OPERATOR MANUAL

ProLyte®

Electrolyte Analyzer

Na^+ / K^+ / Cl^- / Li^+

DIAMOND
Smart Lab Solutions

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If the system is used in a manner differently than specified by Diamond Diagnostics Inc., the protection provided by the equipment may be impaired. See warning and hazard statements.

PROLYTE ELECTROLYTE ANALYZER is a Trademark of Diamond Diagnostics Inc.

The Diamond Diagnostics PROLYTE analyzer is for In Vitro Diagnostic use.

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1.1 Product Description

The PROLYTE analyzer has been designed with you, the user, in mind. It is fully automated with simple YES or NO commands for menu navigation. This simple interface ensures that not only will the analyzer be easy to use for quick analysis, (one minute for most samples), but also that the testing of samples can be done by even non-skilled operators with relative ease. The PROLYTE has been enhanced with a mini-keyboard which has function keys linked to the PROLYTE to further facilitate use of the instrument.

The outputs of the analyzer are displayed on an easy to read LCD screen and also as a hard copy provided by the on-board printer. The analyzer also provides the option to store up to 1000 patient samples in memory. It can be programmed to self-calibrate at set intervals. The PROLYTE can interface with an LIS system for automatic transference of instrument data to a computer.

The analyzer has the capability to test whole blood, serum, plasma and diluted urine. Sampling takes one minute and returns values for Sodium, Potassium, Chloride and Lithium.

All the functions of the PROLYTE analyzer have been designed for ease of use, the ergonomic design and the simple user interface make learning the operation of the analyzer simple. Also incorporated into the programming of the analyzer is an easy to use set of troubleshooting and diagnostic functions to help the user diagnose error messages. The analyzer has incorporated an upgrade feature for the software portion of the system to keep the analyzer functioning at its best for years to come.

Table of Symbols

✦ NOTES	*Information which may be useful or refers to another section of the manual.*
♦ KEY INFORMATION	*May damage or cause the PROLYTE analyzer to malfunction.*
☣ BIOHAZARD WARNING	*Biohazard material may be present on or around this equipment.*

1.2 Maintenance and Precautions

Maintenance of the analyzer is a simple process, all components have been designed such that replacement requires little or no training and does not take much time to accomplish, ensuring that the analyzer will not be out of service for very long periods of time.

♦ *Read this manual before setting up or operating the PROLYTE analyzer.*

Observe all warnings and procedures as outlined herein.

Unplugging or removing the Fluid Pack for an extended period of time may cause serious damage to the electrodes or electrical components of the PROLYTE analyzer.

All consumables, replaceable parts and their respective maintenance schedules have been listed in this manual. Attempting any other repairs to this analyzer is not recommended. Should it become necessary to repair any electromechanical components of the PROLYTE analyzer contact Diamond Diagnostics service professionals or authorized dealer.

The environment should be as dust-free as possible and between 15˚C and 32˚C. Do not install the PROLYTE near any heat-generating equipment or in proximity to incandescent lighting. Do not operate the analyzer near any equipment that may cause electrical, mechanical or magnetic interference. Do not place PROLYTE near brush-type motors (such as certain types of centrifuges), diathermy machines, and avoid placing the analyzer under flickering fluorescent lights, arcing contacts or any other hostile environments as this will interfere with the proper operation of the PROLYTE analyzer. The analyzer must also be isolated from mechanical vibration to ensure the proper function of its precise mechanical components.

Ensure that the analyzer is properly grounded and connected to an approved power supply; 100-240V 50/60Hz 1.6 A. Ground must be maintained when equipment is connected to Mains. Replace fuse with 5 x 20 mm, 250V AC, 1.6 A, fast acting fuse.

♦ ***Do not operate with open cover, risk of electrical shock if operated with open cover.***

1.3 Disposal of Consumables

Proper care must be taken when disposing of replaced components as exposure to test samples may contaminate the consumables and therefore classify them as biohazardous waste. These components include, but are not limited to: Electrodes, Pump Tubing, Probe Wipers, Membrane Assembly, Electrode Connectors, Sample Detector, Solution Valve, Sample Tubing, Sample Probe and Fluid Pack.

The solutions contained in the PROLYTE analyzer Fluid Pack have been formulated specifically for the analyzer. The Fluid Pack also houses the disposal chamber for samples, calibrators, and reagents consumed during the operation of the analyzer. Cleaning and sterilization of these components can be accomplished with 10% bleach solution; however it is recommended that these components be disposed of using the same standards as for any biohazard material. Protective clothing, goggles and gloves should be worn during handling of these consumables.

The Center for Disease Control (CDC) advises that all samples be considered biohazardous waste and that precautions be taken when disposing of any consumables that have come in contact with these samples.

1.4 Operator Manual Outline

The sections of this manual will take the user through the correct installation and operation of the analyzer as well as any maintenance that may be required.

This Manual will cover all relevant topics necessary for the proper installation and operation of the PROLYTE analyzer as well as the principles behind the ISE technology used in the analyzer. Also covered are the specifications and limitations of the functions of the analyzer.

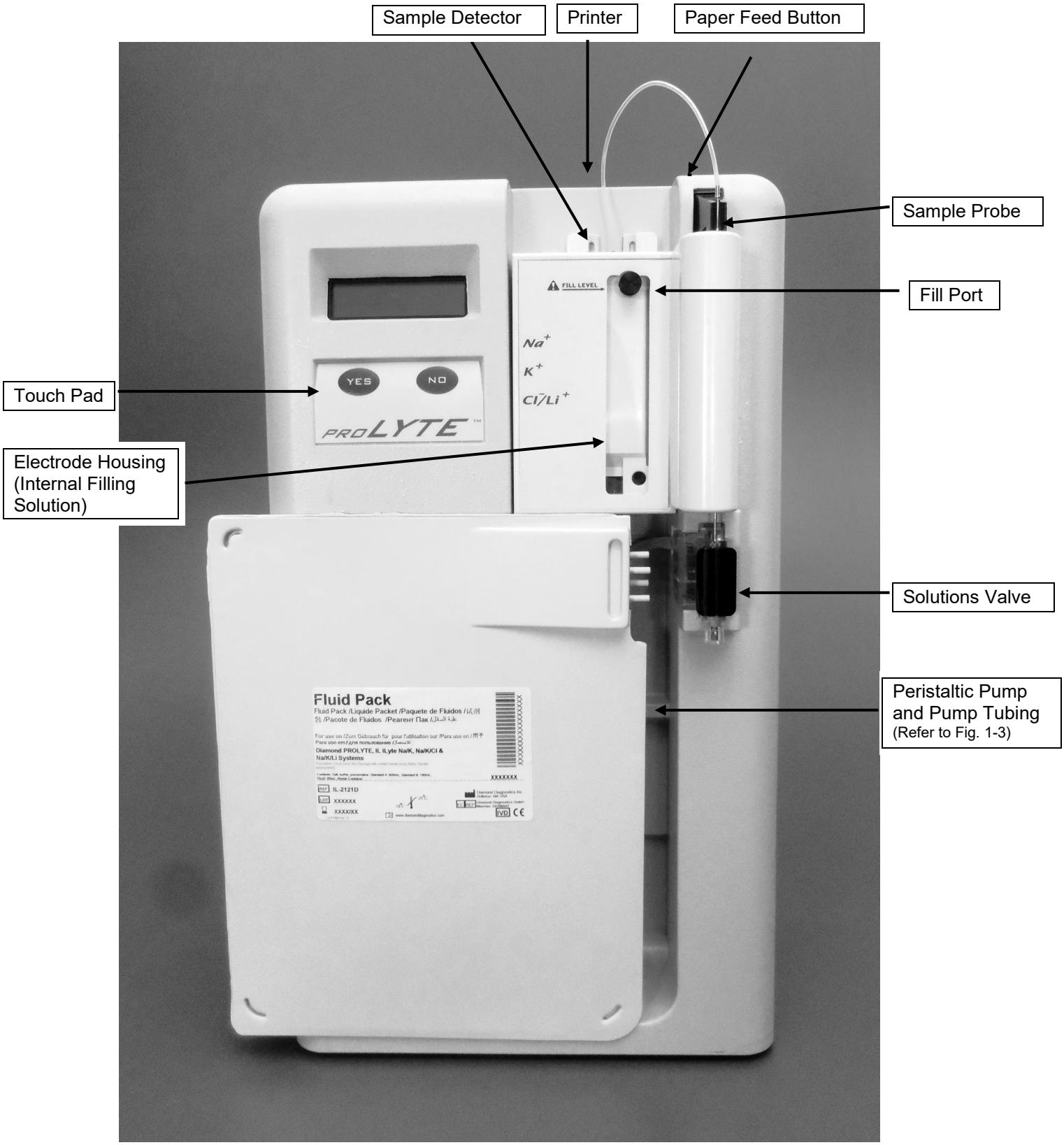
2.1 *Unpacking the PROLYTE analyzer*

The PROLYTE analyzer is shipped with all necessary components for proper set up and operation. This section will cover installation and replacement of all consumable components. When replacing any consumables refer to this chapter of the manual.

After receiving the analyzer, carefully remove all components from their protective packing and inspect to make sure all components are present and have not sustained damage during shipping. If missing or damaged parts are discovered immediately notify Diamond Diagnostics service professionals or your authorized dealer.

Below is the list of all the components that should have been sent with your PROLYTE:

Part Number	Product Description
CN-3109	Power Cord, 120VAC
CN-3110	Power Cord, 250VAC
ME-2108D	Solutions Valve
IL-2121D	Fluid Pack Na/K/Cl/Li
ME-2257D	Sample Detector
ME-2107D	Sample Probe
CN-A3021	Start-Up Kit (includes Below)
ME-2541D	Printer Paper
ME-2101D	K^+ Electrode
ME-2102D	Na^+ Electrode
ME-2113D	Cl^- Electrode
ME-2106D	Li^+ Electrode
ME-2103D	Reference Electrode
ME-2572D	Troubleshooting Kit
ME-2118D	Daily Cleaner/ Rinse Kit
ME-2095D	Maintenance Kit
CN-4146	Fuse, 1.6A, 250V
DD-0206	Mini-Keyboard
DD-0202	Barcode Scanner (Optional)
SOP05-5048F	Quick Start Guide
SOP05-5049F	Operator's Manual
SOP05-5050F	Upload Application Kit


Sample Detector
Printer
Paper Feed Button
Sample Probe
Fill Port
Touch Pad
Electrode Housing (Internal Filling Solution)
Solutions Valve
Peristaltic Pump and Pump Tubing
(Refer to Fig. 1-3)
FILL LEVEL
YES
NO
PROLYTE
Fluid Pack
Diamond PROLYTE, IL iLyte Na/K, Na/KCl & Na/K/Li Systems
IL-2121D

2.2 *Component Installation and Replacement*

Installation and replacement of all consumable components is outlined in the following sections. Please refer to this section when replacing any components following the maintenance schedule outlined below:

Part Number	Product Description	Replacement Schedule
IL-2121D	Fluid Pack	Replace as Necessary, Use Before Expiration Date
ME-2101D	K^+ Electrode	Replace as Necessary, Typical Use Life of 6 Months
ME-2102D	Na^+ Electrode	Replace as Necessary, Typical Use Life of 12 Months
ME-2103D	Reference Electrode	Replace as Necessary, Typical Use Life of 12 Months
ME-2104D	Tubing Kit	Replace as Necessary, Typical Use Life of 3 Months
ME-2106D	Li^+ Electrode	Replace as Necessary, Typical Use Life of 3 Months
ME-2107D	Sample Probe	Replace as Necessary, Typical Use Life of 12 Months
ME-2108D	Solutions Valve	Replace as Necessary, Typical Use Life of 12 Months
ME-2113D	Cl^- Electrode	Replace as Necessary, Typical Use Life of 6 Months
ME-2257D	Sample Detector	Replace as Necessary (see 3.11- *Diagnostics Menu*)
ME-2258D	Membrane Assembly	Replace as Necessary, Typical Use Life of 3 Months
ME-2323D	Probe Wiper	Replace after 100 Serum/Plasma Samples, or 50 Whole Blood Samples or 2 Weeks, whichever comes first
ME-2492D	Internal Filling Solution	Replace as Necessary, Typical Use life of 3 Months
ME-2541D	Printer Paper	Replace as Necessary

2.2.1 *Solutions Valve, ME-2108D*

The Solutions Valve connects the Fluid Pack to the fluid path of the analyzer. The Solutions Valve is specifically designed to prevent mixing of calibration solutions. It also is the outlet for the self-contained waste storage chamber.

Install the Solutions Valve by pressing it firmly into position in the analyzer base as shown on the following page. Label the Solutions Valve on the black finger grip with the date of installation. It is recommended to replace the Solutions Valve every 12 months. The Solutions Valve contains precise check valves and gaskets that will wear over time and need to be replaced to ensure no mixing of fluids takes place between the calibration solutions.

*When the Solutions Valve has excessive wear, errors such as **[AIR IN STD A]** will be displayed on the analyzer's screen, making function of the analyzer unreliable for calibration, control and sample testing. It is important to replace the Solutions Valve on a regular schedule to prevent this malfunction.*

To replace the Solutions Valve, first remove the Fluid Pack and cap to prevent spilling or leakage of calibration solutions and waste chamber contents. Next, disconnect the Pump Tubing from both the Electrode Housing and the Solutions Valve, (both Blue and red sides of tubing.) Disconnect and remove the Electrode Housing to expose the Sample Probe. Unsnap the Sample Probe from the probe arm by gently pulling it towards you and away from the probe arm. Then pull the probe up and out of the Solutions Valve. Once all components have been disassembled as described above, pull the Solutions Valve towards you using the black finger grip and remove from the analyzer.

*Install the new Solutions Valve using the method described above. Place the probe into the Solutions Valve. Replace the Electrode Housing. Reconnect the Pump Tubing, checking to make sure it has been installed correctly and securely to the fittings at both the Solutions Valve and Membrane Assembly. Visually inspect the analyzer for any spills or leaks that may have occurred during installation and wipe away as necessary. Finally insert the Fluid Pack into the Solutions Valve and perform a **[SOLUTION PRIME?]** to ensure proper flow through the Solutions Valve. (See **[SOLUTION PRIME?]** page 10)*

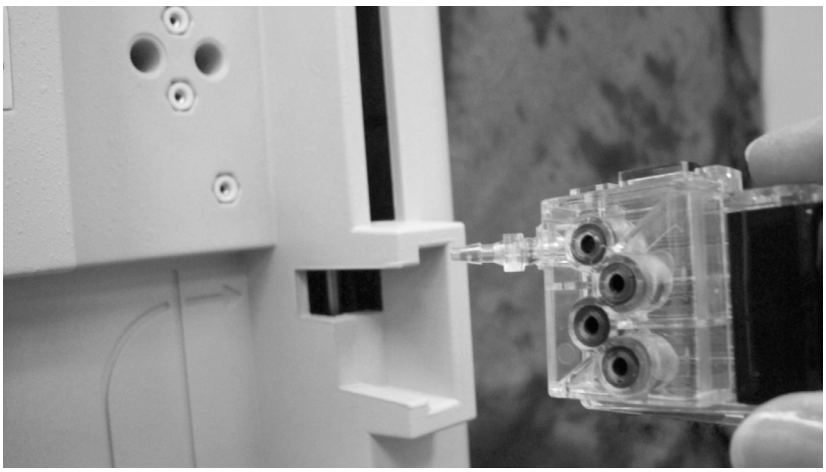


Fig 1-1

Fig 1-2

2.2.2 *Probe Wiper, ME-2323D*

Line up the 4 locking tabs on the top of the Probe Wiper with the bottom of the Solutions Valve and snap it into place. The Probe Wiper should be replaced minimally every two weeks. If whole blood samples are tested regularly, replace after 50 samples or weekly if fewer whole blood samples are tested each week. Depending on use, more frequent replacement may be necessary. Record the date of installation on the label provided and adhere it to the Probe Wiper.

Fig 1-3

✦ *A package of Probe Wipers is provided with the Fluid Pack, IL-2121D.*

2.2.3 *Sample Probe, ME-2107D*

Place the Sample Probe into the top of the Solutions Valve. Make sure the hole (near the rounded closed end of the probe) is facing to the left. Slide the probe down the Solutions Valve until the probe collar ring (at the top of the probe) aligns with the notch in the probe arm (See figure below). Keep the Sample Probe straight. Do not bend it as this will cause fluidics errors.

