

Operator Manual



DIAMOND
Smart Lab Solutions

Electrolyte Analyzer

Na⁺ / K⁺ /Cl⁻ / Ca⁺⁺ / Li⁺



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



DIAMOND DIAGNOSTICS Kft
6 Óradna Street
1044 Budapest Hungary



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-Important Information!-

These Instructions for Use contain vital warning and safety information.

This analyzer 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 analyzer is used in ways other than those described or if the necessary prerequisites and safety measures are not observed.

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

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.

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

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

Operation of the analyzer with solutions whose composition is not consistent with that of the original solutions can negatively affect, 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 analyzer, but also on a number of other factors (such as preanalytics), the results produced by the analyzer 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 analyzer 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 analyzers 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 analyzer is classified under the protection class I according to EN 60000-1 / IEC 1010-1.
- The analyzer meets the conditions for overvoltage category II.
- The analyzer meets the conditions for contamination level 2.
- Do not operate the analyzer 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 analyzer, remove the analyzer from its power supply and allow an expert to check it thoroughly before using it again.
- The analyzer 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 analyzer or a loose ground connection may result in hazardous operating conditions. Intentional disconnection of the grounding is not permitted.
- The analyzer is not suitable for operation with a direct current power supply.

Use only the original mains plug delivered with the analyzer.

-Operating Safety Information-

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1. Introduction

The SMARTLYTE[®] PLUS Electrolyte Analyzer is designed to conduct basic electrolyte analysis accurately, efficiently and quickly 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.





Figure 1-1 SMARTLYTE[®] PLUS Electrolyte Analyzer


1.1 General Notes


1.1.1. General Symbols

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

 Lot Number

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



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


 $+2^{\circ}\text{C}$ -30°C 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! Must be observed to avoid potential injuries (to patients, users and third parties)

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

 Serial Number (model plate)

 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[®] PLUS Electrolyte Analyzer, and which therefore should never be attempted.

TIP: Describes safe procedures that are intended to provide the user with additional help.



Next data



Previous data



Print



Returns to Sample Menu if calibrated, Operations Menu if not



Toggle between main menus



Previous screen



Confirm and Save



QC Graph



Previous



Next



Save



Delete




Edit


YES


Are you sure confirmation?


NO


1.1.2. Analyzer Symbols Color Conventions

 **Orange:** Caution: Indicates Not Ready or Proceed Cautiously since action could cause undesired consequences such as the loss of data.

 **Red:** These buttons indicates that saved setting and/or data will be deleted.

 **Blue:** Active button/process.

 **Dark Blue:** Inactive button/process

 **Green:** Save changes

1.2 Measurement Overview

1.2.1. Calibration Procedure

A 2-point (non-Li configuration) or a 3-point (Li configuration) calibration is performed automatically in 4 hours if auto calibration is enabled. 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.

1.2.2. Measurement Procedure

The SMARTLYTE[®] PLUS Electrolyte Analyzer methodology is based on ion selective electrode measurement to determine the analyte values (see chapter 7, section "The Measurement Principle").

There are six different electrodes used in the SMARTLYTE[®] PLUS Electrolyte Analyzer: sodium, potassium, chloride, ionized calcium, lithium and a reference electrode. At any one time, five electrodes can be installed on the analyzer, of which one must be reference. Each analyte electrode has an ion selective membrane that undergoes a specific interaction with the corresponding ions contained in the sample being analyzed. The membrane interacts with specific ions 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 precisely known ion concentrations.

1.2.3. Measurement Evaluation

The validity of the test results from the SMARTLYTE[®] PLUS 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[®] PLUS 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 CLSI document M29-A4, "Protection of Laboratory Workers from Occupationally Acquired Infections", Approved Guidelines – 4th Edition 2014 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 Analyzer



Dispose of used Fluid Pack, electrodes and the analyzer 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 Analyzer Description

1.3.1. Analyzer Components




Figure 1-2 SMARTLYTE® PLUS Electrolyte Analyzer



Figure 1-3 SMARTLYTE® PLUS with front cover open

Display

The color display is a 5 inch touch screen which provides direct access to analyzer functions. Analyzer access can be changed by pressing the desired function or the  icon to access additional or secondary functions.

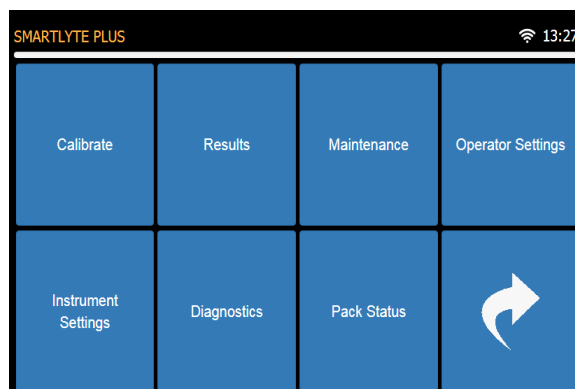


Figure 1-4 Main Operations Menu

Printer

The graphic printer, with 192 pixels/line, uses thermal paper to output results and other information. The analyzer will print measured values and calibration values. The unit allows convenient storage of a second roll of paper in the rear of the paper tray.



Figure 1-5 Printer with paper

Measuring chamber

The measuring chamber consists of five electrodes, a sample sensor with connector on the right, and an electrode tray with movable locking mechanism on the left.



Figure 1-6 Electrode tray, locking mechanism closed

Peristaltic pump

A peristaltic pump transports operating fluids and samples inside the analyzer.

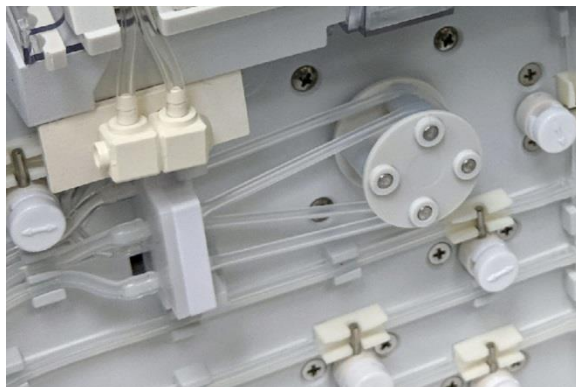


Figure 1-7 Pump Tubes wound around roller of peristaltic pump

Sample probe and cover

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



Figure 1-8 Opened door with Sample probe in

Valves

There are five pinch valves that control the movement of liquid and air within the analyzer. [Figure 1-9](#) shows the pinch valves and the liquid it controls the flow of.

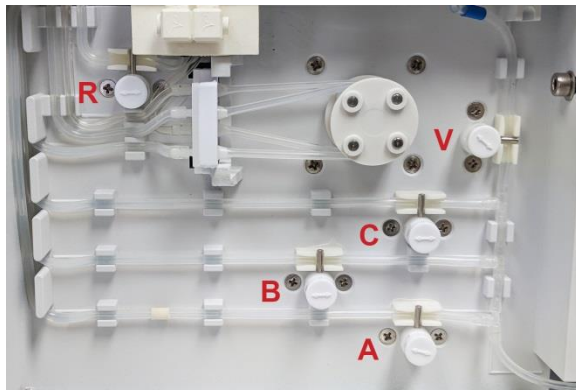


Figure 1-9 Pinch valves for fluids

Fluid Pack

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



Figure 1-10 Fluid Pack and packaging

Rear panel

The rear panel of the unit contains a serial number plate, four USB connections, one Ethernet connection, an RS232 interface port, and a power switch/power receptacle module.



Figure 1-11 Back cover with connections/ports

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 [Figure1-12](#).
- Avoid exposure to explosive gases or vapors.
- Check for correct voltage: 100V to 240V AC, 50/60Hz.



Figure 1-12 SMARTLYTE® PLUS Electrolyte Analyzer

After setting up the SMARTLYTE® PLUS Electrolyte Analyzer in a location that meets the above requirements, perform the following steps to ensure the analyzer 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 Diagnostics representative immediately.

If the analyzer 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[®] PLUS Electrolyte Analyzer:

- AV-BP5194D – Startup Kit
- AV-BP5014D – Shutdown Kit

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.

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.

- Place 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. ([Figure 1-13](#))

TIP: Save the clamps for reuse to prevent damaging the tubes if the analyzer is later shut down for any reason. (“See Section 1.8 Shutdown”)



Figure 1-13 Removing red relief clamps



Figure 1-14 Pump windings on pump rollers

- Slip the two pump windings around the analyzer pump rollers, making sure not to over stretch the tubing. ([Figure 1-14](#))

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.
- Remove liquid pathway seals from the sides of the electrodes so that the fluidic pathway is open and clear. Ensure the black O-ring is not adhered to the removed seal and remains on the electrode. [Figure 1-15](#) shows the black O-ring in position around the pathway.
- Check that all measurement electrodes and reference housing have the black O-ring properly seated on the left side of the electrode as shown in [Figure 1-15](#).
- **Note:** If Dummy electrodes will be used, ensure the black O-ring is in place for each one.

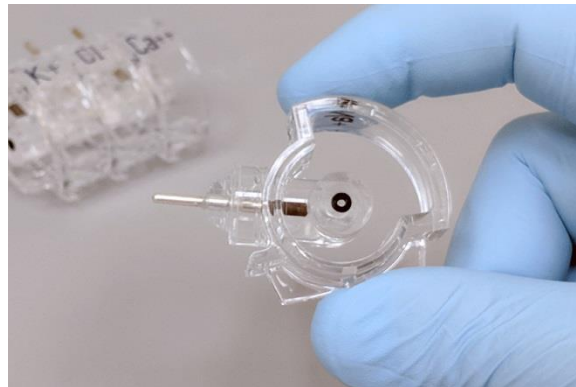


Figure 1-15 Electrode with black O-ring

- Unscrew the transport housing from the reference electrode and check that the O-ring on the electrode is properly seated. ([Figure 1-16](#))
- 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.

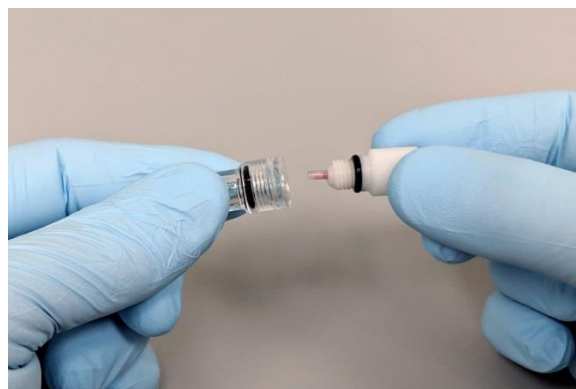


Figure 1-16 Transport housing & reference electrode

- Carefully screw the reference electrode into the reference electrode housing as shown in [\(Figure 1-17\)](#).



Figure 1-17 Electrode housing with Reference electrode

- Slide the measurement chamber forward until it locks in the front position. ([Figure 1-18](#))
- Release the electrode clamp, on the left side of the electrode tray, by rotating the lever up and towards the back. ([Figure 1-18](#) and [Figure 1-19](#))



Figure 1-18 Electrode tray pulled forward (locked position)



Figure 1-19 Unclamped electrode tray (unlocked position)

TIP: When the clamp lever is in the horizontal position, it is locked ([Figure 1-18](#))
When the clamp lever is in the vertical position, it is opened ([Figure 1-19](#))

- Locate the sample sensor on far right of the electrode tray. Check that the cable is connected correctly to the analyzer. ([Figure 1-20](#))
- Check that an O-ring is present on the left side of the sample sensor. ([Figure 1-20](#))

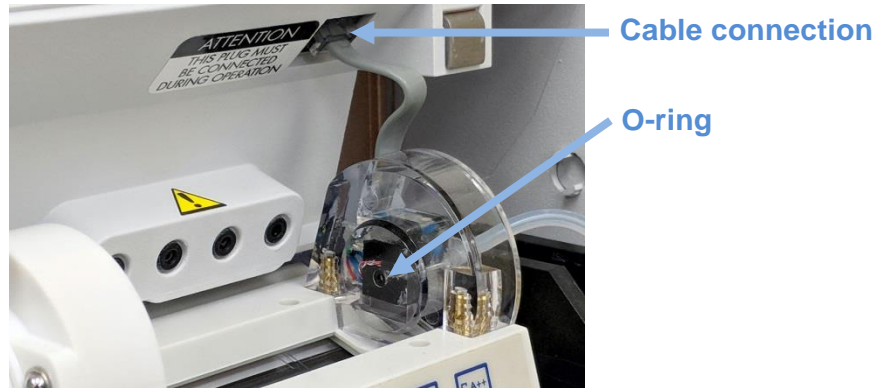


Figure 1-20 Sample sensor

Now install the electrodes in the measurement chamber, beginning on the left and working to the right; the reference electrode the housing is installed first. ([Figure 1-21](#))

TIP: See [Figure 1-25](#) for possible configuration of electrode.

- 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.



Figure 1-21 Electrodes in tray

- After all electrodes have been installed, lock the clamp on the left electrode tray by bringing it forward and down until it locks. Ensure that the electrodes are properly seated by checking position of each. ([Figure1-22](#))



Figure 1-22 Move clamp down to locking position

- Slide the measurement chamber back until it snaps into position. ([Figure 1-23](#))

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.*



Figure 1-23 Electrode Tray in position

- Plug the tubing connector of the reference housing assembly in the receptacle below the left side of the measurement chamber. ([Figure1-24](#))



Figure 1-24 Plugging in reference connectors

- Possible parameter configurations are shown below ([Figure 1-25](#)).

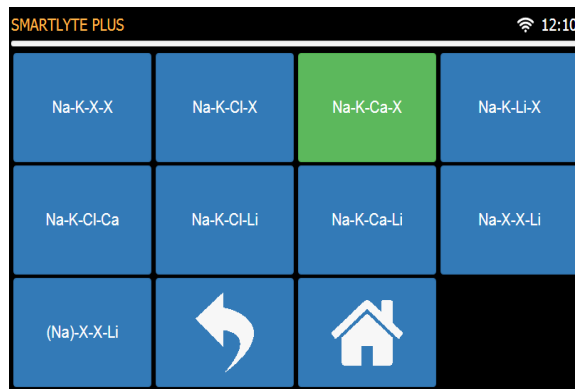


Figure 1-25 Electrode configurations

- The “X” indicates that a Dummy electrode should be installed in place of a measurement electrode. See [Figure 1-26](#).

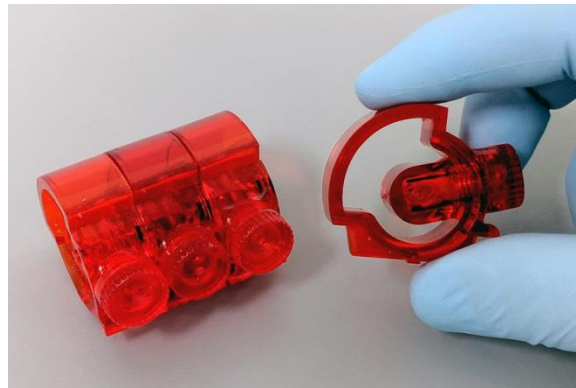


Figure 1-26 Dummy Electrode

- For details to access menu to select parameters, see **Section 7** "Selecting parameter configurations" which is under Operator Settings.

1.5 Preparing the Analyzer for Operation

1.5.1. Installing Accessories

- Install optional accessories, such as barcode scanner or keyboards or RS232 connectors – You may use any wired/wireless USB barcode scanner or keyboard for entering patient information. Same can be done using onscreen touch keyboard.
- Connectors are located on the back of the analyzer as shown in [Figure 1-11](#).

1.5.2. Installing the Fluid Pack

- Remove the protective strip ([Figure 1-27](#)) and slide the Fluid Pack into position ([Figure 1-28](#)) on the left side of the analyzer. Save the red protective strip for disposal of the used fluid pack.

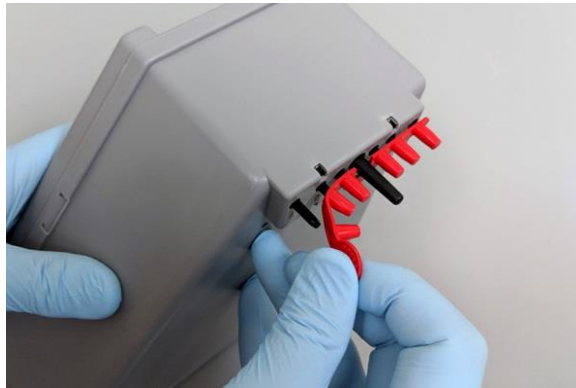


Figure 1-27 Red Protective Cover Removed

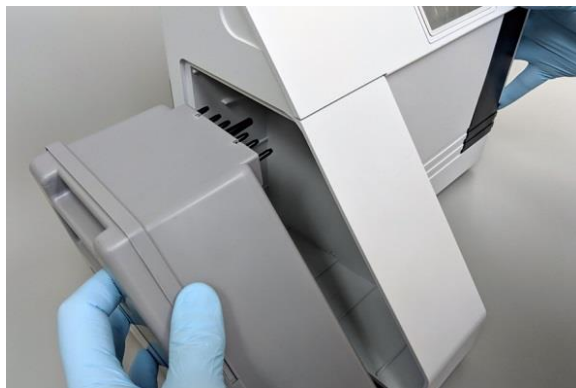


Figure 1-28 Fluid pack installation



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

1.5.3. 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 - 240V, 50/60Hz).



Figure 1-29 Connecting power cord to analyzer

- Push the power switch to the ON (I) position



Figure 1-30 Power up

- The unit will automatically begin initialization. Approximately 2 minutes are needed for this process.



Figure 1-31 Initialization at power up



Figure 1-32 Initialization in progress

1.5.4. Setting Wi-Fi

After initialization is complete, WiFi setup screen will be shown. WiFi should be setup prior to proceeding. Optionally, you can skip this step at this time by clicking the blue right arrow button. Alternatively, you may connect a LAN Ethernet cable for wired network connection.

Settings up provides following advanced options –

- Auto date time adjustment
- Auto software updates
- Data export and download
- Remote Access
- Remote Customer Support

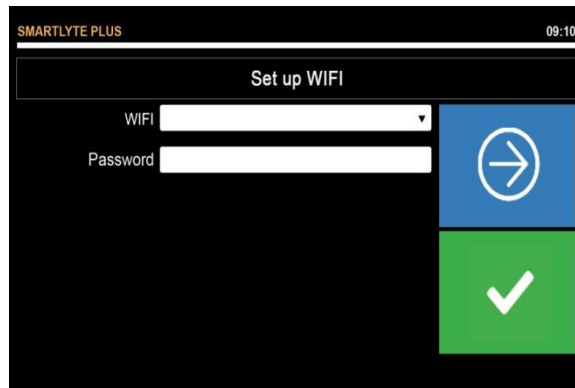




Figure 1-33 Set up WiFi

TIP: To setup WiFi, the user must have WiFi network name and password. From the Main Operations Menu ([Figure 1-33](#)) press **[INSTRUMENT SETTING]**, then **[NETWORK]**, [Figure 1-45a](#).

Once successfully connected, the instrument will automatically step to Date Time Setup.

1.5.5. Setting Date and Time

If Wi-Fi is enabled, the time will automatically set according to your time zone. The analyzer allows the user to display and print the date in 3 formats. Follow the instructions below to customize.

