts [**NO PACK INSTALLED**]. In addition, the printer will print the current status of the Fluid Pack

Do not remove the Fluid Pack during a calibration or measurement procedure.

Dispose of the Fluid Pack according to local regulations for hazardous waste.

Prepare the new Fluid Pack by carefully removing the protective strip. Save this cover to close the connectors prior to disposal of the used Fluid Pack. Write the installation date on the label of the new Fluid Pack.

Once the protective strip is removed, be sure to keep the Fluid Pack upright to avoid spillage.

Slide the new Fluid Pack into position on the left side of the analyzer. The analyzer will prompt [**ISE PACK INSTALLED?**].

Fig. 5-21

Fig. 5-22

- Press **YES** to indicate that a Fluid Pack is installed. If a new Fluid Pack is installed, you will be prompted to enter the Pack Barcode. The barcode can be entered using the keyboard or a barcode scanner. After receiving a valid barcode, the SMARTLYTE will step to maintenance if it is required or directly to a calibration.

5.7.3 Replacing sample probe and fill port

***TIP*:** *It is recommended to replace the sample probe and the fill port at the same time as the main tubing harness is replaced (see section 5.6.1: Exchanging main tubing harness).*

Always wear gloves! Danger of infection!

*To make sure that the pump does not turn on during this procedure, press **NO** until **[MAINTENANCE?]** is displayed. Press **YES** and **[CLEAN?]** will appear. Then, do not press any keys.*

- Open the front door.
- Open the sample door.
- Remove the needle carefully from the holder. Unplug the tubing.
- Reattach the new needle to the tubing and snap the needle back into the holder.

Fig. 5-23

Then replace the fill port as follows:

- Remove the fill port holder from the sample probe mechanism.
- Carefully remove the fill port from the fill port holder. Unplug the tubing.
- Mount the new fill port into the fill port holder in the reverse way and attach the tubing.
- Mount the fill port holder at its default position.
- Close the sample door and the front cover.
- Press **NO** until **[PERFORM CALIBRATION?]** will be displayed.
- Press **YES** to start the calibration.

Dispose of the sample probe and the fill port according to local regulations (hazardous waste!).

5.7.4 Replacing printer paper

TIP: *The printer paper is heat sensitive on one side only. Please make sure that you insert the paper roll correctly. (See figure 5-24)*

The thermal printer paper supplied by DIAMOND DIAGNOSTICS, INC. contains an indicator strip to alert you when the paper roll should be changed. To change the roll:

- Open the front cover of the analyzer.
- Remove the remaining paper by pressing the paper feed button.
- Place a new paper roll in the paper tray and fold as shown in figure 5-24.
- Press the paper feed button, figure 5-25, to completely feed the paper through the printer.

Fig. 5-24

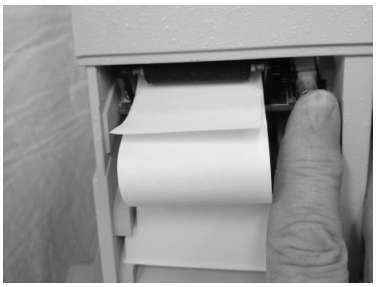


Fig. 5-25

TIP: *Pressing the paper advance button once, advances the paper 10 lines.*

- Close the front cover and tear off any excess paper.

Do not pull the paper out of the printer to avoid damage to the printer.

(Page intentionally left blank)

6 Troubleshooting

Your SMARTLYTE Electrolyte Analyzer is designed to provide long, trouble-free service. However, any scientific measuring device may occasionally malfunction, requiring the operator to identify the cause of the problem.

The following information lists messages displayed and recommends steps that should help you return your SMARTLYTE Electrolyte Analyzer to operation. If your SMARTLYTE Electrolyte Analyzer does not perform correctly after conducting the basic steps outlined in this chapter, you should contact DIAMOND DIAGNOSTICS, INC. for technical assistance.

6.1 Error messages

Message	Cause	Action
Invalid calibration	Calibration has been interrupted. Calibration was not performed. Calibration failed for all electrodes.	Perform system calibration to return the instrument to the [**H-READY**] mode.
Standard A not found	As the analyzer aspirates a sample of Standard A, the solution is detected by the sample sensor which must detect its presence without encountering any air bubbles. If the sample sensor is unable to detect the presence of Standard A solution in the programmed time period, the error message is displayed.	Check the Fluid remaining in the Fluid Pack. If less than 5% remains, replace the Fluid Pack. Check for clots or crystals that may have formed in the Standard A tubing or the electrode chamber Replace the Fluid Pack. Ensure the sample sensor is securely plugged in and perform the sample sensor test to ensure that the sensor is operating correctly. If necessary, clean the sample sensor. Replace the peristaltic pump tube set to ensure correct aspiration of Standard A.
Standard B not found	If Standard A is aspirated properly, but Standard B is not detected, check Standard B tubing for crystallization or leaks. If no crystallization or leaks are found, see Action.	Replace the Fluid Pack. PRIME first.
Standard C not found (Li activated)	Detection of Standard C aspiration is the same as for Standard B.	Replace the Fluid Pack. PRIME first.

Message	Cause	Action
Inspect Sample Sensor	The sample sensor is calibrated with air during each calibration. For proper functioning, the sensor must provide a reading of 80 to 120 units when air is detected. To check sample sensor response, perform sample sensor test. Open the sample door and press the YES button to aspirate various Fluids through the sensor. For transparent Fluids (e.g. water), the reading should increase by at least 40 units. For blood samples (not transparent), the reading should decrease by at least 40 units. The pump can be stopped at any time by pressing NO.	Clean sample sensor by using the Electrode Maintenance procedure Check for correct drying of the measuring chamber during the wash cycle. Replace the peristaltic pump tube set. Perform a calibration to remove the error message.
Inspect Reference Housing	When the analyzer fails to detect a flow of Reference Solution into the measuring chamber, this message will be displayed. This test is performed at the beginning of each calibration cycle.	Check for proper filling of the reference housing Ensure that the reference tubing is securely connected to the receptacle. Since this test utilizes Standard A, make sure that it is aspirated properly into the measuring chamber. If not, replace the Fluid Pack. Check that reference electrode is firmly installed in the housing. Clean the reference housing. (See chapter 5.4: "Monthly maintenance"). Check for the presence of o-rings and for proper sealing of the electrodes.
Please shut sample door	This message occurs when the sample door is not closed within 20 seconds after the sample is in place, or when the door has been opened and no sample is detected.	Close the sample door within time allowed.
Sample not found	Under certain conditions, the analyzer may not detect the presence of a sample and an error message will occur: sample door remaining open more than 20 seconds after samples are in place air bubbles in the sample a sample volume too small to analyze no sample being aspirated through the sampling mechanism. To abort a sample, close the sample door during sample aspiration.	Repeat the sample to see if it is detected properly on a second trial. Close the sample door within time allowed. Check sample aspiration and look for the presence of clots in the sampling system. Check for the presence of o-rings and for proper sealing of the electrodes. Ensure that the sample sensor is plugged in and perform the Sample Sensor Test to verify that it is operating correctly. Replace pump tubing.

