MaxLYTE

ELECTROLYTE ANALYZER

OPERATOR'S MANUAL

CE IVD ISO 9001 ISO 13485

MaxLYTE

ELECTROLYTE ANALYZER

Operator's Manual

Manufactured in India by:

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The operators should read the entire manual
before installing and operating the analyzer.

Table of Contents

1. Introduction

1. Introduction

This manual provides all necessary instructions for the routine operation of the MaxLYTE Electrolyte Analyzer. Please read this manual carefully. It has been prepared to help you attain optimum performance from your Analyzer.

***WARNING**: Blood samples and blood products are potential sources of infectious agents. Handle all blood products and flow path components with care. Gloves and protective clothing are recommended when performing maintenance and troubleshooting procedures.*

About this Manual:
This manual is for the MaxLYTE Electrolyte Analyzer. ***Throughout this manual***
***NOTE:** indicates especially important information.*
CAUTION: indicates information that is critical to avoid instrument damage or incorrect results, and
WARNING: indicates possible hazard to the operator.

1.1 Safety

Personnel operating this analyzer must be proficient in the operating and replacement procedures of the analyzer. The following safety procedures must be followed.

General Safety

- Read the safety and operating instructions before operating the analyzer.
- Follow all operating and use instructions.
- Use only the provided power cord and adapter.
- Place the analyzer so that its location or position does not interfere with its proper ventilation.
- Place the analyzer away from heat sources.
- Connect the analyzer to a power supply only of the type described in the operating instructions or marked on the analyzer.
- Do not use damaged power cord, adapter, or loose outlet. Never touch the power supply accessories with wet hands. Keep dust away from the outlet and power cord.
- Do not use or store any hot equipment or flammable material near the analyzer or power supply accessories.
- Do not allow water or foreign substances to get into the analyzer or power supply accessories.

Safety, *continued*

General Caution

- Power cord must be plugged into a grounded outlet.
- The rear vent of the analyzer must be free of obstruction and not covered by cloth or any other material.
- Before long term storage of the analyzer, remove the Reagent Pack, turn off the power, and clean any contamination from the analyzer.
- There are no operator serviceable parts inside the product. Do not disassemble, repair, or modify the product.
- If Electro-mechanical problems are suspected, call a service engineer to report the problems.
- When disposing the analyzer and provided electrical accessories, contact your local distributor where you purchased them.
- You must not discard this electrical/electronic product in domestic household waste.

Bio Hazard Caution

- All materials used in collecting blood and/or other samples from humans should be treated as bio-hazardous materials with the potential carrying infectious agents capable of producing disease.
- All bio-hazardous materials should be handled and disposed of in accordance with applicable rules and regulations of the hospital, laboratory, or other testing facility.
- Operate the analyzer in the appropriate environment.
- Wear appropriate laboratory attire, e.g., gloves, lab coat, and breathing apparatus, when working with hazardous materials.
- Be careful not to let the sample and/or collecting tools directly touch the mouth, eyes, mucus membranes, or any area with broken skin.
- Wash hands after collecting the sample or using the analyzer.

1.2 Symbols and Terms

1.2.1 Symbols

The symbols described below are used on the packaging of MaxLYTE Electrolyte Analyzer related products.

Symbol	Description
	This product fulfils the requirements of Directive 98/79/EC on in-vitro diagnostic medical devices.
	*In Vitro* diagnostics medical device
	Please read pack insert. / Follow the instrument's instructions for use!
	Serial number
	Caution: Attention, see operating instructions.
	Manufactured by
	Temperature Limit Symbol – Products and/or components which contain this symbol must be stored within the specified temperature range.
	Catalog number
	Batch Code Symbol – Manufacturing lot number is located to the right of this symbol. This symbol is located on all products, which are controlled via a lot number.
	Expiration / Use By Symbol – Product to be used by the expiration date indicated to the right of this symbol. This symbol is located on all consumables, which are controlled via an expiration or use by date.

1.2.2 Terms

Term	Description
Na^+	Sodium ion
K^+	Potassium ion
iCa^{++}	Ionized Calcium ion
Li^+	Lithium ion
pH	Potential of Hydrogen
Cl^-	Chloride ion
nCa	Normalized Calcium
TCa	Total Calcium

1.3 Product Description

1.3.1 Intended Use

The MaxLYTE Electrolyte Analyzer is intended for in-vitro diagnostics use in the quantitative determination of Sodium, Potassium, Ionized Calcium, pH, Chloride & Lithium in Whole Blood, Serum/Plasma/CSF and Diluted Urine. Measurements obtained by this device are used for the diagnosis, monitoring, and treatment of diseases involving electrolyte imbalance.

To obtain accurate results, the MaxLYTE must be operated with our company's specially packaged Calibrant and proven based control materials and be maintained as described in this manual.

1.3.2 Measured Parameters

MaxLYTE Electrolyte Analyzer: Na^+, K^+, iCa^{++}, Cl^-, pH & Li^+ (optional)

Na^+	Sodium measurement is used in the diagnosis and treatment of aldosteronism, diabetes insipid us, adrenal hypertension, Addison's disease, dehydration, or diseases involving electrolyte imbalance.
K^+	Potassium Measurement is used to monitor electrolyte balance in the diagnosis and treatment of disease conditions characterized by low or high potassium levels.
Cl^-	Chloride measurement is used in the diagnosis and treatment of electrolyte and metabolic disorders such as cystic fibrosis and diabetic acidosis.
iCa^{++}	Calcium measurements are used in the diagnosis and treatment of parathyroid disease, a variety of bone diseases, chronic renal disease and tetany (intermittent muscular contractions or spasms).
pH	pH is a measure of hydrogen ion concentration are used in the diagnosis and treatment for Kidney disease, Lung disease and Asthma.
Li^+	Lithium measurement are used in the diagnosis and treatment for muscular weakness, Kidney and for mental disorder.