- If not at **[CHANGE DATE/TIME]** screen, press the home button,  or  to access the Main Menu.
- Press **[OPERATOR SETTINGS]** then **[SET DATE/TIME]**.

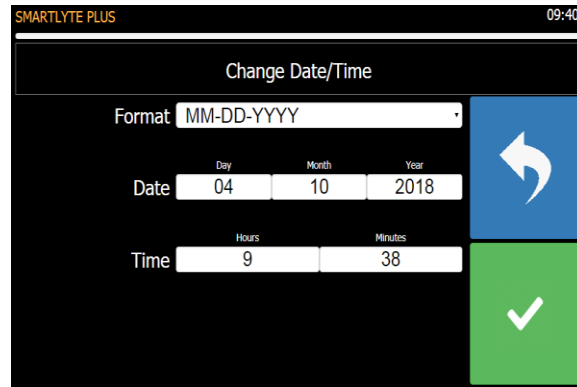



Figure 1-34 Change Date Time Screen

- Use the drop down menu on Format to select the format of dates for printing and display.
- If Wi-Fi is ON, the date will be set automatically
- If Wi-Fi is OFF, the date and time can be customized. When Wi-Fi is turned on at any time, the date will revert to time and location of the analyzer
- Once complete, press  to save changes.

TIP: *If SMARTLYTE® Plus will be tested in Veterinary mode, the changeover to Vet mode should be done at this time because all settings entered after this point will be erased. See section 8.6 for conversion procedure.*

1.5.6. User Set-Up

When initialization is complete, the Main Menu will be displayed ([Figure 1-33](#)).

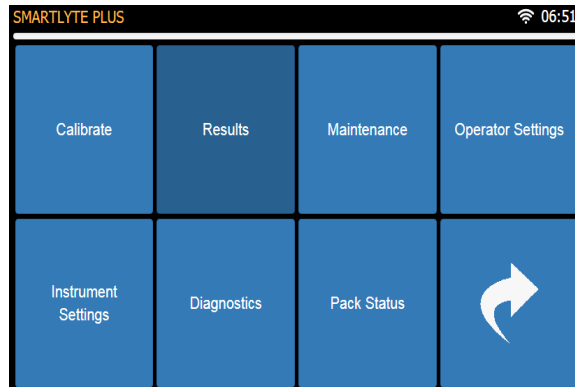


Figure 1-35 Main Operations Menu

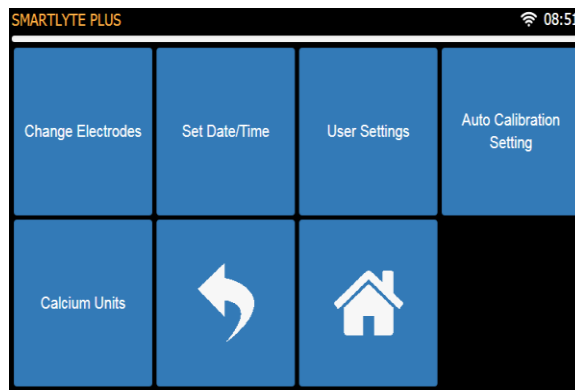


Figure 1-36 Operator Settings Menu

Follow the steps below starting from the Main Operations Menu to login for the first time. ([Figure 1-35](#))

- Press [**OPERATOR SETTINGS**] ([Figure 1-35](#)) then [**USER SETTINGS**] ([Figure 1-36](#))



Figure 1-37 User Settings Menu for login

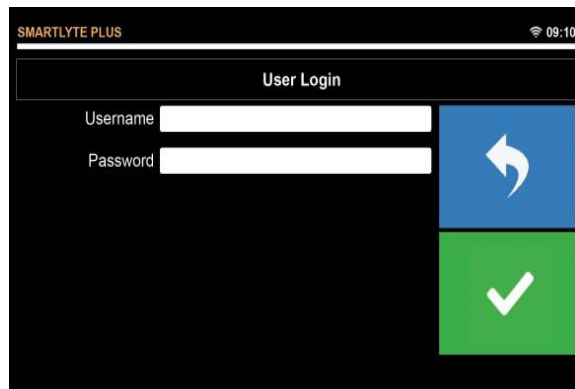


Figure 1-38 User login entry

- Press [**LOGIN**] on User Settings Menu ([Figure 1-37](#)). The User Login entry screen will be displayed.
- Touch the Username cell to bring up the screen keyboard.
- Enter the default username (“admin”) when setting up the first time. Press Enter
- Touch the password cell to bring up the keyboard again.
- Enter the default password (“admin”) then press Enter.

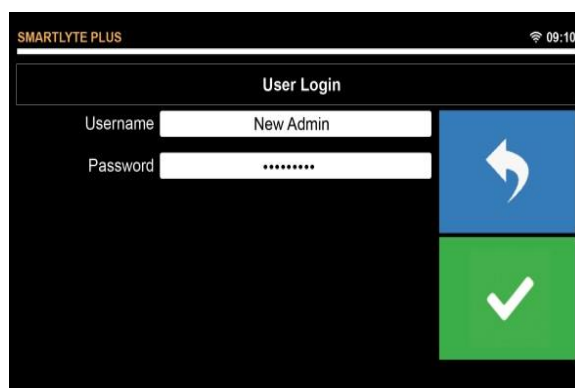


Figure 1-39 First time Login screen

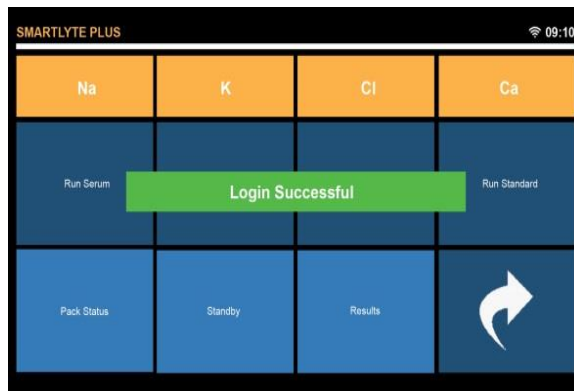



Figure 1-40 Username and password accepted.

- Press  [Figure 1-37](#).
- If successful, [LOGIN SUCCESSFUL] ([Figure 1-38](#)) will be displayed for a few seconds.
- If not successful [INVALID USERNAME/PASSWORD] will be displayed for a few seconds. Try again.

TIP: Username and password are case sensitive.

1.5.7. Administrator Set-Up

To limit access to the analyzer settings and its data, a new administrator with a secure password needs to be set up. Be sure to save the username/password since the default admin account will be deleted. The new admin username and password is needed to login and advance settings.

- Press [OPERATOR SETTINGS] on main operations menu [Figure 1-4](#), [USER SETTINGS] on Operator Settings Menu, [Figure 1-34](#), and then [ADD USER].

TIP: Admin must be logged in to add new users who will be classified as Operator or Administrator.



Figure 1-41 User Settings, admin logged in

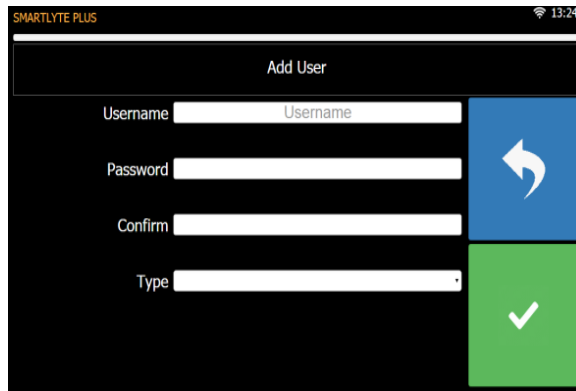


Figure 1-42 Add user screen

- Enter the information for the new administrator, [Figure 1-40](#). At type, select Admin.

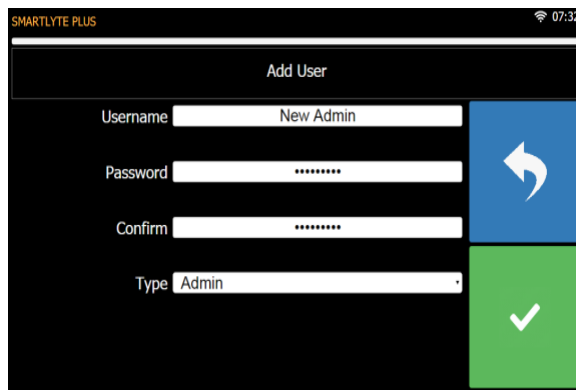


Figure 1-43 Information for New Admin

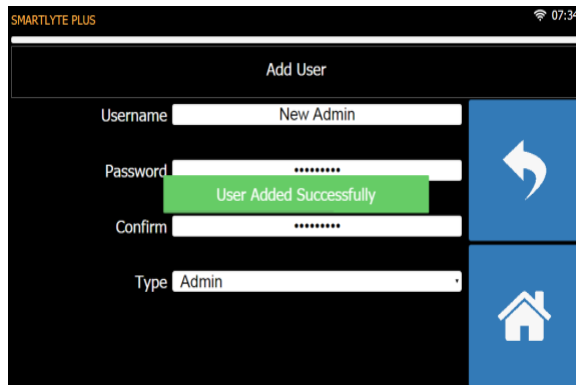






Figure 1-44 Successfully created admin user

- Once information is entered and password saved elsewhere for future reference, press  to save the data [Figure 1-41](#).
- After User Added Successfully, press  then press [USER LIST] on User Settings Menu to verify addition of New Admin ([Figure1-39](#))
- To delete default admin, press  and then .

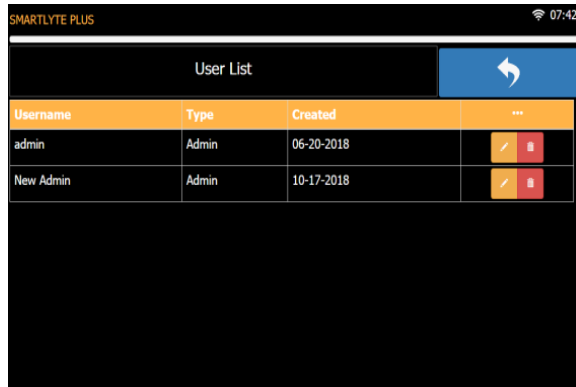


Figure 1-45 User list

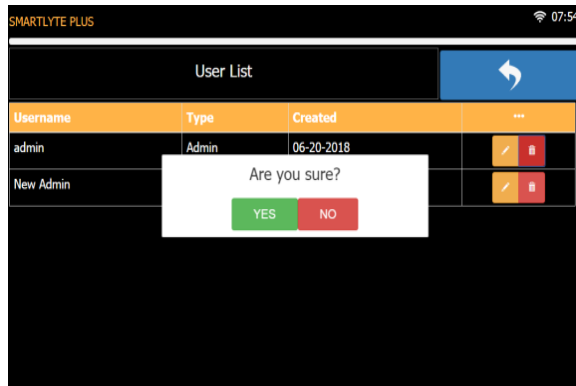


Figure 1-46 Confirmation of deletion

- After deletion the screen will show the updated User List.

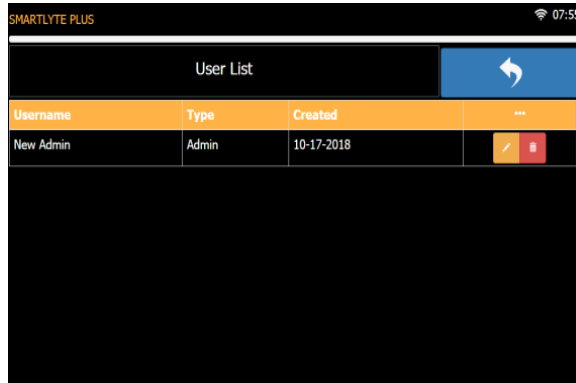


Figure 1-47 Updated User List

- Press to return to Operator Settings Menu. (Figure1-34)
- Press [ADD USERS] to add other users or to return to main operations menu.

TIP: *The administrator can add users at any time when logged in. It is recommended that administrators log out after completion of set up so that settings cannot be changed by other users.*

1.5.8. Selecting Language

The factory-set language is English. To change the language, the admin must be logged in.

- From the Main Operations Menu ([Figure 1-33](#)) press **[INSTRUMENT SETTING]**, then **[SET LANGUAGE]**, [Figure 1-48](#).

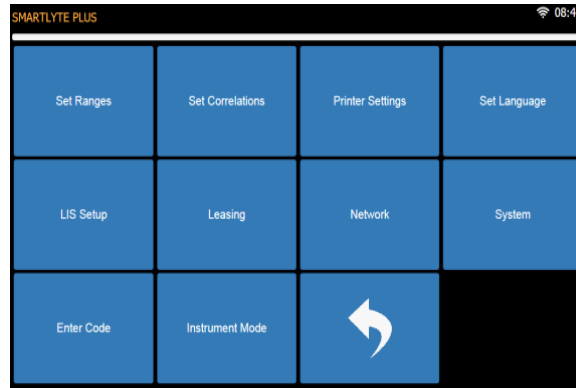


Figure 1-48 Instrument Settings Menu

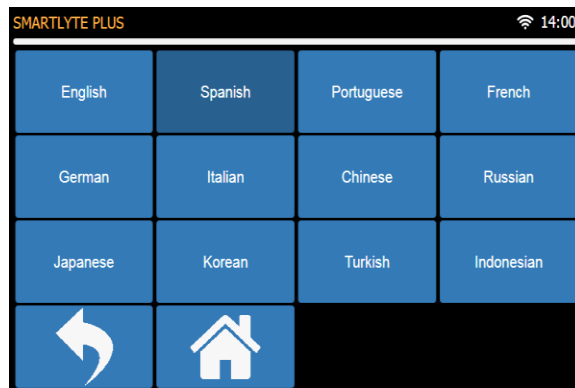


Figure 1-49 Language Selection

- Press the button for desired language ([Figure 1-48](#)). To confirm selection, press. ([Figure 1-49](#))

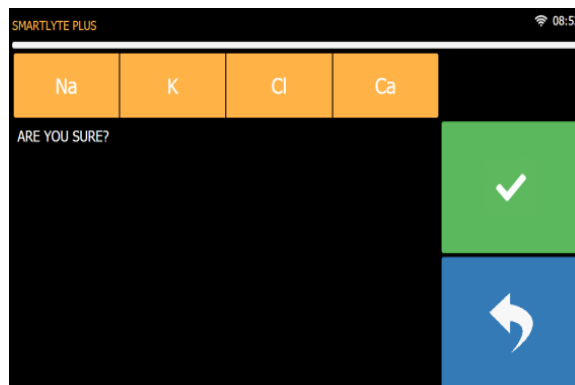


Figure 1-50 Language change confirmation

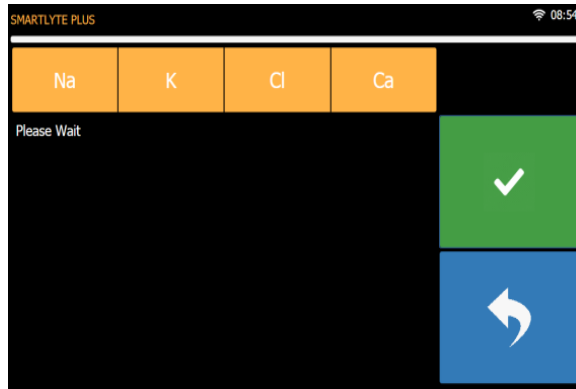


Figure 1-51 Language change in process

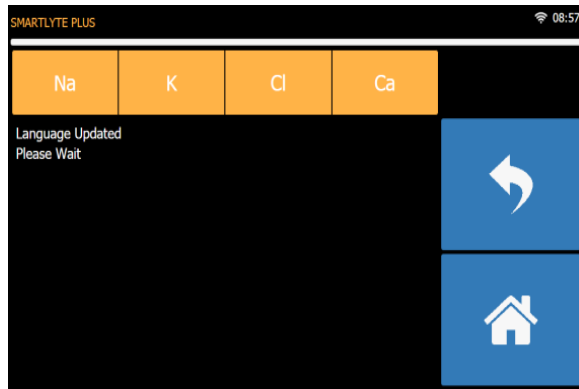




Figure 1-52 Confirmation language updated

- Once language change is confirmed (Figure 1-51), press  to step back to Instrument Settings Menu (Figure 1-47) or  to access the Main Operations Menu (Figure 1-33).

1.5.9. 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.

- Open main door and place a new paper roll in the paper tray.

- Fold the printer paper as shown below and feed the creased end into printer below the rollers. ([Figure 1-52](#))



Figure 1-53 Insert paper

- Press the paper feed button to completely feed the paper through the printer. ([Figure 1-53](#))



Figure 1-54 Paper feed button

TIP: *By pressing the paper advance button once, the paper will automatically advance 4 lines. More than once may be needed to feed folded paper completely through the printer.*



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.

1.5.10. Check Fluid Pack Status

The analyzer will automatically read the pack information. To check pack status,

- Access fluid pack information by pressing the **[PACK STATUS]** button on the either of the Main Menus. ([Figure 1-54](#) and [Figure 1-55](#)).

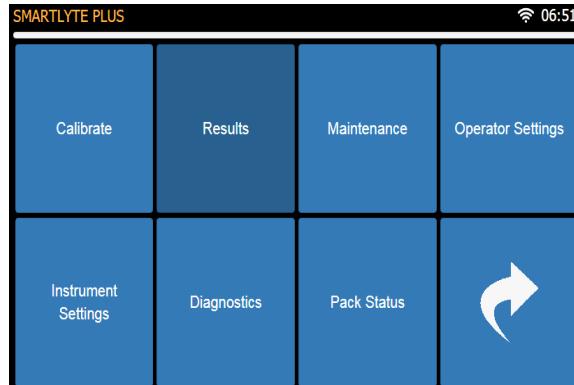


Figure 1-55 Main Operations Menu



Figure 1-56 Main Measurement Menu

The information about the pack includes its lot number, expiry date, number of samples remaining and the volume consumed as shown in [Figure 1-56](#).

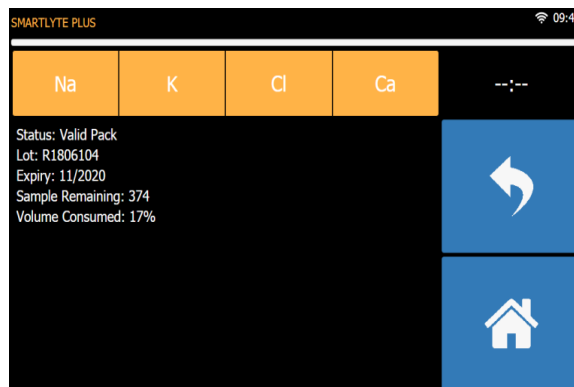


Figure 1-57 Pack Status

1.5.11. Selecting Parameter Configuration

Factory set configuration is Na-K-Cl-Ca. To select a different parameter configuration, start from the Main Operations Menu, ([Figure 1-54](#)).

- Press **[OPERATOR SETTINGS]** ([Figure 1-53](#)), then **[CHANGE ELECTRODES]** ([Figure 1-58](#)). This brings up the selection of parameter configuration ([Figure 1-57](#)).