Message	Cause	Action
Cleaning solution not found	Under certain conditions, the analyzer may not detect the presence of cleaning solution: Air bubbles in the cleaning solution. Too small volume of cleaning solution. The cleaning solution not being aspirated properly through the sampling mechanism.	Check for presence of o-rings and proper sealing of the electrodes. Check for aspiration of cleaning solution and look for presence of clots in the sampling system. Check for the proper sealing of the pump windings. Ensure that the sample sensor is plugged in and perform the Sample Sensor Test to verify that it is operating correctly.
Conditioning solution not found	Under certain conditions, the analyzer may not detect the presence of conditioning solution: Air bubbles in the conditioning solution. Too small volume of conditioning solution. The conditioning solution not being aspirated properly through the sampling mechanism.	Check for presence of o-rings and proper sealing of the electrodes. Check for aspiration of conditioning solution and look for presence of clots in the sampling system. Check for the proper sealing of the pump windings. Ensure that the sample sensor is plugged in and perform the Sample Sensor Test to verify that it is operating correctly.
Printer jam or defect	If the printer attempts to print to the paper and the paper jams in the feeder, this message will be displayed briefly, then the sample results will appear on the display.	First turn analyzer off, then remove the printer by placing your index finger behind the back edge of the printer module and pull it forward. Remove the jammed paper and re-insert the printer into the analyzer. *Tip: To ease removal of jammed paper, the printer head can be moved by turning the spindle gear on the left side.* Paper jams should be cleared as soon as possible to avoid damaging the printer
Inspect electrodes	Stable reading of Standard A could not be obtained within 6 aspirations.	Ensure that electrodes are properly plugged in. Check for proper operation of the reference electrode assembly. If necessary, clean the reference electrode housing or replace the reference electrode. Conduct amplifier test. Perform daily maintenance. Conduct electrode test. Replace the Fluid Pack.

Message	Cause	Action
Clog inspect Fluid path	If the unit is unable to clear the sample path or to aspirate any of the 3 Standards at the beginning of a calibration. the cause: defective reference housing (increased discharge of KCL) leaks in Fluid path defective pump tubing defective sample sensor pathway obstruction	Make sure that the electrode O rings are present and the seated properly. Make sure electrodes are installed correctly in electrode tray. Check for clog or crystallization in the Fluid path: especially in the sample probe, the tubing to the sample sensor and in the sample sensor. Ensure that the sample sensor is securely plugged in and perform a sample sensor test to ensure the sensor is operating correctly. If necessary, clean the sample sensor. Replace the reference electrode housing.
↑↑↑↑ ↓↓↓↓	In case the unit displays arrows up or arrows down instead of the sample results, the concentration of the sample is outside of the measurement range (see chapter 2: "Specifications").	In the case of a urine sample, arrows up instead of the K^+-result indicate that further dilution is necessary (see chapter 3.3.4: "Urine samples"). Check for Proper sample preparation (see chapter 3). Check for small air bubbles in the sample after aspiration into the sample chamber. Check for proper aspiration of standard A.
↑↓	The calibration report will print an arrow up or down instead of the actual temperature, if the temperature is measured out of range (Range 10.0°C - 40°C). The temperature sensor is located in the right side electrode holder.	Ensure the sample sensor cable is securely plugged in. Make sure room temperature is within specified limits (15°C to 32°C/60°F to 90°F). Perform the Amplifier Test to measure the actual temperature. With the front door opened, the temperature displayed should be approx. 5°C above the actual room temperature.
Err.	If this message is displayed instead of the sample results, no valid voltage reading could be obtained from the electrode.	Check for proper sample preparation (see chapter 3). Check if electrode holder is locked in the back position. Check for proper filling of the reference housing. Check for air bubbles in the sample.
Change Fluid Pack	When the monitored Fluid level in the Fluid Pack reaches less than zero % remaining, the analyzer will display **[Change Fluid Pack].**	Replace the Fluid Pack (see chapter 5.7.2:"Checking reagent Fluid level and changing the Fluid Pack).

Message	Cause	Action
Invalid Fluid Pack	Fluid Pack is not authentic.	Ensure pack barcode is correctly entered Go to [Verify Pack] under [Operator Settings] and reenter the pack barcode. Ensure pack is properly inserted. Ensure RFID tag is detected by the instrument. Under [**Service Menu**], perform [CHECK RFID SENSOR] Contact Customer Support
Fluid Pack is empty	Pack used to its maximum capacity.	Insert new pack
Expired Fluid Pack	Inserted Fluid Pack has passed expiry date..	Insert new pack
Duplicate Fluid Pack or Invalid Fluid Pack	Inserted pack not valid.	Contact Customer Support
**Li Calculation out of range	The lithium result can only be calculated for a Na^+ range:89.6 – 169.5 mmol/L for blood/serum. If the Na^+ value of the sample is outside of this range, this message will be displayed and printed instead of the Li^+ value.	
Interface error	The interface test (see chapter 6.3.8: ”Testing the interface”) was not successful.	Check if pins 2 and 3 of the serial port were connected properly. If the error persists, contact Technical Support.
Check Temp (Ca^{2+} activated)	This message is printed at the end of the sample report and displayed while the measurement is in process in case the temperature of the sample is outside the range (Range 10°C- 40°C).	Check for proper sample preparation (see chapter 3). Ensure the sample sensor cable is securely plugged in. Make sure room temperature is within specified limits (15°C-32°C/ 60°F- 90°F). Perform the Amplifier Test to measure the actual temperature. With the front door opened, the temperature displayed should be approx. 5°C above the actual room temperature.

6.2 Printer error codes

The SMARTLYTE allows for a list of error codes to be printed easily from the **[PRINT REPORTS?]** menu. When in this menu, select **NO** until **[PRINT ERROR CODES?]** is shown and then press **YES**. Here the number of error codes printed can be selected. Press **NO** to scroll through the digits and **YES** to select the desired number. Upon confirming the number entered is correct, the SMARTLYTE will begin printing the error codes.

6.3 Service functions

The SMARTLYTE Electrolyte Analyzer has various built-in functions that you can access to evaluate the performance of the instrument. Starting at the [**H-READY**] display, press **NO** until [**SERVICE MENU?**] is displayed, and enters **YES**.

6.3.1 Testing the electrodes

The voltage levels of the electrodes can be tested by using standard solutions or an external sample.

- Press **NO**, until **[CHECK ELECTRODES?]** is displayed.
- Press **YES** and the prompt **[CHECK STD A?]** will be displayed.
- Press **YES** and the electrode voltages will be displayed.
- Record the values.

- To exit this function, press **NO**.
- The prompt **[CHECK STD B?]** will be displayed.
- Press **YES** and the electrode voltages will be displayed.
- Record the values.