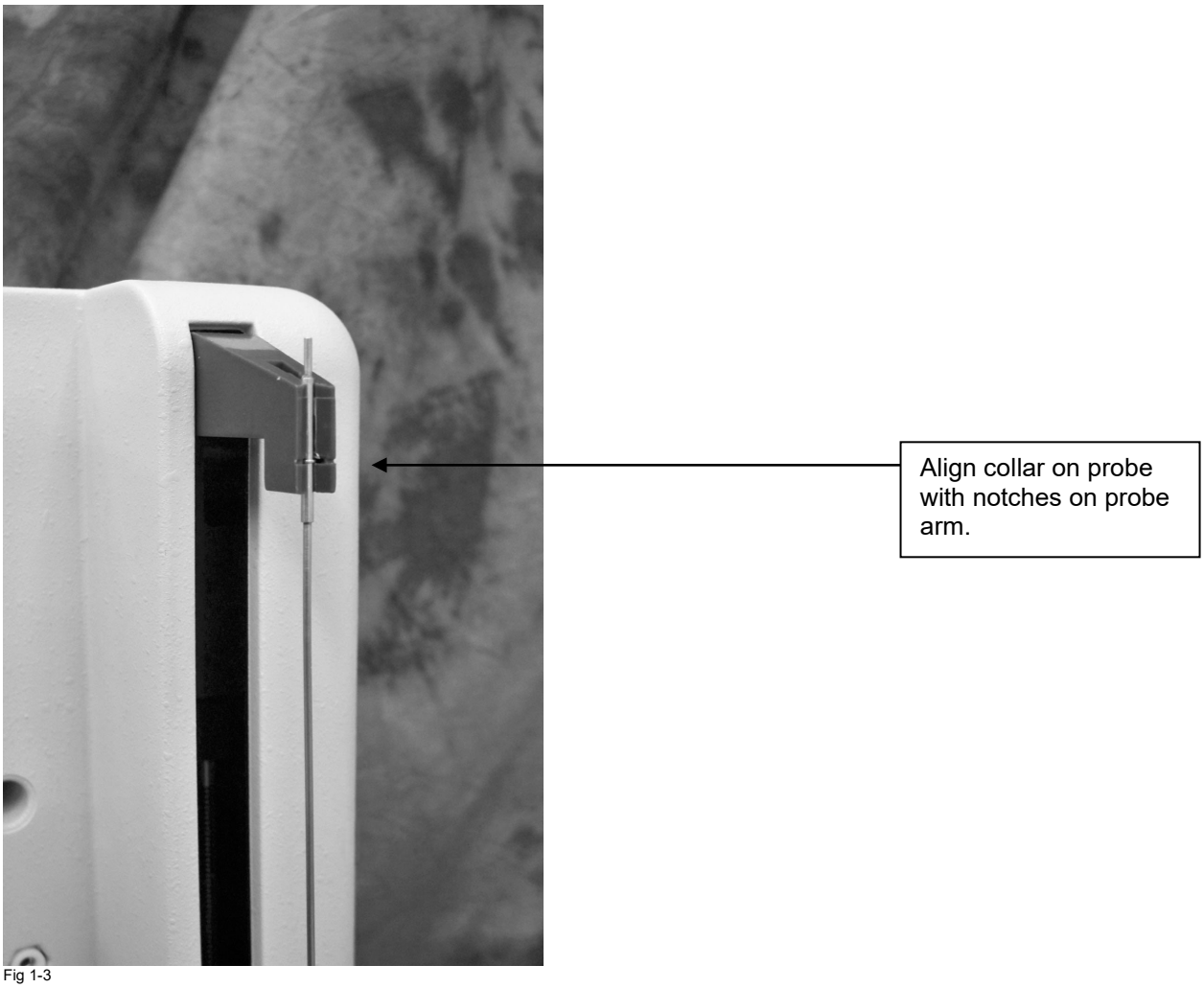


Fig 1-3

To remove the Sample Probe, place one hand above the probe arm and one below, with thumb positioned in front of the notch. Pull the Sample Probe forward until it is free from the probe arm. Your thumb should keep the Sample Probe from moving too far forward. This should help keep the Sample Probe straight. Pull upwards to remove it from the Solutions Valve.

2.2.4 *Membrane Assembly, ME-2258D*

The Membrane Assembly is located at the base of the Electrode Housing (See illustration below). It is visible from both the window as well as the base of the housing where the Pump Tubing connects. The Membrane Assembly is a part of the fluid path. It forms a junction between the measurement electrodes and the reference electrode via the fill solution, which keeps the Reference Electrode in equilibrium with its surroundings. The Membrane Assembly is a vital part of the analyzer, providing accurate results for both samples and calibration.

When removing the membrane assembly from its shipping container, handle the broad end of the assembly. Do not touch the area between the O-rings as this may damage the assembly and adversely affect performance. Orient the Membrane Assembly so the small clear window in the center of the assembly is oriented towards the window of the Electrode Housing. Press the Membrane Assembly firmly into the bottom of the Electrode Housing. Inspect to ensure proper installation. The Membrane Assembly should be evident through the window and the top and bottom O-rings should be barely visible.

During operation, any bubbles seen entering the Internal Filling Solution through the Membrane Assembly junction will indicate failure or malfunction. If this occurs, the Membrane Assembly should be replaced immediately. To ensure proper function of the analyzer the Membrane Assembly should be replaced every 3 months.

When replacing the Membrane Assembly first remove the electrode stack and drain the Electrode Housing of all fluid. The fluid can be drained by removal of the fill plug. Remove the Membrane Assembly from the Electrode Housing over a basin. Make sure to follow proper procedure for disposal of Internal Filling Solution as described in section 2. 2. 8. The Membrane Assembly is designed to prevent leaks and fits tightly into the Electrode Housing sometimes making it difficult to remove. Grip the exposed end of the Membrane Assembly and pull firmly for removal.

Fig 1-4

2.2.5 *Reference Electrode, ME-2103D*

Carefully remove the Reference Electrode from its protective package. The packaging and the vinyl cap will not be needed and may be discarded.

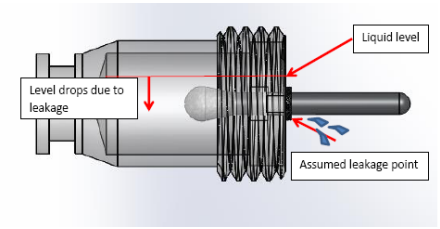
Using the Reference Electrode tool supplied in the Troubleshooting Kit, screw the new Reference Electrode into the Electrode Housing as shown. The flat surface of the electrode should be flush with the back of the Housing.

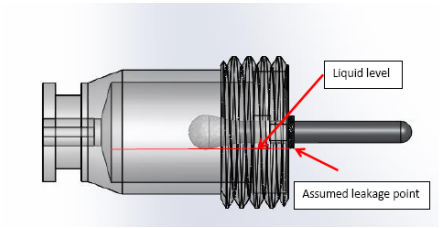
- *Do not over tighten the Reference Electrode as this could strip the thread and cause Internal Filling Solution to leak out of the Electrode Housing. A firm tightening of the Reference Electrode with the included tool is all that is necessary.*

- *If the Reference Electrode is not properly seated into the housing the required seal will not form, causing a large leak. Pressing the electrode housing too far into the instrument may loosen the electrode pin and create a leak around the pin area which then spreads onto the cap around the pin of the electrode.*

  How to determine if the source of leak is the Reference Electrode or the Electrode Housing?

Reference Electrode

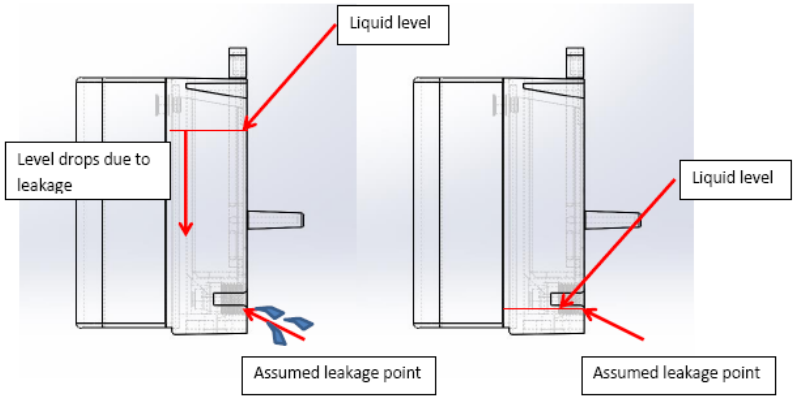




Fluid above the pin line *Fluid level below the pin line*

The pictures above show how the reference electrode hydrostatics works. If the seal between the pin & the cap is damaged and the liquid level is above the pin line, then the leak will happen. Leaking will continue until the internal fluid level falls below the pin line. In this scenario, the leaked liquid will be minimal given the amount of liquid inside the electrode. The electrode needs to be replaced.

Electrode Housing



If the reference electrode is not threaded properly to reference housing, then there will be leak around the housing and reference body junction. The leakage and salt buildup will be significantly higher in this case as the reference housing holds comparatively larger fluid volume. Leak will stop only when the housing fluid is drained below the leakage point as shown in above picture. Reference electrode internal fluid volume will be unchanged in this case. Properly sealing the reference electrode with housing or replacing the housing will resolve this issue.

To replace the Reference Electrode, remove the electrode stack and drain the housing of internal fill solution as described in Section 2.2.8. Remove the reference electrode by using the Reference Electrode tool. Install the new reference electrode according to the instruction above.

Whenever the reference electrode is replaced, use fresh Internal Filling Solution to refill the housing.

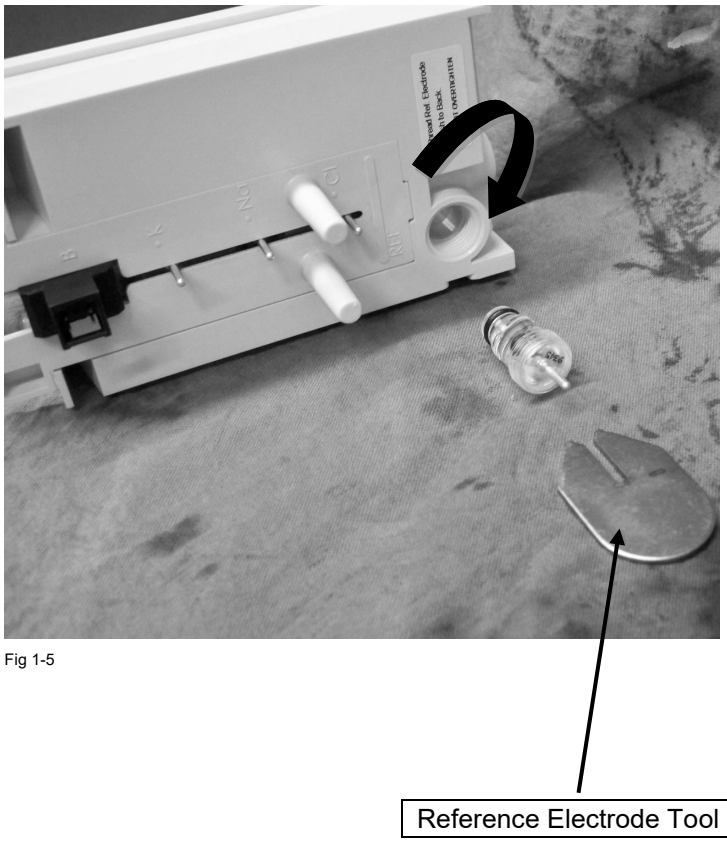


Fig 1-5

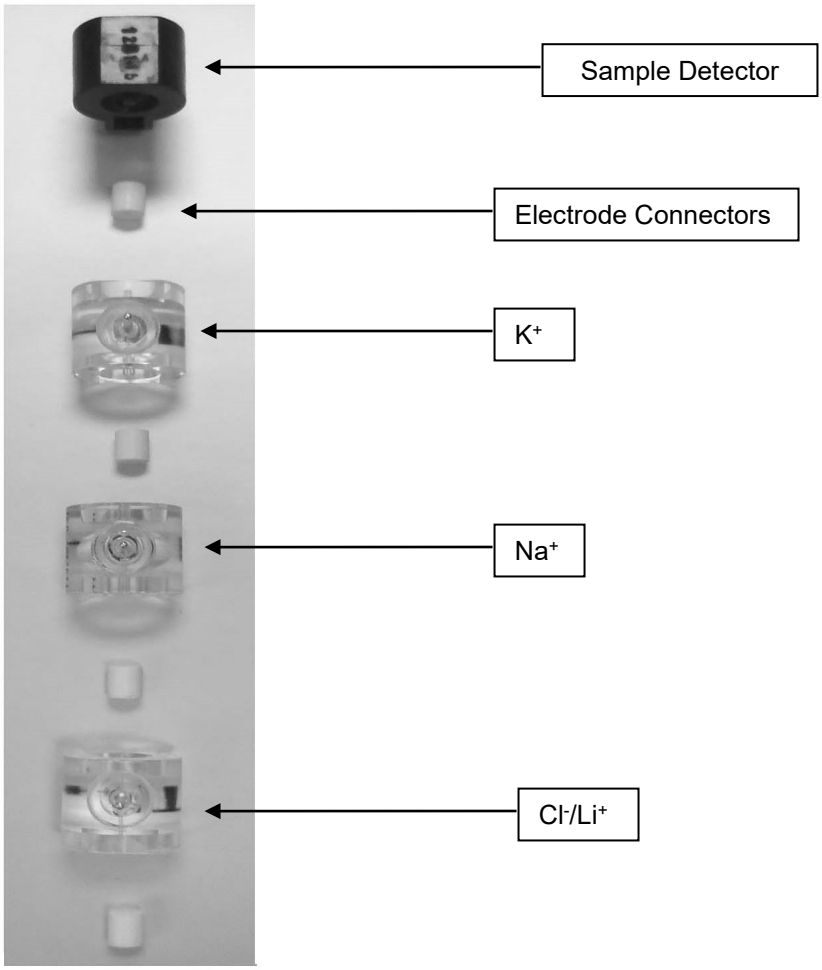
2.2.6 *Constructing the Electrode Stack*

Carefully remove the electrodes and Electrode Connectors from their protective packaging. Check the electrode label for Install By date prior to discarding the packaging. Prior to connecting the electrodes together, remove the yellow tape from each electrode.

Make sure all components are clean and dry. The stack should be assembled as shown below, with the Sample Detector on top followed by K^+, Na^+, and finally Cl^- or Li^+. Notches on K^+, Cl^-, Li^+ must be orientated away from the Na^+ electrode. Failure to install correctly can lead to electrode damage.

Electrode Connectors must be installed between the Sample Detector and the K^+ electrode, between K^+, Na^+, and Cl^- or Li^+ electrodes and finally between Cl^- or Li^+ and Membrane Assembly. There should be a total of four Electrode Connectors in the stack. Save unused connectors for future use.

When replacing with new electrodes, be sure to use new connectors.



Fg1-6

2.2.7 *Sample Detector, ME-2257D*

The sample detector is located at the top of the Electrode Stack. After constructing the Electrode Stack, slide it into place so the Sample Detector is flush with the top of the Electrode Housing. If it is not, check that all components of the electrode stack are correctly assembled.

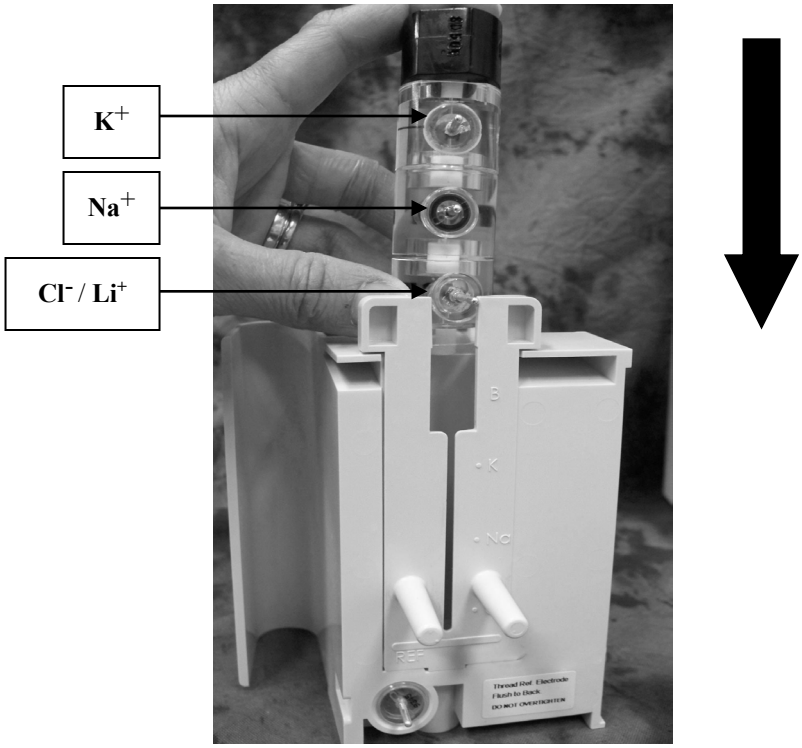


Fig 1-7

The Electrode Housing is now ready for use on the PROLYTE. Install the Electrode Housing by lining up the guides with their respective holes in the PROLYTE base. After checking that all the electrode pins and the Sample Detector port line up, press the housing gently into place. The Electrode Housing should now be flush with the front of the PROLYTE analyzer.

♦ *Do not use force to push the Electrode Housing into place. If the Electrode Stack is assembled correctly, the housing should install easily. Forcing the assembled Electrode Housing into place can damage components.*

When removing the electrode stack, remove the Sample Detector first. Then gently push up on the Cl⁻ electrode pin and remove the electrode stack as a single unit. The stack should be easily displaced. If there is any resistance, remove each electrode individually.

2.2.8 *Internal Filling Solution, ME-2492D*

Once the assembled Electrode Housing is on the PROLYTE, it can be filled with Internal Filling Solution. Remove the plug from the window of the housing to expose the fill hole. **Fill the housing with solution until it reaches the fill line.** Then replace the Fill Plug to prevent evaporation of the salt solution.

- *It is very important to fill the internal fill solution up to fill line for measurement stability and accuracy. Instrument may produce invalid results with improperly filled electrode housing.*

When filling the Electrode Housing, be sure not to spill solution into or behind the Electrode Housing as this may impair the electrode connections and cause the PROLYTE to malfunction.