1.3.3 Calculated Parameters

nCa & TCa

1.3.4 The Sample

Lithium heparin or Sodium heparin whole blood samples from syringes, open tubes and capillary tubes can be used on the MaxLYTE Electrolyte Analyzer. The minimum sample size for analysis is 120 µL.

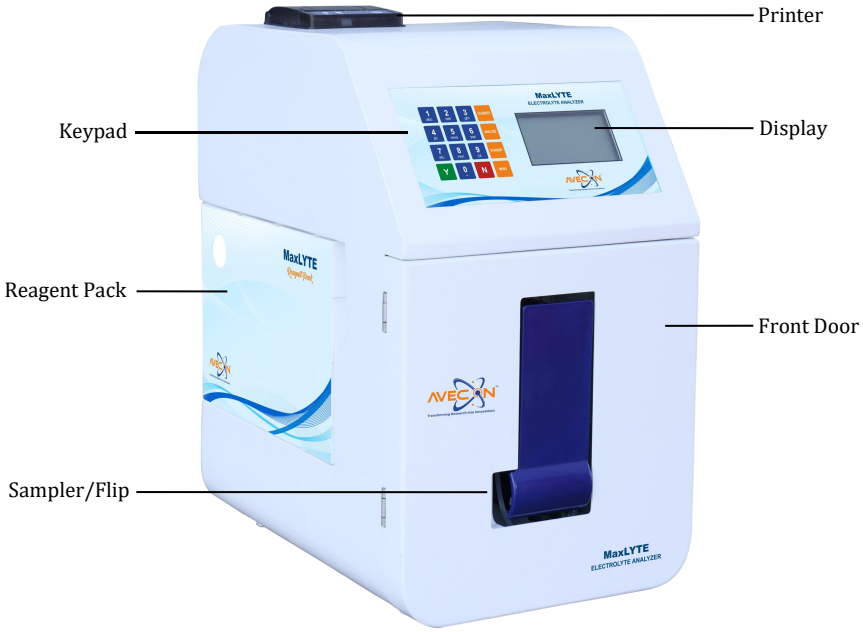
1.3.5 Suitable Anticoagulants

- Lithium heparin and Sodium heparin are the acceptable anticoagulant for use with the analyzer.
- EDTA, citrate, oxalate and sodium fluoride **ARE NOT** acceptable for use.
- Depending on the amount of heparin used in the collection syringe and whether it is filled to capacity with blood, heparin concentrations of result may vary.
- Liquid or dry heparin when present in **excess** may **cause errors.** Ensure blood collection devices are filled per manufacturer instructions.

CAUTION:

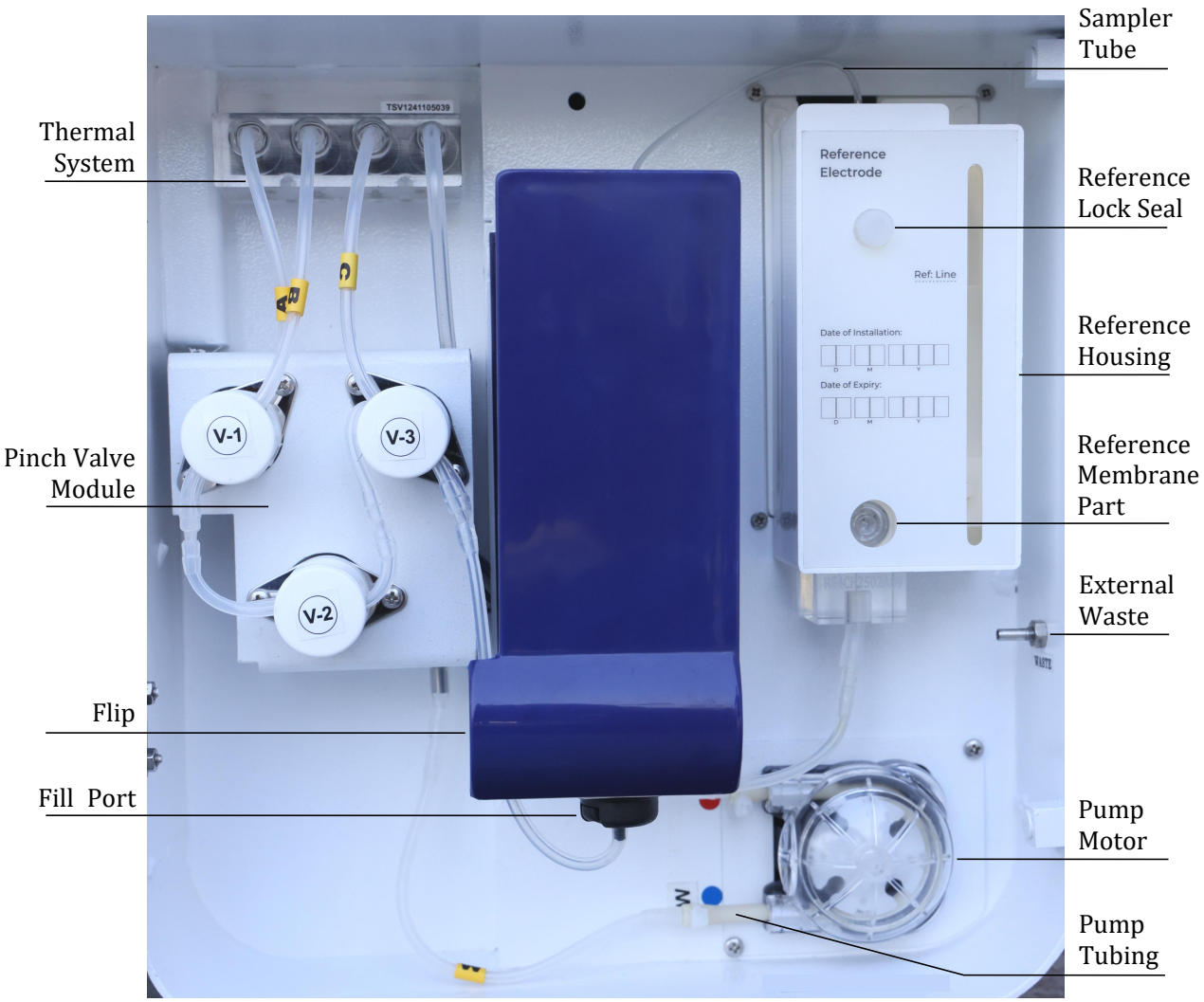
MaxLYTE Electrolyte Analyzer users should take careful note of these considerations when establishing reference intervals and interpreting results.