- To exit this function, press **NO.**
- The prompt **[CHECK STD C?]** will be displayed.
- Record the values.
- Press **YES** and the electrode voltages will be displayed.
- Compare the measured values to the following table:

				Allowed difference	
Electrode	**Standard A**	**Standard B**	**Standard C**	**A-B**	**A-C**
Na^+	- 600 to +2400	-1600 to +2000	-600 to +2400	+250 to +680	-50 to +50
K^+	- 700 to +1000	-2500 to +500	-700 to +1000	+470 to +1200	-40 to +40
Cl^-	- 3100 to +500	-1000 to +3000	-3100 to -100	-370 to -860	not used
Ca^{++}	- 3100 to +1000	-2300 to +2500	-3100 to +1000	-350 to -660	-150 to +150
Li^+	- 3100 to +1900	-3600 to +1400	-2600 to +3400	+1 to +760	-1730 to -285

***TIP**: If the voltage difference A-B or A-C is outside the allowable difference, perform daily maintenance or replace the electrode.*

- After testing the electrodes against the standard solutions, the SMARTLYTE Electrolyte Analyzer will prompt **[CHECK SAMPLE?].** Press **YES**.
- The instrument will prompt **[LIFT DOOR LOAD SAMPLE**].
- After introducing the sample, the analyzer will display [**THANK YOU]** shortly, followed by the electrode voltages.
- Check for stable readings.
- Press **NO** to exit and after a short [PLEASE WAIT] message, the prompt **[CONTINUE ELECTRODE TEST?]** will appear.
- Press **NO** to exit or to perform other service functions.

6.3.2 Testing the sample sensor

The dry sample sensor should indicate a value of 80-120, aspiration of a clear Fluid should increase this value by at least 40 Units.

- Press **NO**, until **[CHECK SAMPLE SENSOR?]** is displayed.
- Press **YES** and the analyzer will display the current sample sensor reading:

DRY:80-120: 99
YES=PUMP/NO=EXIT

- Press **YES** introduces an external sample through the probe. The display will be like:

EXTERNAL: 236
PUMP: NO=OFF

- Press **NO** to exit and after a short [**PLEASE WAIT**] message, the prompt [**TEST FLUID PACK SENSOR?**] will appear.

6.3.3 Testing the Fluid Pack sensor

- Press **NO**, until **[CHECK PACK SENSOR?]** is displayed.
- Press **YES** and the current Fluid Pack sensor status will be displayed:

FLUID PACK:
I=IN O=OUT

- Remove the Fluid Pack to test the Fluid Pack sensor.

If the Fluid Pack has been removed during this test, a calibration should be performed to prime all Fluid lines.

- Press **NO** to exit or to perform other service functions.

6.3.4 Testing the RFID sensor

- Press **NO**, until [**CHECK RFID SENSOR?**] is displayed.
- Press **YES.**
- Insert the Fluid Pack with RFID, and press **Yes** to initiate a scan. RFID tag status will be displayed.
- Tag Found – Tag Present and RFID Sensor is working.
- Tag Not Found – Tag is missing or RFID sensor not working.
- Press **NO** to exit or to perform other service functions.

6.3.5 Testing the sample door

- Press **NO**, until **[CHECK SAMPLE DOOR?]** is displayed.
- Press **YES** and the current status will be displayed:

SAMPLE DOOR: C
C=CLOSED O=OPEN

- Open the sample door to see the changes of the status.
- Press NO to exit or to perform other service functions.

6.3.6 Testing the pump

- Press **NO**, until [**PUMP TEST?**] is displayed.
- Open the front cover and press **YES** to begin the pump test. The analyzer will display:

---PUMP TEST!---

The following tests will be performed and displayed:

- Very low speed
- Low speed
- Medium speed
- Fast speed

An audible change should be heard at the pump's speed change.

- Close the front cover and press **NO** to exit or to perform other service functions.

6.3.7 Testing the valves

- Press **NO**, until **[CHECK PINCH VALVES?]** is displayed.
- Press **YES** and the following will be displayed:

TEST VALVE A:
YES/NO = ON/OFF

- Press **YES** to move the valve to the open position.
- Press **NO** to move the valve back to the closed position.
- Press **NO** once more to test the next valve.
- After **[CHECK VALVE R]** is finished, press **NO** to exit or to perform other service functions.

6.3.8 Testing the interface

- Press **NO**, until **[CHECK INTERFACE?]** is displayed.
- Jump pins 2 and 3 of the serial interface making sure not to short the jumper to ground. Press **YES.**

Be sure not to short pin 2 or pin 3 to ground, otherwise the interface may get damaged.

The analyzer will display [**CHECK INTERFACE?**] and tries to send some characters and checks if they are received within a set time period.

- Check that there was no interface error.
- Press **NO** to exit or to perform other service functions.

6.3.9 Testing the amplifier

- Press **NO**, until **[CHECK AMPLIFIER?]** is displayed.
- Press **YES** and the analyzer will display the current amplifier values:

  Na=#### K=####
  Cl/Ca/Li=####

- Press **NO** and the ground voltage will be displayed:

  GND =0
  -2500mV=-2499

- Press **NO** and the temperature will be displayed:

  TEMP(mV) =-####
  TEMP(°C) = ##.#

- Press **NO** to exit or to perform other service functions.

6.4 Configuration codes

The [**ENTER CONFIG CODE?**] menu allows the programming of special functions into the SMARTLYTE Electrolyte Analyzer.

6.4.1 Entering configuration codes

- Starting at the **[H-READY]** display, press **F10** on the mini-keyboard or **NO** until **[SERVICE MENU?]** is displayed, and enter **YES.**
- Press **NO** until **[ENTER CONFIG CODE?]** is displayed.
- The prompt **[ENTER PASSWORD]** will appear.

Enter the configuration code using the mini-keyboard or as follows:

- Press **NO**, until the first character appears.
- Press **YES** and the cursor will advance to the second position.
- Repeat this procedure for the other characters.
- Pressing **YES** after the third character will activate the configuration code.

***TIP**: If the desired character was missed, keep pressing the* **NO** *key until the correct character appears. If an incorrect code is entered during the process, the analyzer will prompt* [**INVALID PASSWORD RETRY?**]. *Press* **YES** *to correct the code or* **NO** *to exit.*

***TIP**: Configuration codes can be printed by entering PSC.*

6.4.2 Resetting configuration codes

To remove or reset a configuration, enter the codes in the off column below. To clear all service codes at one time, enter CSC (Clear Service Codes).

6.4.3 List of service codes

On	Off	Action
HRS	SRH	The resolution of all parameters in blood, plasma and serum samples can be increased by 1 digit in this configuration. QC and standard samples are always shown in high resolution. Urine samples are always shown in low resolution.
ECM	MCE	This configuration will automatically put the instrument into Standby if no samples are run between two automatic calibrations, a 4 hour interval. This feature helps to conserve reagents. When the unit automatically enters the Standby, it is always necessary to perform a calibration to get back to sample testing mode [H-READY].
TDV	VDT	The measured voltages for each electrode are printed on sample and calibration reports when in this configuration. This code should only be used by trained service technicians. This configuration can be turned off by either entering VDT or turning the instrument off and back on.
MGC	CGM	This configuration reports Ca^{2+} blood, plasma and serum values in mg/dL instead of mmol/L. The unit also automatically converts the normal ranges high and low values to mg/dL. QC and standard measurements are always reported in mmol/L even when the instrument is configured as MGL. This facilitates comparison of measured QC Ca^{2+} values to MISSION CONTROLS assay values.

TBO	TBO	The beeper is turned OFF.
QCF	QCF	When the instrument is configured in QCF mode, the QC measurements will be reported in direct ISE values and no correlation factors are applied. When QCF configuration is turned off, the QC results will be reported as flame equivalent values with correlation factors applied. Note: The default condition is FCQ.
LCR	LCR	The lease counter number is printed.
PSC	PSC	All configuration codes are printed.