- *Replacing/refilling of the Internal Filling Solution to the specified level should be done upon installation of the PROLYTE analyzer and minimally every six months thereafter. The Internal Filling Solution contains potassium chloride that will slowly decrease over time; not refilling the solution will result in inaccurate control and sample results. Due to the concentration of Potassium Chloride in the solution it is also important to replace the fill plug in the Electrode Housing to prevent evaporation.*

To drain and refill the Electrode Housing, first remove the Fluid Pack from the analyzer. Disconnect the Sample Tube and Pump Tubing from the Membrane Assembly, pull the Electrode Housing out, disconnect and remove the electrode stack. Once the components have been removed from the Electrode Housing, place it into a basin or other approved receptacle designated for the disposal of concentrated salt solutions. Remove the Fill Plug from the housing and tip it until all solution has been completely drained. Wipe any fill solution from the Electrode Housing or any surface onto which the solution may have spilled. Replace the Electrode Stack then place the Electrode Housing back onto the analyzer. Reconnect Pump Tubing and fill housing as described above. Through the Electrode Housing window, look for any air bubbles that may have formed around the Membrane Assembly. If visible, tap the housing until they are no longer observed.

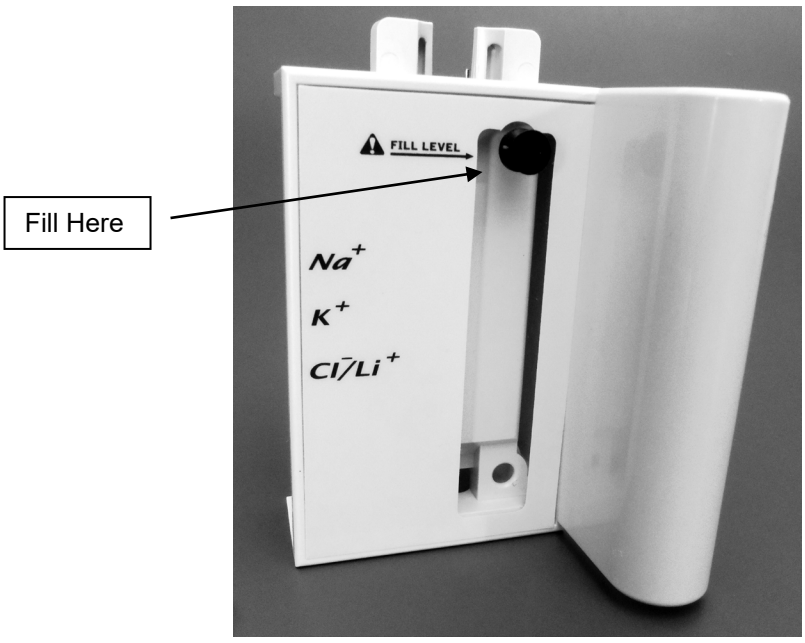


Fig 1-8

2.2.9 *Pump Tubing and Sample Tube, ME-2104D*

The Pump Tubing is installed by fitting the end of tubing with the blue grommet to the Membrane Assembly, which is at the base of the Electrode Housing. Secure the blue grommet to the right side of the shelf positioned above the peristaltic pump. Wrap the tubing around the peristaltic pump rollers, placing the red grommet onto the left side of the shelf. Attach the red grommet end of the tubing onto the barbed fitting of the Solutions Valve (See diagram on page 25). A final check of both connections should be made to ensure proper seating of the pump tubing fluid pathway.

Connect one end of the Sample Tube to the metal connector at the top of the Sample Detector capping the Electrode Stack. Secure the other end to the top of the Sample Probe as shown on the following page.

Replacement of Pump Tubing is an important part of proper analyzer function. Pump Tubing and Sample Tubing should be replaced every 3 months to ensure proper fluid flow through the electrode stack.

Pump Tubing is one of the most important pieces of the PROLYTE analyzer. It is recommended to use only Diamond Diagnostics supplied Pump Tubing for operation on the analyzer. Use of other tubing may have undesirable effects and may cause inconsistent and/or inaccurate test results.

Removal and replacement should be done in the same manner as described above.

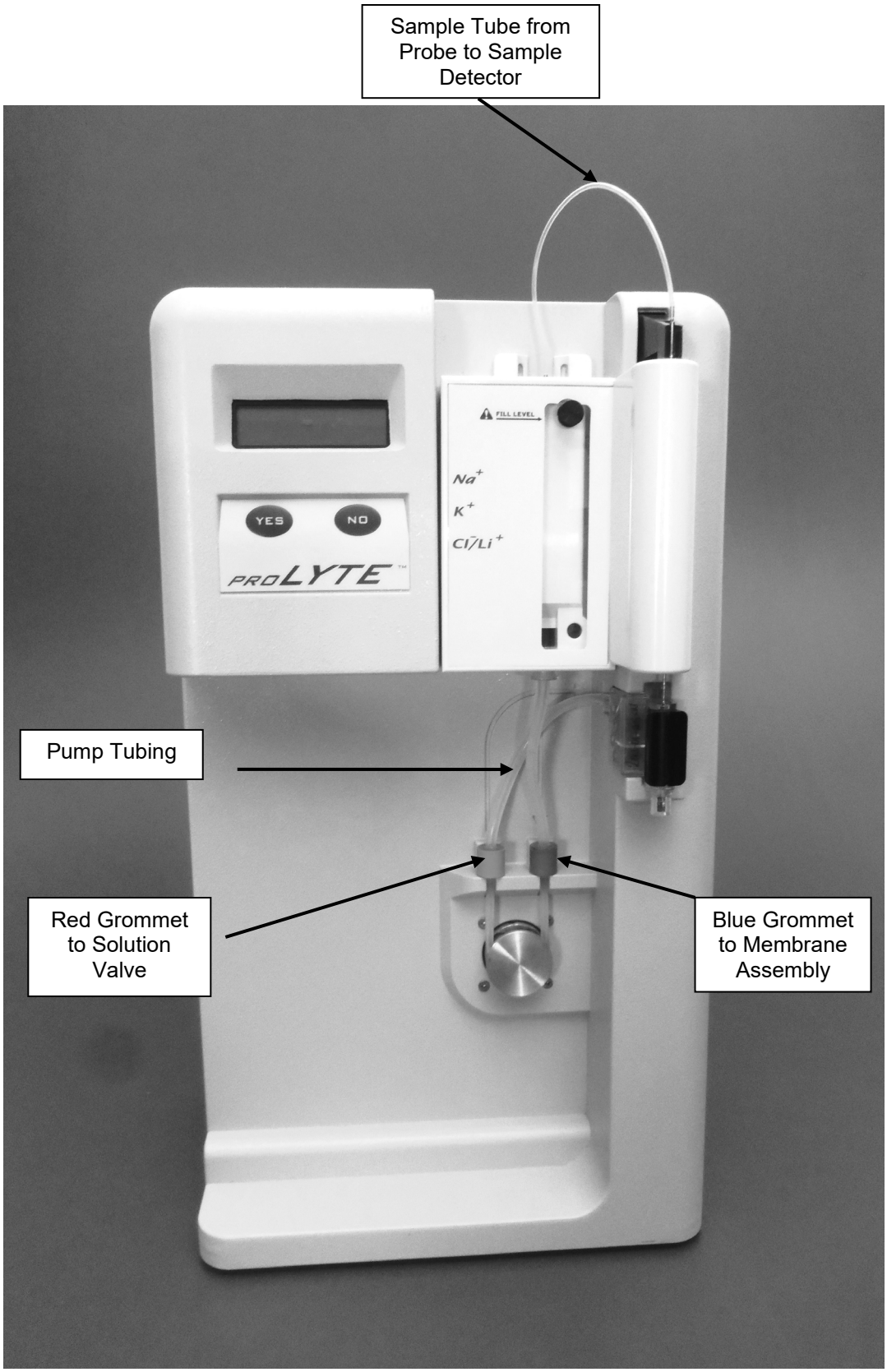

Sample Tube from Probe to Sample Detector
Pump Tubing
Red Grommet to Solution Valve
Blue Grommet to Membrane Assembly
YES
NO
FILL LEVEL
Na+
K+
Cl⁻/Li+

Fig 1-9

2.2.10 *Fluid Pack, IL-2121D*

Remove the Fluid Pack from the outer packaging.

Fig 1-10

With the Fluid Pack in an upright position (as shown above), remove the four red vinyl caps. Be careful not to squeeze the pack once the caps are removed as this may cause solution to leak out.

Fig 1-11

Align the Fluid Pack with the front of the PROLYTE analyzer. Slide it into the Solutions Valve, making sure it is firmly in place. The Fluid Pack should now be flush with the analyzer.

Fig 1-12

- *Do not use a Fluid Pack which has exceeded its expiration date. See the label on the front for expiration date and lot information.*

- *Do not leave electrodes in the analyzer without a Fluid Pack installed. Lack of solution may damage the electrodes and cause them to malfunction.*

2.3 *Accessories*

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

The USB connectors for these items are located on the back of the instrument.

DD-0206 Mini-Keyboard

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

FUNCTION KEY	**DESCRIPTION**
F1	Analyze
F2	Results
F3	QC/STD/Urine
F4	Maint.
F5	Oper. Setting
F6	Inst. Setting
F7	Diag. / Service
F8	Cal.
F9	Standby
F10	Service Login
NAVIGATION KEYS (Lower right side)	
RIGHT ARROW	Next
LEFT ARROW	Previous
DOWN	Yes

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

DD-0202 Barcode Scanner

2.4 *Power Up*

Insert the power cord into the back of the PROLYTE and plug into a grounded outlet.

Turn the switch to the ON position. You will know the analyzer is on when you hear a beep and **[**PROLYTE**]** is displayed on the LCD screen.

✦ *Check to make sure the correct date and time is set-up. If incorrect, the information may be changed by using the following procedure.*

- Press **NO** until **[INSTRUMENT SETTING?]** (**F6**) is displayed. Then press **YES**.
- Press **NO** until **[CHANGE DAY/TIME?]** is displayed. Then press **YES**.
- Press **NO** until the correct day, month and year is reached. Then press **YES**.
- Press **NO** until **[RUN CALIBRT'N?]** (**F8**) is displayed again.

2.5 *Language Setting*

PROLYTE supports the following eight languages:

- ENGLISH (Factory Default)
- GERMAN
- FRENCH
- SPANISH
- ITALIAN
- PORTUGUESE
- CHINESE
- RUSSIAN

PROLYTE language can be changed under "**[NSTRUMENT SETTINGS**] (**F6**).

- Press **NO** until **[INSTRUMENT SETTING?]** (**F6**) is displayed. Then press **YES**.
- Press **NO** until **[SELECT LANGUAGE?]** is displayed. Then press **YES.**
- Select the desired language and press **YES.**
- To successfully change the language, respond to [**Are You Sure**?] by pressing **YES.**

2.6 *Parameter selection*

PROLYTE measurement parameters can be changed under [**OPER FUNCTS**] (**F5**).

- Press **NO** until **[SELECT PARAMETER]** is displayed. Then press **YES**.
- Select the desired parameter combination.
    - **[Na-K-Cl]** or **[Na-K-Li]**
- Confirm parameter change by responding **YES** to [**ARE YOU SURE**?]

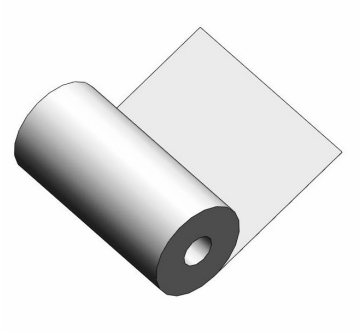
2.7 *Printer Setup*

To install the printer paper into the PROLYTE, first unroll the paper slightly and cut any adhesive that keeps the paper in a tight roll. With the roll on top, as shown below, center the paper in paper feed slot and gently slide into the printer until there is resistance. Press the paper feed button to load the paper in the printer. The feed button may need to be pressed multiple times to completely feed the paper through the printer.

A permanent record of all data collected from the PROLYTE can be obtained as hard copy. However, if a hardcopy is not required, the printer can be turned off.

- Press **NO** until **[INSTRUMENT SETTINGS?]** (**F6**) is displayed. Then press **YES**.
- Press **NO** until **[PRINTER SETTINGS?]** is displayed. Then press **YES**.
- Press **NO** until **[PRINTER OFF?]** is displayed**.** Press **YES.** This process turns the printer off completely. No reports will print when requested under [**SEE RESULTS?**] (**F2**), at completion of calibrations or sample analysis.

♦ *Make sure to only use printer paper supplied by Diamond Diagnostics.*



3.1 Calibration

The PROLYTE will not analyze any samples until calibration is complete. When **[RUN CALIBRATION?]** (**F8**) is displayed, press **YES** to initiate a calibration.

If barcode of reagent pack has not been entered, **[PACK BARCODE]** is displayed. Enter barcode using keyboard or barcode reader, if available. Note all characters are in caps. Once entered press **Yes,** calibration will start.

The PROLYTE analyzer will now go through the calibration process. If successful, the display will read **[ANALYZE BLOOD?]** (**F1**). Parameters available for analysis will be displayed on second line.

The default calibration interval is 4 hours. If the PROLYTE is idle for 4 hours, it will automatically go into **[***STANDBY***]** (**F9**). Once in **[***STANDBY***]**, a calibration must be performed before samples may be run.

3.2 Analyzing Quality Controls

For best results use Quality Controls (QC) supplied by Diamond Diagnostics daily to make sure the PROLYTE is functioning properly. If the analyzer is successfully calibrated and all levels of QC are in range, you can be sure that patient results are accurate.

Recommended Material

Three levels of ready to use assayed Quality Controls supplied by Diamond Diagnostics.

Level 1 – DD-92001, Qty: 30

Level 2 – DD-92002, Qty: 30

Level 3 – DD-92003, Qty: 30

Tri-Level- DD-92123, Qty: 10 x Level 1, 10 x Level 2, 10 x Level 3

Recommendations

Follow the recommended Local, State and Federal Guidelines for Quality Control. Run control levels at least once a day. Make sure to store QC results in the PROLYTE's memory when prompted for future use.

For the most recent revision of use instructions, storage and stability information, and expected results, please visit www.diamonddiagnostics.com.

♦ *Do not use any control material which contains Ethylene glycol and/or other stabilizers. These may damage the PROLYTE or may cause the analyzer to yield incorrect results.*

RUN CONTROL?

To run a Quality Control, press **YES** to **[RUN CONTROL 1, 2, or 3?]** under **[URINE/QC/STD?] (F3).** After making this selection, the probe will descend and the display will read **[PROBE IN CONTROL?]** Align the QC vial under the Sample Probe, making sure the probe hole is submerged. Then press **YES**. The instrument will aspirate the QC material and begin analysis.

After the results are displayed, check that they fall within the limits provided on the QC inserts. If QC limits are set, then results that are above or below the user entered limits will be flagged **HIGH** or **LOW.** To accept the data, and store it, press **YES** when **[STORE RESULTS?]** is displayed. If not, press **NO** and the results will not be stored. If the memory is full, the oldest stored result will be replaced with the newest results.

The PROLYTE can store 500 results for each parameter for each level.

3.3 Whole Blood, Plasma, Serum Analysis

✦ *Before running patient samples, Quality Controls should be run to ensure the PROLYTE analyzer is in proper working order. See section 3.2 Quality Controls/Statistical Analysis for more information.*

After a successful calibration, **[ANALYZE BLOOD?]** (**F1**) will be displayed. The analyzer is now ready to run patient samples. To run a sample, press **YES**. This will lower the Sample Probe through the Probe Wiper. When the analyzer prompts **[PROBE IN BLOOD?]** position the probe in the sample. Make sure the hole at the base of the Sample Probe is submerged through the entire aspiration process.

Pressing **YES** will cause the PROLYTE to begin aspirating the fluid through the sample path. Once sufficient sample fluid has been aspirated, the Sample Probe will automatically retract and the fluid will be pulled into the electrode measurement path. After **[ANALYZING…]** is complete, the PROLYTE will beep and both display and print results. You may immediately run another patient sample.

If there is air in the sample or the sample size is insufficient, the analyzer will display and print out the error message **[AIR IN SAMPLE]**. If this occurs, realign the sample under the Sample Probe, double check that the probe hole is submerged in the sample, and try **[ANALYZE BLOOD?]** (**F1**) again.

The standard mode **[ANALYZE BLOOD?] (F1)** is designed for sample containers such as vacutainers, test tubes and sample cups. If your laboratory or office prefers to use syringes, you may change to the **[SYRINGE SAMPLE?]** option.

With the **[SYRINGE SAMPLE?]** option, the Sample Probe does not descend as far as the normal sample mode. This ensures there is plenty of room for the syringe to be placed under the probe. The Probe Wiper must be removed. Ensure the probe hole is immersed in the sample prior to aspiration. After the sample is aspirated, the instrument will prompt the operator to remove the sample and wipe the probe.

✦ *Patient results outside the preset normal ranges will be flagged as either high or low as described under **[INST SETTINGS]** in **[RANGES?]***

3.4 Urine Analysis

After receiving patient urine samples, follow the procedure outlined below to test the samples on the analyzer:

1. Using Urine Diluent supplied by Diamond Diagnostics, dilute the urine 9 parts Urine Diluent to 1 part patient urine sample. Do not attempt to run undiluted urine through the analyzer.
2. From the **[URINE/QC/STD?] (F3)**menu, select **[*ANALYZE URINE?*]** by pressing **YES**.
3. When the Sample Probe lowers, the display will prompt, **[DILUTED 1:10?]** If the sample has been diluted, press **YES**. (If **No** is pressed, the probe will retract to allow for sample dilution.)
4. The display will now read **[PROBE IN URINE?]** At this time, place the Sample Probe in the diluted urine sample making sure the hole in the probe is well below the fluid level since a larger volume is required for diluted urine.
5. Press **YES**. Hold the sample container in place, ensuring the Sample Probe hole is immersed during the entire aspiration period. The Sample Probe will retract automatically.
6. While sample measurement is in process the display will show **[ANALYZING…].** Once complete, the analyzer will display and print out the results. A correction has already been made to account for the dilution.