1.3.6 Analyzer



- **Keypad** guides user through all aspects of analyzer operation, including analyzer setup, information entry and testing.
- **Display** displays the results, parameters.
- **Printer** provides hard copies of test results and information.
- **Sampler/Flip** aspirates the sample for analysis.
- **Reagent Pack** is used for calibration and analysis of parameters.


J-TAG Port
ON/OFF Switch
Serial Port
Power Adaptor Port
Grounding Port
Air Vent
MaxLYTE
Reagent Pack
QC PASS



1.3.7 Reagent Pack

1.3.8 Accessories

Power Adapter

Power Cord

Paper Rolls

2. Installation

2.1 Installation Requirement

Before you begin installing your MaxLYTE Electrolyte Analyzer, take a moment to look over the contents to ensure that you have the following :

- Power supply with power cord
- Quality Control material
- MaxLYTE Reagent Pack
- Thermal printer paper rolls
- Reference Electrode Kit
- Troubleshooting Kit

2.1.1 Unpacking

- Inspect the shipping package of the product for any signs of damage from shipment.
- Ensure all listed components are included in the package.

2.1.2 Environmental Requirements

Working Area Requirements (Environmental):

Keep the working area around the system free of dirt, corrosive fumes, vibration, and excessive temperature changes.

- Location : Indoors
- Operating Temperature : 5 - 40°C (41-104°F)
- Relative Humidity : 10 - 90%

Note:

- ✓ The analyzer should be installed on a horizontal, stable surface in a well-ventilated area without direct sunlight or heat.
- ✓ Allow enough space to place the reagent pack in reagent pack slot.
- ✓ Allow at least 10 cm of space from the back of the analyzer for adequate ventilation.

2.1.3 Electrical Requirements

- Operating Voltage Range : 100 - 240 V AC
- Amp : 1.4 A
- Operating Frequency : 50/60 Hz
- Power cord : 3 wire
- Power Adapter : Output- 12V, 5.0A, 60 W MAX

2.2 Power Cable Connection

Caution

- *Check that the power switch is in OFF position.*
- *Always connect the power according to the steps described in this manual.*
- *Always use a grounded electrical outlet.*
- *Use only the power cord and power adapter provided by the manufacturer.*
- *Electrical plugs and sockets vary by countries. If necessary, use appropriate power plug or power strips to connect the provided power cord to the outlet.*

Plug in the Power Supply

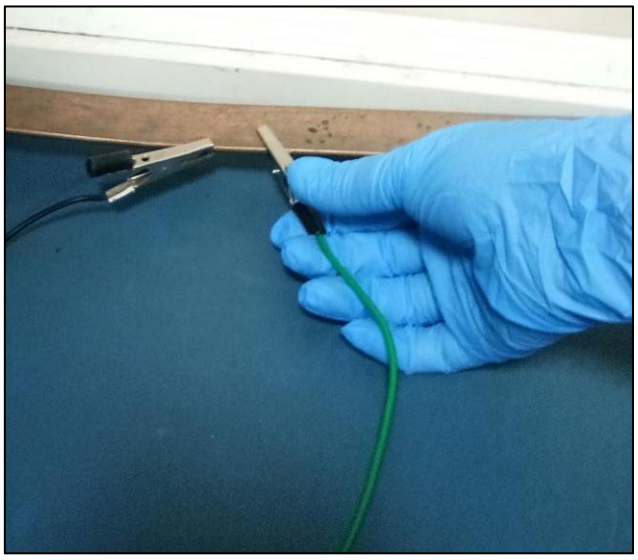
1. Plug the power cord into the socket of the power adapter.
2. Plug the power supply into the receptacle on the back side of the analyzer.

3. Plug the power cord into an grounded electrical outlet.

2.3 External Grounding Cable Connection

1. Connect the External Grounding cable into a Grounding port on the back side of the analyzer.

2. Connect other end of the cable to any of the metal part.



2.4 Printer Paper Installation

Install Printer Paper

1. Facing the top of the analyzer, pull the lever of the printer to open the cover.

2. Place the paper roll in paper compartment.

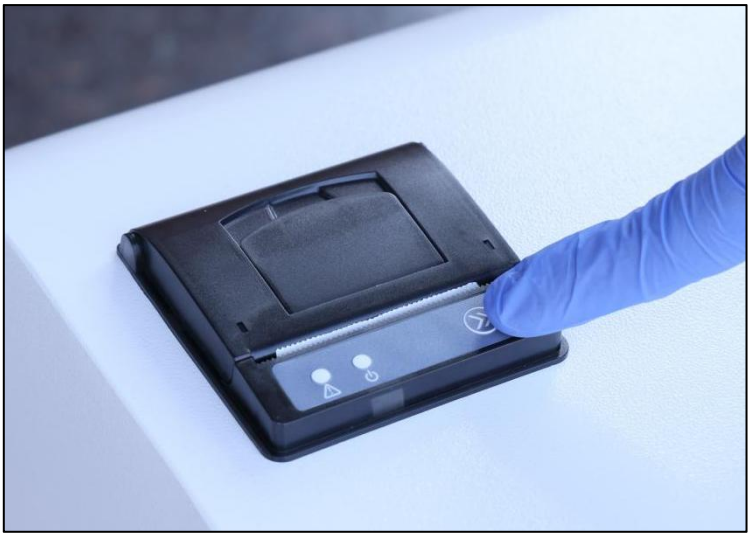
3. Fix the paper roll in the paper compartment such that end of the paper is outside the printer.