(Page intentionally left blank)

7 Theoretical foundations

7.1 Principles of Operation

7.1.1 The measurement principle

The SMARTLYTE Electrolyte Analyzer is a sophisticated medical instrument that uses the Ion Selective Electrode (ISE) measurement principle to precisely determine electrolyte values. Although the technology itself is quite complicated, understanding how the instrument performs sampling analysis is relatively simple. Basically, the analyzer compares an unknown value against a known value to compute the sample's electrolyte level.

An ion-selective membrane undergoes a specific reaction with the type of electrolyte contained in the sample. The membrane is an ion exchanger, reacting to the electrical change of the ion causing a change in the membrane potential, or measuring voltage, which is built up in the film between the sample and the membrane.

A galvanic measuring chain within the electrode determines the difference between the two potential values on either side of the membrane.

The galvanic chain is closed through the sample on one side by the reference electrode, the reference electrolyte and the "open terminal". The membrane, inner electrolyte and inner electrode closed the other side (see Fig. 7-1).

The different ion concentrations between the inner electrolyte and the sample cause an electro-chemical potential to form on the membrane of the active electrode. The potential is conducted by the inner electrode to the input of an amplifier. The reference electrode is connected to ground as well as the second input of the amplifier.

Since the reference electrode is on ground, amplification of the electrode potential allows further signal processing.

The ion concentration in the sample is then determined and displayed by using a calibration curve determined by two measured points of standard solutions with precisely known ion concentrations (two-point calibration), and by using the measured voltage of the sample and the Standard-A (one-point calibration).

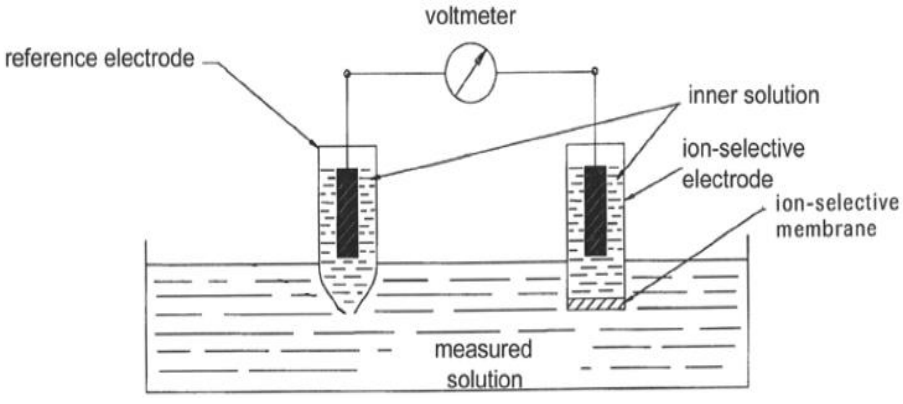


Fig 7-1

7.1.2 Physical principle

An ion-selective electrode is connected with a reference electrode to form a measuring system (see Fig. 7-2). When immersed in a solution that contains the relative ion, the Nernst equation applies:

$$1.\ E = E' \pm [(R \cdot T)/n \cdot F)] \cdot \ln a_i$$

or

$$2.\ E = E' \pm [(R \cdot T)/n \cdot F)] \cdot [\ln (f_i \cdot c_i)]$$

(+) for cations; (-) for anions

The equation can also be written

$$3.\ E = E' \pm S - log\ (f_i \cdot c_i)$$

E the measured electrical potential
E' the e.m.f. of the system in a standard solution
a activity of the ion measured
R the general gas constant (8.31 J/Kmol)
T temperature
n valence of the measured ion
F Faraday constant (96.496 A.s/g)
f the activity coefficient
c the concentration of the measured ion
S the slope of the electrode

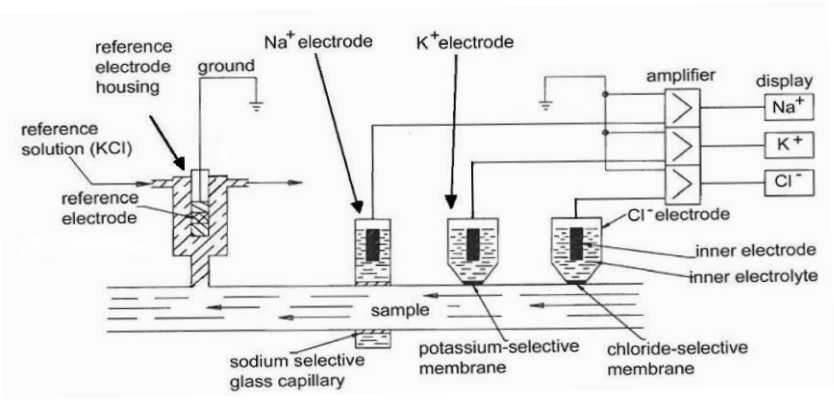


Fig. 7-2

If the ion concentration of one measuring solution is known, the ion concentration of the sample can be determined on the basis of the difference of two measured potentials.

$$4.\ E_{sample} = E' + S \cdot log\ (f_i \cdot c_{i,\ sample})$$

$$5.\ E_{standard} = E' + S \cdot log\ (f_i \cdot c_{i,\ standard})$$

$$6.\ \Delta E = E_{sample} - E_{standard} = S \cdot log \frac{c_{i,\ sample}}{c_{i,\ standard}}$$

ΔE	the difference between the measured potentials of the sample and the standard
S	the potential difference of the electrode, determined from the potential difference of two measured standard solutions
$C_{i,sample}$	concentration of the measured ions in the sample
$C_{i,standard}$	concentration of the measured ions in the standard solutions

The unknown ion concentration in the sample can now be determined by:

$$7. \quad c_{i,sample} = c_{i,standard} \cdot 10^{\Delta E/S}$$

As demonstrated by these equations, the ion selective electrodes do not measure the ion concentration but the activity of the ions concerned. This activity is a criterion of the ion's ability to interact with other ions, in which each ion binds a proportion of its energy.

The ion concentration is calculated on the basis of the ion activity. The correlation is affected by the total number of ions in the solution. Since sodium is the predominant ion in whole blood and serum, the known value of the sodium concentration makes it possible to ascertain and adjust for total ion effect and strength.

7.2 Electrode specifications

7.2.1 Sodium electrode

The sodium electrode is a glass capillary electrode used for in-vitro diagnostic measurement of sodium ions present in Fluid samples. It is designated with a Na^+ marking on the top surface of the housing.

Construction

Electrode housing: transparent acrylic plastic
Measuring capillary: sodium selective glass
Electrolyte chamber: filled with electrolyte solution for Na^+ electrodes
Pin connector: silver, silver chloride (Ag / AgCl)

Use and care

Sodium electrodes are manufactured for use in SMARTLYTE Electrolyte Analyzers.

Proper care should be used in handling and storage of the electrode. Never use strong or abrasive cleaners such as alcohol or amphyl on the electrode since these will attack the plastic housing.

Store the electrode in a clean, dry place only after the electrode has been cleaned and rinsed with distilled water and dried with a lint-free cloth.

The o-ring seal should be installed in the electrode during storage.

7.2.2 Potassium electrode

The potassium electrode is a membrane electrode used for in-vitro diagnostic measurement of potassium ions present in Fluid samples. It is designated with a K^+ marking on the top surface of the housing.