✦ *Urine mode requires 4 times the amount of sample as blood (400 uL versus 100uL). Make sure you have plenty of diluted urine prior to beginning analysis.*

✦ *Lithium is not measured in Urine samples.*

Out of Range Sodium, Potassium and/or Chloride/Lithium

Any values outside of the normal ranges set by the user for urine will be flagged as either high or low. To set the normal ranges or to view what the ranges are, see **[RANGES?]** under **[INSTRUMENT SETTING?] (F6)**

Sometimes the ion concentrations in urine are too high for the measurement limits of the machine. In these cases, the ion will be flagged with **[ERROR]**, and an additional dilution is necessary.

For these samples,

1. Dilute patient urine sample with 19 parts Urine Diluent to 1 part urine.
2. Follow the same procedure above by pressing **YES** to **[DILUTED 1:10?].** However, this time, the results need to be multiplied by 2.

Another possible error message is **[MV RANGE Na]**, **[MV RANGE K]** and/or **[MV RANGE Cl].** This means the electrode voltage of the diluted sample is too low for the analyzer to yield an accurate result. If this occurs, the dilution must be decreased as follows;

1. Dilute patient Urine sample with 4 parts Urine Diluent to 1 part urine.
2. Follow the same procedure above by pressing **YES** to **[DILUTED 1:10?]**. The displayed/printed results need to be divided by 2 for the correct sample value.

3.5 Analyzing Standard

To run a standard, press **YES** to **[ANALYZE?]** The Probe will descend and the display will read **[PROBE IN STD?]** Align container of Standard under the sample probe making sure the probe hole is submerged. Press **YES**. The instrument will aspirate the standard and analysis begins.

3.6 Retrieving Sample and Standard Results

Previous results which are stored in the analyzer can be found by selecting **[SAMPLE REPORTS?]** under **[SEE RESULTS?] (F2)** and pressing **YES** to **[SAMPLE REPORTS?]**.

LAST RESULTS?

Results from the last serum, urine or standard sample analyzed will print and be displayed.

BY SAMPLE ID?

Results can be retrieved by sample ID.

BY NAME?

A specific result can be retrieved by name.

BY DATE?

All results from a specific day can be retrieved.

DAILY SUMMARY?

All results from the day are printed.

WEEKLY SUMMARY?

All results from the last 5 days will be printed out.

ALL RESULTS?

All the results stored in the analyzer are printed. Please note that the PROLYTE can store a maximum of 1000 sample results. Be sure to print out **[ALL RESULTS?]** prior to the analyzer reaching storage capacity if copies are needed. Older results are over written by new results once 1000 patient samples are stored.

DELETE RESULTS?

Deletes all results stored in the analyzer. Make sure you have all the information you require before pressing **YES** to this option, because the results are permanently deleted from memory.

3.7 QC Results

Previous results which are stored can be found by selecting **[SEE RESULTS]** and pressing **NO** until **[QC REPORTS?].** Press **YES**.

LAST CONTROL?

Answering **YES** to this option will display and print the last QC result stored.

STATISTICS?

The PROLYTE is capable of storing up to 500 results per level. If a minimum of 5 results are stored, the analyzer will use this data to calculate the mean, standard deviation, and coefficient of variation. If less than 5 results are stored, the instrument will display **[NOT ENOUGH DATA].** To access this information simply press **YES** when **[STATISTICS?]** is displayed and the results will print.

DELETE CONTROLS?

Pressing **YES** to this option will delete all the Quality Control data stored in the PROLYTE Analyzer. When starting a new lot of controls, it is advisable to delete data for previous lot so that statistical calculations are only for 1 lot.

3.8 Retrieving Calibration Results

LAST CAL VALUES?

Acceptable calibration values are shown below. These values are the electrode slopes from the last calibration. The values will print and be displayed when **YES** is pressed at **[LAST CAL VALUES?]** under **[SEE RESULTS?] (F2)**

Electrode	Calibration values
Na^+	50-64
K^+	50-64
Cl^-	40-64
Li^+	50-64

The PROLYTE will save a maximum of 20 Calibration results.

3.9 Maintenance

These procedures help maintain the PROLYTE so that it is available for use upon request.

DAILY CLEANER?

Protein deposits must be removed from the fluid path at the end of each day. This is the only user initiated daily maintenance required for the analyzer. It will help keep all the components in proper working order.

To clean the sample path, follow the procedure below:

1. Press **NO** or F4 for **[MAINTENANCE?].** Press **YES** and **YES** again at **[DAILY CLEANER]**. The Sample Probe will descend and **[PROBE IN CLEANER?]** will show on the display.
2. Position the opened bottle of cleaner so the hole in the Sample Probe is fully submerged in the solution. Press **YES**.
3. The display will be **[ASPIRATING…]** until sufficient cleaner has been aspirated. The probe will retract.
4. The analyzer displays **[CLEANING…]**. When complete, the analyzer will step into **[***STANDBY***].**

[DAILY CLEANER?] must be performed at the end of each day. If cleaning is not done, the PROLYTE analyzer will remain in **[***STANDBY***].** Automatic Calibration will not take place on the following day. When **NO** is pressed, the instrument displays **[MUST USE CLEANER! DAILY CLEANER?]** Cleaning must be performed before the instrument allows a calibration.

FLUSH?

This option pumps Flush solution from the Fluid Pack through the system when requested. The Flush solution is made up of ammonium bifluoride and is used to condition the Na^+ electrode. The analyzer automatically goes into **[***STANDBY***]** after this cycle is complete and a calibration is necessary before analysis can resume.

If Flush is no longer available from the Fluid Pack, External Flush may be used.

SOLUTION PRIME?

This primes each line from the Fluid Pack to ensure that all solutions are free of air. **[SOLUTION PRIME?]** should be performed whenever installing a used Fluid Pack. After **[SOLUTION PRIME?]** a calibration will be needed before samples analysis can continue.

MAINTENANCE?

Prior to performing any routine maintenance on the PROLYTE, it is recommended that you first put the analyzer in **[***STANDBY***]** by pressing **F9.** For routine maintenance consult the Recommended Maintenance/Replacement Schedule outlined on page 7 of this manual. If further action is required follow the guidelines set in the Troubleshooting and Repair section of the manual or consult Diamond Diagnostics or your authorized dealer.

3.10 Operator Functions

[OPER FUNCTS?] (F5) allows you to do a variety of important functions when necessary.

STANDBY MODE?

To conserve solution when the PROLYTE is not in use, place the analyzer in Standby Mode by pressing **F9**. When ***[STANDBY MODE?]*** is displayed, press **YES** and **YES** again. In **[***STANDBY***],** the analyzer will cease automatic calibrations but will continue to pump a small amount of Standard A from the Fluid Pack. This protects all the components and keeps the electrodes from drying out.

✦ *If the operator accidentally presses **YES** to the **[STANDBY MODE?] (F9)** option, the operator has 1 minute to escape by pressing **NO** again before the analyzer switches into **[***STANDBY***].** The time remaining to escape **[***STANDBY***],** is displayed. Once **[***STANDBY***],** is entered, a calibration must be completed upon exiting before sample test can begin.*

The PROLYTE will also automatically go into **[***STANDBY***]** if the analyzer has not been used in 4 hours since the last calibration.

The PROLYTE will automatically return to its primary screen if left in any other menu screen for a period of 10 minutes. When calibrated, it will return to **[ANALYZE BLOOD?] (F1)** If not calibrated, it will return to **[***STANDBY***].**

RUN CALIBRT'N? (F8)

This option initiates a calibration at request.

PACK USAGE?

The PROLYTE tracks how much fluid is used. The PROLYTE can then warn the operator when fluid consumption is reaching 100% and reduces risk of losing patient sample when there is insufficient Standard A for sample analysis.

To check how much fluid has been consumed thus far, press **YES** to **[PACK USAGE?]** under **[OPER FUNCTS?] (F5)** the analyzer will print and display the percentage of the Fluid Pack used up. For those instruments with SW version 700 and higher, the lot number as well as the expiration date will print.

✦ The instrument will request the entry of a Pack Barcode if the code in memory does not match the one found in the Fluid Pack.

When greater than 90% of the Fluid Pack is used, the PROLYTE will display **[SOL'N PACK LOW!]** At greater than 99% consumption, the display will read **[CHANGE PACK!]** and sample measurements will not be allowed until the Fluid Pack has been changed.

To change the Fluid Pack, complete the following steps.

1. Remove the used Fluid Pack. Cover each connector with vinyl caps to prevent fluid and waste leakage.
2. With the new Fluid Pack in the upright position, remove the 4 vinyl caps. Be careful not to squeeze the pack once the caps are removed as this may cause solution to leak out. Align the Fluid Pack with the front of the PROLYTE analyzer. Slide it into the Solutions Valve, making sure it is firmly in place. The Fluid Pack should now be flush with the analyzer.

When disposing of the used Fluid Pack, keep in mind that it now contains human bodily fluids and may be contaminated with a variety of pathogens including HIV. Handle and dispose of the used Fluid Pack following the appropriate safety procedures for Biohazardous waste products.

For instruments with RFID capability, each time a new Fluid Pack is installed, the barcode must be entered. This can be accomplished through the keyboard or a barcode scanner. If the Fluid Pack is not accepted, **INVALID FLUID PACK** will be displayed. Verify that the barcode entered is correct. If the error message is displayed again, proceed to **DIAGNOSTICS (F7)**. Press **YES**, followed by **NO** until **CHECK RFID SENSOR** is displayed. Press **YES**. Press **YES** again to verify **RFID** function. If **RFID TAG IS FOUND**, contact your Diamond Representative.

Each time a new Fluid Pack is installed, the percentage counter will need to be set to zero. To do this, press **YES** to **[XX%PCKUSED.NEW?]** under **[*PACK USAGE?*]** in **[OPER FUNCTIONS?]**. When prompted, **[RESET TO 0?]** press **YES.** The analyzer will then step to **[***STANDBY***].** After a new pack has been installed, the next calibration will automatically prime the solution from the pack.

If a Fluid Pack does not contain an RFID tag and is being used on an instrument that does not need an RFID tags, you can adjust the percentage of solution already consumed. After pressing **YES** to **[XX%PCKUSED.NEW?],** press **NO** to **[RESET TO 0?]. [SET USAGE TO 00%?]** will be displayed. Change the value by pressing **NO** until the correct number is displayed, then press **YES**. Repeat for the second numeral. When asked if this is **[CORRECT?]**, pressing **YES** will place the instrument in **[***STANDBY***].** Pressing **NO** will allow you to re-enter the percentage if you made an error.

♦ *Do not use a Fluid Pack which has exceeded its expiration date. See the label on the front of the Fluid Pack for expiration date and lot information.*

♦ *Do not leave electrodes in the analyzer without a Fluid Pack installed. Lack of fluid may damage the electrodes and cause them to malfunction.*

SELECT PARAMETER? (SOFTWARE REV 603 or Higher)

The analyzer default configuration is sodium, potassium, chloride. To select a different parameter configuration, press **YES** to **[SELECT PARAMETER?]**. Insert the desired electrodes, select parameter configuration from the options shown below and press **YES**.

Parameter
Na-K-Cl
Na-K-Li

3.11 Instrument Setting

The PROLYTE can be configured to operator requirements using this menu.

RANGES?

The PROLYTE comes preset with "normal" ranges for Na^+, K^+, and Cl^- for both blood and urine. Patient results falling above or below these ranges will be displayed and indicated as being high or low accordingly. To view or edit these values, press **YES** to **[RANGES?]** then **YES** to **[BLOOD NA LIMITS?]** When the number flashes, press **NO** until the desired number is displayed, and then press **YES**. Repeat this step throughout. When complete, press **YES** at **[CORRECT?].** Continue the same procedure until all ranges are set:

Blood

Na^+	135 – 148 mEq/L (SI units mmol/L)
K^+	3.5 – 5.3 mEq/L (SI units mmol/L)
Cl^-	98 – 107 mEq/L (SI units mmol/L)
Li^+	0.6 – 1.2 mEq/L (SI units mmol/L)

Urine

Na^+	40 – 220 mEq/L (SI Units mmol/L)
K^+	25 – 120 mEq/L (SI Units mmol/L)
Cl^-	110 – 250 mEq/L (SI Units mmol/L)

♦ *For urine, the ranges were assumed based on a 24 hour urine collection of approximately one liter*.

Human bodily fluids may be contaminated with a variety of pathogens including HIV. Handle and dispose of samples following the appropriate safety procedures for Biohazard waste products.

SET CORRELATION?

This function allows the PROLYTE to yield patient results similar to other electrolyte testing instruments. To view and/or edit the preset correlation equations, press **YES** to **[SET CORRELATION?]** then **YES** to **[CORRELATE BLOOD?].**

Each lab can set up its own correlation equations. It is recommended that the laboratory tests a minimum of 10 patient serum samples in low, normal, and high concentrations on both the PROLYTE and the comparison instruments and then perform a regression analysis to determine the correlation values. Correlation values that are not based on serum samples which span the entire measurement range of the PROLYTE may not be accurate.

After pressing **YES** to **[CORRELATE BLOOD?]** the preset Na^+ equation will be shown first. Here, X equals the standard measurement when the correlation mode is off. When asked if the equation is **[CORRECT?]** press **NO** to edit. Press **NO** until the correct number is displayed, then press **YES**. If you do not wish to change the equation, press **YES** when asked if the equation is **[CORRECT?]** Follow this same procedure for K^+ and Cl^-.

Below are the correlation equations for blood established on the PROLYTE:

Parameter	**Correlation (700 and Higher)**
Na^+	1.00x + 0.00
K^+	1.00x + 0.00
Cl^-	1.00x + 0.00
Li^+	1.00x + 0.00

To change the correlation equations for urine, press **YES** to **[CORRELATE URINE?]** and follow the same procedure outlined under **[CORRELATE BLOOD?]**. Below are the correlation equations for urine established on the PROLYTE:

Na^+	1.00X – 0.00
K^+	1.00X + 0.00
Cl^-	1.00X + 0.00

After changing the correlation values, the PROLYTE will print out **[BLOOD/URINE CORRELATION ON]**. Changes made to the correlation equations will not affect results run under the **[CONTROL LEVEL 1, 2, OR 3]** option. However, results run in **[ANALYZE BLOOD?] (F1)** or **[*ANALYZE URINE?*]** will be printed as correlated values.

After you change the correlation equations, you may want to adjust the values for the normal ranges. This can be accomplished by going to **[INST SETTINGS]** and pressing **YES** when **[RANGES?]** is displayed.

In order to return to the standard correlation simply press **YES** to **[SET CORRELATIONS?]** then **NO** to **[CORRELATE BLOOD?]** and/or **[CORRELATE URINE?]** the PROLYTE will then print **[CORRELATION OFF].**

CHANGE DAY/TIME?

To change the date or time, press **YES** to **[CHANGE DAY/TIME?]** press **NO** while the month is flashing to move to the next month. Press **NO** until the correct month is displayed, then press **YES**. Repeat this step for the year and then time. If the date and time are now correct, press **YES** when the display asks **[CORRECT?]**. If a mistake is made, press **NO** at **[CORRECT?]** and try again.

✦ *After pressing **YES** to **[CORRECT?]**, the display will read **[NEXT SAMPLE?]** press **YES** to return to **[ANALYZE SAMPLE?].***

AUTOCAL SETTINGS?

Each day the PROLYTE can calibrate automatically at a specific time, provided that **[DAILY CLEANER?]** is run at the end of each day that samples are analyzed. To change the set time for the first automatic calibration of the day, press **YES** to **[AUTOCAL SETTINGS?]** Press **YES** at **[CHANGE HOUR?]** to change the time. Press **NO** until the correct hour is displayed, then press **YES**. Repeat this step for setting minutes. Press **YES** to confirm when **[CORRECT?]** is displayed.

To turn this option off, press **YES** to **[AUTOCALOFF?].** The PROLYTE will print AUTOCAL OFF.

PRINTER SETTINGS?

This menu allows for entry of header text on print outs. It also allows the printer to be turned off.

HEADER TEXT?

The printer can be set up to have a header text which prints with each sample report. To set up the text, press **YES** to **[HEADER TEXT?]** then press **NO** and **YES** to enter the desired header.

PRINTER OFF?

To turn off the printer, simply press **YES** when **[PRINTER OFF?]** is displayed. If the printer is shut off, it is advisable to insert the thermal printer protector into the printer to allow easy installation of paper when required in the future.

MANUAL PROBE WIPING?

To turn on **[PROBE WIPING?]** simply press **YES** when the option is displayed. Manual Probe Wiping must be turned on when using a **[SYRINGE SAMPLE?]** After the sample is aspirated, this option gives a 5 second delay so the operator can wipe the Sample Probe before it retracts for sample analysis. During this delay, the analyzer will beep, informing you to remove the sample container and wipe the probe. Below is the outline of steps when **[PROBE WIPING?]** is on.