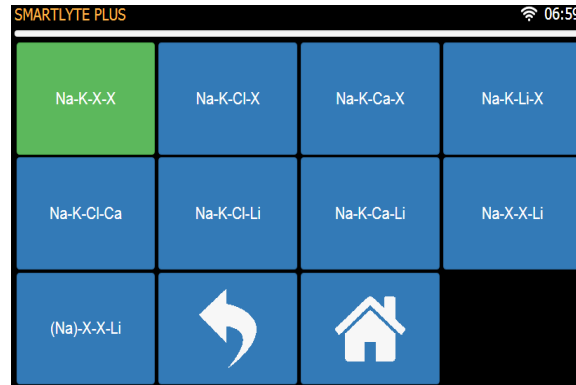


Figure 1-58 Parameter Configurations

- The configuration in green is the current configuration. Press the desired configuration in blue to change.
- Open the main door and verify electrodes configured as selected.

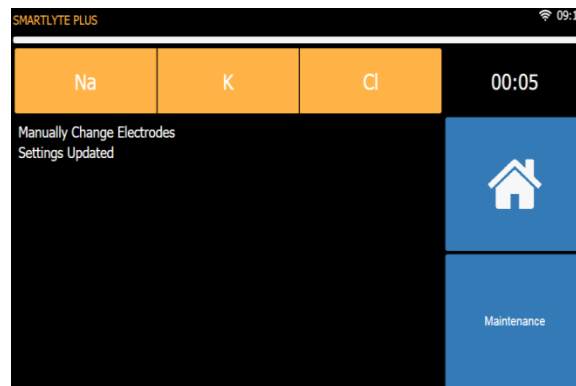


Figure 1-59 Change Electrodes

- Once electrodes are in closed tray, press **[MAINTENANCE]** ([Figure 1-58](#)) and proceed to clean and condition according to steps in section, 1.5.12.

TIP: *Maintenance should be done on electrodes after installation.*

If [(Na)-X-X-Li] is selected, only lithium results are reported. However, a working sodium electrode is required for lithium measurements. Install the sodium electrode and calibrate for lithium.

1.5.12. Maintenance

Prior to performing the first calibration or running the first sample, the SMARTLYTE® PLUS Electrolyte Analyzer needs to undergo a simple cleaning and conditioning procedure that helps ensure that the analyzer will perform properly. It should be performed at the end of each day when samples have been tested.

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



Maintenance is mandatory under the following conditions:

1. Upon installation of the analyzer
2. Upon installation of electrodes
3. Daily or 24 hours after the last cleaning and conditioning.
4. Diamond recommends cleaning and conditioning the analyzer at the end of each day for optimum performance and readiness.



Check expiration date on the bottles of the Cleaning Solution 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.

- Press [**MAINTENANCE**] after installing electrodes or in Main Operations Menu. ([Figure 1-33](#)) If the Clean and Condition buttons are orange, these tasks are required before calibration.



Figure 1-60 Maintenance Menu

- Pour a small amount of Cleaning Solution into a clean container or sample cup
- Press [**CLEAN**] ([Figure 1-59](#))
- Follow the prompt [**OPEN DOOR**]. Upon lifting the sample door, the pump will begin to turn.
- When the prompt, [**LOAD SAMPLE**], is displayed, dip the probe into the Cleaning Solution until [**WIPE PROBE & CLOSE DOOR**] is displayed.



Figure 1-61 Sample probe in sample

- Use a lint-free tissue to remove the cleaning solution from the probe. Close the sample door.

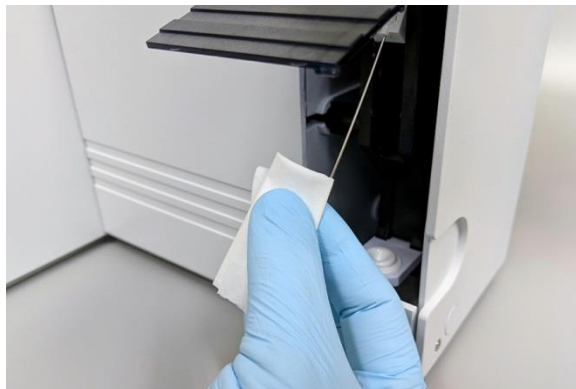




Figure 1-62 Wiping sample probe

- Pour a small amount of Conditioner into a clean container or sample cup.
- Press **[CONDITION]**
- Follow the prompt **[OPEN DOOR]**. Upon lifting the sample door, the pump will begin to turn.
- When the prompt, **[LOAD SAMPLE]**, is displayed, dip the probe into the Conditioner until **[WIPE PROBE & CLOSE DOOR]** is displayed. Use a lint-free tissue to remove the Conditioner from the probe. Close the sample door.
- Press  or , then **[CALIBRATE]**.
- Upon completion, the analyzer displays parameters in green for successful calibration. The analyzer is now ready for sample analysis.



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 analyzer. Occasionally additional time is required, and the analyzer displays an asterisk.

1.6 Auto Calibration

There are two calibration settings for the SMARTLYTE[®] Plus Analyzer –the **4 Hour Calibration** and **Daily Timed Auto Calibration**. When **4 HR CAL** is enabled, the analyzer will perform an automatic calibration 4 hours after the previous calibration only if samples have been run. If no samples were analyzed, the 4 hour calibration will not be triggered. If 4 hour calibration is disabled, all calibrations must be manually initiated by the user except if Daily Cal is enabled.

An automatic **Daily Timed Auto Calibration** can be set to occur once each day if [DAILY CAL] is enabled. The time for the single automatic calibration is set by the user. This allows the analyzer to be ready when the operator requires it at a specific time each day. Factory setting is 7:30am.

To set the Auto Calibrations,

- Select [OPERATOR SETTING] ([Figure 1-62](#)) in the Main Menu, then [AUTO CALIBRATION SETTING] ([Figure 1-63](#)).

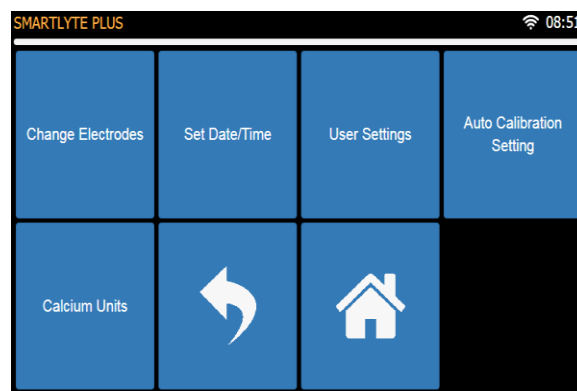


Figure 1-63 Operator Settings Menu

- The 4 Hour Cal can be turned off or on by selecting [DISABLED] or [ENABLED]. ([Figure 1-62](#))

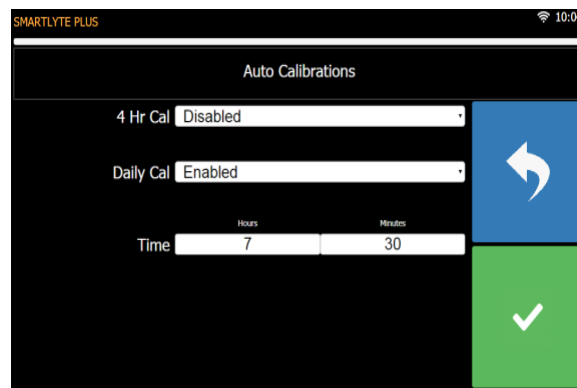


Figure 1-64 Auto Calibration Setting

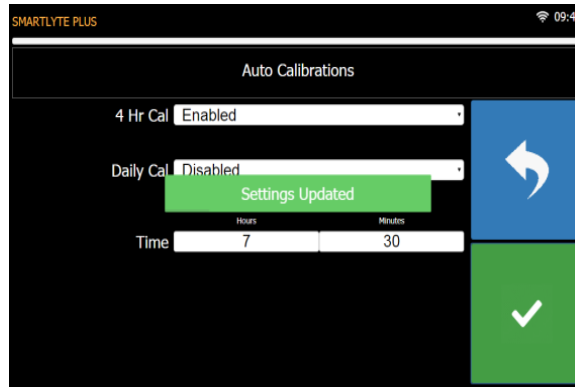




Figure 1-65 Auto Calibration setting saved

- Daily Cal can be [**DISABLED**] or [**ENABLED**]. If enabled, enter the time for the calibration to be done each day.

TIP: For minimum fluid consumption and maximum readiness, Disable 4Hr Cal and enable Daily Cal with the time sample testing is expected to start.

- Once entries are complete, press  to save changes. ([Figure 1-64](#))
- Pressing  will discard the changes.

1.7 Calcium Units

Calcium test results can be reported in two ways on the analyzer, Results can be reported as mmol/L (default) or mg/dL. To select the units for calcium, start from the Main Operations Menus,

- Press [**OPERATOR SETTINGS**] ([Figure 1-34](#)), then [**CALCIUM UNITS**].

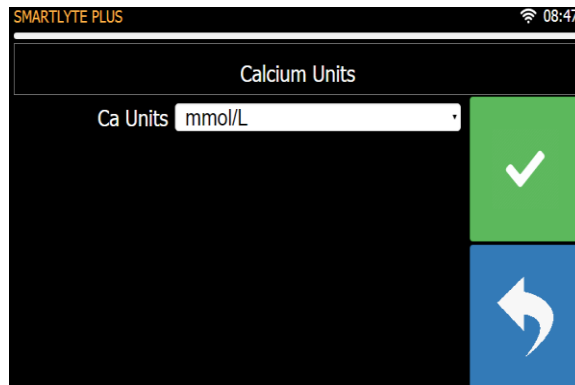



Figure 1-66 Calcium unit selection

- Select mmol/L or mg/dL from the drop down menu.
- Press  to save selection.

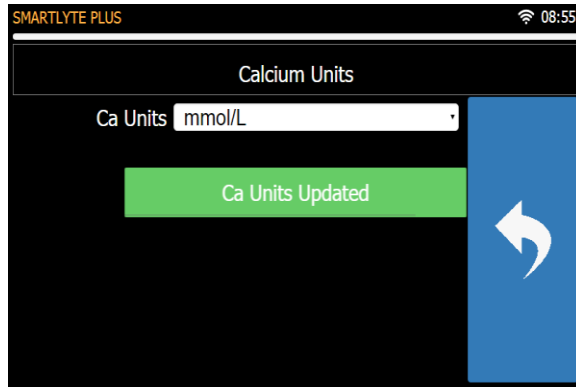


Figure 1-67 Calcium units updated message

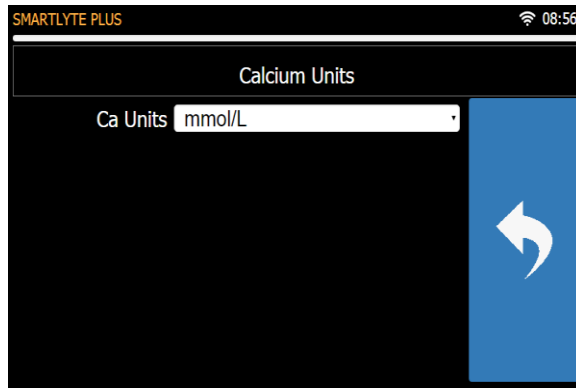



Figure 1-68 Calcium units selected

- After “Ca Units Updated” is displayed, press  to return to Operator Settings Menu.

1.8 Screen Saver

The touch screen of the SMARTLYTE® PLUS Electrolyte Analyzer has an automatic screen saver that is activated 10 minutes after the analyzer is last used. The screen saver is shown below.



Figure 1-69 Screen Saver

To use the analyzer, touch the screen. If the analyzer was in calibration and a calibration did not occur within the last 4 hours, a calibration will be needed before sample measurements can be made.

1.9 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 leave the analyzer in Standby Mode.

To perform the shutdown, you will need the items from the Shutdown Kit, AV-BP5014D.

- 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).
- One reference electrode transport housing (saved from installation section 1.4.3).
- 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 Main Operations Menu:

- Press **[INSTRUMENT SETTINGS]**, then **[SYSTEM]** to obtain the system menu ([Figure 1-69](#)).

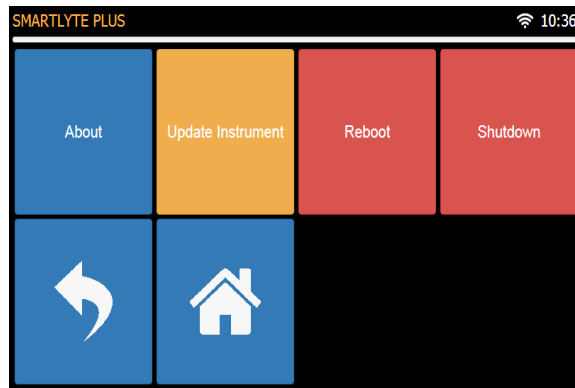



Figure 1-70 System Menu

- Select **[SHUTDOWN]**.
- Confirm **[ARE YOU SURE?]** by pressing .

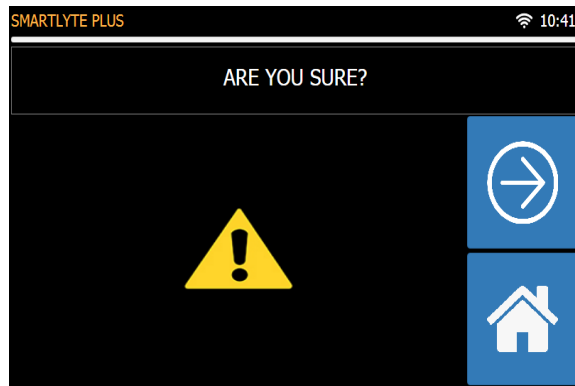



Figure 1-71 Shutdown first step

- Press  to start shutdown process.
- Follow the step by step instructions on the display and described in detail below.

1.9.1. Remove Measurement Electrodes and Install Dummy Electrodes

The analyzer prompts **[INSTALL DUMMY ELECTRODES]**.

- Obtain one Dummy electrode for each measurement electrode.
- Pull the electrode tray forward and remove each measurement electrode.
- Replace each measurement electrode with a Dummy. Ensure O-ring is on each Dummy electrode before installing.
- Carefully unscrew the reference electrode from the reference electrode housing. ([Figure 1-71](#)).
- Temporarily place the reference electrode on a clean, soft cloth or towel.
- Pour the reference solution remaining in the reference housing into the reference transport housing from the reference electrode when first installed.
- Carefully screw the reference electrode into the filled transport housing.


- The shutdown kit transport housing is screwed into the reference housing. ([Figure 1-71](#))
- Place the reference housing back into the electrode tray and move the lever forward and down, making sure all electrodes are seated properly. The electrode tray remains in the forward position. ([Figure 1-72](#))



Figure 1-72 Remove Reference Electrode



Figure 1-73 Reinstall housing with transport carrier

- Press  to proceed with shutdown process.

1.9.2. Installing Pack Shutdown Plug

- Remove the Fluid Pack and push the protective strip firmly onto the Fluid Pack connectors.
- Insert the shutdown plug carefully into the Fluid Pack receptacle.

1.9.3. Installing Water

- Fill one container of the shutdown kit about halfway with distilled water.
- Place the blue marked line into the container filled with water
- Place the red marked line into the empty container. ([Figure 1-73](#))



Figure 1-74 Shutdown installed

1.9.4. Washing the Lines

The analyzer will take approximately one minute to flush all lines with water. Upon completion, you will receive the prompt



- Begin the tubing wash procedure by pressing . The screen will display **[FLUSHING – PLEASE WAIT]**.
- When prompted **[REMOVE WATER]**, remove the tubing with the blue mark from the water and place it on a clean absorbent material. ([Figure 1-74](#))
- Press  to continue shutdown process.
- The pump will turn to remove all water from tubing. **[DRYING – PLEASE WAIT]** will be displayed.



Figure 1-75 Water bottle removed

1.9.5. Removing the Electrodes and the Shutdown Plug

- Upon completion, **[REMOVE ELECTRODES]** will be displayed.
- Remove the shutdown plug from the Fluid Pack receptacle.
- Unplug the reference connector below the left side of the electrode tray.
- Move the lever on the left side up and remove all dummy electrodes and reference housing. Place them on a soft clean towel.
- Move the lever down and push the empty electrode tray into its back position. Unscrew the transport housing from the reference housing.
- Empty the reference electrode housing of any residual water.

- Place all electrodes into their protective boxes.

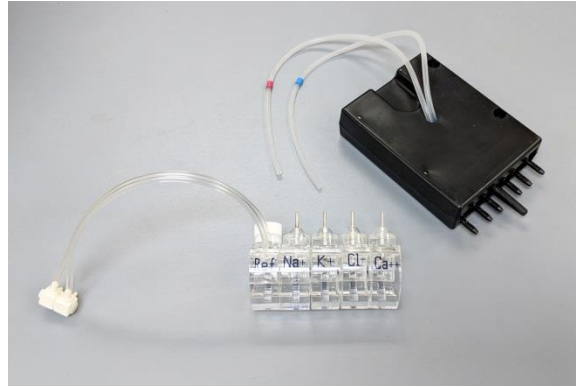


Figure 1-76 Parts removed from analyzer

1.9.6. Installing the Relief Clamps and Removing the Pump Windings

The display will prompt **[INSTALL VALVE CLAMPS]**.

- Install the red relief clamps making sure that each is snapped securely into position.



Figure 1-77 Installing red relief clamps



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



- Press  to continue.
- The next step is to unwind pump tubing from pump roller. **[RELEASE PUMP TUBING]** appears.
- Grasp the front winding close to the pump roller and gently pull it off the roller. Do not use fingernails which may cut into the tubing.
- Repeat the same procedure for the rear pump winding.



Figure 1-78 Remove pump tubing from pump roller

- Press .
- The prompt **[ERASE DATA]** will appear.
- Select the desired option based on description below.
 - **KEEP ALL Data** will not be erased.
 - **ERASE DATA:** Measurement data, therefore samples, QC and calibrations will be erased
 - **ERASE SETTING:** All user entered setting such as QC lot numbers and ranges, correlation factors service codes will revert to default numbers.
 - **ERASE DATA & SETTINGS**

1.9.7. Turning the Analyzer “Off”

- The prompt **[POWER OFF]** 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.

2. Specifications

2.1 Measurement Parameters

	Matrix	Specified Range	Measurement Resolution
Na ⁺	B/P/S/Q	40 – 200 mmol/L	0.1 mmol/L
	U	3 – 300 mmol/L	
K ⁺	B/P/S/Q	1.5 – 15 mmol/L	0.01 mmol/L
	U	5 – 120 mmol/L	
Cl ⁻	B/P/S/Q	50 – 200 mmol/L	0.1 mmol/L
	U	15 – 300 mmol/L	
iCa ²⁺	B/P/S/Q	0.3 – 4.5 mmol/L	0.001 mmol/L
Li ⁺	B/P/S/Q	0.2 – 5.0 mmol/L	0.001 mmol/L

Key

B - Whole Blood
P - Plasma
S - Serum
Q - Aqueous QC
U - Urine

2.2 Performance Parameters

2.2.1 Reproducibility

Typical Within-Run Precision is determined from 30 samples run between calibrations.