Construction

Electrode housing: transparent acrylic plastic
Measuring membrane: potassium ion selective
Electrolyte chamber: filled with electrolyte solution for K^+ electrodes
Pin connector: silver, silver chloride (Ag / AgCl)

Use and care

Potassium electrodes are manufactured for use in SMARTLYTE Electrolyte Analyzers.

Proper care should be used in handling and storage of the electrode. Never use strong or abrasive cleaners such as alcohol or amphyl on the electrode since these will attack the plastic housing.

Store the electrode in a clean, dry place only after the electrode has been cleaned and rinsed with distilled water and dried with a lint-free cloth.

The o-ring seal should be installed in the electrode during storage.

7.2.3 Chloride electrode

The chloride electrode is a membrane electrode used for in-vitro diagnostic measurement of chloride ions present in Fluid samples. It is designated with a Cl^- marking on the top surface of the housing.

Construction

Electrode housing: transparent acrylic plastic
Measuring membrane: chloride ion selective
Electrolyte chamber: filled with electrolyte solution for Cl^- electrodes
Pin connector: silver, silver chloride (Ag / AgCl)

Use and care

Chloride electrodes are manufactured for use in SMARTLYTE Electrolyte Analyzers.

Proper care should be used in handling and storage of the electrode. Never use strong or abrasive cleaners such as alcohol or amphyl on the electrode since these will attack the plastic housing.

Store the electrode in a clean, dry place only after the electrode has been cleaned and rinsed with distilled water and dried with a lint-free cloth.

The o-ring seal should be installed in the electrode during storage.

7.2.4 Calcium electrode

The calcium electrode is a membrane electrode used for in-vitro diagnostic measurement of calcium ions present in Fluid samples. It is designated with a Ca^{2+} marking on the top surface of the housing.

Construction

Electrode housing: transparent acrylic plastic
Measuring membrane: calcium ion selective
Electrolyte chamber: filled with electrolyte solution for Ca^{2+} electrodes
Pin connector: silver, silver chloride (Ag / AgCl)

Use and care

Calcium electrodes are manufactured for use in SMARTLYTE Electrolyte Analyzers.

Proper care should be used in handling and storage of the electrode. Never use strong or abrasive cleaners such as alcohol or amphyl on the electrode since these will attack the plastic housing.

Store the electrode in a clean, dry place only after the electrode has been cleaned and rinsed with distilled water and dried with a lint-free cloth.

The O-ring seal should be installed in the electrode during storage.

7.2.5 Lithium electrode

The lithium electrode is a membrane electrode used for in-vitro diagnostic measurement of lithium ions present in Fluid samples. It is designated with a Li^{+} marking on the top surface of the housing.

Construction

Electrode housing: transparent acrylic plastic
Measuring membrane: lithium ion selective
Electrolyte chamber: filled with electrolyte solution for Li^{+} electrodes
Pin connector: silver, silver chloride (Ag / AgCl)

Use and care

Lithium electrodes are manufactured for use in SMARTLYTE Electrolyte Analyzers.

Proper care should be used in handling and storage of the electrode. Never use strong or abrasive cleaners such as alcohol or amphyl on the electrode since these will attack the plastic housing.

Store the electrode in a clean, dry place only after the electrode has been cleaned and rinsed with distilled water and dried with a lint-free cloth.

The o-ring seal should be installed in the electrode during storage.

7.2.6 Reference electrode housing (Reference Electrode Assembly)

The reference electrode assembly is a device used as an electrical junction between the sample and electrical ground.

Construction

The reference electrode assembly consists of two parts: the reference electrode housing and the reference electrode.

Reference electrode housing

In the reference electrode housing, reference electrolyte solution establishes the electrical contact between the reference electrode and the sample. At the beginning of each measurement, reference electrolyte is pumped into the housing. At the same time a capillary allows a small amount of reference electrolyte to pass into the measuring capillary, thus establishing electrical contact between the sample and the reference electrode.

Use and care

Reference electrode housings are manufactured for use in SMARTLYTE Electrolyte Analyzers.

Proper care should be used in handling and storage of the electrode housing. Never use strong or abrasive cleaners such as alcohol or amphyl on the housing.

Store the Reference Electrode Housing in a clean, dry place only after the Reference Electrode has been removed and the housing cleaned and rinsed with distilled water and dried with a lint-free cloth.

The o-ring seals should be installed in the housing during storage.

7.2.7 Reference electrode (Reference Electrode Assembly)

The reference electrode completes the electrical circuit between the reference electrolyte and electrical ground.

Construction

This is accomplished by a cotton wool (saturated with reference electrolyte)-calomel (Hg_2C1_2)- mercury (Hg)-platinum wire-connecting pin junction

Use and care

Reference electrodes are manufactured for use in SMARTLYTE Electrolyte Analyzers.

Proper care should be used in handling and storage of the reference electrode. Never use strong or abrasive cleaners such as alcohol or amphyl on the electrode.

Store the reference electrode in the transport housing provided with the electrode at the time of purchase. Make sure that the transport housing is filled with reference electrolyte solution (you may use the reference electrolyte solution remaining in the reference electrode housing at the time of disassembly).

Never rinse the reference electrode with distilled water!
Never allow the reference electrode to become dry!

7.3 Calibration procedure

7.3.1 ISE calibration

The SMARTLYTE Electrolyte Analyzer calibrates Na^+, K^+, Ca^{2+} and Cl^- electrodes, using only two aqueous base solutions. Lithium calibration is achieved with a third calibrator in order to make a sodium correction.

(Page intentionally left blank)