[ANALYZE BLOOD?] ⟶ [PROBE IN BLOOD?] ⟶ [ASPIRATING…] ⟶ [REMOVE SAMPLE] ⟶ [WIPE PROBE] ⟶ [ANALYZING…]

♦ *Make sure you have either a Probe Wiper installed, or if **[PROBE WIPING?]** is ON, that the probe is wiped every time. If any bodily fluids are on the probe when it retracts, it will carry the fluids into the Solution Valve and may dry inside. This can clog the valves and cause fluidics errors.*

SYRINGE SAMPLE?

If this option is selected, make sure the probe wiper is removed since the probe will not be lowered as far as in the normal sampling mode. This is to make sure there is plenty of room for the syringe to fit under the Sample Probe and line up properly. The instrument will prompt [**REMOVE WIPER/WIPER REMOVED?**] when syringe sample is enabled. If **NO** is pressed, the probe will not descend and sample analysis cannot proceed. When the display asks **[PROBE IN BLOOD?]** place the Sample Probe in the needle-less syringe so the fluid level is above the hole at the base of the probe.

To return to the normal sample mode, simply press **NO** when **[SYRINGE SAMPLE?]** is displayed and re-install the probe wiper.

SELECT LANGUAGE?

Under this menu option, PROLYTE display and print language can be changed. PROLYTE supports the following languages:

- ENGLISH (Factory Default)
- GERMAN
- FRENCH
- SPANISH
- ITALIAN
- PORTUGUESE
- CHINESE
- RUSSIAN

Diagnostics Menu

This menu allows you to test a variety of important functions when necessary. The troubleshooting section to follow, will describe when to use the tests to diagnose various problems.

TEST	DESCRIPTION
ELECTR'D VALUES?	Measures direct Electrode millivolt (mV).
FLUID FLOW TEST?	Checks fluid flow from probe through electrode path.
SAMPLE DET. TEST?	Checks that Sample Detector is in working order.
PUMPCAL TEST?	Checks solution movement through the valve.
CHECK RFID SENSOR?	Checks that the RFID system is functioning correctly.
SERVICE LOGIN?	Allows service functions to be accessed.

ELECT'D VALUES?

Electrode values are the direct millivolt (mV) readings of the electrodes. Acceptable range for Standard A is 35 to 125 mV for Na, K, Cl and Li. Typical values are shown in the table below These results will print and be displayed if **YES** pressed at **[ELECTRD VAL'S].**

FLUID FLOW TEST?

This test determines if fluid is aspirated correctly through the entire sample path, starting from the Sample Probe. To run this test, simply pres **YES** to **[FLUID FLOW TEST?]** and run the Red Dye Test Solution (ME-2578D) found in the Troubleshooting Kit as a sample. If the PROLYTE passes this test, **[FLUID FLOW OK]** will be displayed and printed. This shows that the analyzer is free of obstruction. If it fails, see the Troubleshooting section for more instruction.

SAMPLE DET. TEST?

To verify that the Sample Detector is working properly, press **YES** to **[SAMPLE DET, TEST?]**. The Sample Detector is designed to detect air and liquid. During this test the PROLYTE will pump a small amount of Standard A followed by air. After this test is performed, two values will print, one for the liquid and one for the air. If the difference between the two values is less than 50, **[SAMPLE DETECTOR!]** will display and the test was unsuccessful. See the Troubleshooting section for more information. If the test passes, **[SAMPLE DETECT OK]** will be displayed and printed.

PUMPCAL TEST?

This test is to ensure that the pump turns the proper number of times to pull solutions from the Fluid Pack through the electrodes. To initiate this test, press **YES** to **[PUMPCAL TEST?]. [PUMPCAL OK]** will display if the test is successful. If there are any problems, **[PUMPCAL FAILURE!]** will be displayed and printed. Failure occurs if the Pumpcal value is not between 500 and 1100. If the test fails, try again. If it continues to fail, see the Troubleshooting section for more information.

CHECK RFID SENSOR?

This test ensures the RFID system is functioning correctly. Check that the IL-2121D Fluid Pack with barcode on the label is correctly installed on the PROLYTE. Press **YES** to [**CHECK RFID SENSOR?**] followed by pressing **YES** to [**TAG STATUS:YES → SCAN**]. If the functioning correctly, [**TAG STATUS:TAG FOUND**] will be displayed. Failure will occur if the wrong Fluid Pack is present

SERVICE LOGIN?

This function allows for the programming of various functions into the PROLYTE Electrolyte Analyzer.

The table below shows the various functions which can be programmed.

To turn **ON** or **OFF** each function, press **YES** to **[SERVICE LOGIN?]** which is under **[DIAGNOSTICS?] (F7).** Enter the desired code from the table below when **[PASSWORD:]** is displayed by pressing **NO** until the correct letter is displayed, then press **YES**. If the mini-keyboard is already connected to the PROLYTE, ensure that CAPS LOCK is on. The code can then be entered by typing the keys. If the code is correct, **[PASSWORD VALID!]** is displayed. If the code is not correct, then **[PASSWORD INVALID!]** is displayed and the instrument steps back to **[SERVICE LOGIN?]**.

ON	OFF	FUNCTION
APM	MPA	When on, this feature saves printer data when the printer runs out of paper. When paper is inserted and detected, saved data is printed automatically.
CPC		Enables uploading of new SW to the PROLYTE from a computer.
CSC		Restore service codes to factory settings
ECS		Enter auto calibration time span. Allowable range is 1 hour to 4 hours.
HRS	SRH	This service code will increase the resolution by one digit of Lithium results in blood and serum samples. QC and standard samples are always shown in high resolution.
LCR		Lease counter report is printed
MVE	MVD	The millivolt result for each measurement is printed
PIE	PID	Patient ID Number can be entered for each sample analyzed
PMI		Print instrument details
PNE	PND	Patient Name can be entered for each sample analyzed
PSC		Print all active service codes for verification
RST		This function deletes all saved data as well as any operator entered parameters such as QC ranges, First AUTOCAL, Blood and Urine limits.
LIS	SIL	Turns on communication between PROLYTE and PC in format shown in Section 3.14

3.12 Sample Handling and Collection

✦ *Users should refer to the Standard Clinical Chemistry Procedures published by NCCLS.*

WHOLE BLOOD

Take caution when drawing whole blood samples to avoid hemolysis. If you suspect a sample has hemolyzed, draw a fresh sample before analysis is performed. If Potassium levels are elevated, this may indicate a hemolyzed specimen. Do not use the finger-stick method. The procedure below should be followed to ensure accurate data readings:

1. Collect a blood sample by venipuncture into a Heparin evacuated blood collection tube only. Do not use Na Citrate, EDTA, ammonium heparin, or NaF tubes.

2. Record collection times.

3. Do not shake the sample. Mix gently by inverting and rotating the sample tube.

4. For best results, make sure to analyze patient samples within one hour. Results tested after one hour may yield inaccurate high Potassium levels.

PLASMA

1. Collect a blood sample by venipuncture into a Heparin evacuated blood collecting tube only. Do not exceed 15 IU per mL of heparin. Do not use Na Citrate, EDTA, ammonium heparin, or NaF tubes.

2. Record collection time.

3. Do not shake the sample. Mix gently by inverting and rotating the sample tube.

4. Within an hour of collection, spin the blood samples in a centrifuge. Using a pipette, carefully remove the top layer of plasma for analysis.

5. Make sure to run plasma samples within 4 hour. If refrigerated, bring the samples back to room temperature and spin them again in the centrifuge before analyzing.

✦*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.*

SERUM

1. Collect a blood sample by venipuncture into an untreated (red capped) tube. Be sure to fill the tube at least two-thirds full.

2. Record collection time.

3. Allow the blood sample to rest for 20-30 minutes to allow clotting to occur.

4. With an applicator stick, rim the clot, then place in a balanced centrifuge and allow spinning for 10-15 minutes. After the blood has separated, pipette the serum on top to a clean test tube.

5. While serum may be tested immediately, it can also be stored at 4˚C (refrigerated) for 24 hours or 20˚C (freezer) for up to a week. Cold or frozen samples must be brought to room temperature and well mixed before testing.

♦ *For the most accurate results, make sure all samples are free from obstructions, such as clots or fibrin, which could inhibit sample flow and yield incorrect results. Serum clearing reagents should be used.*

♦ *Be careful not to push the Sample Probe into the gel layer of a serum separator tube. Doing so may cause flow problems in the Sample Probe and fluid path.*

♦ *For statistical analysis, plasma samples are comparable to whole blood. If samples are to be stored before use, serum is preferred over plasma.*

SYRINGE SAMPLING

✦ *When using Sodium-Heparin syringes for collecting samples, fill the syringe to minimize the effect of sodium heparin on the sodium measurements.*

URINE

For more information on urine sample storage and preparation, see the standard Clinical Chemistry Procedures by NCCLS. Then the follow the procedure below:

1. Follow the above mentioned procedures for urine collection. Obtain both random and 24-hour samples.

2. Place samples in a refrigerator until you are ready to run samples.

3. Spin the urine samples in a centrifuge to remove solids.

4. Using Urine Diluent supplied by Diamond Diagnostics, dilute urine samples 9 parts Urine Diluent to 1 part urine. Do not run undiluted urine through the analyzer.

3.13 Expected Values

The values in the table below [1,2] are to be used as a guideline only. Each laboratory should establish its own reference ranges to account for factors that could affect patient electrolyte levels.

Whole Blood, Serum, Plasma (mEq/L or mmol/L)

Electrodes		Minimum	Maximum
Sodium	Na+	135	148
Potassium	K+	3.5	5.3
Chloride	Cl-	98	107
Lithium	Li+	0.6	1.2

Urine (mEq/L or mmol/L)

Electrodes		Minimum	Maximum
Sodium	Na+	40	220
Potassium	K+	25	120
Chloride	Cl-	110	250

[1] Tietz, N.W. (ed.) Fundamentals of Clinical Chemistry, 2nd ed. (1976), p. 875-877
[2] Geige Scientific Tables, Vol. 3, 8th edition

Serial LIS Protocol

A serial cable with straight through configuration is required for this process.
*To turn on communication, enter LIS service code in **[SERVICE LOGIN?]**.*

Serial communication protocol

Result Format

PARAMETER	NO OF CHARACTERS	EXAMPLE
START	1	(02 H)
CODE1	1	'S' SAMPLE
CODE2	3	ANA ANALYSIS
CODE3	3	000 RESERVED FOR FUTHER USE
DATA LENGTH	5	00037
DATE	6	ddmmyy
TIME	4	hhmm
RACK NOS	4	0000
TUBE NOS	4	0000
TEST NOS	5	00010
ID	16	PATIENT ID
NAME	16	PATIENT NAME
PATIENT TYPE	2	Human, Control, Animal
SAMPLE TYPE	1	B Blood
RESULT 1	33	Electrode Result (see break up)
RESULT 2	33	Electrode Result (see break up)
RESULT 3	33	Electrode Result (see break up)
RESULT N	33	Electrode Result (see break up)
Temperature	8	Temperature
STOP	1	(03 H)

Rows Highlighted in Green are only valid for Sample Analysis. During calibration, these are not passed in the LIS data packet.

Start Code
Hexadecimal value [02] marks the start of data packet

Analysis Code

Description	**Code1**	**Code3**	**Code3**
Sample Analysis	S	ANA	000
Calibration	C	ION	000

Data Length
Determines the data length that follows after this block

Date
Represents date in DD-MM-YY format

Time
Represents time in HHMM format

Rack Number
Represent the rack number. Not used here. Reserved for future use!

Tube Number
Represent the sample tube number. Not used here. Reserved for future use!

Test Number
Default internal sample test number give to each sample.
Patient Id
Operator assigned 16 characters long Patient Id. Default Patient Id is 16 white spaces.
Patient Name
Operator assigned 16 characters long Patient Name. Default Patient name is 16 white spaces.

Patient Type

Patient Type	Patient Type Code
Control Sample	01
Standard Sample	02
Human Sample	03
Dog Sample	04
Cat Sample	05
Cow Sample	06
Horse Sample	07
Pig Sample	08
Sheep Sample	09
Other Animal	10

Sample Type

Sample Type	Sample Type Code
Serum	1
Blood	2
Urine	3
Standard	4
QC1	5
QC2	6
QC3	7
Bicarbonate	8
Acetate	9

Sample Result [X]

Ion result is sent out in 33 characters. Table below shows the result format:

PARAMETER	NO OF CHARACTERS	EXAMPLE
ION CODE	2	01
Unit Code	1	M
Value Sign	1	+ Positive number
Value	7	0100000 1000 times Conc result
Correlation Flag	1	D Default
Error Flag	1	L Low
Sample milli-volt sign	1	+ Positive number
Sample milli-volt	7	0343400 1000 times Sample mV
Sample try Count	2	01 Number of tries for successful result
Standard milli-volt sign	1	+ Positive number
Standard milli-volt	7	0343400 1000 times Sample mV
Standard try Count	2	01 Number of tries for successful result

Ion Code List

Ion Code Parameter	Code
Na	01
K	02
Cl	03
Ca	04
Li	05
Na (Std C)	06
K (Std C)	07
Cl (Std C)	08
Ca (Std C)	09
Li (Std C)	10

Unit Code List

Unit Code	Unit Code
mmol/dL	M
mg/dL	G

Value Sign

This character represents if value is positive or negative. “+” represents positive and “-” negative numbers

Value

Ion concentration value is sent out in 7 Digits. This number is 1000 times the concentration determined in the analysis. For example, 01234560 represent value of 1234.56

Correlation Flag

Correlation Type	Flag Code
Default	D
User Correlation	U
MGL Correlation (for Ca)	M
Flame Correlation	F

Error Flag

Correlation Type	Flag Code
MV Range Error	V
Noise Error	N
Drift Error	D
Range Low	L
Range High	H
Too Low	<
Too High	>
Not Calibrated	X
Not Consistent	!
Cannot Measure	@
Li Cannot Measure	M

Reading 1 mV Sign
This character represents if value is positive or negative. “+” represents positive and “-” negative numbers. During calibration, this represents STD-A. During sample analysis, it represents Sample mV.

Reading 1 mV Value
Ion concentration value is sent out in 7 Digits. This number is 1000 times the concentration determined in the analysis. For example, 01234560 represent value of 1234.56. During calibration, this represents STD-A. During sample analysis, it represents Sample mV.

Reading 1 mV Try Count
The number represents number of tries instrument ran the standard fluid before producing stable results. During calibration, this represents STD-A.

Reading 2 mV Sign
This character represents if value is positive or negative. “+” represents positive and “-” negative numbers. During calibration, this represents STD-B. During sample analysis, it represents Standard Fluid mV.

Reading 2 mV Value
Ion concentration value is sent out in 7 Digits. This number is 1000 times the concentration determined in the analysis. For example, 01234560 represent value of 1234.56. During calibration, this represents STD-B. During sample analysis, it represents Standard Fluid mV.

Reading 2 mV Try Count
The number represents number of tries instrument ran the standard fluid before producing stable results. During calibration, this represents STD-B.

Temperature

PARAMETER	NO OF CHARACTERS	EXAMPLE
Constant	1	T
Unit Code	1	C Celsius
Value	7	0100000 100 times Actual temperature
Error Flag	1	L Low

Temperature Unit Code

Units	Unit Code
Celsius	C
Kelvin	K

Temperature Value
100 times recorded temperature value is give these 5 characters.

Temperature Flag

Flag Name	Code
Low	L
High	H

Stop Code
Hexadecimal value [03] marks end of data packet

3.14 Analyzer Surface Cleaning / Long Term Storage

Make sure the PROLYTE analyzer is in **[***STANDBY***]** before attempting to remove, clean, or replace components and before cleaning the outside of the analyzer.

Using 10% bleach solution, wipe down the outside surfaces. Do not spray bleach solution directly onto the analyzer. Be sure to wear protective equipment including gloves and safety goggles.

♦ *Do not allow the bleach solution to come in contact with the Membrane Assembly*

To take the PROLYTE analyzer out of use for more than a few days, follow the procedure outline below for disassembly and storage.

1. Turn power off and unplug the power cord from the outlet at the back of the analyzer.
2. Slide the Fluid Pack off and cover the connectors with the 4 vinyl caps from the Troubleshooting Kit.
3. Disconnect the blue end of the Pump Tubing from the Electrode Housing and remove the housing from the instrument.
4. Slide the electrodes and Sample Detector out of the Electrode Housing and separate them. Using vinyl caps filled with a few drops of Standard A Solution seal the Potassium and Chloride electrode sample path. The Solution will help prevent electrode from drying out.
5. Pour the Internal Fill Solution out of the Electrode Housing. Rinse the internal cavity with deionized or distilled water. Drain well and allow to air dry.
6. Pull the red end of the Pump Tubing from the Solutions Valve and unwind the tubing from the pump rollers. Clean up any spills. Drain any liquid from the pump tube.
7. Rinse the Solutions Value with deionized or distilled water. Dry off the Solutions Valve.
8. When the Electrode Housing is dry, place back on the PROLYTE analyzer.
9. Record the date the PROLYTE was placed into storage.

4.1 Introduction

To keep the PROLYTE running smoothly it is important to follow all maintenance procedures outlined in this manual.

When the PROLYTE analyzer experiences a problem, the display will read **[***ERROR***].** Press **YES** and the specific error will be printed out. To begin troubleshooting, look further in this section for a list of typical error messages and how to proceed with correcting them.