Blood/Serum/Plasma		
Na ⁺	C.V. ≤ 1%	65 – 180 mEq/L
K ⁺	C.V. ≤ 1.5%	2.3 – 10 mEq/L
Cl ⁻	C.V. ≤ 2%	50 – 180 mEq/L
Ca ²⁺	C.V. ≤ 0.02 mmol/L	0.5 – 1.6 mmol/L
Li ⁺	C.V. ≤ 0.03 mEq/L	0.4 – 1.8 mEq/L
Urine		
Na ⁺	C.V. ≤ 2%	5 – 280 mEq/L
K ⁺	C.V. ≤ 1%	7 – 115 mEq/L
Cl ⁻	C.V. ≤ 3%	21 – 270 mEq/L

Calcium & Lithium are not measured in urine samples

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[®] PLUS to the SMARTLYTE[®] with whole blood, plasma, serum and spot urine samples.

Whole Blood in mmol/L						
Parameter	Slope	Intercept	R ²	Range	n	Ste _{yx}
Sodium	0.9889	0.12	0.9995	40 – 205	69	1.00
Potassium	1.0349	-0.06	0.9988	1.4 – 15	48	0.15
Chloride	0.9758	0.48	0.9988	40 - 205	69	0.02
Calcium	1.0346	-0.03	0.9998	0.3 - 5.0	69	0.12
Lithium	1.0013	-0.07	0.9989	0.2 - 5.5	64	0.05
Plasma in mmol/L						
Parameter	Slope	Intercept	R ²	Range	n	Ste _{yx}
Sodium	1.0237	-12.8	0.9972	40 – 205	66	2.80
Potassium	1.0081	0.6001	0.9994	1.6 – 15	66	0.11
Chloride	1.0248	-2.4898	0.9993	40 - 200	48	1.55
Calcium	0.9834	-0.01	0.9997	0.3 - 5.0	72	0.03
Lithium	0.9825	-0.07	0.998	0.2 - 5.5	90	0.07
Serum in mmol/L						
Parameter	Slope	Intercept	R ²	Range	n	Ste _{yx}
Sodium	1.0047	-0.73	0.9994	40 – 205	48	1.40
Potassium	1.0039	-0.03	0.9997	1.4 – 15	48	0.07
Chloride	0.9952	-0.06	0.9994	40 - 200	48	1.34
Calcium	1.0006	-0.001	0.9998	0.2 - 5.0	58	0.02
Lithium	1.0100	-0.01	0.9995	0.2 - 6.0	93	0.04
Urine (Spot) in mmol/L						
Parameter	Slope	Intercept	R ²	Range	n	Ste _{yx}
Sodium	1.0145	-3.18	0.9996	5 – 305	58	1.80
Potassium	1.0000	-0.51	0.9917	5 – 130	56	2.03
Chloride	1.0004	-0.45	0.998	15 - 300	58	8.52

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	Interference	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. 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, or plasma 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.

Please 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 0.5 or 50%. These relationships may be altered when using citrate in blood, or when the acid base metabolism is disturbed.

2.6 Bibliography

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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 Samples

Sample Throughput	100 per hour
Sample Volumes	95 µL typically, Whole Blood, Serum, Plasma, QC material 180 µL typically, Urine
Sample Types	Whole Blood, Serum, Plasma, Urine & QC material
Calibrations	1-point calibration after each sample
	2-point or 3-point calibration every 4 hours

2.8 Environmental Parameters

Temperature/Humidity/Stability

Analyzer Operating Conditions	
Ambient Temperature	5 - 32°C
Relative Humidity	< 15% - 85% (not condensing)
Storage & Transport Conditions	
Temperature	-20 - 40°C
Humidity	85% (not condensing)
Electrode 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	85% (not condensing)

2.9 Reagents

Fluid Pack (PN AV-BP5186D)

For calibration of sodium, potassium, chloride, ionized calcium and lithium in the SMARTLYTE® PLUS Electrolyte Analyzer contains three standards for calibration:

	Standard A	Standard B	Standard C
<i>Content</i>	350 mL	85 mL	85 mL
<i>Active Ingredients</i>	Na ⁺ 150 mmol/L	Na ⁺ 100 mmol/L	Na ⁺ 150 mmol/L
	K ⁺ 5.0 mmol/L	K ⁺ 1.8 mmol/L	K ⁺ 5.0 mmol/L
	Cl ⁻ 115 mmol/L	Cl ⁻ 72 mmol/L	Cl ⁻ 115 mmol/L
	Ca ²⁺ 0.9 mmol/L	Ca ²⁺ 1.5 mmol/L	Ca ²⁺ 0.9 mmol/L
	Li ⁺ 0.3 mmol/L	Li ⁺ 0.3 mmol/L	Li ⁺ 1.4 mmol/L
<i>Additives</i>	Germicides	Germicides	Germicides
<i>Storage Temperature</i>	18 - 25°C	18 - 25°C	18 - 25°C
<i>Stability</i>	Expiration Date & Lot Number are printed on each container label	Expiration Date & Lot Number are printed on each container label	Expiration Date & Lot Number are printed on each container label
<i>On-board Stability</i>	14 weeks	14 weeks	14 weeks

Reference Solution

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

Reference Solution	
<i>Content</i>	85 mL
<i>Active Ingredients</i>	K ⁺ 1.2 mmol/L
	Cl ⁻ 1.2 mmol/L
<i>Additives</i>	Germicides
<i>Storage Temperature</i>	18 - 25°C
<i>Stability</i>	Expiration Date & Lot Number are printed on each container label
<i>On-board Stability</i>	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[®] PLUS Electrolyte Analyzer.

Urine Diluent	
Content	500 mL of Solution
Active Ingredients	Na ⁺ 120 mmol/L
	Cl ⁻ 120 mmol/L
Additives	Germicides
Storage Temperature	18 - 25°C
Stability	Expiration Date & Lot Number are printed on each container label

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

Mission Controls		
Content	30 ampules total	
	- Single Level 1	DD-92001
	- Single Level 2	DD-92002
	- Single Level 3	DD-92003
	- Tri-Level (10 ampules of each)	DD-92123
Storage Temperature	18 - 25°C	

2.10 Product Data

Electrical Data	
Main Voltage Range	100 to 240 VAC
Frequency	50/60 Hz (Self Adjusting)
Required Power	50W Max
Amperage	1.4 Amps Max
Classification	
Safety Category	I
Oversvoltage Category	II
Contamination Level	2
Dimensions	
Height	33.5 cm
Width	31.5 cm
Depth	29.5 cm
Weight	< 6 kg
Printer	
Type	Graphic Thermal Printer
Resolution	192 pixels per row
Printing Speed	28 mm/sec
Paper Width	38 mm
Paper Length	~30 m
Display	
Type	Touch Screen Graphic Display
Resolution	800 x 480 pixels

2.11 Interfaces

• RS232

• WIFI

• USB

• LAN

3. Measurement

3.1 Preamalytics

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[®] PLUS has not been tested.

Acceptable Anticoagulants

The only clot inhibitors that may be used for analyses in the SMARTLYTE[®] PLUS 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[®] PLUS 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 CO₂ 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[®] PLUS 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.

Aqueous Solutions

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



The Standard Mode ALWAYS reports direct FLUID.

3.1.3 Limitations of Clinical Analysis

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

3.1.3.1. 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[®] PLUS 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.

3.1.3.2. 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 analyzer. Diamond recommends that quality controls to be tested at least once daily or more often in accordance with local regulations.

3.2.1 Sample Measurement

The SMARTLYTE® PLUS Electrolyte Analyzer provides fast and easy operation. After Calibration, the display will indicate calibration values and the electrodes that calibrated successfully will be highlighted in green. The analyzer is ready for sample measurements and values will be reported for all electrodes that calibrated successfully.

Na	K	Cl	Ca	
53.89	49.56	-40.38	28.40	Home
Min: 0	Min: 0	Min: -100	Min: 0	Calibrate
Max: 65	Max: 65	Max: 0	Max: 55	
B: -2.80	B: -43.59	B: 6.09	B: -86.10	
A: 6.69	A: -21.60	A: -2.00	A: -92.40	

Figure 3-1 Calibration Successful Calibration Results in Green



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® PLUS provides the ability to enter the patient name and ID associated with the sample being tested.

TIP: Sample information can be entered during measurement cycle. No name or ID# will be assigned to the sample if the ID cell is left blank.
If a parameter indicator is not green, the electrode failed calibration. ([Figure 3-2](#))

To take a sample measurement, follow procedure below.

- From the Calibration results display, press  or  to access Sample Measurement Menu.
- Press the button to select sample type.

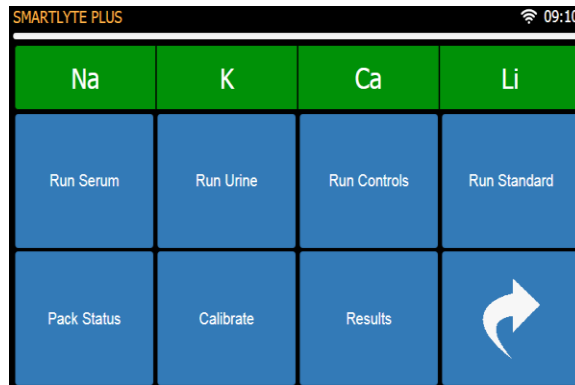


Figure 3-2 Sample Measurement Menu

Note: *If a parameter is not green, the electrode failed calibration and results will be NOT reported for that ion (Figure 3-2)*

- Open the door when the analyzer displays **[OPEN DOOR]**.
- Introduce the sample only when the analyzer displays **[LOAD SAMPLE]**
- Introduce sample by moving the sample container to the sample probe ensuring the probe opening is immersed in solution.



Figure 3-3 Sample probe in sample

- Remove sample when **[WIPE PROBE & CLOSE DOOR]** is displayed. Use a lint-free tissue to wipe the probe. Then close the sample door.



Figure 3-4 Wiping sample probe



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

A 30 seconds countdown will begin if the sample is successfully found. Sample ID can be entered at this time by touching the input field on the screen, directly scanning a barcode, or typing on keyboard. At completion of analysis, the test results will be displayed and printed if printer is enabled.

SMARTLYTE PLUS				06:52	
Serum	09-19-2018 16:54	1/102		→	
Test# 102	ID/LOT:				←
Na: 104.52 mmol/L LOW	K: 10.15 mmol/L HIGH	Ca: 3.676 mmol/L HIGH	Li: 2.970 mmol/L V. HIGH	🖨️	
Min: 136 Max: 145 S: 28.75 A: 37.40	Min: 3.5 Max: 5.1 S: -15.70 A: -32.90	Min: 1 Max: 1.3 S: 10.32 A: -5.20	Min: 0.6 Max: 1.2 S: 16.28 A: -10.34		
					↺

Figure 3-5 Display of sample results

SMARTLYTE® PLUS
SN 44-10181100
HOSPITAL EAST
TEST # 00483
ID: AADT8971452637
95541258972154
SERUM
Na= 143.9 mmol/L
K = 4.93 mmol/L
Cl = 103.5 mmol/L
TEMP= 25.65°C
10-08-2018 17:51

Figure 3-6 Serum sample printout



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® PLUS can store a large volume of data. It is recommended that the user delete some test results after collecting approximately 10000 test results. To view individual measurement results, access the Results Menu.

- Press **[RESULTS]** button in Main Menu or Sample Measurement Menu.

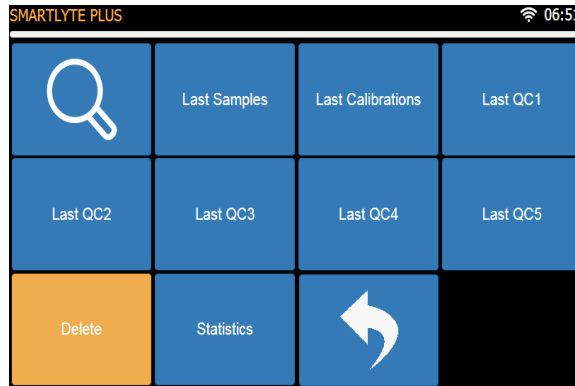


Figure 3-7 Results Menu

- Select the sample type to view. The most recent result will be displayed first.

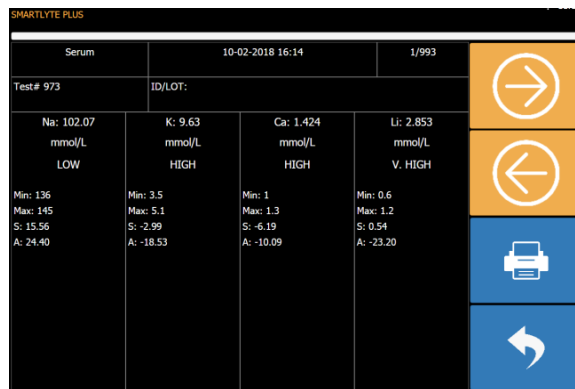


Figure 3-8 Results

- Use the Arrow buttons to access different sample results.
- Press the button to print to thermal printer
- To access a specific sample ID, press

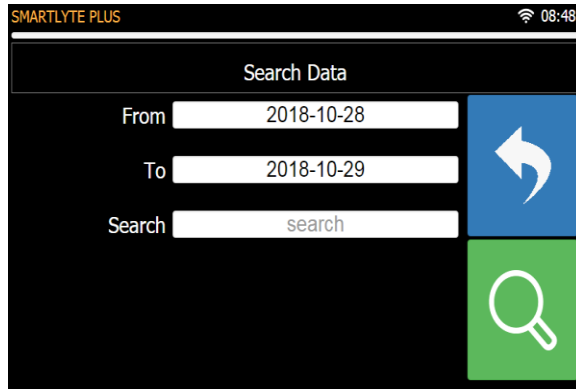



Figure 3-9 Search Data

- Enter sample ID in Search cell. Then press .
- The most recent result for that sample ID will be displayed on the screen.

Measurement data can be downloaded remotely by accessing the analyzer from a computer through the internet. See Section 8.1.2

3.2.2 Direct ISE

- The **[RUN STANDARD]** mode will provide sample measurement results without internal correlation.

3.2.3 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.

When the analyzer is calibrated, **[RUN URINE]** can be accessed on the Sample Measurement Menu. Upon completion of measurement, the analyzer will display and print out the results.

Na: 102.07 mmol/L LOW	K: 9.63 mmol/L HIGH	Ca: 1.424 mmol/L HIGH	Li: 2.853 mmol/L V. HIGH
Min: 136 Max: 145 S: 15.56 A: 24.40	Min: 3.5 Max: 6.1 S: -2.99 A: -18.53	Min: 1 Max: 1.3 S: -6.19 A: -10.09	Min: 0.6 Max: 1.2 S: 0.54 A: -23.20

Figure 3-10 Urine sample results

```

SMARTLYTE® PLUS
SN 44-10181100
HOSPITAL EAST

TEST # 00485
ID: AADT8971452637
95541258972154
URINE

Na= 343.9mmol/L
K = 14.93 mmol/L
Cl = 203.5 mmol/L

TEMP= 25.65°C
10-08-2018 18:00

```

Figure 3-11 Urine sample printout



Ca²⁺ 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 analyzer has preset normal ranges for whole blood, plasma and serum samples and urine. They are:

	Serum/Blood/ Plasma	Urine
Na ⁺	136 - 145 mmol/L	40 - 220 mmol/L
K ⁺	3.5 - 5.1 mmol/L	25 - 120 mmol/L
Cl ⁻	97 - 111 mmol/L	110 - 250 mmol/L
Ca ²⁺	1.0 - 1.3 mmol/L	
Li ⁺	0.6 - 1.2 mmol/L	

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 requirements².

Changes can be made through **[INSTRUMENT SETTINGS]**.

- Press **[INSTRUMENT SETTINGS]** followed by **[SET RANGES]** then **[SERUM RANGES]** or **[BLOOD RANGES]** to access Set Ranges Main Menu

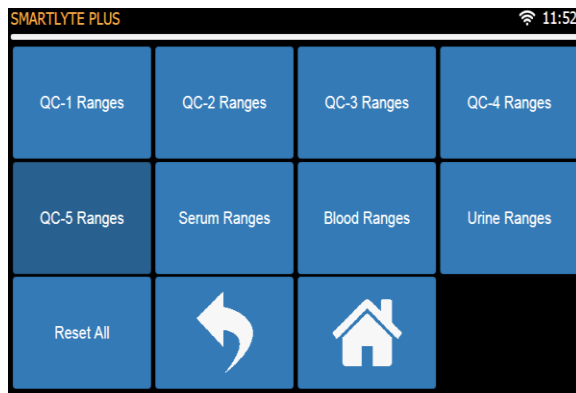


Figure 3-12 Set Ranges Main Menu

- Press the desired parameter range to change.

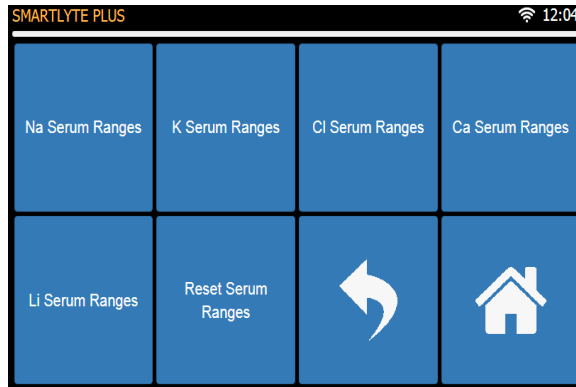


Figure 3-13 Set Ranges Menu by Sample Type

- Once range to be changed is selected, the analyzer will display the screen to make changes.

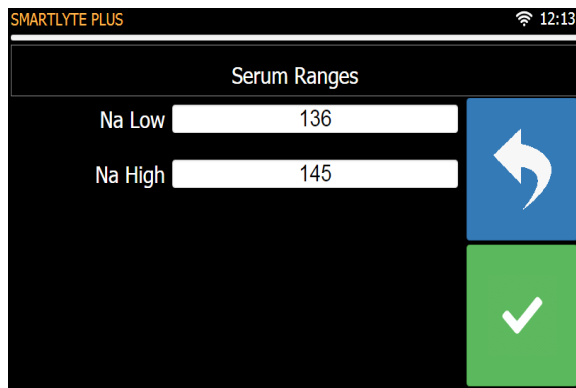





Figure 3-14 Serum Ranges displayed


- After entering the new range, Press  to accept or  to reject changes.
- Once “Ranges Updated” is displayed, press  to return to Set Ranges Menu.

Repeat the above procedure for all parameters and sample types.

The expected normal urine values 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.

3.4 Correlation Factors

The correlation factor allows for the correlation of SMARTLYTE® PLUS 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. A separate set of correlation factors is available for urine samples. The default settings are slope = 1 and Offset = 0.

 *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.*

- To add a custom correlation factor, press **[INSTRUMENT SETTINGS]** followed by **[SET CORRELATIONS]** then the specific sample type. Since Standard is a direct measurement of the sample, no correlation factor is allowed.

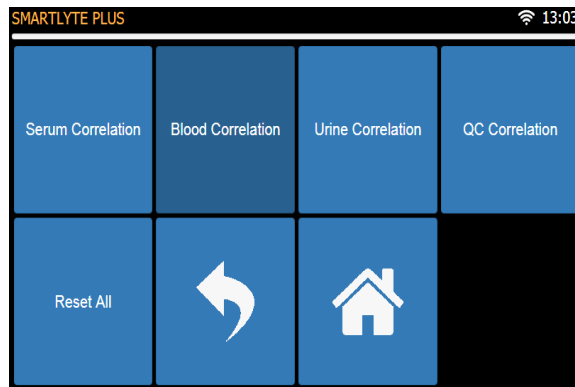


Figure 3-15 Set Correlation Menu

- Press the parameter for which a correlation factor will be entered.