8 Appendix

8.1 Description of reports

8.1.1 Measurement report

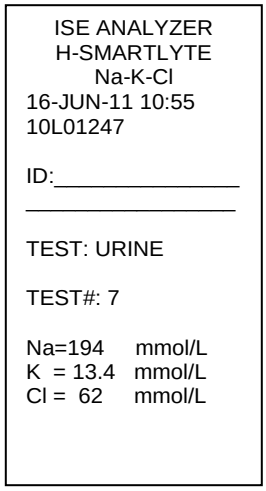


Fig. 8-1

8.1.2 QC report

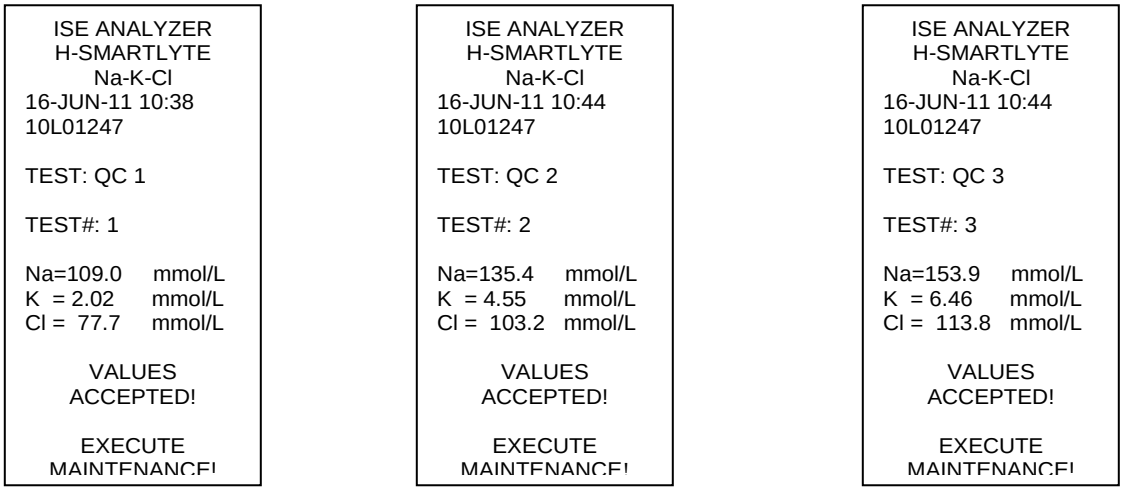


Fig. 8-2

8.1.3 Calibration report

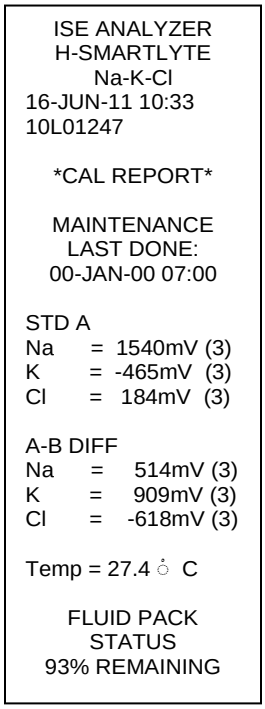


Fig. 8-3

8.1.4 Error Report

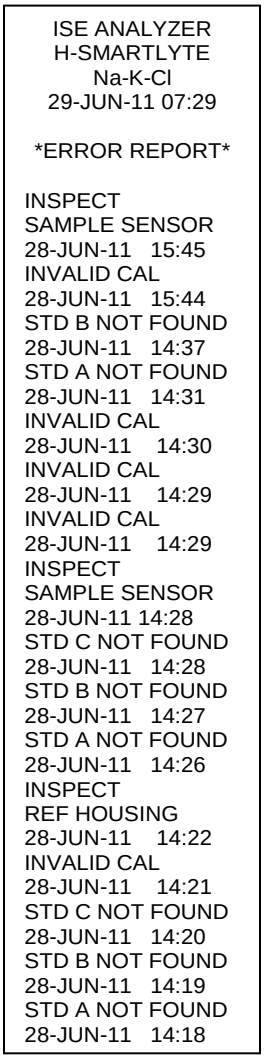


Fig. 8-4

8.1.5 Configuration Report

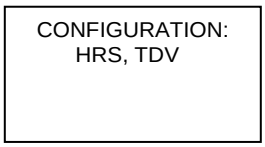


Fig. 8-5

8.1.6 Normal Range Report

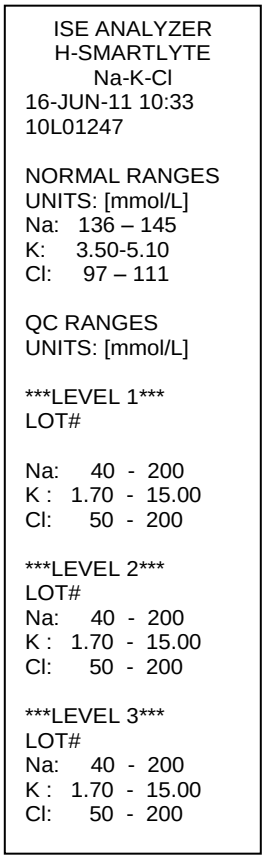
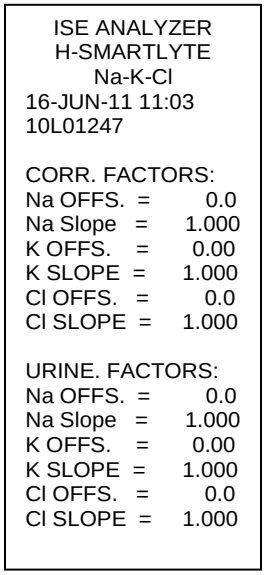


Fig. 8-6

8.1.7 Correlation Factors Report



ISE ANALYZER
H-SMARTLYTE
Na-K-Cl
16-JUN-11 11:03
10L01247

CORR. FACTORS:
Na OFFS. = 0.0
Na Slope = 1.000
K OFFS. = 0.00
K SLOPE = 1.000
Cl OFFS. = 0.0
Cl SLOPE = 1.000

URINE. FACTORS:
Na OFFS. = 0.0
Na Slope = 1.000
K OFFS. = 0.00
K SLOPE = 1.000
Cl OFFS. = 0.0
Cl SLOPE = 1.000

Fig. 8-6

8.2 Fluid Pack

nts are to be used for in-vitro diagnostic use only.