Prior to troubleshooting the analyzer, be sure to first put it in **[***STANDBY***].**

After troubleshooting, removing any components, or performing maintenance, the Fluid Pack will need to be primed prior to performing a calibration. Press **YES** to **[MAINTENANCE?]** then **YES** to **[SOL'N PRIME?]** Once this process is complete, press **YES** to **[RUN CALIBRT'N?] (F8).**

Human bodily fluids may be contaminated with a variety of pathogens including HIV. Handle and dispose of samples following the appropriate safety procedures for Biohazard waste products.

For Help

If the troubleshooting procedures that follow do not solve the errors shown by your analyzer, contact Diamond Diagnostics or your PROLYTE distributor for more assistance.

Troubleshooting Kit

The Troubleshooting Kit contains a variety of tools to help determine and correct analyzer errors. Below is a list supplied in this kit:

10cc syringe	Reference Electrode Tool
18 gauge blunt needle	Sodium Electrode Brush Tool
Tubing Segments	Filling Plug
Electrode Connectors	Red Vinyl Caps

Membrane Assembly, REF: ME-2258D

Red Test Dye Solution 50 ml , REF: ME-2578D

4.2 Fluid Path System

The fluid path on the PROLYTE analyzer is a closed-loop, one way system that ensures that the electrodes have fluid contact at all times. No tools are required in putting together the fluid path as all the connections can simply be pushed together.

When removing PROLYTE components to assist in troubleshooting, remove them in the following order:

1. Fluid Pack
2. Sample Tube and Pump Tubing
3. Electrode Housing
4. Sample Probe
5. Solutions Valve

Listed below is the order in which the problem areas will be discussed. Approach the problem logically by isolating the trouble area and avoiding any unnecessary processes.

PROBLEM AREA	TYPICAL ERROR MESSAGES
Fluid Flow Problems	AIR IN STD A, AIR IN STD B, AIR IN SAMPLE, AIR IN FLUSH, FLUID PATH!, SAMPLE DETECTOR! NOISE, DRIFT, AIR IN CLEANER
Membrane Assembly	LOW, HIGH, NOISE, DRIFT
Electrodes	LOW, HIGH, NOISE, DRIFT
Fluid Pack	AIR IN STD A, AIR IN STD B, AIR IN FLUSH, SOL'N PACK LOW, CHANGE PACK!, RFID MISSING
Sample Detector	SAMPLE DETECTOR!
Solutions Valve	PUMCAL FAILURE! FLUID PATH!
Printer	NO PRINTER ACTIVITY, PAPER JAM
Electromechanical	SPR SEE MANUAL! PMP SEE MANUAL!

4.2.1 Fluid Path Problems

Air leaks or blockages in the sample path will yield one or more of the following error messages, **[AIR IN STD A], [AIR IN STD B], [AIR IN SAMPLE], [FLUID PATH!],** and **[SAMPLE DETECTOR!].** These messages mean there is a fluid flow problem that needs to be corrected. Sometimes, other messages, such as **[NOISE]** or **[DRIFT]** may also indicate fluid flow problems.

If the error messages **[AIR IN STD A], [AIR IN STD B],** or **[AIR IN FLUSH],** the problem may be the Fluid Pack. If a pack is running low or is empty, solution cannot be pumped and the sample path will be empty. If this is a possibility, refer to section **4.2.4-Fluid Pack** for troubleshooting information. If the Fluid Pack has been eliminated as the source of the problem, proceed with the following.

If **[AIR IN STD A], [AIR IN STD B],** or **[FLUID PATH!]** errors occur during a **[SOLUTION PRIME?]** or **[RUN CALIBRT'N?] (F8)** remove the Electrode Housing and check to make sure all the electrodes are installed correctly, with the letters all facing right side up, and all the Electrode Connectors properly fitted between the electrodes. After re-installing the Electrode Housing, try the **[SOLUTION PRIME?]** or **[RUN CALIBRT'N?] (F8)** again. If the problem persists, continue below.

1. Test the analyzer to see if the fluidics system is working properly by pressing **YES** to **[FLUID FLOW TEST?]** under **[*DIAGNOSTICS?*]** Run the Red Dye Test Solution from the Troubleshooting Kit as a sample and watch the fluid flow through the sample path. If the red dye is drawn properly and there are no problems with the Sample Detector, you will see **[FLUID FLOW OK].** If this test is successful, try a **[SOLUTION PRIME?]** again.

2. If the **[FLUID FLOW TEST?]** is unsuccessful, you will see **[FLOW TEST FAIL!]** on the display and also on the print out. Make sure all the tubing is connected properly. This failure may cause air leaks. Check to see if there is cracking on the ends of the Sample Tubing and replace if necessary. Remove the Pump Tubing to check for crimping and replace if necessary. Attempt the **[FLUID FLOW TEST?]** again.

3. If the test still fails and no air leaks or obstructions are seen in the Sample or Pump Tubing, you will now have to remove each individual component to make sure there is no blockage. First check the Sample Probe as it has the greatest chance of having an obstruction due to the small hole at the base. To remove the Sample Probe, first remove the Fluid Pack, followed by the Sample Tube from the probe and the Pump Tubing from the Electrode Housing. Then remove the Electrode Housing and slide the Sample Probe out of the Solutions Valve. Check to see if there are any obstructions in the probe by using the 10cc syringe and the tubing segment found in the Troubleshooting Kit. Force warm water through the probe followed by air. The water should flow freely from the probe without any interruption. Reinstall all the components back on the PROLYTE and attempt **[FLUID FLOW TEST?]** again. If successful, perform a **[SOLUTION PRIME?]**

4. If the blockage is not in the Sample Probe, continue component check with the electrode stack. Using the 10cc syringe and 18 gauge blunt needles, insert the needle into the Sample Tube which is connected to the Sample Detector. Ensure the Pump Tube is not wound around the pump rollers and is disconnected from the Solutions Valve. **Gently** push water through the Sample Tube, electrode stack, and Pump Tubing. If the fluid flow is uninterrupted, reconnect the tubing as appropriate and try the **[FLUID FLOW TEST?]** again. If there is resistance, disconnect each component and push water through them individually. If all components are clear, the blockage may be in the Membrane Assembly. Replace the Membrane Assembly. Prior to reassembly of the electrode stack, wipe all components dry, especially the electrode pins. Reassemble the electrode stack and ensure the Solution Valve and Sample Probe are installed correctly before placing the Electrode Housing on the instrument. Perform **[FLUID FLOW TEST?]**, **[SOLUTION PRIME?]** and **[SAMPLE DET. TEST?].** If the tests are successfully completed, initiate **[RUN CALIBRT'N?] (F8).**

4.2.2 Membrane Assembly

Low or erratic sample readings, low Na^+ cal values occurring at the same time as high K^+ cal values, and some NOISE error are possible signs of Membrane Assembly problems. Partial blockage of the membrane assembly can cause irregular (normal then slow or fast) fluid flow.

1. Check to see if there are air bubbles around the Membrane Assembly. Tap the Electrode Housing window to remove any bubbles that may be present, if tapping does not remove the bubbles. Remove the Electrode Housing and tip it over a few times, making sure to securely block the fill port to prevent leaking. Also check to make sure all electrode pins and instrument jacks are clean and dry. Clean the Reference Electrode pin and instrument jack particularly if low or erratic readings occur. Run the **[FLUID FLOW TEST?]** again.

2. If this instrument passes the **[FLUID FLOW TEST?]** and there are no bubbles around the Membrane Assembly but the errors continue, the Membrane Assembly should be replaced. Run the **[FLUID FLOW TEST?]** again.

Diamond Diagnostics only guarantees the Membrane Assembly's performance for 3 months. Since the replacement greatly depends on sample volume and type of samples, high volume of lipemic and high protein samples require more frequent changes of the Membrane Assembly. The Membrane Assembly may need to be replaced more or less frequently than this (3 month = about 100 samples a week). However, do not leave the Membrane Assembly on for more than 6 month.

✦ *Change the Internal Filling Solution when the Membrane Assembly is replaced.*

4.2.3 Electrodes

If after Calibration, **[LOW], [DRIFT],** or **[NOISE]** is observed, this may be indicative of electrode failure. Electrodes with **[HIGH]** calibration errors are usually indicative of a faulty Membrane Assembly.

1. If the calibration values for the electrodes fall outside of their ranges (50-64 for Na^+/K^+, 40-64 for Cl^-), the values will be flagged as either **[HIGH]** or **[LOW].** If the PROLYTE does not calibrate successfully on its first attempt, a second will begin automatically. After the second calibration, the analyzer will report sample results on any electrode not flagged for calibration errors.

2. If only Na^+ has: **[LOW], [DRIFT],** or **[NOISE]** errors, the electrode may need to be conditioned again. Use the **[FLUSH?]** option in **[MAINTENANCE?] (F4)**. After the **[FLUSH?]** cycle, the PROLYTE will go into **[***STANDBY***]**. Exit Standby and attempt a calibration. If the Na^+ calibration value continues to be low the electrode may have protein built up on its surface.

♦ *Do not attempt the following procedures as preventative maintenance. Do not attempt to clean the electrodes if the calibration values are within range and without errors.*

   Remove the Na^+ electrode from the electrode stack. Slide the Sodium Electrode Brush Tool from the Troubleshooting Kit through the electrode sample path then slowly pull it back out. Never use the Sodium Electrode Brush Tool on the Potassium, Chloride or Lithium electrodes. Reassemble the electrode, prime the system using **[SOLUTIONS PRIME?],** run **[DAILY CLEANER?]**, then **[RUN CALIBRT'N]**. If the sodium cal values remain low, replace the Na electrode.

3. If only K^+ has: **[LOW], [DRIFT]** or **[NOISE]** error, the electrode may need replacing. Before replacing first clean the electrode using **[DAILY CLEANER?].** Then perform another calibration, if the error message persists, replace the K^+ electrode.

4. If only Cl^- has: **[LOW], [DRIFT]** or **[NOISE]** error, the electrode may need replacing. Before replacing, first clean the electrode using **[DAILY CLEANER?].** Then perform another calibration, if the error message persists, replace Cl^- Electrode.

5. If only Li^+ has: **[LOW], [DRIFT]** or **[NOISE]** error, the electrode may need replacing. Before replacing, first clean the electrode using **[DAILY CLEANER?].** Then perform another calibration, if the error message persists, replace Li^+ Electrode.

6. If Na^+ (around 55) and Cl^- (around 48) are low, whereas K is high (approx. 64), membrane assembly is problem source. Changing membrane assembly should fix the issue.

7. When all the electrodes have low or high cal values the Membrane Assembly or Reference Electrode is probably the cause of the problem. However another possibility is that the wrong Fluid Pack is installed. Verify installed Fluid Pack's part number is IL-2121D. Do not use any other Fluid Pack.

8. If **[DRIFT]** or **[NOISE]** errors occur on all electrodes, ensure that the internal fill solution is filled to the fill line. Internal fill solution eliminates external noise and produces stable measurements. In addition, instrument must have proper electrical grounding. If the problem persists, Fluid Flow problems (see Sec 4.2.1) or a Membrane Assembly (see Sec 4.2.2) issue is more probable. Refer to these sections for more information on Troubleshooting. Also check to make sure all electrode pins and outlets are clean and dry, including the Reference Electrode. After reinstalling the Electrode Housing, run **[SOLUTIONS PRIME?]** and **[RUN CALIBRT'N].** If **[DRIFT]** or **[NOISE]** persists, please contact your Diamond Diagnostics Representative or your PROLYTE Distributor.

4.2.4 Fluid Pack

The following errors may imply that your Fluid Pack is low and in need of replacement: **[AIR IN STD A], [AIR IN STD B], [SOL'N PACK LOW!], [CHANGE PACK!]**

The PROLYTE tracks Fluid Pack consumption. When the Fluid Pack consumption reaches 90% **[SOL'N PACK LOW!]** is reported. At 99% consumption, **[CHANGE PACK!]** will be displayed. No additional analysis can be done. The Fluid Pack must be changed. Each time a new Fluid Pack is installed, The Fluid Pack consumption counter needs to be changed to zero (see Fluid Pack Usage on page 27 for more details).

1. The Fluid Pack, on rare occasion, can have an air leak resulting in **[AIR IN STD A], [AIR IN STD B]** and/or **[AIR IN FLUSH].** Keeping the Fluid Pack upright, attach the 10cc syringe with the tubing segment from the Troubleshooting Kit to the appropriate fluid connector. Withdraw the syringe barrel to draw solutions into the syringe. A continuous stream of reagent without air bubbles means the pack is working properly. If the fluid has air bubbles or there is no liquid at all, there is an internal problem with the Fluid Pack. Install a new Fluid Pack.

♦ *Discard any solution drawn into the syringe. Refilling the pack with the solution in the syringe may lead to inaccurate results.*

2. The waste compartment in the Fluid Pack stores waste from samples and standards. The compartment has a check valve which allows waste to flow in but not back out. The check valve occasionally will seal and fluid cannot flow from the analyzer into the waste compartment. This may cause the error message **[AIR IN STD B].** To open the check valve, perform the following steps:

   - Remove the Fluid Pack from the Solutions Valve.
   - Fill the 10cc syringe with 3-5mL of water and attach the tubing segment from the Troubleshooting Kit.
   - Attach the tubing segment to the waste connector of the Fluid Pack, which is the top connector
   - Force the water into the Fluid Pack to open the check valve.
   - Remove the tubing and syringe and slide the Fluid Pack back into the Solutions Valve.
   - Run **[SOLUTION PRIME?]**

3. If the Fluid Pack runs out of Flush solution, it can still be used until it runs out of Standards A or B. The error message **[AIR IN FLUSH]** will display during **[RUN CALIBRT'N?] (F8)**. **[USE EXT. FLUSH?]** will be displayed. During a **[SOLUTION PRIME?]**, **[AIR IN FLUSH]** may also occur but it will not interrupt the prime process when **[AIR IN FLUSH]** occurs. When **[FLUSH?]** is initiated, **[USE EXT. FLUSH?]** will be displayed. After flushing **[RUN CALIBRT'N?] (F8)** must be completed before sample analysis**.**

✦ *If external flush is not on hand, you may use the Red Dye Test Solution as a temporary fix. However, it is not recommended for long term use. Flush solution is needed for proper maintenance of sodium electrodes.*

4.2.5 RFID Errors

Below are the errors and troubleshooting steps for RFID:

a. [**INVALID PACK**] – Installed pack has invalid RFID tag. This error can be due to wrong RIFD tag, invalid barcode entry, or instrument is not able to detect the RFID tag.
    a. Troubleshooting – Under Diagnostics Menu, select Check RFID Sensor. With fluid pack installed, press YES button to scan the tag. If tag is found, there is no issue with RFID reader. Please input the barcode again to see if the error persists. Contact Diamond Diagnostics if needed.
b. [**Expired Pack**] – Installed pack is expired. Each pack has limited shelf life. Using the pack beyond this period, produce unreliable results. To prevent this, instrument gives this error.
    a. Troubleshooting – Confirm the expiry date on the pack label.
c. [**Change Pack**] – PROLYTE monitors pack usage. When the calculated consumptions reaches 100%, instrument gives this error to prevent sample wastage.
    a. Troubleshooting – Check the pack volume under Operators Menu>Pack Usage?
d. [**Duplicated Pack**] – This error indicates pack RFID tag has an unexpected value. Please contact Diamond Diagnostics if you receive this error frequently.
    a. Troubleshooting – Re-enter the pack barcode to confirm the error was not due to invalid barcode.
e. **[Missing RFID]** – RFID tag not found in Fluid Pack.
    a. Troubleshooting – Verify Fluid Pack label has a barcode. Ensure the Fluid Pack is pushed into solutions valve and fluid pack front is flush with the instrument. Press**(F7)** for **[DIAGNOSTICS?],** then press **YES**. Press **NO** until **[CHECK RFID SENSOR]** is displayed, Then press **YES.** At **[TAG STATUS],** press **YES.** If **[TAG FOUND]** is displayed, proceed with test. If **[TAG NOT FOUND],** then replace the pack.

4.2.6 Sample Detector

The Sample Detector senses air and fluid differently. This allows for correct positioning of all fluids, including sample, flush and standards. To verify that the Sample Detector is working properly, press **YES** to **[SAMPLE DET. TEST?]** under **[*DIAGNOSTICS?*].** During this test the PROLYTE will draw a small amount of Standard A followed by air. The detected liquid and the air values are displayed and printed.

The Sample Detector is not functioning correctly if the difference between the liquid and air values is less than 50. **[SAMPLE DETECTOR!]** will be displayed which indicates the Sample Detector needs cleaning. Separate the Sample Detector from the electrode stack. Slide the Sodium Electrode Brush Tool from the Troubleshooting Kit gently into the pathway and pull back out. Return the Sample Detector to the electrode stack. Initiate a **[SOL'N PRIME?],** followed by **[DAILY CLEANER?].** Perform the **[SAMPLE DET. TEST?]** again.

If the Sample Detector is working properly, the Sample Detector liquid value is usually less than 150 and the Sample Detector air value is usually greater than 200.

If both the liquid and air values are 255, or the same value, the Sample Detector has a poor connection to the PROLYTE. Verify the Electrode Housing is correctly positioned and the Sample Detector is pushed into the instrument completely. Look down to the left of the Sample Detector from above the Electrode Housing. A red light should be reflected off the surface. If the light is not on and the Sample Detector is positioned correctly on the instrument, remove the Electrode Housing. Check the pins on the back of the Sample Detector if damaged, bent or broken. If the detector appears undamaged, return to the analyzer. Check for the red light again. If the Sample Detector is on, then it is installed correctly. If the red light is not on, replace the Sample Detector.