Printer Paper Installation, *Continued*

Remove Printer Paper

1. Flip down the printer cover (press hard) and remove the remaining paper.

2. Hold down the pause button to advance the paper.



Note:

- ✓ Do not use force to pull out the paper from the printer.
- ✓ Never pull the paper in the reverse direction of printing.
- ✓ The play and pass buttons are only active when the printer detects paper in the printer.

2.5 Reagent Pack Installation

Install Reagent Pack

1. Unpack Reagent pack from the packing box.
2. Take out the stoppers from reagent pack.

3. Facing the reagent pack label outside, insert the reagent pack into the Analyzer through guiding slot.

Note:

✓ Do not place the MaxLYTE reagent pack open to atmosphere, ensure to insert stoppers when reagent pack left ideally.

2.6 Reference & Electrode Installation

Electrode Installation

1. Unpack electrodes, seals and reference housing from packing box.
2. Stack the electrodes according to Electrode parameters by inserting seals in between every Electrode, also connect sample detector.

3. Slide the stacked electrode set in Reference Housing. Push down firmly until the sample detector snaps into its position and insert the Reference lock to complete the stacking.
4. Connect the sample tube to the top of the bubble detector.
5. Connect the pump tube to the base of the Reference housing.

Note:
Electrode Parameters

Electrolyte Analyzer Models

Electrode Parameters

1	2	3	4	5	6	7	8	9	10
BD	BD	BD	BD	BD	BD	BD	BD	BD	BD
K	K	K	K	K	K	K	K	K	K
Na	Na	Na	Na	Na	Na	Na	Na	Na	Na
B	B	iCa	iCa	iCa	iCa	iCa	iCa	iCa	iCa
B	B	B	B	Li	pH	Li	pH	Li	Li
B	B	B	B	B	B	pH	B	B	pH
B	Cl	B	Cl	B	B	B	Cl	Cl	Cl

Note: Please arrange the electrodes as per the parameter selection

Removal of electrodes

✓ Slide the electrode stack up at least one inch by gently pushing up on the bottom electrode pin. This process will remove electrodes from the reference housing.

FRONT VIEW

BACK VIEW

2.7 Power ON

Turn ON the Power:

1. Facing the back of the analyzer, flip the red power switch on the lower left side, to "ON" position to start the machine.
2. System starts initializing by displaying **"Initializing"** message on the display.
3. After initializing it automatically performs Self Check. The **"Self Check"** message displays on the display.
4. System asks to calibrate.
5. During the first time of installation, user is advised to perform reagent priming option in menu and then perform calibration. If any of the parameter is Uncalibrated, re-calibrate the instrument. Calibrate the analyzer by pressing Calibrate button on the keypad.

Note:

- ✓ Calibration is required for Sample Analysis.

2.8 Initiating Start-up Process

After completing the whole flow path connections from reagent pack to the waste outlet via reference housing. Perform, Reagent priming option which does reagent priming.

- ✓ The way to prime the reagents is as follows
  - Go to **Menu > Diagnostics > Flow > Reagent priming**
  - Select Prime Cal A for priming Cal A reagent.
  - Select Prime Cal B for priming Cal B reagent.
  - Select Prime Wash for priming Wash reagent.
  - Select Prime All for priming all reagents.

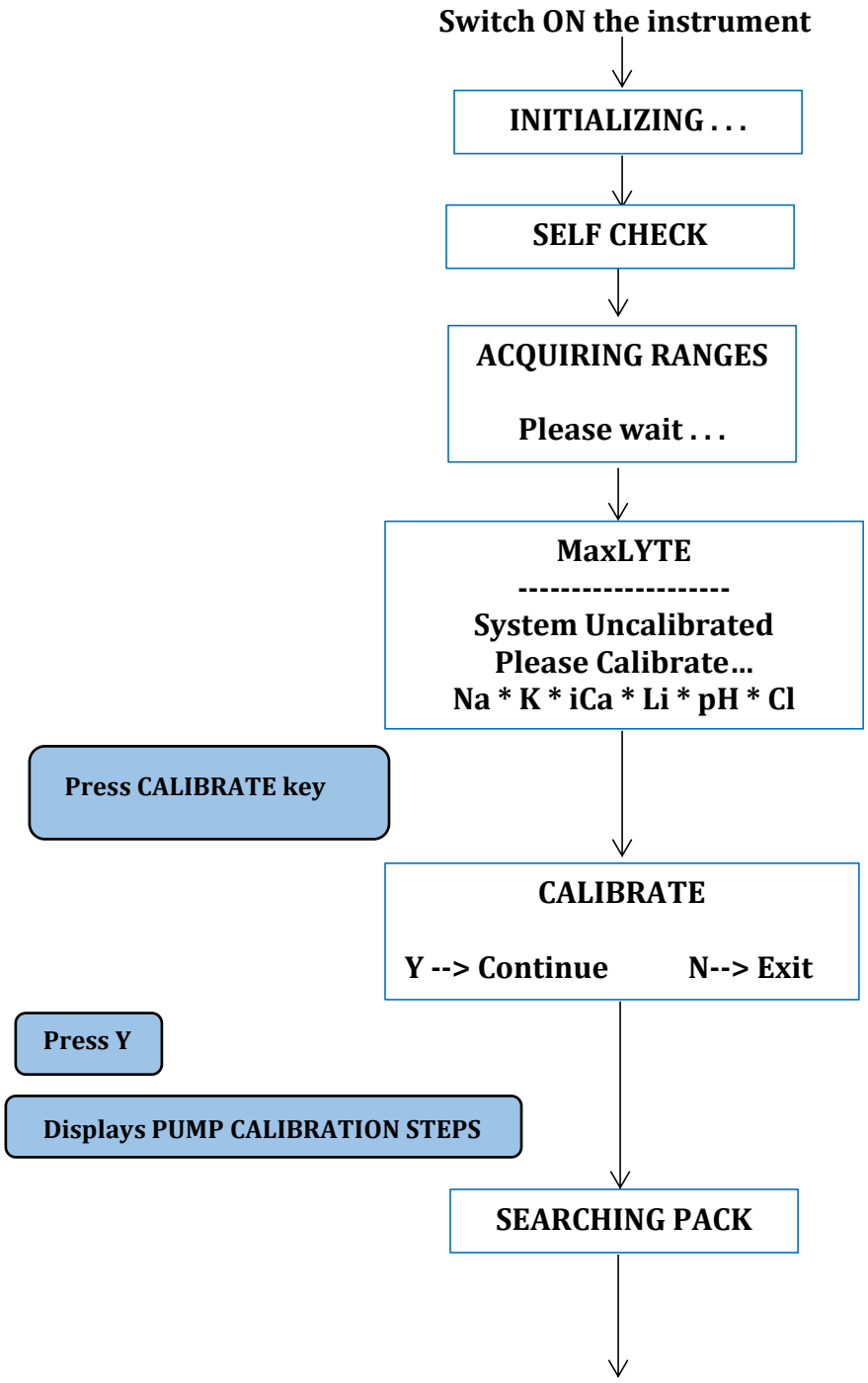
Press **Exit** to exit the present screen.