The Fluid Pack contains the following solutions

Standard A

Standard B

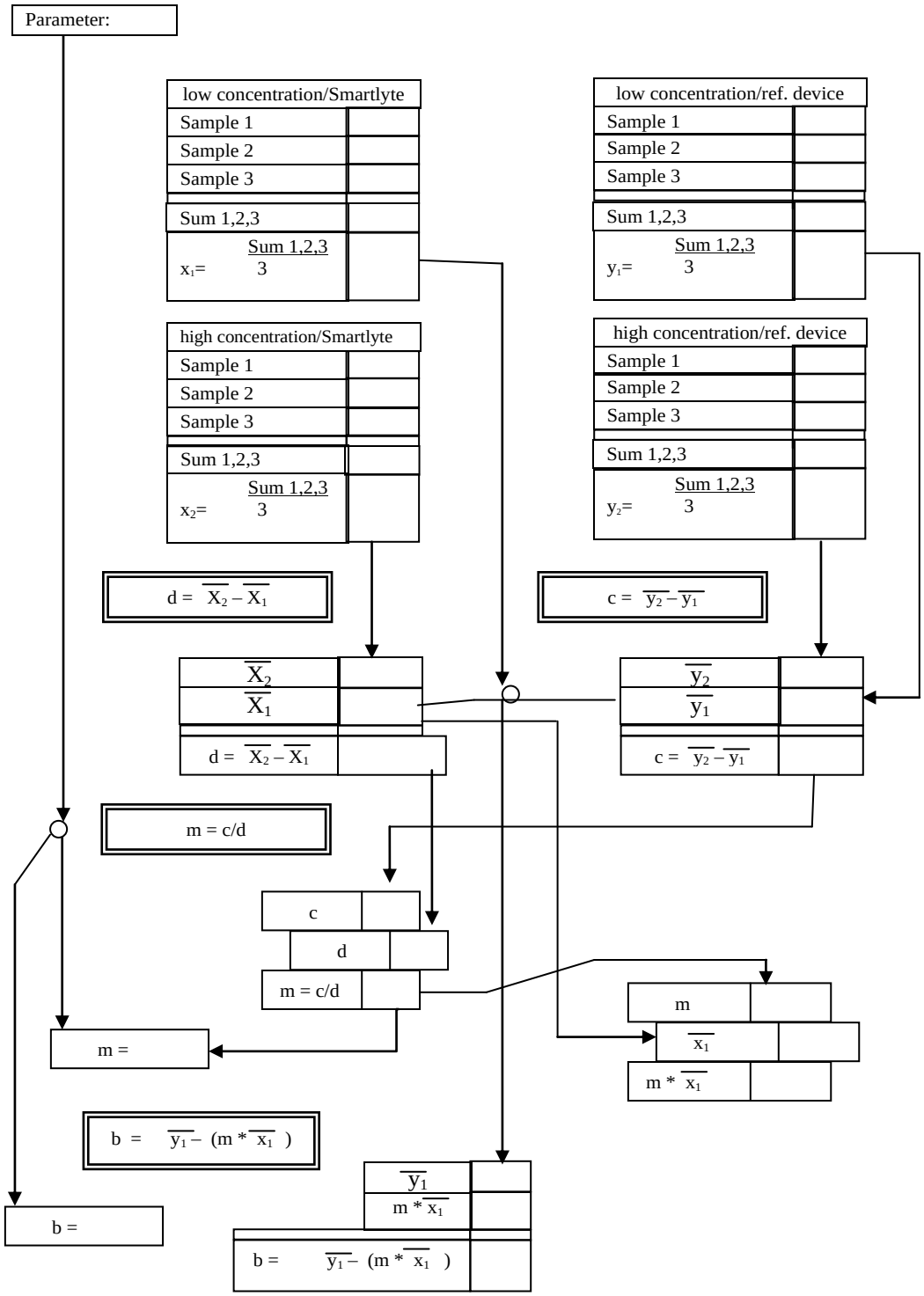
Standard C

Reference Solution

Caution: *A waste container is provided inside the Fluid Pack which contains potentially infectious materials. Handle with appropriate care to avoid skin contact or ingestion!*

8.3 Worksheet for determination of the correlation coefficients

TIP: *This page can be used as template for duplication.*



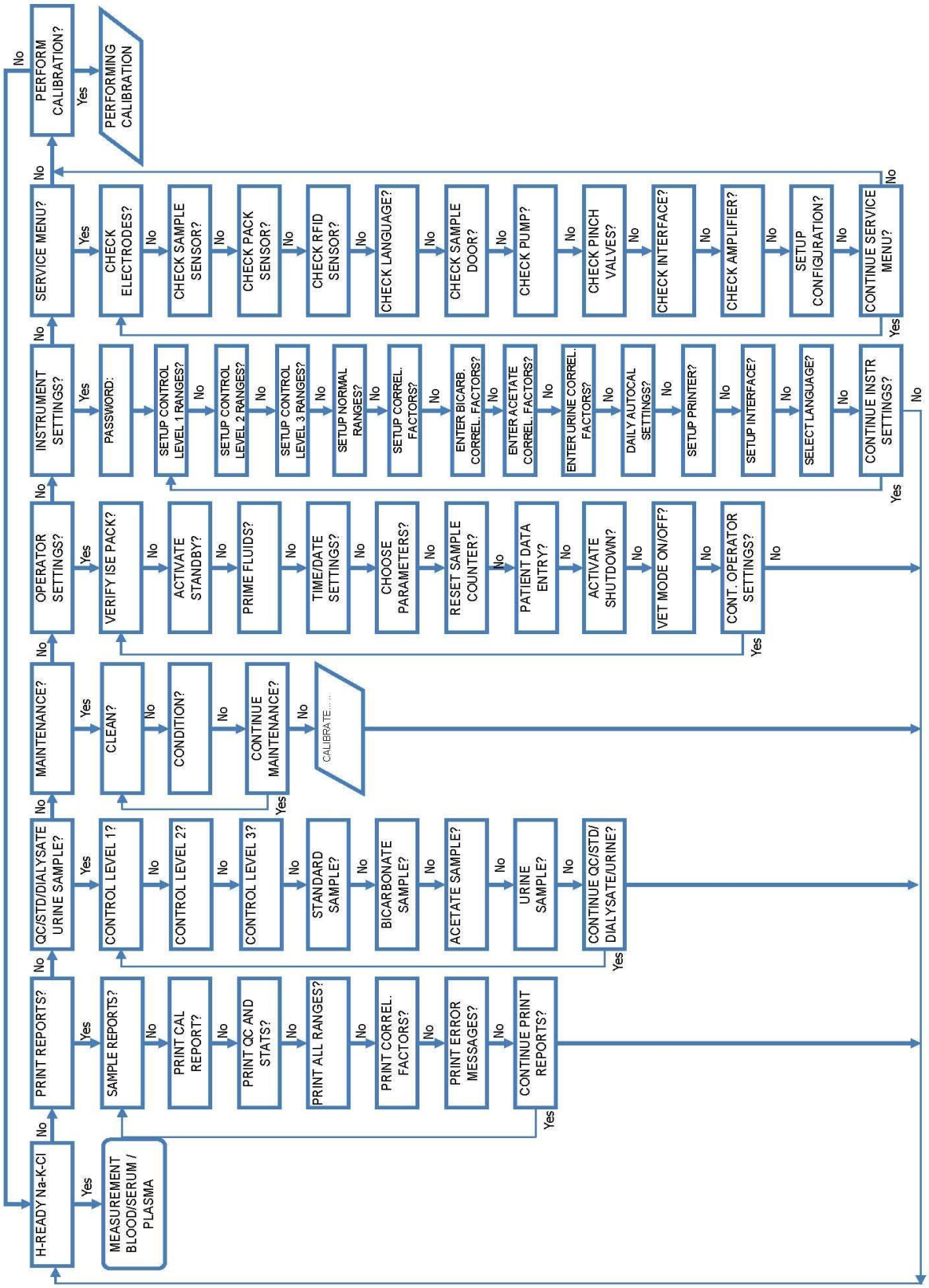
8.4 Maintenance Schedule Template

SmartLyte Electrolyte Analyzer
Maintenance Schedule

Month:_____

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
DAILY																															
Perform cleaning																															
Perform conditioning																															
WEEKLY																															
Clean Sample probe/fill port																															
Clean analyzer surfaces																															
MONTHLY																															
Clean reference electrode housing																															
SEMI-ANNUALLY																															
Change pump tubing																															
ANNUALLY																															
Change main tubing harness																															
UNSCHEDULED MAINTENANCE																															