4.2.7 Solutions Valve

If **[PUMPCAL FAILURE!]** or **[FLUID PATH!]** errors are observed during a calibration and the analyzer passed **[SOL'N PRIME?],** Solutions Valve needs to be checked for correct functionality.

Initiate **[PUMPCAL TEST?],** under **[*DIAGNOSTICS*].** If the test is successful **[PUMPCAL OK]** will be displayed and print. If the test is not successful **[PUMPCAL FAILURE!]**, will be displayed and no pump cal values will print.

To correct **[PUMPCAL FAILURE!]**, using the finger grip on the Solutions Valve pull the Solutions Valve off the analyzer. Flush each valve opening with air using the syringe. Fill the syringe with warm tap water. Insert the syringe into each Solutions Valve opening and flush. After flushing, fill the syringe with air again and flush each Solutions Valve opening. Slide the Solutions Valve back on the analyzer, after reinstalling all components initiate [**SOLUTION PRIME?]**, then run the following tests under **[*DIAGNOSTICS?*] – [FLUID FLOW TEST?], [SAMPLE DET TEST?], [PUMP CAL TEST?].** If all tests are successful, **[RUN CALIBRT'N?] (F8).** If **[PUMPCAL FAILURE!]** or **[FLUID PATH!]** occur during calibration, replace the Solutions Valve.

4.2.8 Printer

Follow the procedure outlined below if the PROLYTE analyzer does not print:

1. Ensure the printer is turned on. Under **[*OPER FUNCTS?*]** then **[PRINTER SETTINGS?]** press **NO** when prompted **[PRINTER OFF?]**.

2. PRINTER ON and Date/Time will print. If PRINTER ON does not print, press the paper feed button. If paper does not advance, check to make sure the printer head is clear of all paper jams and, if necessary, carefully remove to avoid damaging the printer.

3. Reload the paper into the printer. Use the feed button if necessary.

4. If the printer still does not print and paper has wrinkled left or right edge, press the feed button until the paper is centered in the printer.

Press **NO** until **[DIAGNOSTICS?] (F7)** is displayed. Press **YES** and the printer should print Diagnostics.

4.2.9 Electromechanical

For SPR errors, no power, or a blank display follow the procedures below:

1. Turn the power off for 5 seconds, and then turn the analyzer back on. **[**PROLYTE**]** should now be displayed, the Sample Probe should move down, and then up, and the pump should turn.
2. The display should have **[RUN CALIBRT'N].**
3. If calibration is successful, continue as usual.
4. If the error messages continue, contact Diamond Diagnostics or your PROLYTE distributor.

4.3 Performance Verification

Some laboratories or offices may require that you confirm the analyzer is performing properly. If this is the case, follow the procedures outlined below:

Calibration

1. Perform a calibration by pressing **YES** at the **[RUN CALIBRT'N?] (F8)** prompt.
2. Check that Standard B and Standard A are drawn from the Fluid pack and measured in the electrode stack.
3. When **[ANALYZE BLOOD?] (F1)** is displayed, the calibration has been successful. If the calibration is unsuccessful, refer to Troubleshooting for instructions.

Accuracy

1. Perform a calibration by pressing **YES** at the **[RUN CALIBRT'N?] (F8)** prompt
2. Run three levels of Quality Control materials in triplicate and record results.
3. Verify that the average QC value for each parameter is within the expected ranges for the given electrode on the assay sheet provided with the Quality Controls.
4. Repeat for three days.
5. The average values should be within the expected ranges for the given electrode on the assay sheet provided with the Quality Controls.

Precision

1. Obtain 5 patient samples. Measure each sample 10 times in a row and record the data.
2. For each sample determine the Mean, S.D. and C.V.
3. The CV of each parameter for each sample should be comparable to the specifications on page 69.

Correlation

Compare the PROLYTE to a reference electrolyte analyzer available in your laboratory or office, complete the following:

1. Obtain at least 20 patient samples.
2. Measure on both the PROLYTE and the other analyzer.
3. For each sample determine the difference between the values collected on the PROLYTE and the other analyzer.
4. Have the laboratory manager review the results to determine if the results are acceptable.

Understanding the display messages of the PROLYTE analyzer

Display Message	Explanation
AIR IN CLEANER	Daily Cleaner improperly detected.
AIR IN CONTROL	Quality Control sample improperly detected.
AIR IN SAMPLE	Sample improperly detected.
AIR IN STD A	Standard A improperly detected.
AIR IN STD B	Standard B improperly detected.
AIR IN FLUSH	Flush improperly detected.
ALL LEVEL 1?	Deletes all stored Level 1 Quality Control results.
ALL LEVEL 2?	Deletes all stored Level 2 Quality Control results.
ALL LEVEL 3?	Deletes all stored Level 3 Quality Control results.
ALL RESULTS?	Prints all stored results.
ANALYZE BLOOD?	Displayed after successful calibration. Mode for Blood, Serum, and Plasma.
ANALYZE URINE?	Urine analysis mode.
ANALYZING…	Sample measurement in process.
ASPIRATING…	Sample is drawn into probe.
AUTOCAL?	Activates AUTOCAL and allows the time to be set for automatic daily calibration.
BLOOD CL LIMITS?	Edit/View normal Cl range for Blood, Serum, and Plasma.
BLOOD K LIMITS?	Edit/View normal K range for Blood, Serum, and Plasma.
BLOOD Li LIMITS?	Edit/View normal Li range for Blood, Serum, and Plasma.
BLOOD NA LIMITS?	Edit/View normal Na range for Blood, Serum, and Plasma.
CAL VALUES?	Displays last calibration values.

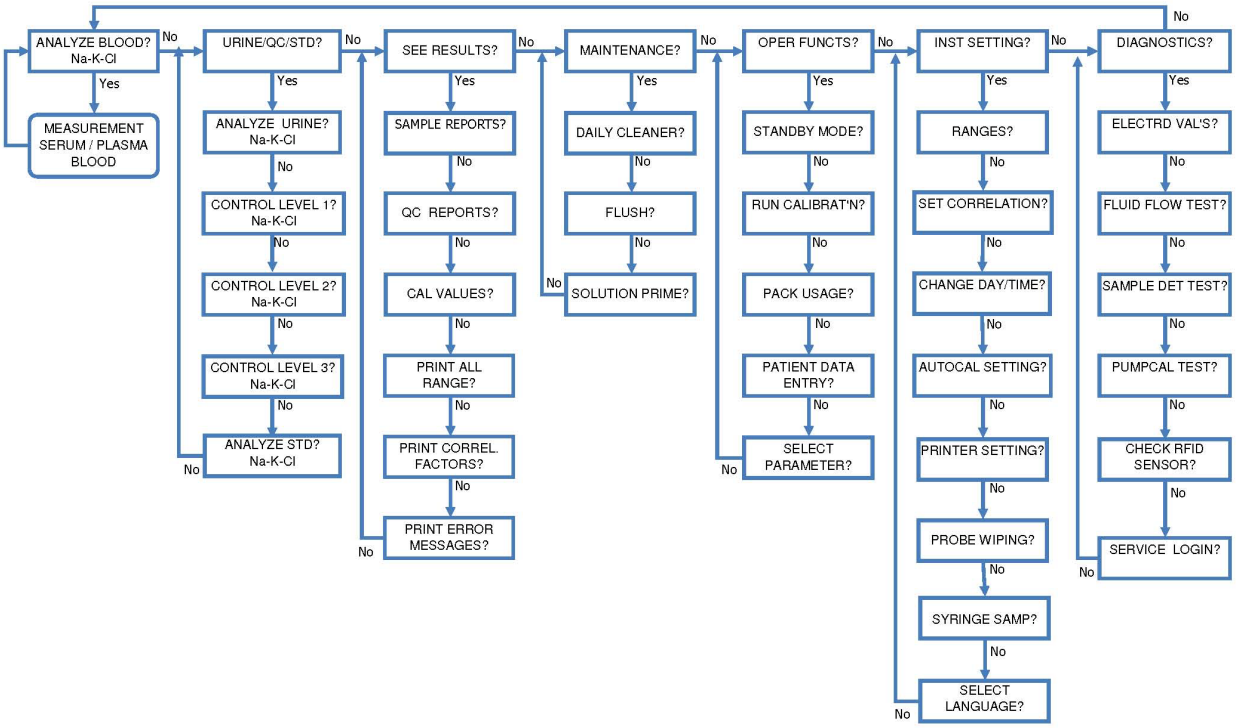
Display Message	Explanation
CALIBRATING…	Calibration in process.
CALIBR'TING STD A	Standard A being calibrated currently.
CALIBR'TING STD B	Standard B being calibrated currently.
CHANGE DAY/ TIME?	Edit/View the date and time.
CHANGE HOUR?	Edit/View the time when first auto calibration will occur.
CHANGE PACK!	Fluid Pack must be replaced. Displays when more than 99% of pack consumed.
CLEANING…	Daily Cleaning in process.
Cl HIGH…	Chloride result is higher than normal range.
Cl LOW…	Chloride result is lower than normal range.
CONTINUE?	Confirm to proceed.
CONTROL LEVEL 1?	To run and print Quality Control Level 1.
CONTROL LEVEL 2?	To run and print Quality Control Level 2.
CONTROL LEVEL 3?	To run and print Quality Control Level 3.
CORRELATE BLOOD?	Edit/View correlation equations for whole blood, serum and plasma.
CORRELATE URINE?	Edit/View correlation equations for urine.
CORRELATED VALUES	Printed under results when correlation option is on.
CORRELATION ON?	Edit/View correlation equations.
C.V. VALUES?	Displays and prints out % C.V.'s of Quality Control results.
DAILY CLEANER?	Performs Daily Cleaning.
DAILY SUMMARY?	Prints all results for the last day.
DELETE CONTROLS?	Deletes stored control results from memory.
DELETE RESULTS?	Deletes patient sample results from memory.
DIAGNOSTICS?	Check key analyzer functions.
DILUTED 1:10?	Confirms that urine has been diluted before analyzing.
DRIFT CL	Chloride electrode drifts outside of acceptable range.
DRIFT K	Potassium electrode drifts outside of acceptable range.
DRIFT Li	Lithium electrode drifts outside of acceptable range.
DRIFT NA	Sodium electrode drifts outside of acceptable range.
DRIFT, RECAL…	Automatic recalibration due to electrode drift.
ELECTR'D VALUES?	Displays current electrode millivolt readings.

Display Message	Explanation
ERROR	Indicates an error has occurred. Press **YES** or **NO** to show precise error.
FLUID FLOW OK	Fluid Flow Test passed.
FLUID FLOW TEST?	Tests sample path with Red Test Dye Solution.
FLUID PATH!	Fluid or air not detected properly.
I.D # ---	Print out of assigned identification number for patient sample.
K HIGH…	Potassium result is higher than normal range.
K LOW…	Potassium result is lower than normal range.
LAST CONTROL?	Displays and prints out last Quality Control result.
LAST RESULT?	Displays and prints out last sample result.
LEVEL 1 RANGES?	Edit/View /Set Level 1 QC ranges.
LEVEL 2 RANGES?	Edit/View /Set Level 2 QC ranges.
LEVEL 3 RANGES?	Edit/View /Set Level 3 QC ranges.
Li HIGH…	Lithium result is higher than normal range.
Li LOW…	Lithium result is lower than normal range.
MEAN VALUES?	Displays and Prints out mean values of Quality Control results.
MUST USE CLEANR!	Daily Cleaner must be used before calibration can occur.
MV RANGE CL	Cl electrode is outside mV range.
MV RANGE K	K electrode is outside mV range.
MV RANGE Li	Li electrode is outside mV range.
MV RANGE NA	Na electrode is outside mV range.
NA HIGH…	Sodium result is higher than normal range.
NA LOW…	Sodium result is lower than normal range.
NEXT SAMPLE?	Proceed to ANALYZE BLOOD? for sample analysis.
NOISE	Denotes an erratic signal from electrodes.
NOISE, RECAL…	Automatic recalibration due to electrode noise.
NORMAL RANGES?	Edit/View /Set normal ranges.
NOT ENOUGH DATA!	Displays when less than 5 data points are available to calculate statistics.
OPER FUNCTS?	Select on-demand Standby, Flush, Calibration.
PACK USAGE	Displays and prints percentage of Fluid Pack used.
PATIENT ID#?	Turns on function that allows operator to enter patient identification numbers.

Display Message	Explanation
CONTROL 1 RANGE?	Edit/View Control Level 1 Na, K, Cl, Li ranges.
CONTROL 2 RANGE?	Edit/View Control Level 2 Na, K, Cl, Li ranges.
CONTROL 3 RANGE?	Edit/View Control Level 3 Na, K, Cl, Li ranges.
SPR	Mechanical problems with Sample Probe.
PRIMING STD A	Standard A fluid line is being primed.
PRIMING STD B	Standard B fluid line is being primed.
PRIMING FLUSH	Flush Solution fluid line is being primed.
PRINTER OFF?	Turns printer function on or off.
PRINTING…	Requested data is printing.
PRNT STATISTICS?	Prints Quality Control statistical summaries.
WEEKLY SUMMARY?	Prints all results from the last five days.
PROBE IN BLOOD?	Confirms that probe is in the patient sample.
PROBE IN CLEANER?	Confirms that probe is in Daily Cleaner.
PROBE IN CONTROL?	Confirms that probe is in Quality Control sample.
PROBE IN DYE?	Confirms that probe is in Red Test Dye Solution.
PROBE IN URINE?	Confirms that probe is in urine.
PROBE IN FLUSH?	Confirms that probe is in external flush solution.
PROBE WIPING ON?	Turns on probe wiping, Probe retraction delayed for wiping.
PUMP CAL…	Pump calibration in process.
PUMPCAL FAILURE!	Pump calibration failed.
PUMPCAL OK	Pump calibration passed.
PUMPCAL TEST?	Test pump calibration.
QUAL CONTROLS?	Choose Quality Control functions.
REMOVE CONTROL	Remove Quality Control sample from probe (probe wiping on).
REMOVE SAMPLE	Remove sample from probe (when probe wiping on).

Display Message	Explanation
RUN CALIBRT'N?	Calibrates analyzer.
RUN CONTROL?	Analyzes Quality Control Samples.
SAMPLE CAL…	Sample Detector calibration in process.
SAMPLE DETECT OK	Sample Detector test passed.
SAMPLE DETECTOR!	Sample Detector test failed.
SAMPLE DET. TEST?	Tests Sample Detector.
STATISTICS?	View/print QC statistics.
SELECT PARAMETERS?	Allows the operator to switch between Cl and Li.
STANDBY/INVALID	Fluid Pack Error and barcode needs to be entered.
STANDBY/AIR IN STD A	Standard A improperly detected.
STANDBY/RFID MISSING	RFID Tag is not detected.

5.1 Overall Program Flow



5.2 PROLYTE Specifications and Reportable Ranges

Sample:	Whole Blood, Serum, Plasma or Urine
Sample Size:	100 uL Whole Blood, Serum, Plasma or 400 uL diluted (1:10) Urine
Measurement Range:	Blood Na^+: 45 - 205 mEq/L (SI Units mmol/L) K^+: 1.5 - 11 mEq/L (SI Units mmol/L) Cl^-: 45 - 205 mEq/L (SI Units mmol/L) Li^+: 0.15 – 5.0 mEq/L (SI Units mmol/L) Urine (spot) Na^+: 25 - 1020 mEq/L (SI Units mmol/L) K^+: 10 - 505 mEq/L (SI Units mmol/L) Cl^-: 25 - 505mEq/L (SI Units mmol/L) Li^+ is not measured in Urine
Display Resolution:	Na^+: 0.1 mEq/L (SI Units mmol/L) K^+: 0.01 mEq/L (SI Units mmol/L) Cl^-: 0.1 mEq/L (SI Units mmol/L) Li^+: 0.01 or 0.001 mEq/L (SI Units mmol/L)
Analysis Time:	60 sec. (blood), 70 sec. (Urine)
Data Storage, (on board RAM)	1000 Patient results 500 Level 1 QC results 500 Level 2 QC results 500 Level 3 QC results
Calibration:	Automatic or on demand
Connectivity:	Analyzer has an output for a printer/computer

Expected Performance:

Reproducibility: Typical Within Run Imprecision

Whole Blood, mEq/L

	Na+	K+	Cl-
Mean	114.27	2.678	70.79
SD	0.69	0.021	0.57
%CV	**0.60**	**0.79**	**0.80**
N	30	30	30
Pass/Fail	P	P	P

	Na+	K+	Cl-
Mean	136.11	4.103	96.02
SD	0.80	0.032	0.62
%CV	**0.58**	**0.78**	0.64
N	30	30	30
Pass/Fail	P	P	P

	Na+	K+	Cl-
Mean	160.57	6.887	125.42
SD	1.47	0.083	0.91
%CV	**0.91**	**1.20**	0.72
N	30	30	30
Pass/Fail	P	P	P

Plasma, mEq/L

	Na+	K+	Cl-
Mean	93.07	2.376	61.27
SD	0.89	0.036	0.46
%CV	0.95	1.50	0.75
N	30	30	30
PASS/FAIL	P	P	P

	Na+	K+	Cl-
Mean	142.95	4.354	103.69
SD	0.78	0.037	0.59
%CV	0.55	0.85	0.57
N	32	32	32
PASS/FAIL	P	P	P

	Na+	K+	Cl-
Mean	165.80	6.622	123.57
SD	1.04	0.031	0.58
%CV	0.63	0.46	0.47
N	30	30	30
PASS/FAIL	P	P	P