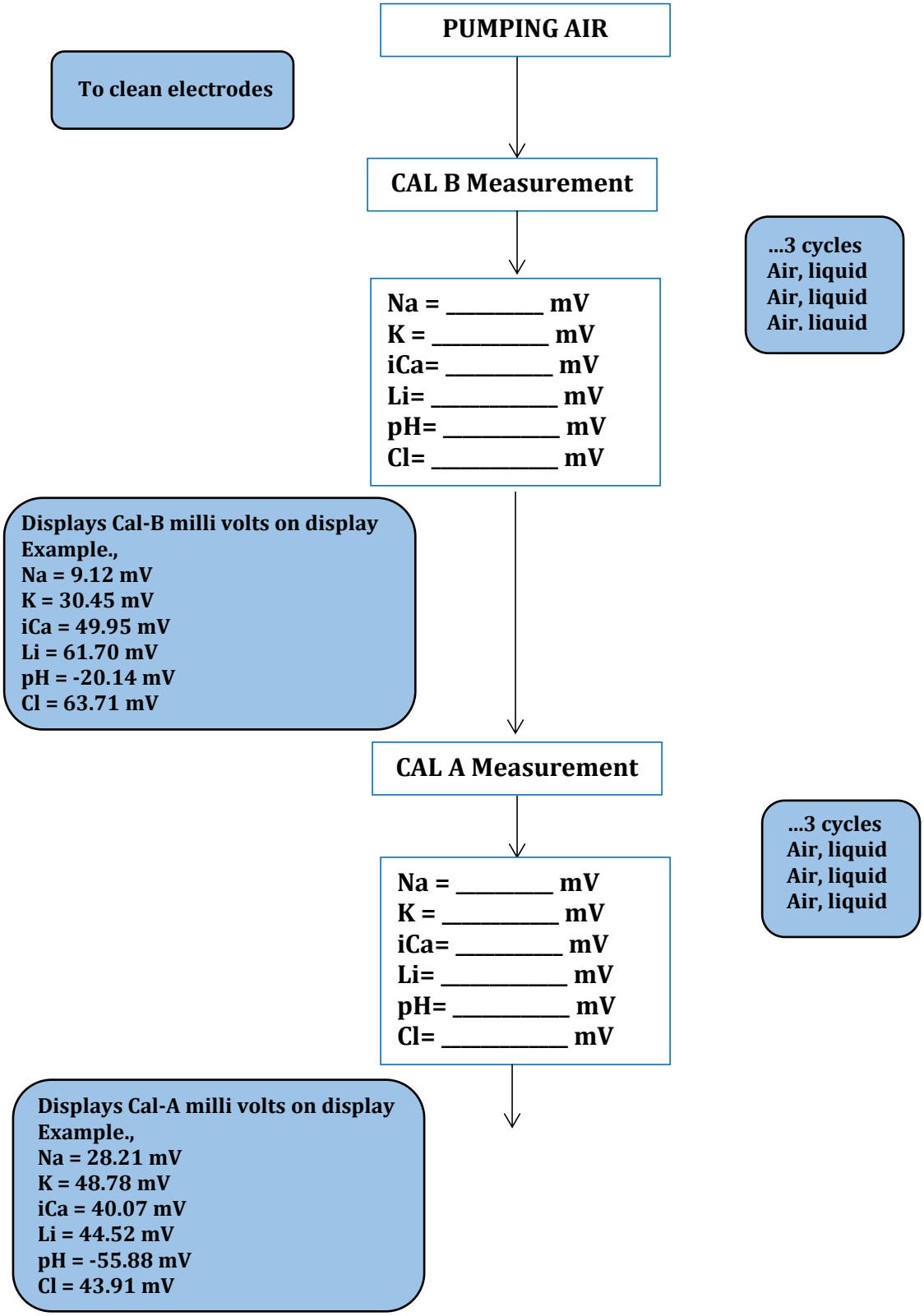
3. Operating the Analyzer

3.1 Calibration

The instrument has to be calibrated when it is switch ON or it automatically calibrates on set calibrated frequency after 6 hours or 12 hours as per set frequency.