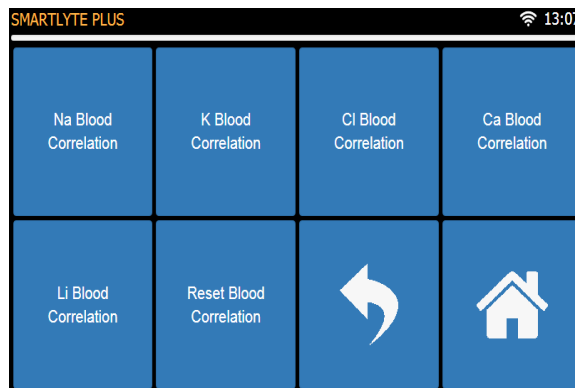


Figure 3-16 Set Blood Correlation Menu

- Enter the Slope and Offset factors.

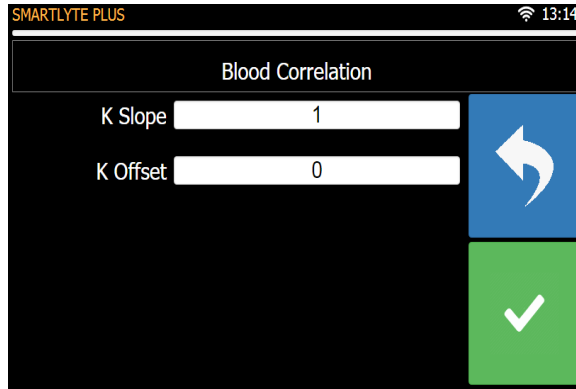





Figure 3-17 Blood Correlation Factors

- After entering the new factors, Press  to accept or  to reject changes.
- Once “Correlation Updated” is displayed, press  to return to Set Correlation Menu.

Repeat the above procedure as need for all parameters and sample types requiring change.

Sample results printouts will have # next to analyte to indicate correlation applied. Moreover, **[#MODIFIED#]** is printed below the sample results. ([Figure 3-18](#))



Only activated parameters can be programmed.

```

SMARTLYTE® PLUS
SN 44-18061100
HOSPITAL EAST

TEST#: 00010
ID: AADT8971452637
95541258972154
SERUM

Na #= 144.2mmol/L
K #= 4.4mmol/L
Cl = 88mmol/L

#MODIFIED#
TEMP = 22.29 °C
06-11-2018 12:55
  
```

Figure 3-18 Sample report showing Na & K with correlation factors

4. Quality Control

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[®] PLUS 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 analyzer. 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 $\pm 2SD$ are acceptable.

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

QC measurement results that are greater than the target value $\pm 2SD$, but less than the target value $\pm 3SD$, 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 Main Menu, Press **[INSTRUMENT SETTING]** then **[SET RANGES]** followed by the pressing the QC level to enter lot and limit information.

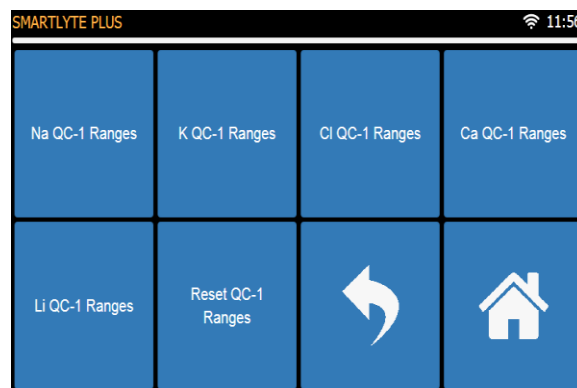


Figure 4-1 QC material set up screen

- Press the parameter for which changes will be made.
- Enter lot number and the lower limit and upper limit.

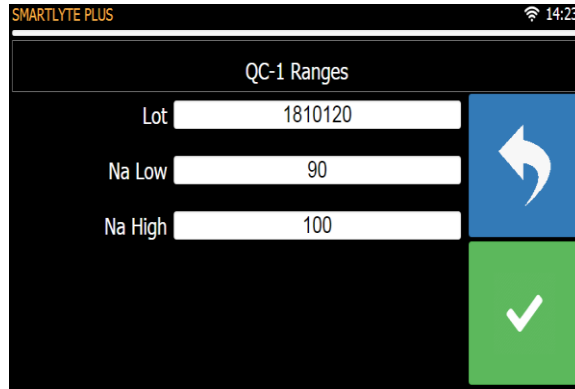




Figure 4-2 Screen for entering QC-1 information

- After entering the new information, Press  to accept.
- Once “Ranges Updated” is flashed, press  to return to menu to set ranges for remaining parameters or return to Main Menu.

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 analyzer. Local regulations or your operating procedure may require quality control tests daily or more often.

TIP: *A large number of QC measurements- can be stored per level. The values can be stored and the statistics printed at any time. It is recommended that the*



MISSION 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.

- 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.



Protect fingers by using gloves or tissue while breaking ampule.

Starting from the Sample Measurement Main Menu, press **[RUN CONTROLS]**.

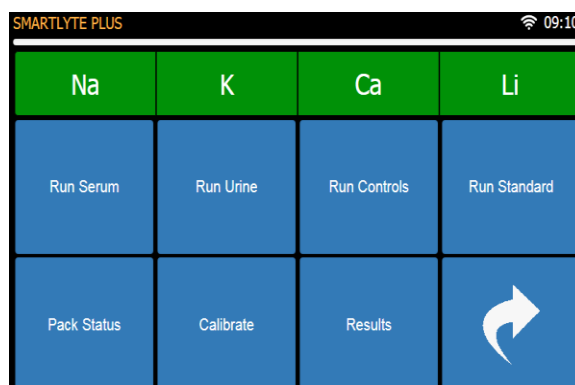


Figure 4-3 Sample Measurement Main Menu

- Press the Control to be tested.

- Upon the prompt **[OPEN DOOR]** lift the door.
- When prompt **[LOAD SAMPLE]** is displayed, place sample probe into the ampule ensuring the probe opening is immersed.
- 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 analyzer will display **[CONTROL LEVEL 1 TESTING...]** and a countdown will begin, during which the QC will be analyzed. Upon completion, the results will be displayed, such as:

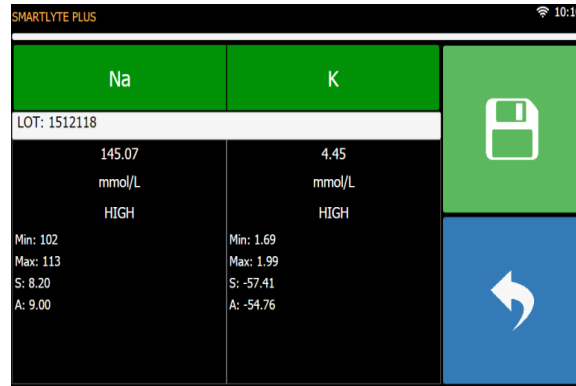





Figure 4-4 QC1 results screen, values outside of range



The SMARTLYTE[®] PLUS Electrolyte Analyzer displays "flags" for values that are above (HIGH) or below (LOW) the programmed target ranges.



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

- To discard the values, press  to return to QC test menu and repeat the test
- Press  to save the values, or  to return to QC test menu and continue testing.

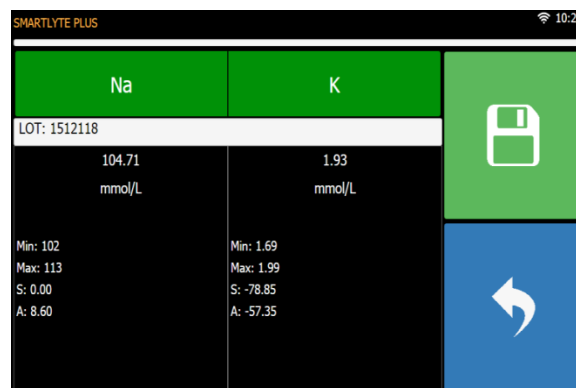



Figure 4-5 QC1 results screen, values in range

- If values are in range, press  to save the values.

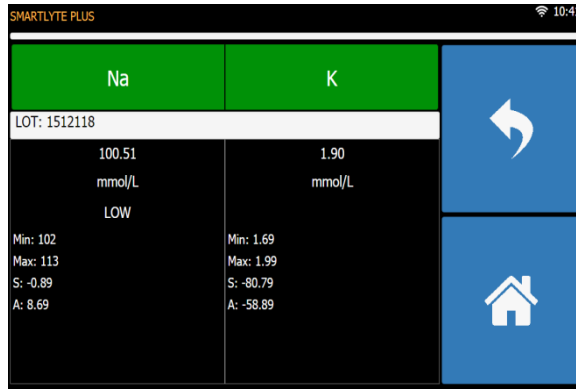


Figure 4-6 QC1 results screen after saving data

- Press or to return to QC test menu and continue testing or to test menu.

4.4 Printing a QC Report

The SMARTLYTE[®] PLUS Electrolyte Analyzer will store in memory the last 500 QC measurement values for each of the three QC levels. It can also present a graph of the data generated

- To print the saved QC values, press **[RESULTS]** in Main Operations Menu or Main Sample Test Menu:

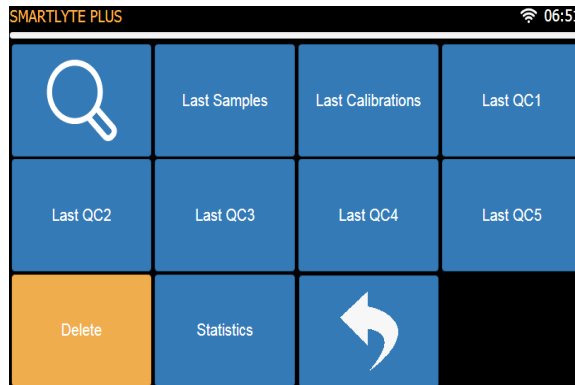


Figure 4-7 Results Menu

- Press button to obtain desired level of QC results.

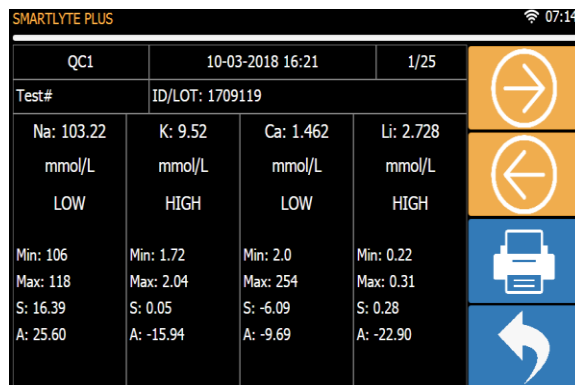


Figure 4-8 QC results recalled from saved data




- The most recent result will be displayed. Older results can be accessed by pressing . More recent results can be viewed by pressing 
- To print the result displayed, press 
- Statistical analysis and graphical presentation of the QC data can be obtained.
- To obtain Statistical results, press **[STATISTICS]** on the Results Menu.



Figure 4-9 QC Main menu

- Select control level to view.

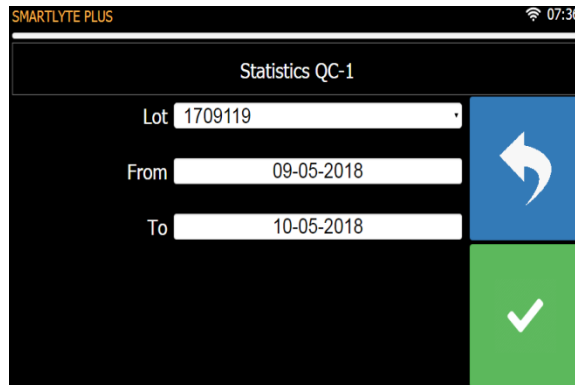




Figure 4-10 QC Statistics


- Enter Lot number and date range for the analysis. Press 

Na	K	Cl	Ca
QC1	QC1	QC1	QC1
N : 25	N : 25	N : 17	N : 13
MN: 106.11	MN: 8.13	MN: 76.61	MN: 1.70
SD: 6.92	SD: 3.01	SD: 6.35	SD: 0.26
CV: 6.53%	CV: 37.04%	CV: 8.29%	CV: 15.28%

Figure 4-11 QC Results

- Press  to print statistics.

The Levy-Jennings plot displays 10 days on the screen. To obtain hard copy of the graph, use PC to access the analyzer and take screen shots of the graphs.

- To view Levy Jennings Plot, press 

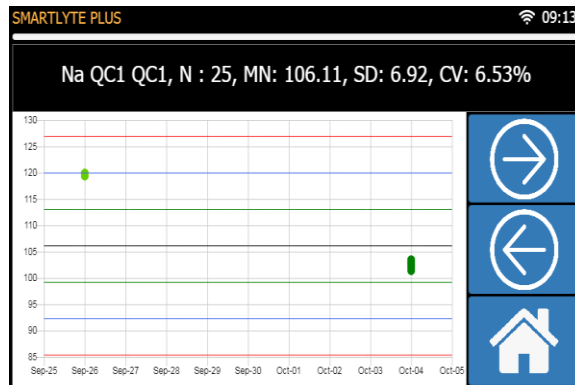





Figure 4-11 Levy Jennings Graph Line Colors indicate,
Black = Mean, Green = 1SD, Blue = 2SD, Red = 3SD

- To view different parameters, press  or 
- Press  to return to Main Menu.



If correlation factors are changed, ALL values in memory are recalculated.

5. Maintenance



After use, components of the SMARTLYTE[®] PLUS 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 analyzer before shutting it down and unplugging it from the power source.

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

Regularly decontaminate the following parts of the analyzer:

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

Sample probe mechanism

See "Clean sample probe and fill port" on page 75.

Surfaces of the Analyzer

See "Cleaning analyzer surfaces" on page 75.

5.1.2. Recommended Disinfectant

Surfaces

Protein remover (PN AV-BP0521D)

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.



IMPORTANT: Refer to SDS for additional information.

5.2 Daily Maintenance (See Section 1.5.12)



IMPORTANT: If samples have been tested and cleaning and/or conditioning has not been performed within the last 24 hours, the analyzer will require cleaning and/or conditioning before calibration or samples can be tested.

5.3 Weekly Maintenance

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

5.3.1 Clean Sample Probe and Fill Port

- Open the sample door.



Figure 5-1 Open door for probe and port cleaning

- Clean the fill port, probe and surrounding area with a damp cotton swab.
- The interior surfaces should be wiped clean with a soft, damp cloth.
- Close the door when cleaning is complete.



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

5.3.2 Cleaning Analyzer Surface



**Never use alcohol based disinfectants!
Never use disinfectant sprays.**



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

Before plugging the analyzer 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 Home screen, press **[MAINTENANCE?]**.
- Press **[HOLD IN MAINTENANCE]** No liquids will be pumped through the analyzer in this state. The beeper will sound every 2 minutes to notify the operator that the analyzer is still in HOLD. If the operator does not take the analyzer out of HOLD, it will step out of hold after 10 hours automatically.
- 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.



Figure 5-2 Unplug reference housing connector

- Slide the measuring chamber forward until it locks in the front position. ([Figure 5-3](#))
- Unclamp the electrode tray by moving the clamp up. ([Figure 5-4](#))



Figure 5-3 Pull electrode tray forward



Figure 5-4 Move clamp to release tension

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



Figure 5-5 Remove reference housing and electrode

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 tray by moving forward and down until it locks in position. Ensure the electrodes are seated properly.



Figure 5-6 Move clamp down

- 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*



Figure 5-7 Plug in reference connector



Figure 5-8 Push electrodes back into position.

- At this time, daily maintenance is recommended.
- If daily maintenance is not needed, press  and proceed with a calibration.

5.5 Quarterly Maintenance

5.5.1 Exchanging the Pump Tubing Set

To make sure that the pump does not turn on during this procedure, press **[MAINTENANCE]** then **[STOP]**.

TIP: Entering **[STOP]** will clear calibration so a calibration is required after stopping the analyzer.

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. ([Figure 5-9](#))

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



Figure 5-9 Un-wind pump tubing

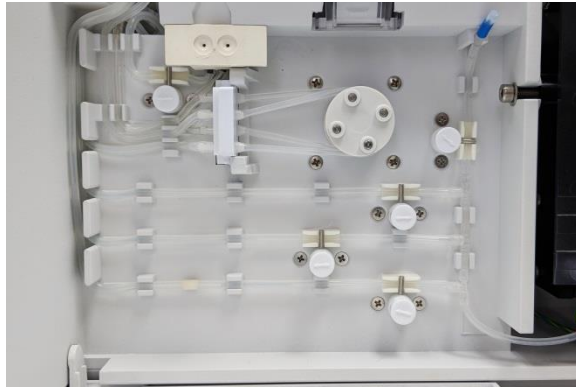



Figure 5-10 Pump tubes wound on roller

- Install the new pump winding plate and slip the new pump windings over the pump rollers, being careful not to cross the tubes. (Figure 5-10)
- Press  to exit Stop state.



Dispose of the pump tubing 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!

- From the Main Operations Menu, press **[DIAGNOSTICS]**, then **[CHECK VALVES]** to access Valve Operations Menu



Figure 5-11 Valve Operations Menu

- Open each valve and remove the valve caps, sliding them in the direction of the arrow.

TIP: *Each valve will stay open for 10 seconds then automatically shuts OFF and screen reverts to Valve Operations Menu.*

- 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 tray.
- 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 ON, then slide the pinch bar on and snap on the valve cap in the direction of the arrow.

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 to return to the Main Operations Menu.
- Press [CALIBRATE].

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 tray
- Place and secure new Sample Probe into tray
- 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 Tray by moving the clamp upward.



Figure 5-12 Electrode Tray



Figure 5-13 Electrode Tray Lever

- Remove the used electrode from the measuring chamber.



Figure 5-14 Remove Electrode

- Remove the new electrode from its protective box.
- Remove seals or adhesive coverings along the sides of the electrodes.
- 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.



Figure 5-15 Electrode



Figure 5-16 Electrode seated position

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

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



Figure 5-17 Rotate clamp down




Figure 5-18 Slide tray back

After installing a new electrode, the SMARTLYTE[®] PLUS 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® PLUS 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:

- On the Main Menu, Operation or Sample, press [**PACK STATUS**]. The number of samples remaining in the pack as well as the volume consumed will be displayed.