Serum, mEq/L

	Na+	K+	Cl-
Mean	120.10	3.026	70.30
SD	0.77	0.020	1.03
%CV	**0.64**	**0.66**	**1.47**
N	30	30	30
PASS/FAIL	P	P	P

	Na+	K+	Cl-
Mean	145.16	4.755	97.02
SD	0.86	0.034	0.65
%CV	**0.59**	**0.70**	**0.67**
N	30	30	30
PASS/FAIL	P	P	P

	Na+	K+	Cl-
Mean	163.21	6.536	118.80
SD	1.12	0.056	1.48
%CV	**0.68**	**0.85**	**1.25**
N	30	30	30
PASS/FAIL	P	P	P

Urine, mEq/L

	Na+	K+	Cl-
Mean	33.26	31.967	52.89
SD	0.18	0.290	0.91
%CV	0.54	0.91	1.72
N	30	30	30
PASS/FAIL	P	P	P

	Na+	K+	Cl-
Mean	121.83	78.548	184.34
SD	0.83	0.384	1.15
%CV	0.68	0.49	0.62
N	30	30	30
PASS/FAIL	P	P	P

	Na+	K+	Cl-
Mean	202.84	112.432	274.38
SD	1.11	0.945	1.52
%CV	0.55	0.84	0.56
N	30	30	30
PASS/FAIL	P	P	P

Reproducibility: Typical Total Imprecision

Whole Blood, mEq/L

	Na+	K+	Cl-
Mean	113.69	2.649	71.24
SD	1.06	0.032	0.92
%CV	**0.93**	**1.23**	**1.30**
N	40	40	40
Pass/Fail	P	P	P

	Na+	K+	Cl-
Mean	136.36	4.103	96.51
SD	0.99	0.024	1.09
%CV	**0.72**	**0.59**	1.13
N	39	40	39
Pass/Fail	P	P	P

	Na+	K+	Cl-
Mean	161.22	6.924	126.41
SD	1.37	0.149	1.37
%CV	**0.85**	**2.15**	**1.09**
N	40	40	40
Pass/Fail	P	P	P

Plasma, mEq/L

	Na+	K+	Cl-
Mean	118.98	2.902	74.01
SD	0.85	0.050	0.93
%CV	0.71	1.73	1.25
N	40	40	40
PASS/FAIL	P	P	P

	Na+	K+	Cl-
Mean	143.89	4.502	99.58
SD	1.00	0.056	0.83
%CV	0.70	1.25	0.83
N	40	40	40
PASS/FAIL	P	P	P

	Na+	K+	Cl-
Mean	160.66	6.230	121.81
SD	0.94	0.092	0.99
%CV	0.59	1.48	0.81
N	40	40	40
PASS/FAIL	P	P	P

Serum, mEq/L

	Na+	K+	Cl-		Na+	K+	Cl-		Na+	K+	Cl-
Mean	119.04	2.970	69.02	**Mean**	144.03	4.732	100.13	**Mean**	160.71	6.502	119.93
SD	0.91	0.027	1.24	**SD**	1.26	0.038	0.83	**SD**	1.66	0.078	1.05
%CV	0.76	0.91	1.80	**%CV**	0.88	0.80	0.83	**%CV**	1.03	1.19	0.87
N	40	40	40	**N**	40	40	40	**N**	40	40	40
PASS/FAIL	P	P	P	**PASS/FAIL**	P	P	P	**PASS/FAIL**	P	P	P

Urine, mEq/L

	Na+	K+	Cl-		Na+	K+	Cl-		Na+	K+	Cl-
Mean	119.04	2.970	69.02	**Mean**	144.03	4.732	100.13	**Mean**	160.71	6.502	119.93
SD	0.91	0.027	1.24	**SD**	1.26	0.038	0.83	**SD**	1.66	0.078	1.05
%CV	0.76	0.91	1.80	**%CV**	0.88	0.80	0.83	**%CV**	1.03	1.19	0.87
N	40	40	40	**N**	40	40	40	**N**	40	40	40
PASS/FAIL	P	P	P	**PASS/FAIL**	P	P	P	**PASS/FAIL**	P	P	P

Reproducibility: Within Run Imprecision at Instrument Reporting Limits

Whole Blood, mEq/L

	Na+	K+	Cl-
Mean	53.15	1.678	47.90
SD	0.53	0.025	0.88
%CV	1.0	1.5	1.8
N	30	30	30
Pass/Fail	P	P	P

	Na+	K+	Cl-
Mean	193.33	10.363	196.26
SD	1.48	0.056	2.00
%CV	0.76	0.54	1.0
N	30	30	30
Pass/Fail	P	P	P

Plasma, mEq/L

	Na+	K+	Cl-
Mean	53.10	1.753	49.64
SD	0.65	0.025	0.83
%CV	1.23	1.41	1.68
N	30	30	30
Pass/Fail	P	P	P

	Na+	K+	Cl-
Mean	189.21	9.6407	197.15
SD	1.10	0.0934	1.26
%CV	**0.58**	0.97	0.64
N	30	30	30
Pass/Fail	P	P	P

Serum, mEq/L

	Na+	K+	Cl-
Mean	54.01	1.693	53.38
SD	0.46	0.024	0.88
%CV	0.85	1.41	1.65
N	30	30	30
Pass/Fail	P	P	P

	Na+	K+	Cl-
Mean	187.37	9.914	180.09
SD	0.94	0.070	1.42
%CV	**0.50**	**0.71**	0.79
N	30	30	30
Pass/Fail	P	P	P

Urine, mEq/L

	Na+	K+	Cl-
Mean	28.52	11.63	39.91
SD	0.56	0.14	0.99
%CV	1.95	1.17	2.47
N	30	30	30
Pass/Fail	P	P	P

	Na+	K+	Cl-
Mean	908.9	493.1	420.9
SD	6.4	3.1	1.8
%CV	0.70	0.62	0.42
N	30	30	30
Pass/Fail	P	P	P

Reproducibility: Total Imprecision at Instrument Reporting Limits

Whole Blood, mEq/L

	Na+	K+	Cl-
Mean	53.46	1.667	48.93
SD	0.71	0.030	0.83
%CV	1.33	1.82	1.70
N	40	40	40
Pass/Fail	P	P	P

	Na+	K+	Cl-
Mean	195.85	10.337	190.47
SD	1.91	0.109	3.05
%CV	0.98	1.05	1.60
N	40	18	40
Pass/Fail	P	P	P

Plasma, mEq/L

	Na+	K+	Cl-
Mean	55.43	1.7795	50.07
SD	0.83	0.0297	0.87
%CV	1.49	1.67	1.73
N	40	40	40
Pass/Fail	P	P	P

	Na+	K+	Cl-
Mean	189.28	9.709	198.86
SD	1.39	0.065	1.97
%CV	0.74	0.67	0.99
N	40	40	40
Pass/Fail	P	P	P

Serum, mEq/L

	Na+	K+	Cl-
Mean	55.26	1.700	53.56
SD	0.75	0.028	0.93
%CV	1.36	1.66	1.73
N	40	40	40
Pass/Fail	P	P	P

	Na+	K+	Cl-
Mean	187.10	9.9300	181.39
SD	1.70	0.1050	1.68
%CV	0.91	1.06	0.93
N	40	40	40
Pass/Fail	P	P	P

Urine, mEq/L

	Na+	K+	Cl-
Mean	28.67	11.48	35.52
SD	0.66	0.17	1.01
%CV	2.30	1.44	2.83
N	40	40	40
Pass/Fail	P	P	P

	Na+	K+	Cl-
Mean	907.82	501.53	447.05
SD	6.26	6.06	2.89
%CV	0.69	1.21	0.65
N	40	40	40
Pass/Fail	P	P	P

Lithium within run and total precision results

Whole Blood, mEq/L

Within Run	V Low	Low	Mid	High	V High
Mean	0.216	0.607	1.035	1.727	4.153
SD	**0.010**	**0.008**	**0.009**	**0.010**	**0.030**
%CV	4.76	1.24	0.82	0.57	0.72
N	30	30	30	30	30
Spec, BLD	0.03	0.03	0.03	0.03	0.03
PASS/FAIL	P	P	P	P	P

Run to Run	V Low	Low	Mid	High	V High
Mean	0.227	0.607	1.031	1.740	4.171
SD	**0.014**	**0.009**	**0.010**	**0.009**	**0.036**
%CV	6.31	1.56	0.95	0.52	0.85
N	40	40	40	40	40
Spec, BLD	0.09	0.09	0.09	0.09	0.09
PASS/FAIL	P	P	P	P	P

Plasma, mEq/L

Within Run	V Low	Low	Mid	High	V High
Mean	0.32130	0.62003	1.09253	2.29560	4.41513
SD	**0.00531**	**0.00482**	**0.00308**	**0.01336**	**0.06310**
%CV	1.65	0.78	0.28	0.58	1.43
N	30	30	30	30	30
Spec, BLD	0.03	0.03	0.03	0.03	0.03
PASS/FAIL	P	P	P	P	F

Run to Run	V Low	Low	Mid	High	V High
Mean	0.32668	0.62789	1.09495	2.28523	4.37893
SD	**0.01462**	**0.00682**	**0.00666**	**0.02444**	**0.06651**
%CV	4.47	1.09	0.61	1.07	1.52
N	40	44	40	40	41
Spec, BLD	0.09	0.09	0.09	0.09	0.09
PASS/FAIL	P	P	P	P	P

Serum, mEq/L

Within Run	V Low	Low	Mid	High	V High
Mean	0.25563	0.59367	1.05813	1.99907	4.30820
SD	**0.00844**	**0.00646**	**0.00445**	**0.01166**	**0.04239**
%CV	3.30	1.09	0.42	0.58	0.98
N	30	30	30	30	30
Spec, BLD	0.03	0.03	0.03	0.03	0.03
PASS/FAIL	P	P	P	P	F

Run to Run	V Low	Low	Mid	High	V High
Mean	0.2928	0.5956	1.0610	2.0073	4.3562
SD	0.0280	0.0164	0.0074	0.0425	0.0824
%CV	9.56	2.76	0.70	2.12	1.89
N	40	40	40	40	40
Spec, BLD	0.09	0.09	0.09	0.09	0.09
PASS/FAIL	P	P	P	P	P

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.

Correlation Studies

Studies were conducted comparing the PROLYTE to the Original PROLYTE prior to the software change with whole blood, plasma, serum and spot urine samples.

Whole Blood Comparison, New PROLYTE versus Original PROLYTE

Parameter	Slope	Intercept	R2	Range	n
Sodium	1.0054	-2.9043	0.9875	48-205	110
Potassium	1.0095	-0.0675	0.9891	1.59-10.2	111
Chloride	0.9987	-2.1711	0.9844	45-203	108

Plasma Comparison, of New PROLYTE and Original PROYLTE

Parameter	Slope	Intercept	R2	Range	n
Sodium	1.0243	-4.1003	0.9971	49 - 205	101
Potassium	0.9875	-0.1004	0.9961	1.5 -11.0	104
Chloride	1.0176	-7.9389	0.9965	45-204	101

Serum Comparison, of New PROLYTE and Original PROYLTE

Parameter	Slope	Intercept	R2	Range	n
Sodium	1.0119	-4.2748	0.9936	46 - 204	103
Potassium	0.9800	0.106	0.9950	1.5 -10.8	100
Chloride	1.0144	-4.8408	0.9922	49-203	106

Urine Comparison, of New PROLYTE and Original PROYLTE

Parameter	Slope	Intercept	R2	Range	n
Sodium	0.9798	4.5946	0.9995	25 - 1020	102
Potassium	0.9879	0.0762	0.9991	11 -499	105
Chloride	1.0179	-1.809	0.9933	26-504	101

Lithium Comparison, PROLYTE to SMARTLYTE

Parameter	Slope	Intercept	R^2	Range	n
Whole Blood	1.0096	0.0719	0.9947	0.15 – 5.0	94
Plasma	0.9806	0.1292	0.9971	0.16 - 5.0	100
Serum	0.9977	0.0133	0.9881	0.17 - 4.7	91

Interferences

Negatively charged ions are known to interface with the chloride electrode causing a positive bias. Salicylate is a common interferent and in its clinical range causes a positive bias of 1 mM which is clinically insignificant. Other negatively charged ions such as Thiocyanate and Bromide will cause a significant positive bias in the chloride. Below is listed the concentrations of interferents that would shift chloride results by at least 2 mEq/L with the error increasing with increasing concentration of the interferent,

Interferent	Interferent Concentration	Effect
Bromide	24 mg/dL	Increases Chloride results
Thiocyanate	116 mg/L	Increases Chloride results

Bilirubin at 29 mg/dL (500 umol/L), Triglycerides at 2650 mg/dL (30 mmol/L), Albumin at 12g/dL (120 g/L), Bicarbonate at 40 mEq/L and Salicylic Acid at 690 mg/dL (5 mmol/L) did not have a significant effect on test results. Lithium at 3.2 mEq/L did not have a significant effect on Sodium results. Sodium at 160 mEq/L did not have a significant effect on Lithium results.

Limitations

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

In addition, pre-analytical errors can be caused by mishandling of the samples. Potassium concentrations in erythrocytes are much greater than in extra-cellular fluids and hemolysis would increase potassium concentrations in extra-cellular fluids. Rapid separation of serum or plasma from blood cells is therefore desirable.

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5.3 ISE Theory

Traditionally, blood samples have been tested for electrode concentrations on flame photometers. With this method, the blood sample is diluted using a known concentration of either Cesium or Lithium. These diluted samples are then forced through the flame where the cations are excited. Once excited, they transmit their energy at different frequencies, each representing a specific ion. The concentration of each ion is then recorded.

The PROLYTE uses Ion Selective Electrode (ISE) measurement technology to determine Sodium, Potassium, Lithium and Chloride values in whole blood, serum, plasma, and urine. Although the technology itself is quite complicated, understanding how the instrument performs sampling analysis is relatively simple. Basically, the analyzer compares an unknown sample against a known value to compute the sample's electrolyte level.

An ion-selective membrane undergoes a specific interaction with a specific electrolyte contained in the sample. The membrane interaction is dependent on both the size and charge of the electrolyte. This interaction results in a change in the membrane potential, or measuring voltage, between the sample and the membrane. The Sodium electrodes utilize a glass tube which is Sodium Ion Selective. The Potassium and Lithium electrodes use neutral ionophore membranes. Chloride electrodes use an anion sensitive ionophore. With these electrodes the potential varies depending on the ion concentration in a given sample. The electrical potentials measured in the electrode are compared to a Silver/Silver Chloride Reference Electrode.

This relationship between the concentration of the sensed ions and the voltage is logarithmic and is expressed by the Nernst equation, shown below.

$$E = E^{\circ} + \frac{Rt}{nF}\log(a)$$

E = the total potential (in mV) between the sensing and reference electrodes, (desired output).

E^{o}= a constant, characteristic of the ISE/reference pair, (standard conditions)

R = Gas Constant, (8.314 joules/degree Kelvin/mole).

t = Absolute Temperature, (degree Kelvin = 273.15 ˚C)

n = the charge on the ion (with sign, in this case always equals to +1).

F = the Faraday Constant (96,500 coulombs per mole).

log (a) = the logarithm of the activity of the measured ion

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 Standard A (one-point calibration). If the ion concentration of one measuring solution is known, the analyzer can determine the ion concentration of the sample, in accordance with the Nernst Equation rewritten for our purposes as:

$$E - E^{\circ} = S_{cal} \cdot \log\left(\frac{c_{smp}}{c_{std}}\right)$$

S_{cal} = Slope determined through calibration.

c_{smp} = ionic concentration of the sample.

c_{std} = ionic concentration of the standard solution.

5.4 Warranty

Diamond Diagnostics wants you to be satisfied with the quality of your PROLYTE. We warranty your Diamond PROLYTE for one year. We will repair or replace a product that fails, within this period from the date of shipment, due to defects in material and workmanship. You must use Diamond Diagnostics approved accessories and genuine Diamond Diagnostics spare parts. This warranty does not apply to any instrument that has been abused or repaired without authorization.

THE FOREGOING OBLIGATIONS ARE IN LIEU OF ALL OTHER OBLIGATIONS AND LIABILITIES INCLUDING NEGLIGENCE AND ALL WARRANTIES, OF MERCHANTABILITY OR OTHERWISE EXPRESSED OR IMPLIED IN FACTOR BY LAW. THE FOREGOING STATES OUR ENTIRE AND EXCLUSIVE LIABILITY, AND BUYER'S EXCLUSIVE REMEDY, FOR ANY CLAIM OR DAMAGES IN CONNECTION WITH THE SUITABILITY FOR USE, INSTALLATION, OR OPERATION, DIAMOND DIAGNOSTICS WILL IN NO EVENT BE LIABLE FOR ANY SPECIAL OR CONSEQUENTIAL DAMAGES WHATSOEVER, AND OUR LIABILITY UNDER NO CIRCUMSTANCES WILL EXCEED THE PURCHASE PRICE FOR THE GOODS FOR WHICH LIABILITY IS CLAIMED. IN SOME INSTANCES, UNITS MAY CONTAIN RECONDITIONED (AS NEW) PARTS.

Condition of Returned Equipment

Before returning equipment to Diamond Diagnostics, you must contact Diamond Diagnostics or your dealer and receive a return materials authorization (RMA). All returned units must be decontaminated, free of radioactivity, and free of hazardous and infectious materials. The RMA paperwork includes a Certificate of Decontamination for you to sign indicating that you have performed these steps. Diamond Diagnostics will not accept the shipment until the signed certificate is received.

You must prepay transportation to the service depot.