Following is the Calibration Procedure:




PUMPING AIR
To clean electrodes
CAL B Measurement
...3 cycles
Air, liquid
Air, liquid
Air, liquid
Na = _____ mV
K = _____ mV
iCa= _____ mV
Li= _____ mV
pH= _____ mV
Cl= _____ mV
Displays Cal-B milli volts on display
Example.,
Na = 9.12 mV
K = 30.45 mV
iCa = 49.95 mV
Li = 61.70 mV
pH = -20.14 mV
Cl = 63.71 mV
CAL A Measurement
...3 cycles
Air, liquid
Air, liquid
Air, liquid
Na = _____ mV
K = _____ mV
iCa= _____ mV
Li= _____ mV
pH= _____ mV
Cl= _____ mV
Displays Cal-A milli volts on display
Example.,
Na = 28.21 mV
K = 48.78 mV
iCa = 40.07 mV
Li = 44.52 mV
pH = -55.88 mV
Cl = 43.91 mV

Finally the instrument is ready to display of calibration slope and it is ready for analysis.

Na = _____
K = _____
iCa= _____
Li= _____
pH= _____
Cl= _____

Finally, the instrument displays calibration slope and is ready for analysis.

Displays Calibration Slope on display
Example.,
Na = 64.02
K = 63.07
iCa = 34.24
Li = 84.55
pH = 63.51
Cl = 62.14

If any electrode is Uncalibrated, then it will show (*) besides that parameter in the display screen. So that we can clearly see the status of the instrument.

MaxLYTE

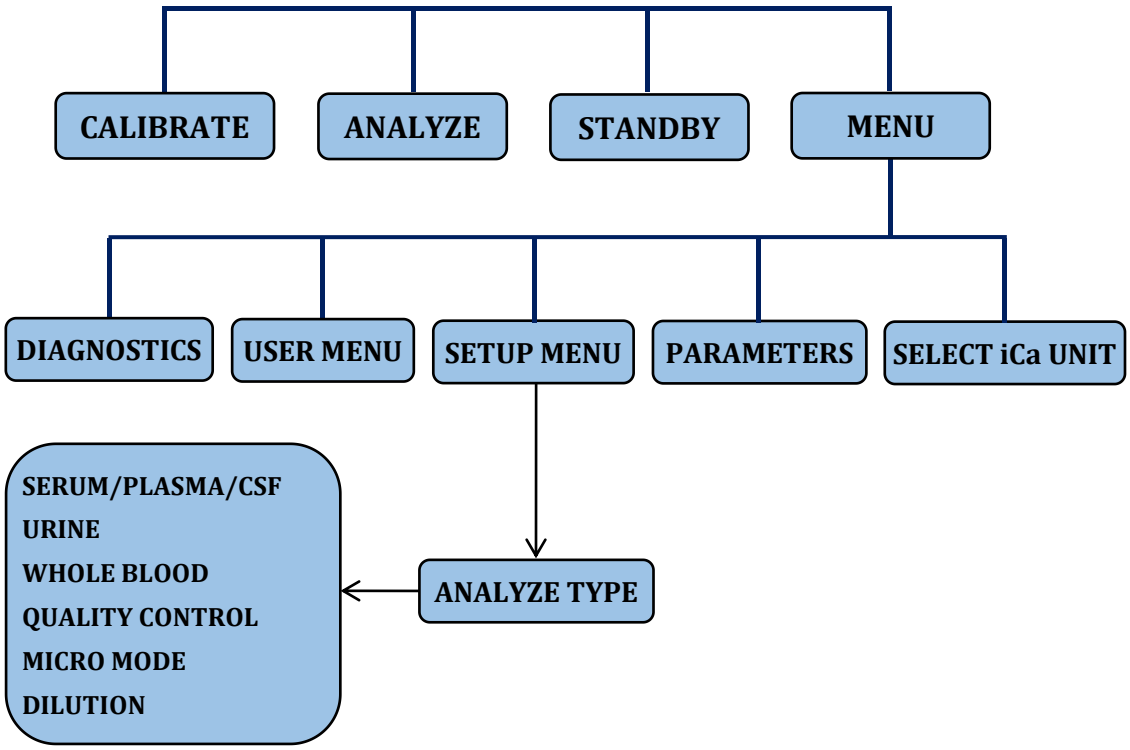
Na K* iCa Li pH Cl*

The above figure shows, the K & Cl is Uncalibrated and Na, iCa, Li, pH are Calibrated.

3.2 Analyze Sample

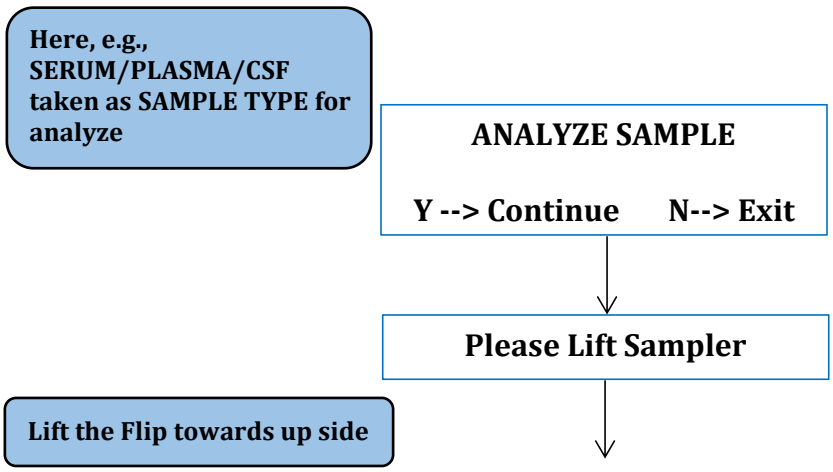
To obtain patient's sample, follow the procedure the precautions described under sample handling and collection. Quality Control materials should be run prior to patient sample analysis.