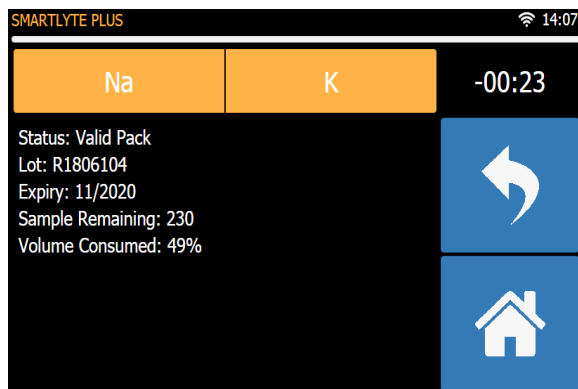


Figure 5-19 Pack Status screen



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



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

To change the Fluid Pack,

- Remove the protective strip from the new Fluid Pack. Do not discard.
- Write the installation date on the label of the new Fluid Pack.
- Remove the used Fluid Pack from the analyzer. Place the protective strip on the used 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. The analyzer will automatically sense a fluid pack has been installed. It will read the enclosed tag for Lot Number, Expiration Date, Number of Samples Remaining and Volume Remaining.



Figure 5-20 Remove Pack

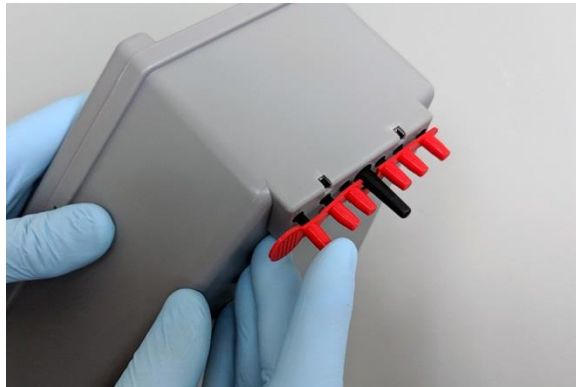


Figure 5-21 Manifold cover installed

- On the Main Menu press **[CALIBRATE]** to initiate a calibration which should be done whenever a fluid pack is replaced.

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 [MAINTENANCE] on the Main Operations Menu. Press [HOLD] to prevent the pump from turning.

Replace the sample probe using the following steps,

- Open the front door.
- Open the sample door.



Figure 5-22 Sample Probe and Fill Port

- Remove the needle carefully from the holder. Unplug the tubing.
- Reattach the new needle to the tubing and snap the needle back into the tray.

Then replace the fill port as follows:

- Remove the fill port tray 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.
- On the Main Menu press **[CALIBRATE]** to start a 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. (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 5-23](#).
- Press the paper feed button, [Figure 5-24](#), to completely feed the paper through the printer



Figure 5-23 Install Paper



Figure 5-24 Feed paper

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.

6. Troubleshooting

SMARTLYTE[®] PLUS 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[®] PLUS Electrolyte Analyzer to operation. If SMARTLYTE[®] PLUS 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
Air in STD-A	As the analyzer aspirates 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.	<ul style="list-style-type: none"> • 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.
Air in STD-B	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.	<ul style="list-style-type: none"> • PRIME STD - B. • Replace the Fluid Pack.
Air in STD-C (Li activated)	Detection of Standard C aspiration is the same as for Standard B.	<ul style="list-style-type: none"> • PRIME STD - C. • Replace the Fluid Pack.
Check Temp (Ca ⁺⁺ 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).	<ul style="list-style-type: none"> • 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.

Message	Cause	Action
Inspect Sample Sensor	The sample sensor is calibrated automatically with air during each calibration. For proper functioning, the sensor must provide a reading of 80 to 120 units when air is detected.	<ul style="list-style-type: none"> • To check sample sensor response, Start SAMPLE SENSOR CHECK to verify air reading. Open the sample door and press LOAD SAMPLE 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 by pressing STOP. • 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 Electrode	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.	<ul style="list-style-type: none"> • Under DIAGNOSTICS/CHECK ELECTRODES, initiate a reference check. • 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 • Contact Customer Support • Clean the reference housing. (See chapter 5.4: "Monthly maintenance").

Message	Cause	Action
Inspect electrodes	Stable reading of Standard A could not be obtained within 6 aspirations.	<ul style="list-style-type: none"> • 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. • Perform daily maintenance. • Conduct electrode tests. • Replace the Fluid Pack.
Interface error	The interface test (see chapter 8: "Testing the interface") was not successful.	<ul style="list-style-type: none"> • Check if pins 2 and 3 of the serial port were connected properly. • If the error persists, contact Technical Support.
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	<ul style="list-style-type: none"> • 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").	<ul style="list-style-type: none"> • For 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.
Change Fluid Pack	When the monitored Fluid level in the Fluid Pack reaches less than zero % remaining, the analyzer will display [Change Fluid Pack] .	<ul style="list-style-type: none"> • Replace the Fluid Pack (see chapter 5.7.2: "Checking reagent Fluid level and changing the Fluid Pack).
Fluid Pack is empty	Pack used to its maximum capacity.	<ul style="list-style-type: none"> • Insert new pack

Message	Cause	Action
Invalid Fluid Pack	Fluid Pack is not authentic.	<ul style="list-style-type: none"> • Ensure Fluid Pack is for SMARTLYTE® PLUS. • Go to [PACK STATUS] in Main Operations Menu and verify pack information. • Ensure pack is properly inserted. • Ensure RFID tag is detected. Under [DIAGNOSTICS], press [CHECK RFID] • Contact Customer Support
Expired Fluid Pack	Inserted Fluid Pack has passed expiry date..	<ul style="list-style-type: none"> • Insert new pack
**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.	
No Acknowledgement	Action is requested, but the analyzer does not respond to the request.	<ul style="list-style-type: none"> • Proceed to previous screen and try again. • Reboot the analyzer
System Busy	Instrument is performing an active task and cannot start another task in parallel.	<ul style="list-style-type: none"> • Wait for a few minutes for active task to finish and try again • Reboot the analyzer if instrument is non-responsive

6.2 Diagnostics

The SMARTLYTE[®] PLUS Electrolyte Analyzer has various diagnostic functions that you can access to evaluate the performance of the analyzer. The Diagnostic Menu can be accessed from the Main Operations Menu.

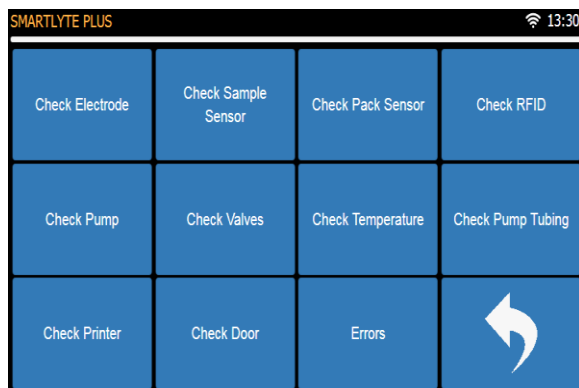


Figure 6-1 Diagnostics Menu

6.2.1 Testing the Electrodes

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

- From the Diagnostic Menu select **[CHECK ELECTRODES]**.
- Select Standard A to test electrode millivolt signal (Offset).

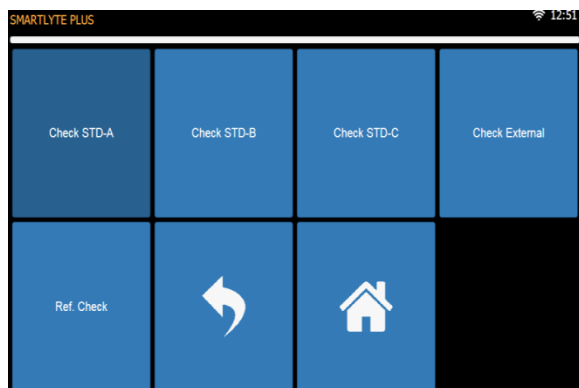


Figure 6-2 Test electrode menu

- Record the values. The expected range of millivolts for Standard A is -100 mV to 100 mV.

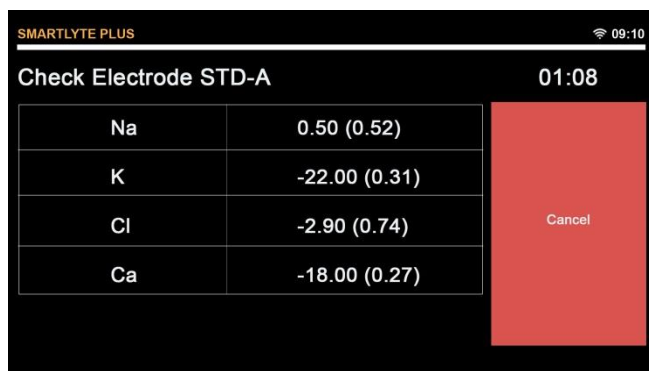


Figure 6-3 Check Electrodes

- To exit Standard A check, press [**CANCEL**].
- The Check Electrodes Menu will be displayed.
- Standard B and Standard C can be tested and viewed in same way as Standard A..
- All values must fall between -100 mV and 100 mV. Additionally, variation factor shown in parenthesis must be below 2 indicating stable reading.
- The SMARTLYTE[®] PLUS can also test an external sample by pressing [**EXTERNAL CHECK**].
- Lift the sample door when prompted [**LIFT DOOR**].
- Introduce sample when prompted with [**LOAD SAMPLE**].
- Electrode voltages will be displayed in same manner as above.
- Check for stable readings and millivolt range within -100 to 100 millivolts.
- Press [**CANCEL**] to discontinue test and return to Check Electrodes Main Menu

The SMARTLYTE[®] PLUS can test the functionality of the Reference Electrode Housing.

- On the Check Electrode Menu, press [**REF. CHECK**]. The SMARTLYTE[®] test the Reference Housing functionality

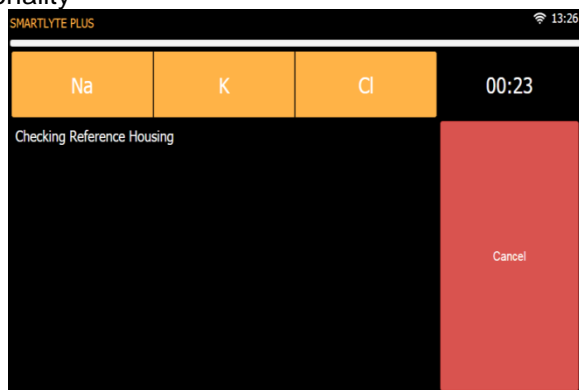


Figure 6-4 Check Reference Housing

6.2.2 Testing the Sample Sensor

The SMARTLYTE® PLUS calibrates the sample sensor automatically at start of each calibration. The dry sample sensor will be calibrated to (approximately) 100. A clear Fluid should increase this value by at least 40 Units.

- Press **[CHECK SAMPLE SENSOR]** in the Diagnostic Menu.

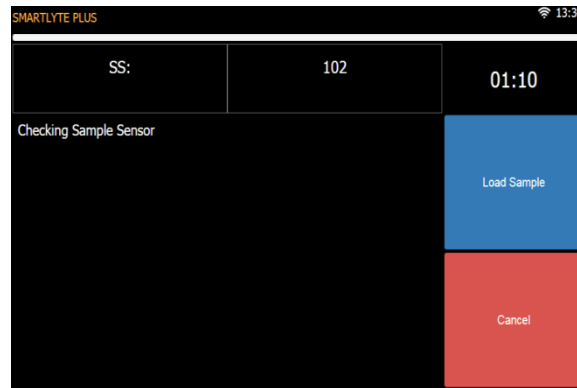


Figure 6-5 Check Sample Sensor

- An external sample can be introduced for troubleshooting purposes. Press **[LOAD SAMPLE]** and following the instructions on the display to test the sample.
- Press **[CANCEL]** return to the Diagnostic Menu.

6.2.3 Testing the Fluid Pack Sensors

There are two sensors for Fluid Pack. One is the optical sensor and the second reads the information encoded in the Fluid Pack.

- Press **[CHECK PACK SENSOR]** to check the optical sensor.

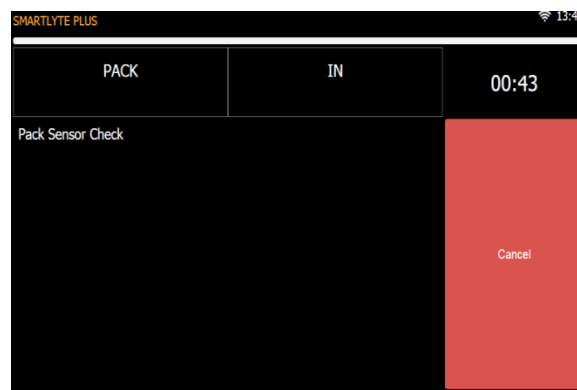


Figure 6-6 Pack Sensor Check

Verify the current Fluid Pack Status is correct

FLUID PACK: IN or OUT

- Remove or insert 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 **[CANCEL]** to exit and return to Diagnostic Menu.

6.2.4 Testing the RFID Sensor

- Press **[CHECK RFID]** on Diagnostic Menu.

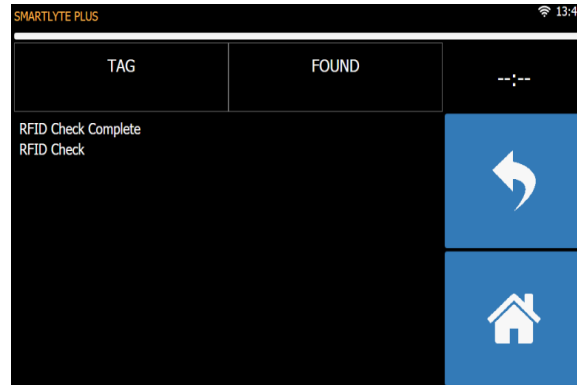


Figure 6-7 RFID Check

- If Fluid Pack with RFID, is in place, the test should indicate **[FOUND]**.
- Press . Remove the fluid pack and press **[CHECK RFID]** again. **[NOT FOUND]** should be the new test result.
- Press to return to Diagnostic Menu, or to return to Main Operations Menu.

6.2.5 Testing the Pump

- Open the front cover.
- In the Diagnostic Menu press **[CHECK PUMP]**.
- The pump will cycle through the 4 speeds starting with SLOW and stepping up to VERY FAST.

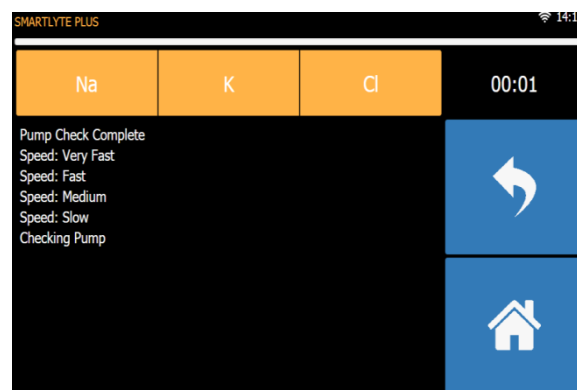


Figure 6-8 Pump Check Complete

- Note the audible change heard in pump as the speed changes.
- Close the front cover and press to return to Diagnostic Menu, or to return to Main Operations Menu.

6.2.6 Testing the Valves

- Open main door. Press **[DIAGNOSTICS]** on Main Operations Menu.

- On Diagnostic Menu, press **[CHECK VALVES]** to obtain access to the different valves ([Figure 6-9](#)).

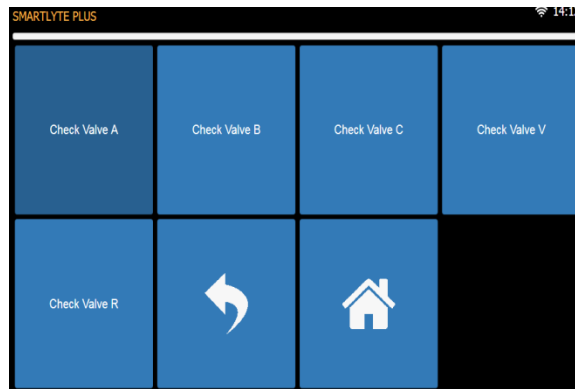


Figure 6-9 Check Valves Menu

- Press the button for the valve to be tested. ([Figure 6-9](#))

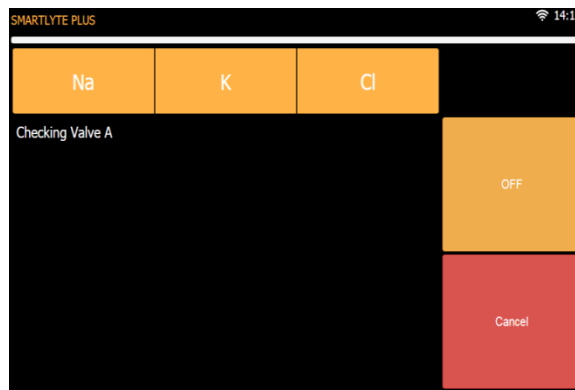


Figure 6-10 Tubing not compressed, ON (open position)



Figure 6-11 Tubing Compressed, OFF (closed position)

- Press **[ON]/[OFF]** button and verify the movement of the valve to its correct position. ([Figure 6-10](#) and [Figure 6-11](#)).
- Press **[CANCEL]** to step back to Check Valve Menu. The screen will step back to Check Valves menu in 10 seconds if no activity.
- Close the front cover and press to return to Diagnostic Menu, or to return to Main Operations Menu.

6.2.7 Testing the Temperature

- Press **[CHECK TEMPERATURE]** button on Diagnostic Menu. ([Figure 6-1](#))
- The live temperature measurement will be displayed with 1 minute count down.
- Press **[STOP]** to escape and return to Diagnostic Menu.

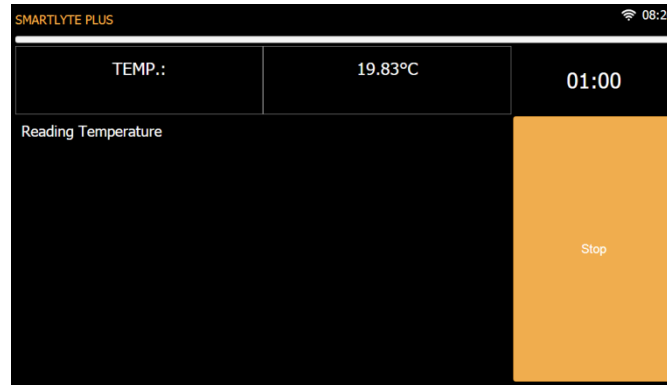


Figure 6-12 Temperature Test

6.2.8 Test Pump Tubing

Pump tube integrity can be checked with this operation.

- On Diagnostic Menu, press **[CHECK PUMP TUBING]**.



Figure 6-13 Pump tubing test in progress



Figure 6-14 Pump tubing test completed

- If pump tubing meets cycle time, **[TUBING GOOD]**, will be displayed. If criteria not met, then **[CHANGE PUMP TUBING]**

6.2.9 Check Printer

Printer functionality, feeding, accuracy, clarity is obtained from this test.

- From the Diagnostics Menu, press **[CHECK PRINTER]**.
- [Figure 6-15](#) and [Figure 6-16](#) show the screens for this test.