8.5 Program Flow Chart (Dialysate Bicarbonate & Acetate Enabled)

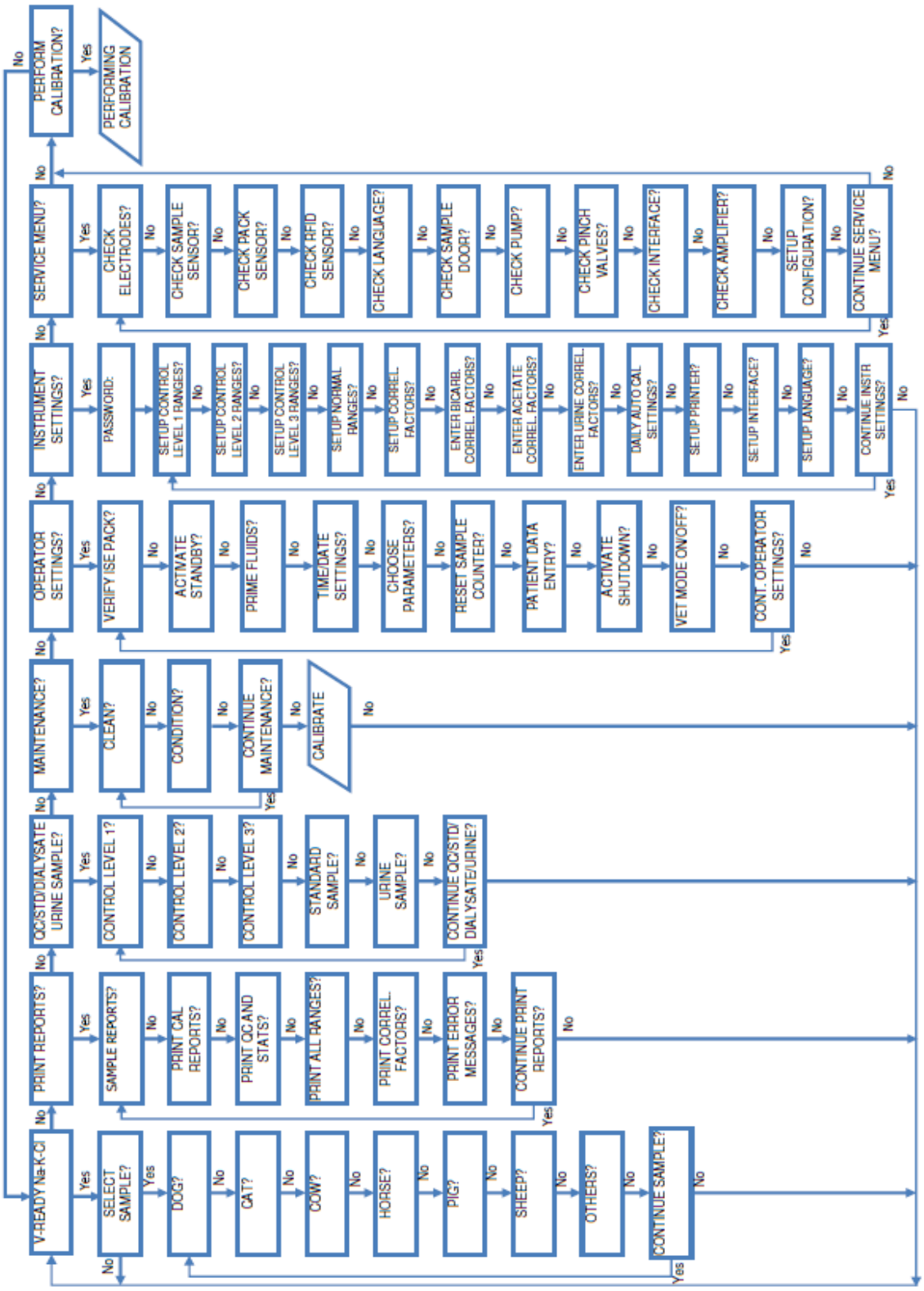


8.6 Parts Warranty

Replacement Part #	Description	Warranty
AV-BP0413D	Na^+ Electrode	12 months
AV-BP0359D	K^+ Electrode	6 months
AV-BP0570D	Cl^- Electrode	6 months
AV-BP0360D	Ca^{2+} Electrode	6 months
AV-BP0962D	Li^+ Electrode	3 months
AV-BP5026D	Reference Electrode	12 months
AV-BP5027D	Peristaltic Pump Tubing	3 months
AV-BP5193D	Pinch Valve Tubing Kit	6 months
AV-BP5186D	FLUID PACK	Use before expiration date
AV-BP0380D	Na Electrode Conditioner Solution	Use before expiration date
AV-BP1025D	Cleaning Solution	Use before expiration date
AV-BP0521D	Deproteinizer Solution	Use before expiration date
AV-BP0344D	Urine Diluent	Use before expiration date
AV-BP5025D	Thermal Printer Paper	Replace as necessary
AV-BP5019D	Reference Electrode Housing	Replace as necessary
AV-BP5006D	Sample Probe	Replace as necessary
AV-BP5036D	Sample Sensor	Replace as necessary
DD-0201	Mini Keyboard	Replace as necessary
DD-0202	Barcode Scanner	Replace as necessary

8.7 Vet Mode Specific Instructions

8.7.1 Program Flow Chart



8.7.2 Veterinary Blood, Serum, Plasma Sample measurement

Whenever [**V-READY**] appears, the analyzer is ready to carry out veterinary blood, serum, plasma and urine measurements.

It is very important that the main door is closed during sampling to provide shielding from sources of electromagnetic interference.

Urine samples require dilution, and must be analyzed in the urine mode. Instructions for analyzing urine samples: see "Urine samples".

- Press **YES** and SMARTLYTE will prompt you to enter the patient species.
- Press **YES** to select the appropriate species.
- Lift the door and load the sample.
- Hold the sample container under the probe until **[WIPE PROBE_SHUT SAMPLE DOOR]** is displayed.
- Use a lint-free tissue to wipe the probe. Then close the sample door.

Veterinary Normal Ranges

Parameter	Na[1]	K[1]	Cl[1]	Ca
Units	mmol/L	mmol/L	mmol/L	mmol/L
Dog[2]	140 - 154	3.8 - 5.6	102 - 117	1.25 - 1.45
Cat[2]	146 - 159	3.8 - 5.3	108 - 130	1.15 - 1.35
Cow	135 - 148	4.0 - 5.8	96 - 109	***
Horse	133 - 147	2.8 - 4.7	97 - 110	***
Pig	139 - 153	4.4 - 6.5	97 - 106	***
Sheep	142 - 160	4.3 - 6.3	101 - 113	***

[1]Kahn, C., et. al., (Eds.), Merck Veterinary Manual, 9th Ed., 2008, Merck & Co., Inc.
[2]DiBartola, S.P., Fluid, Electrolyte, and Acid-Base Disorders, 3rd Ed., 2005, Elsevier Saunders
**** Not Available*

Values that are higher or lower than the programmed normal range will be indicated by an arrow pointing up or down.

The normal ranges can be adapted to the respective laboratory-specific requirements. The ranges can be changed through the programming menu. Follow the instructions for the [**INSTRUMENT SETTINGS?**] in chapter 4.2 and enter 3-digit password.

- Press **NO** until **[SETUP NORMAL RANGES?]** is displayed. Press **YES**.
- Press **YES** when the animal is displayed for which normal ranges will be changed.
- The analyzer will display the normal ranges of the current parameter configuration:

  Na LOW=xxx
  Na HIGH=xxx ok?
- Normal ranges can be entered by pressing **NO**
- Press NO until the desired number is displayed, and press **YES** to advance to the next position. Repeat this for all numbers of the normal range.
- After entering the normal ranges, the new values will be displayed. Verify correctness of the ranges:

  Na LOW=xxx
  Na HIGH=xxx ok?

TIP: *If an incorrect number was entered inadvertently, press* ***NO****, and the analyzer allows for retyping the normal range.*

- Press **YES** and the display will advance to the next parameter.

Repeat the above procedure for all parameters and each animal type. After all activated parameters have been programmed; the display prompts [**SETUP FACTORS FOR CORRELATION?**]. This allows programming of the correlation factors.

TIP: *All other procedures for SMARTLYTE are the same in veterinary mode as in human mode.*

9 Index

Q

R

S

T

V