Before going to analyze the patient sample, select the Sample Type



Note: Select the sample type which you want to measure and Press N --> Press N --> Press N-->. The home screen is display now.

Now, press **Analyze** key



Probe in Sample ?

Y --> Continue N--> Exit

Insert the sample to the sample probe and Press "Y"

Please wait...

Please Remove Sample
&
Close Sampler

Positioning Sample

SAMPLE MEASUREMENT

Sample is positioned into the sensors

Na = _____ mV
K = _____ mV
iCa= _____ mV
Li = _____ mV
pH = _____ mV
Cl = _____ mV

Displays Sample milli volts on display
Example.,
Na = 27.82 mV
K = 53.92 mV
iCa = 49.50 mV
Li = 53.22 mV
pH = -52.18 mV
Cl = 47.79 mV

Processing...

Na = _____ mV
K = _____ mV
iCa= _____ mV
Li = _____ mV
pH = _____ mV
Cl = _____ mV

Displays Cal-A milli volts on display
Example.,
Na = 34.10 mV
K = 57.97 mV
iCa = 35.06 mV
pH = -39.56 mV
HCO3 = 40.03 mV
Cl = 50.81 mV

Now, the Analyze Sample results will displayed on the display.

ANALYZE SAMPLE

Na = 141.6 mmol/L
K = 4.01 mmol/L
iCa= 1.13 mmol/L
Li= 1.36 mmol/L
pH= 7.450
Cl= 101.1 mmol/L

Apart from above results the below mentioned calculated parameters are printed on the paper.

CALCULATED PARAMETERS

nCa = 1.027 mmol/L
TCa = 2.054 mmol/L

Where

1. nCa = Normalized Calcium

Formulae used to calculate nCa is given below

nCa = (iCa result) x 10^(- 0.24 x (7.40 - pH result))

2. TCa = Total Calcium

Formulae used to calculate TCa is given below

TCa = (nCa result) x 2

Result outside the measurement range as follows will not be reported WHOLE BLOOD, SERUM, PLASMA & CSF

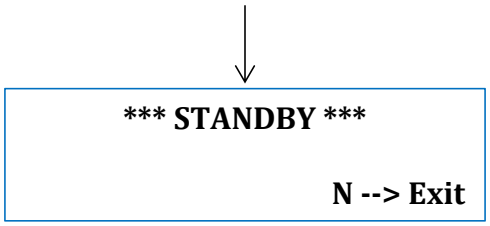
Parameter	Measurement Range	Reproducibility (CV%)
Na^+	20.0 - 200.0 mmol/L	< 1.0 %
K^+	0.2 - 40.0 mmol/ L	<2.0%
iCa^{++}	0.1 - 6.0 mmol/L	<2.0%
Li^+	0.2 - 5.0 mmol/L	<2.0%
pH	6.5 - 8.0	± 0.03
Cl^-	25.0 - 200.0 mmol/L	<1.0%

If iCa unit is measured in mg/dL, then the measurement range is 0.4 - 24 mg/dL.

3.3 Standby

Placing the MaxLYTE in STANDBY mode reduces reagents consumption by discontinuing automatic calibrations. The analyzer does, however, draw a small amount of Calibrant A solution to prevent the electrodes from drying out which is called as “SIPPING”. To place the MaxLYTE in STANDBY mode,
Press **STANDBY** key.