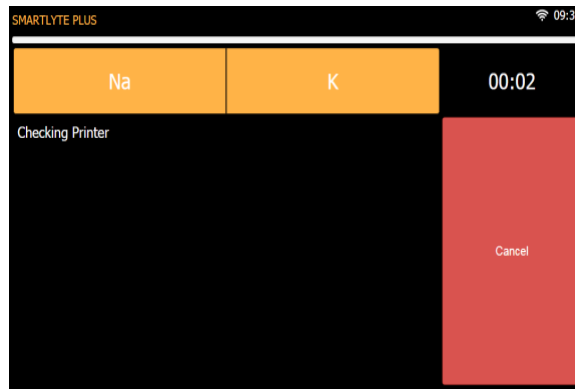


Figure 6-15 Checking Printer



Figure 6-16 Printer Check Complete

- The printer will also print a sequence of characters to verify quality. ([Figure 6-17](#))



Figure 6-17 Printer test print out

6.2.10 Testing the Sample Door

- From the Diagnostic Menu, press **[CHECK DOOR]**.
- Verify position indicated correctly by opening and closing the door. ([Figure 6-18](#) and [Figure 6-19](#)).

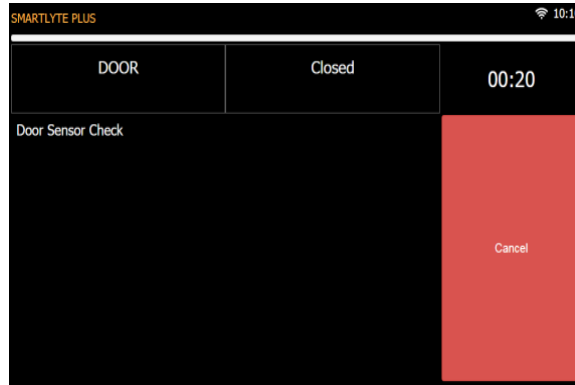


Figure 6-18 Door sensor test in progress closed

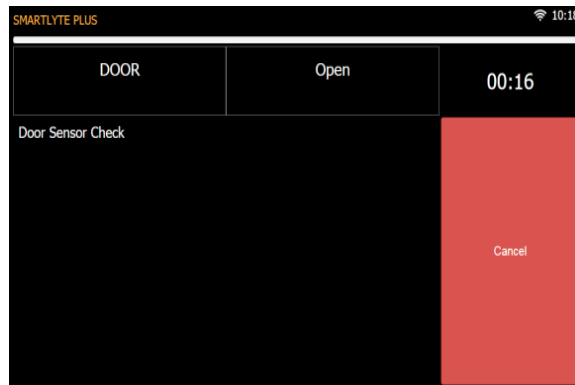


Figure 6-19 Door sensor test in progress open

- Press **[CANCEL]** to return to Diagnostic Menu. If cancel is not pressed, and analyzer is inactive, the analyzer will indicate after 1 minute that the test is complete.

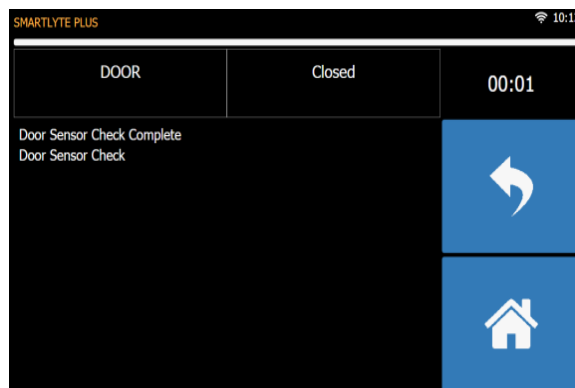




Figure 6-20 End of door sensor test

- Press  to return to Diagnostic Menu, or  to return to Main Operations Menu.
- If left inactive, the screen will revert to Main Operations Menu

6.2.11 Error List

- Pressing the Error button will bring up the Error list, [Figure 6-21](#). The most recent error is shown with date and time error occurred. See section 6.2 for troubleshooting steps.

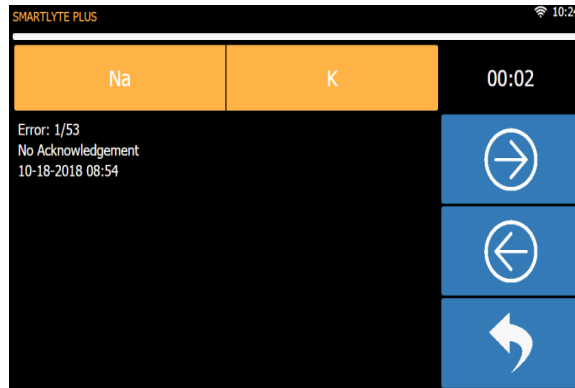





Figure 6-21: Error screen showing “No Acknowledgment” error

- Press  for next error,  for previous error, or  to return to Diagnostic Menu.

7. Theoretical Foundations

7.1 Principles of Operation

7.1.1 The Measurement Principle

The SMARTLYTE[®] PLUS 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 analyzer 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 Figure7-1).

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).

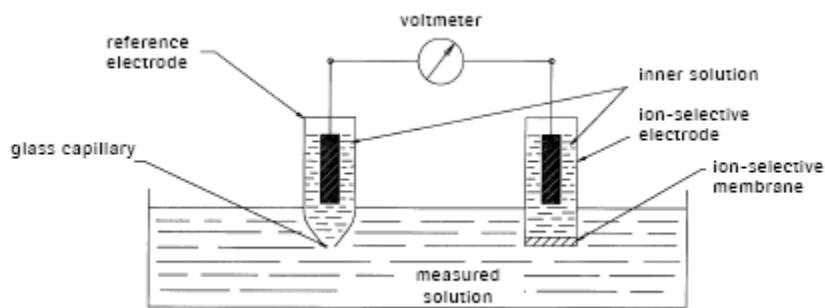


Figure 7-1

7.1.2 Physical Principle

An ion-selective electrode is connected with a reference electrode to form a measuring system (see Figure 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

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

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

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.

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

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

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

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

$c_{i, \text{sample}}$

concentration of the measured ions in the sample

$c_{i, \text{standard}}$

concentration of the measured ions in the standard solutions

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

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

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[®] PLUS Electrolyte Analyzers.

Proper care should be used in handling and storage of the electrode. Never use strong or abrasive cleaners such as alcohol or amphyll 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[®] PLUS Electrolyte Analyzers.

Proper care should be used in handling and storage of the electrode. Never use strong or abrasive cleaners such as alcohol or amphyll 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[®] PLUS Electrolyte Analyzers.

Proper care should be used in handling and storage of the electrode. Never use strong or abrasive cleaners such as alcohol or amphyll 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 Ca²⁺ 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[®] PLUS Electrolyte Analyzers.

Proper care should be used in handling and storage of the electrode. Never use strong or abrasive cleaners such as alcohol or amphyll 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[®] PLUS Electrolyte Analyzers.

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

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[®] PLUS 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 amphyI 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

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 (Hg₂C₁₂)-mercury (Hg)-platinum wire-connecting pin junction

Use and care

Reference electrodes are manufactured for use in SMARTLYTE[®] PLUS 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 amphyI 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[®] PLUS Electrolyte Analyzer calibrates Na⁺, K⁺, Ca²⁺ and Cl⁻ electrodes, using only two aqueous base solutions. Lithium calibration is achieved with a third calibrator in order to make a sodium correction.

The values from measurement of the standards are used to calculate the slope of each electrode. These Calibration values are obtained using the Nernst equation. Calibration values for electrodes should fall within the ranges below.

Electrode	Cal Values, mV/dec
Na ⁺	50 to 64
K ⁺	50 to 64
Cl ⁻	-40 to -64
Ca ⁺⁺	20 to 32
Li ⁺	18 to 35

8. Appendix

8.1 Interfaces

8.1.1 LIS

8.1.1.1. Interface Specifications

The Diamond SMARTLYTE[®] PLUS Electrolyte analyzer is equipped with a standard serial interface output. This interface output is intended to be used with standard commercially available computer systems.

The data transmitted through the serial interface port employs the ASCII code.

The serial interface is terminated on the rear cover with a 9-pin male DB-9 connector.

The signal levels are as follows:

- Binary 1 = -12V to -3V
- Binary 0 = +3V to +12V

Two stop bits follow the eight data bits to complete the 10 bit word.

The baud rate is set at 115200 Baud fixed.

The maximal recommended cable length is 40 feet.

The pin assignment is as follows in RS232 port are:

pin 1... sample ground... GND
pin 2...RS232IN RxD
pin 3 ... RS232OUT... . TxD
pin 4...NC
pin 5... Digital ground... DGND
pin 6...NC
pin 7.. RTS
pin 8...CTS
pin 9...Print VCC
(NC=Not Connected)

8.1.1.2. RS232 Activation Steps

To activate RS232 LIS, follow the steps below

1. Go to Instrument Settings > LIS Setup > RS232 LIS
2. On the activation screen, select "Enabled" from dropdown to enable it.
3. To disable, select "Disabled" from dropdown menu
4. Press the green to save settings
5. Once enabled, calibration and sample analysis data will be transmitted automatically at end of respective tasks over RS232.

8.1.1.3. RS232 Testing Steps

Connect a RS232 DB9 cable between the host PC and analyzer. Open a terminal such as putty or hyper-terminal for testing purposes.

1. Go to Instrument Settings > LIS Setup > Check RS232
2. Type on the terminal application on the host PC.
3. Press enter key to send data to analyzer. If the communication is set up correctly, then the typed characters will be shown on screen.
4. If you have issues, please check the RS232 cable and terminal settings.

8.1.1.4. Network Activation Steps

To activate network LIS, follow the steps below

1. For network LIS, instrument must be connected to network via Ethernet cable or Wifi
2. Go to Instrument Settings > LIS Setup > Network LIS
3. On the settings screen, select enabled to enable the network LIS
4. Set proper communication protocol, Host IP, and communication method
5. Set error timeout in milliseconds
6. You can also optionally enter a custom key-value pair that will be transmitted with each data packet to host.
7. To disable, select "Disabled" from dropdown menu
8. Press the green to save settings

8.1.1.5. Network LIS Testing Steps

Ensure instrument is connected to network before proceed with this test. It is recommended to check instrument IP address and confirm with a network admin.

1. Go to Instrument Settings > LIS Setup > Test Network LIS
2. Analyzer will try to ping the host IP address and provide status message on the screen

8.1.1.6. RS232 LIS Protocol

Data Description	Length	Example	Example Result
Sample Type	2	01	Calibration
Test ID	5	00112	Test# 112
Patient ID/Name	32	00000000000000000000DIAMOND 1	DIAMOND 1
Ion Type	2	00	Na
Ion Conc	6	001421	142.1
Ion Conc Flag	2	00	No Error
Ion Conc Units	1	1	mmol/dL
Ion Conc Correlated	1	0	No User Correlation
Temperature	6	002152	21.52 Degree Celsius
Date Time	12	201810070333	2018-Oct-07 0333hrs

Highlighted section repeats based on selected parameters

8.1.1.7. Network LIS Protocol

Date is sent in JSON format with the following key values

Key	Data Description	Value	Value Result
sampleType	Sample Type Code	10	Whole Blood
sampleTypeStr	Sample Type String	{ str: 'strBlood', en: 'Blood' }	Whole Blood
test	Test ID	00112	Test# 112
pId	Patient ID/Name	00000000000000000000DIAMOND 1	DIAMOND 1
temperature	Temperature in C	21.52	21.52 Degree Celsius
dt	Date Time	1539377450318	2018-Oct-07 0333hrs
correl	User Correlation	0	No User Correlation
customKey	Optional Custom Key	custom Value	Optional Custom Value
ionData	Array of Ion Results	Array of Objects	
ionData[Na][IonData].ion	Ion Code	1	
ionData[Na][IonData].name	Ion Name	Na	
ionData[Na][IonData].mvS	mV Std-B or Sample	6.01	
ionData[Na][IonData].mvA	mV Std-A	8.01	
ionData[Na][IonData].mvC	mV Std-C	0.00	
ionData[Na][IonData].strFlag	Flag String	LOW	
ionData[Na][IonData].temp	Temperature in C	21.52	21.52 Degree Celsius
ionData[Na][IonData].sampleType	Sample Type Code	10	Whole Blood
ionData[Na][IonData].conc	Result	135.88	135.88
ionData[Na][IonData].correl	User Correlation	false	No User Correlation
ionData[Na][IonData].strUnits	Units String	mmol/L	Reported in mmol/L
ionData[Na][IonData].min	Lower Range	135	Lower Threshold
ionData[Na][IonData].max	Upper Range	145	Upper Threshold

Highlighted section repeats based on selected parameters

Please note that additional key-values pairs and can be ignored. These are additional data used internally.

8.1.1.8. Common Codes

Sample Type	Code
Invalid Sample	00
Calibration	01
Serum	02
Urine	03
Standard	04
QC1	05
QC2	06
QC3	07
QC4	08
QC5	09
Whole Blood	10
Dog	11
Cat	12
Cow	13
Horse	14
Pig	15
Sheep	16
Camel	17
Mouse	18
Other Animal	19

Ion Type	Code
Na	01
K	02
Cl	03
Ca	04
Li	05

Error	Code
No Error	00
Very Low	01
Low	02
High	03
Very High	04
No Calibration	05
mV Error	06
Na (Sodium) Error	07
Drift Error	08
Temperature Error	09

Unit Code	Code
No Units	00
mmol/dL	01
mg/dL	02

RS232 LIS Sample
1000199000100000005000200 2000021003076360021004001513031002152201810121630

8.1.1.9. Start Code and Stop Code

For LIS over RS232, each data packet is enclosed within start and stop code. Start code is set to “0x02” (hexa decimal 02) while the stop code is “0x04” (hexa decimal 04)

8.1.2 WiFi

8.1.2.1 Use the following steps to enable the wireless connection

- Access Main Menu and press **[OPERATOR SETTINGS]**, then **[USER SETTINGS]** and finally **[LOGIN]**.
- Enter admin **[USERNAME]** and **[PASSWORD]**
- Press . If login is successful, the analyzer will display “Login Successful”.
- Access Main Menu and press **[INSTRUMENT SETTINGS]**, then **[NETWORK]** and finally **[WIFI SETUP]**.

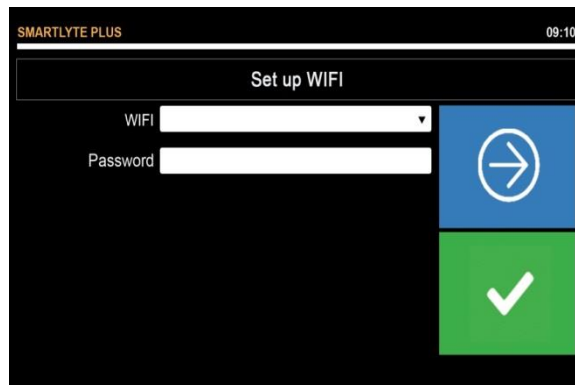


Figure 8-1 WIFI Set up

- After a wireless network search is done, **[SET UP WIFI]** window is displayed.
- Select the network to connect to.
- Enter password, then press to save settings and activate WIFI connection.

8.1.2.2 Use the following steps connect a PC to the analyzer.

- To access the analyzer from a computer, first obtain analyzer IP address from the analyzer by pressing **[INSTRUMENT SETTINGS]**, then **[NETWORK]**, followed by **[SHOW IP]**.
- On computer within in the same network, enter IP address. For example: “10.0.1.61:8000”

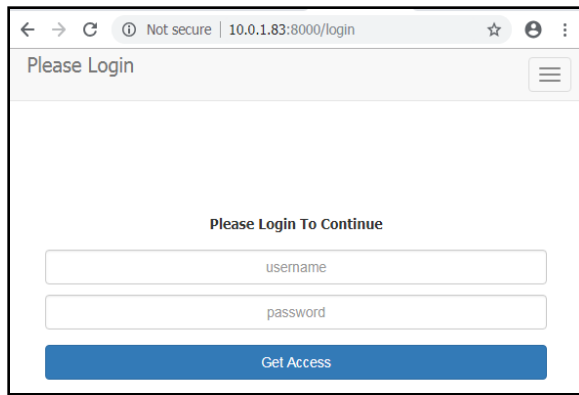


Figure 8-2 Login

- Enter **[USERNAME]** and **[PASSWORD]**. Then press **[GET ACCESS]**. If connection is successful, the Main Menu will be displayed.

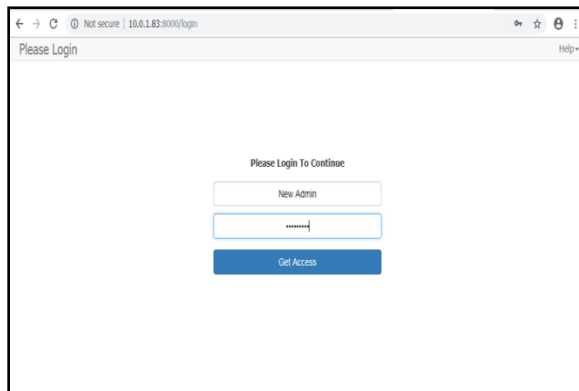


Figure 8-3 Login

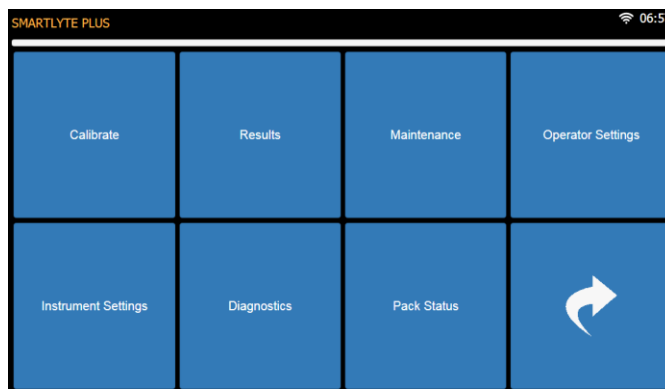


Figure 8-4 Main Operations

To view and download results remotely, follow the steps listed below.

- Press **[RESULTS]** button on Main Operations ([Figure 8-4](#)) or Sample Measurement Menus ([Figure 8-8](#))

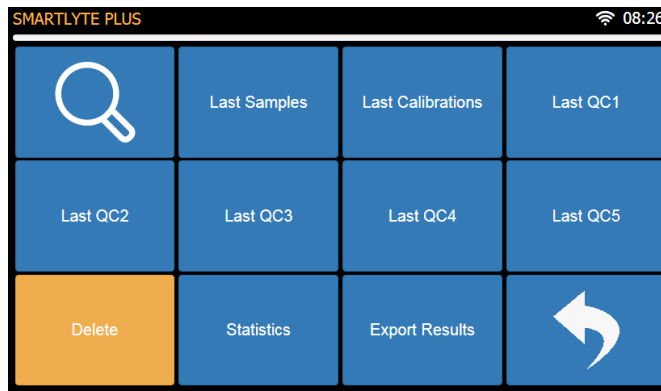


Figure 8-5 Results Menu for Remote Access.

Press the **[EXPORT RESULTS]** button (Figure 8-5) and a table of results will be displayed. (Figure 8-5) All data, samples, controls, calibration, will be displayed. Measurement results can be filtered using the drop down menu. Date range can be delimited to expand or reduce the 1 week default range.

Date (E3)	Time (E3)	Test ID	Temp (F)	Result	Units	Flag	Control	Result	Units	Flag	Control	Result	Units	Flag	Control								
10-03-2018	08:10	QC3	27.45 °C	Na	176.30	mmHg	K	2.18	mmHg/L	Ca	0.751	mmHg/L	U	1.421	mmHg/L								
10-03-2018	08:10	QC4	27.36 °C	Na	164.05	mmHg	K	8.84	mmHg/L	Ca	0.837	mmHg/L	U	2.009	mmHg/L								
10-03-2018	08:10	QC3	27.26 °C	Na	142.74	mmHg	K	4.26	mmHg/L	Ca	1.041	mmHg/L	U	0.896	mmHg/L								
10-03-2018	08:10	Calibration	27.11 °C	Na	56.81	mmHg	K	54.88	mmHg/L	Ca	18.92	mmHg/L	U	22.18	mmHg/L								
10-03-2018	08:10	Calibration	27 °C	Na	54.81	mmHg	K	54.91	mmHg/L	Ca	17.38	mmHg/L	U	22.11	mmHg/L								
10-03-2018	08:10	Calibration	26.95 °C	Na	52.87	mmHg	K	54.36	mmHg/L	Ca	46.28	mmHg/L	U	22.07	mmHg/L								
10-03-2018	07:10	Calibration	27.19 °C	Na	57.41	mmHg	K	58.21	mmHg/L	Ca	18.44	mmHg/L	U	22.90	mmHg/L								
10-03-2018	18:10	Serum	28.45 °C	Na	152.07	mmHg	LOW	K	9.63	mmHg/L	HSD4	Ca	1.424	mmHg/L	HSD4	U	2.853	mmHg/L	v	HSD4			
10-03-2018	18:10	Serum	28.4 °C	Na	133.61	mmHg	LOW	K	2.21	mmHg/L	LOW	Ca	1.214	mmHg/L	U	0.201	mmHg/L	LOW	U	0.201	mmHg/L		
10-03-2018	18:10	Serum	28.37 °C	Na	144.05	mmHg	U	K	4.37	mmHg/L	U	Ca	0.914	mmHg/L	LOW	U	0.924	mmHg/L	U	0.924	mmHg/L		
10-03-2018	18:10	Serum	28.31 °C	Na	160.58	mmHg	HSD4	K	8.82	mmHg/L	HSD4	Ca	0.794	mmHg/L	LOW	U	2.164	mmHg/L	HSD4	U	2.164	mmHg/L	
10-03-2018	18:10	Serum	28.2 °C	Na	176.22	mmHg	HSD4	K	2.21	mmHg/L	LOW	Ca	0.649	mmHg/L	LOW	U	3.750	mmHg/L	v	HSD4	U	3.750	mmHg/L
10-03-2018	18:10	Serum	28.24 °C	Na	170.23	mmHg	HSD4	K	2.20	mmHg/L	LOW	Ca	0.646	mmHg/L	LOW	U	3.750	mmHg/L	v	HSD4	U	3.750	mmHg/L
10-03-2018	18:10	Serum	28.22 °C	Na	160.58	mmHg	HSD4	K	8.83	mmHg/L	HSD4	Ca	0.810	mmHg/L	LOW	U	2.164	mmHg/L	HSD4	U	2.164	mmHg/L	
10-03-2018	18:10	Serum	28.18 °C	Na	142.82	mmHg	U	K	4.26	mmHg/L	U	Ca	0.861	mmHg/L	LOW	U	0.934	mmHg/L	U	0.934	mmHg/L		
10-03-2018	18:10	Serum	28.15 °C	Na	113.51	mmHg	LOW	K	2.20	mmHg/L	LOW	Ca	1.275	mmHg/L	U	0.200	mmHg/L	LOW	U	0.200	mmHg/L		
10-03-2018	18:10	Serum	28.12 °C	Na	151.76	mmHg	LOW	K	8.80	mmHg/L	HSD4	Ca	1.420	mmHg/L	HSD4	U	2.850	mmHg/L	v	HSD4	U	2.850	mmHg/L
10-03-2018	18:10	Serum	28.07 °C	Na	161.76	mmHg	LOW	K	8.80	mmHg/L	HSD4	Ca	1.462	mmHg/L	HSD4	U	2.850	mmHg/L	v	HSD4	U	2.850	mmHg/L
10-03-2018	18:10	Serum	28.02 °C	Na	113.71	mmHg	LOW	K	2.21	mmHg/L	LOW	Ca	1.209	mmHg/L	U	0.203	mmHg/L	LOW	U	0.203	mmHg/L		
10-03-2018	18:10	Serum	27.97 °C	Na	143.81	mmHg	U	K	4.27	mmHg/L	U	Ca	0.813	mmHg/L	LOW	U	0.929	mmHg/L	U	0.929	mmHg/L		
10-03-2018	18:10	Serum	27.97 °C	Na	154.17	mmHg	HSD4	K	8.80	mmHg/L	HSD4	Ca	0.794	mmHg/L	LOW	U	2.170	mmHg/L	HSD4	U	2.170	mmHg/L	
10-03-2018	18:10	Serum	27.97 °C	Na	176.22	mmHg	HSD4	K	2.21	mmHg/L	LOW	Ca	0.638	mmHg/L	LOW	U	3.750	mmHg/L	v	HSD4	U	3.750	mmHg/L
10-03-2018	18:10	Serum	27.97 °C	Na	176.22	mmHg	HSD4	K	2.22	mmHg/L	LOW	Ca	0.637	mmHg/L	LOW	U	3.762	mmHg/L	v	HSD4	U	3.762	mmHg/L
10-03-2018	18:10	Serum	27.95 °C	Na	164.17	mmHg	HSD4	K	6.90	mmHg/L	HSD4	Ca	0.810	mmHg/L	LOW	U	2.170	mmHg/L	HSD4	U	2.170	mmHg/L	
10-03-2018	18:10	Serum	27.98 °C	Na	142.81	mmHg	U	K	4.20	mmHg/L	U	Ca	0.960	mmHg/L	LOW	U	0.928	mmHg/L	U	0.928	mmHg/L		
10-03-2018	13:10	Serum	28.04 °C	Na	113.51	mmHg	LOW	K	2.20	mmHg/L	LOW	Ca	1.275	mmHg/L	U	0.200	mmHg/L	LOW	U	0.200	mmHg/L		
10-03-2018	13:10	Serum	28.07 °C	Na	151.76	mmHg	LOW	K	8.80	mmHg/L	HSD4	Ca	1.464	mmHg/L	HSD4	U	2.850	mmHg/L	v	HSD4	U	2.850	mmHg/L
10-03-2018	13:10	Calibration	28.23 °C	Na	52.87	mmHg	U	K	54.88	mmHg/L	U	Ca	18.98	mmHg/L	U	22.14	mmHg/L	U	22.14	mmHg/L			
10-03-2018	13:10	Calibration	28.71 °C	Na	102.46	mmHg	U	K	8.80	mmHg/L	HSD4	Ca	1.388	mmHg/L	HSD4	U	2.850	mmHg/L	v	HSD4	U	2.850	mmHg/L
10-03-2018	13:10	Serum	28.62 °C	Na	138.58	mmHg	LOW	K	2.19	mmHg/L	LOW	Ca	1.206	mmHg/L	U	0.215	mmHg/L	LOW	U	0.215	mmHg/L		
10-03-2018	13:10	Serum	28.54 °C	Na	143.72	mmHg	U	K	4.24	mmHg/L	U	Ca	0.811	mmHg/L	LOW	U	0.931	mmHg/L	U	0.931	mmHg/L		
10-03-2018	13:10	Serum	28.43 °C	Na	154.17	mmHg	HSD4	K	8.81	mmHg/L	HSD4	Ca	0.791	mmHg/L	LOW	U	2.164	mmHg/L	HSD4	U	2.164	mmHg/L	

Figure 8-6 Computer display of data from accessed analyze

The results can be downloaded by pressing where an excel file is created on a separate tab. The file name follows the convention: data_MM_DD_YY_hh_mm_ss, where M = Month, D = Day, Y = Year, h = hour, m = minute, s = second.

TIP: Pressing or will access the analyzer Main Operations Menu.

Stored results can also be deleted.

8.1.3 LAN/Ethernet

Network connection can also be established by connected a LAN cable to the back of the SMARTLYTE® PLUS.s

8.2 Description of Reports

8.2.1 Measurement Report

SMARTLYTE® PLUS
SN 44-18061100
HOSPITAL EAST

TEST#: 00007
ID: AADT8971452637
95541258972154
URINE

Na= 194.2mmol/L
K = 13.4mmol/L
Cl = 62mmol/L

TEMP = 22.29 °C
06-11-2018 10:55

SMARTLYTE® PLUS
SN 44-18061100
HOSPITAL EAST

TEST#: 00007
ID: AADT8971452637
95541258972154
SERUM

Na# 144.2mmol/L
K # 4.4mmol/L
Cl = 88mmol/L

#MODIFIED#
TEMP = 22.29 °C
06-11-2018 12:55

SMARTLYTE® PLUS
SN 44-18061100
HOSPITAL EAST

TEST#: 00007
ID: AADT8971452637
95541258972154
WHOLE BLOOD

Na# 143.3mmol/L
K # 4.05mmol/L
Cl = 98mmol/L

#MODIFIED#
TEMP = 22.29 °C
06-11-2018 13:11

8.2.2 QC Reports

SMARTLYTE® PLUS
SN 44-18061100
HOSPITAL EAST
LOT: 1512118

TEST#: 00007
ID: AADT8971452637
95541258972154
QC 1

Na= 109.0mmol/L
K = 2.02mmol/L
Cl = 77.7mmol/L

TEMP = 22.26 °C
06-11-2018 10:25

SMARTLYTE® PLUS
SN 44-18061100
HOSPITAL EAST
LOT: 15121145

TEST#: 00007
ID: AADT8971452637
95541258972154
QC 2

Na= 135.4 mmol/L
K = 4.55 mmol/L
Cl = 103.2 mmol/L

TEMP = 22.25 °C
06-11-2018 10:29

SMARTLYTE® PLUS
SN 44-18061100
HOSPITAL EAST
LOT: 1703178

TEST#: 00007
ID: AADT8971452637
95541258972154
QC 3

Na= 153.9 mmol/L
K = 6.46 mmol/L
Cl = 113.8 mmol/L

TEMP = 22.24 °C
06-11-2018 11:06

8.2.3 Calibration Report

SMARTLYTE® PLUS
SN 44-18061100
HOSPITAL EAST

CALIBRATION

Na= 55.65
K = 56.34
Cl = -33.90

Temp = 29.39 °C
06-11-2018 11:15

8.3 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																																
QUARTERLY																																
Change pump tubing																																
ANNUALLY																																
Change main tubing harness																																
UNSCHEDULED MAINTENANCE																																

8.4 Program Flow Chart

8.4.1 Main Menu: Operations

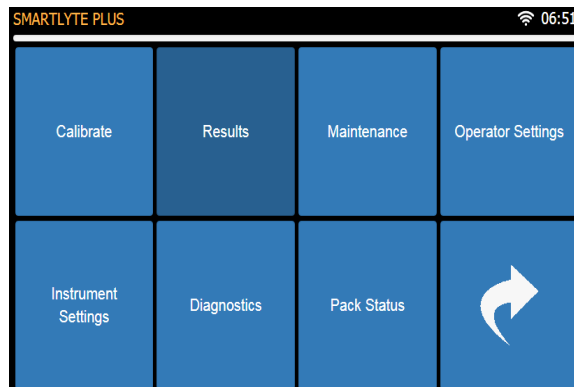


Figure 8-7 Operations Menu

8.4.2 Main Menu: Sample Measurement



Figure 8-8 Sample Measurement Menu

8.5 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
CN-1081	Dummy 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	Electrode Conditioner Solution	Use before expiration date
AV-BP1025D	ISE 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

8.6 Vet Mode Specific Instructions

8.6.1 Selecting Vet Mode

Vet Mode can be selected starting from the Main Menu. During the conversion process, all stored data will be deleted and all settings will be changed to factory default settings.

- On Main Menu ([Figure 1-33](#)), press **[INSTRUMENT SETTINGS]**, followed by **[INSTRUMENT MODE]** ([Figure 8-9](#)).

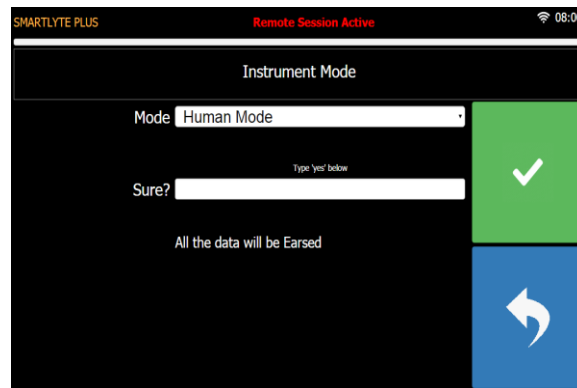


Figure 8-9 Instrument Human Mode

- Select the VET MODE from drop down menu and type YES.



When changing Mode, all data will be deleted. All analyzer and operator settings will need to be re-entered

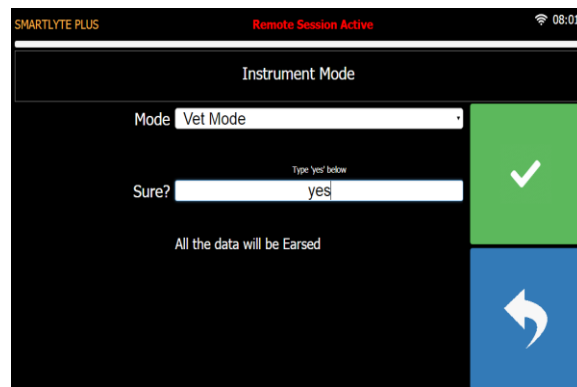


Figure 8-10 Instrument Vet Mode


- Press  to make the change. ([Figure 8-10](#))



Figure 8-12 Vet Mode ON

8.6.2 Program Flow Chart

8.6.2.1. Main Menu: Operations

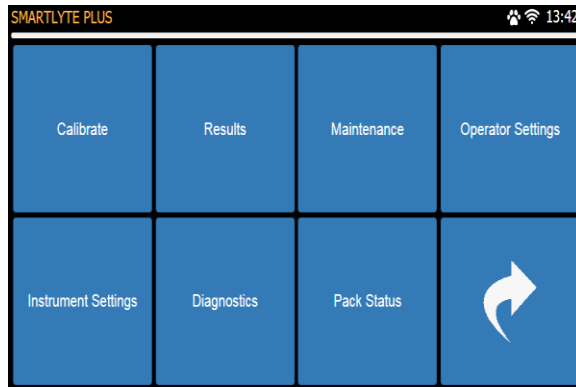


Figure 8-13 Operations Main Menu

8.6.2.2. Main Menu: Sample Measurement

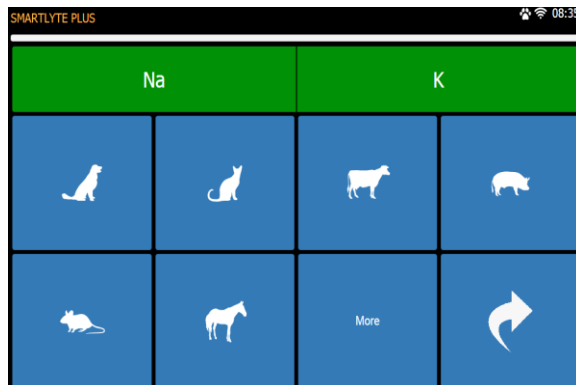


Figure 8-14 Sample Measurement Menu 1

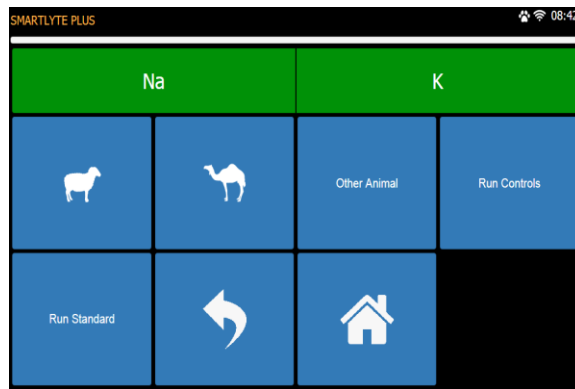



Figure 8-15 Sample Measurement Menu 2

8.6.3 Veterinary Blood, Serum, Plasma Sample Measurement

Whenever the  symbol in upper right section of the display and the analyzer is calibrated, 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".

- On the Main Sample Measurement Menu 1 or 2, [Figure 8-14](#) and [Figure 8-15](#), select the animal to be tested.



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[®] PLUS provides the ability to enter the patient name and ID associated with the sample being tested. Sample information can be entered during measurement cycle. No name or ID# will be assigned to the sample if the ID cell is left blank

- Open the door when the analyzer displays **[OPEN DOOR]**.
- When the analyzer displays **[LOAD SAMPLE]** ([Figure 1-60](#)), introduce the sample by moving the sample container to the sample probe ensuring the probe opening is immersed in solution.
- Remove sample when **[WIPE PROBE & CLOSE DOOR]** ([Figure 1-61](#)) is displayed. Use a lint-free tissue to wipe the probe. Then close the sample door.



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

A countdown will begin. Sample ID can be entered at this time. At completion of analysis, the test results will be displayed and printed if printer is enabled. ([Figure 8-16](#))

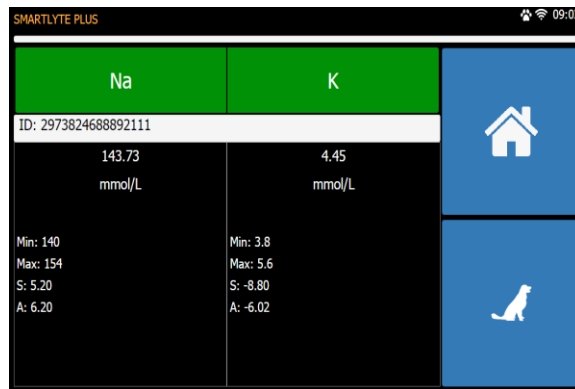


Figure 8-16 Screen display of results

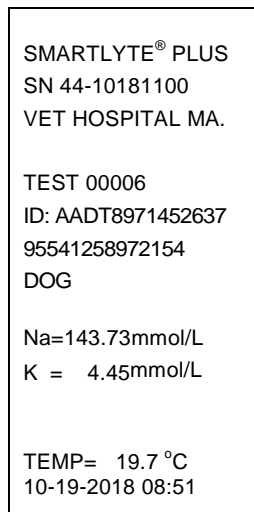


Figure 8-17 Printout of results



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

- If the animal type has not changed, open the door and follow the instructions on the screen.

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	***
Pig	139 - 153	4.4 - 6.5	97 - 106	***
Mouse	140 - 160	5.0 - 7.5	***	***
Horse	133 - 147	2.8 - 4.7	97 - 110	***
Sheep	142 - 160	4.3 - 6.3	101 - 113	***
Camel ³	131 - 165	3.6 - 4.4	***	***
Camel ⁴	145 - 173	4.9 - 6.6	***	***

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

³ Mohamed, h.a., Hussein, A.N., Studies on Normal Haematological and Serum Biochemical Values of the 'Hijin' Racing Camels (Camelus dromedaries) in Kuwait, Veterinary Research Communications, 23 (1999) 241 - 248.

⁴ Aichouni A. Et. Al. Journal of Camelid Science 3 (2010) 19-25

*** 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 in Section 3.3 for each animal type.

Correlation Factors can also be changed by following the procedure in Section 3.4

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

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