After pressing **STANDBY** key

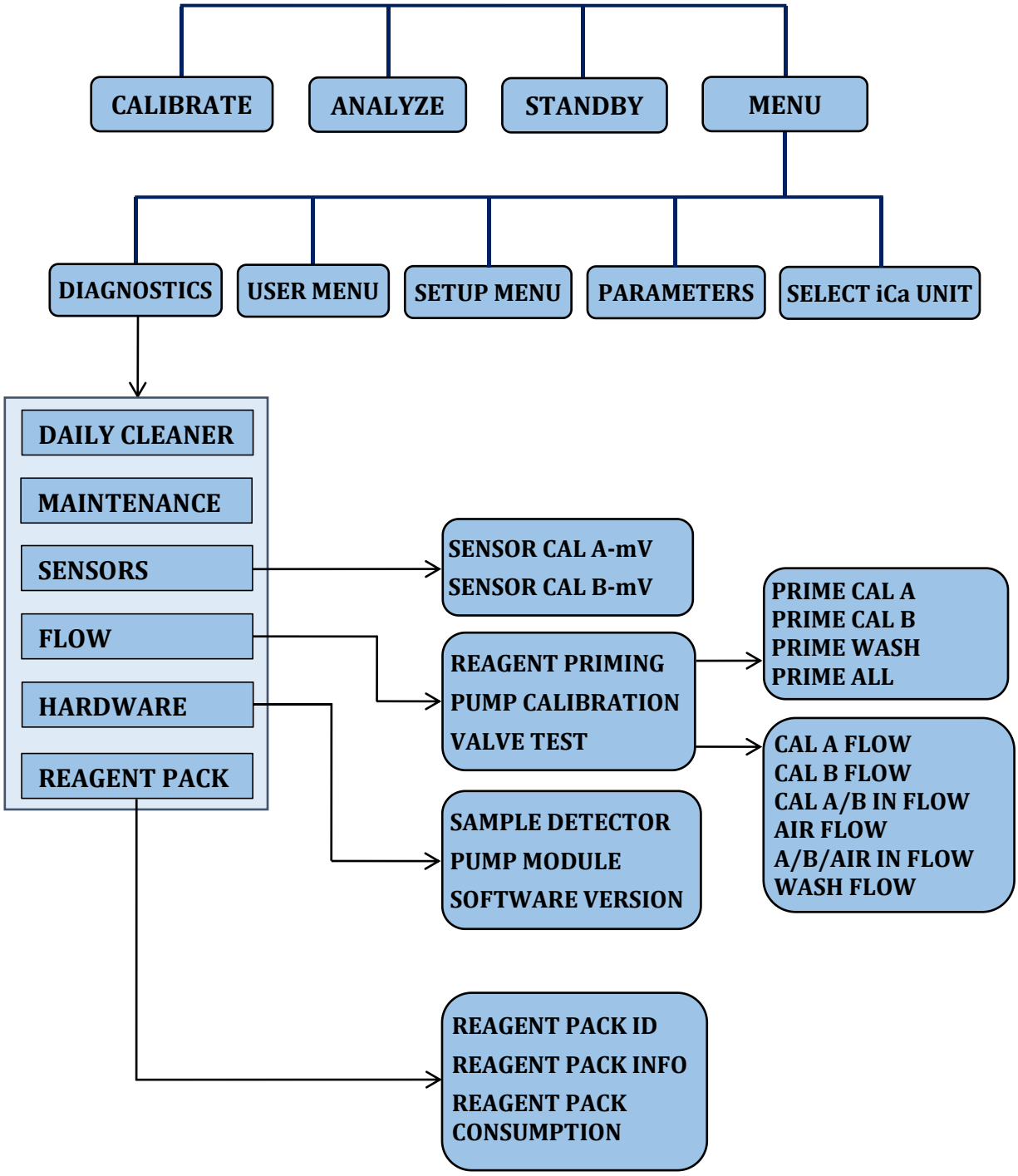


(Analyzer enters in a STANDBY mode, if press N, analyzer exists from STANDBY mode and asks for Calibration)

3.4 Menu Options

3.4.1 Diagnostics:

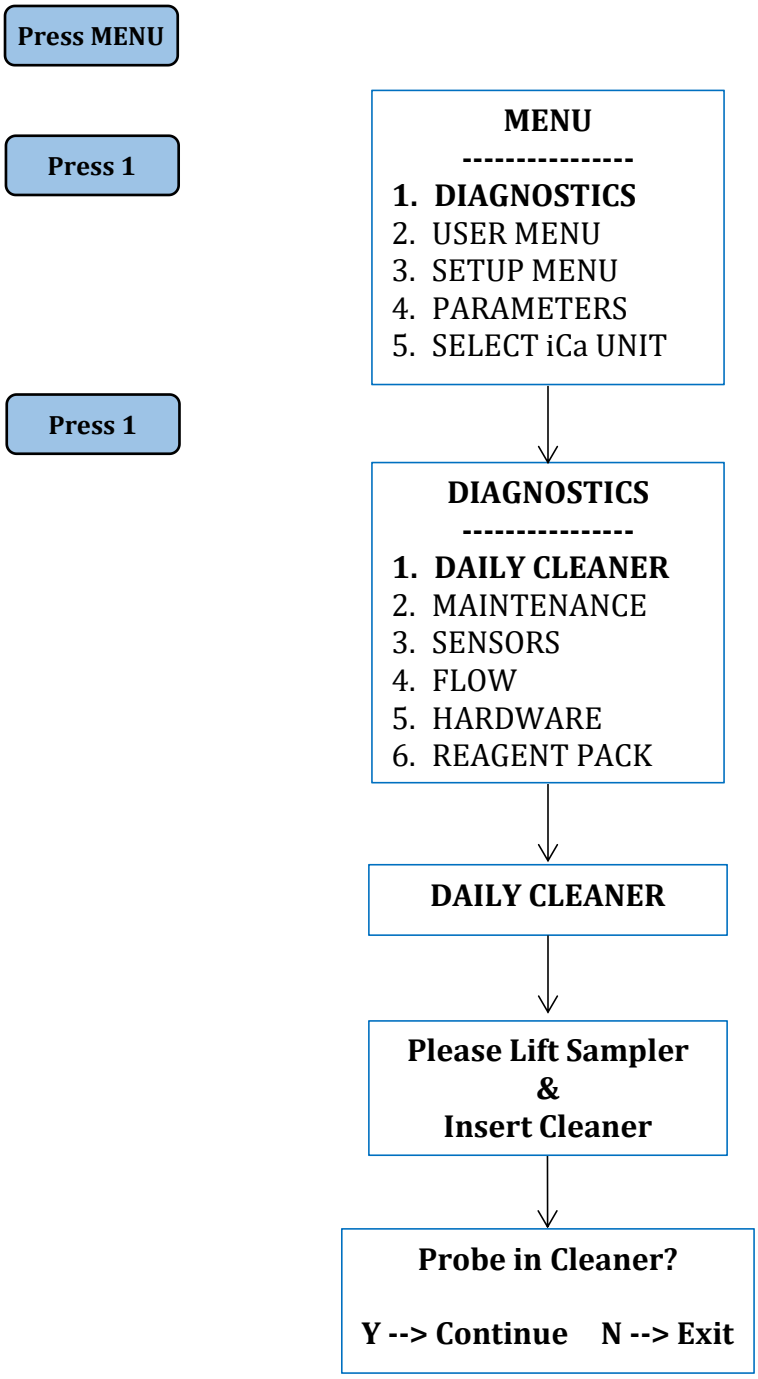
In Diagnostics routine, the operator can check and test key operating functions of the MaxLYTE.



a) DAILY CLEANER:

The fluid path must be cleaned after every 25 samples to remove protein deposition from the sensors. The Daily Cleaner is required and is essential for trouble-free analyzer operation. Following is the procedure of Daily Cleaner.

Following is the flow for Daily Cleaner



Probe in cleaning solution & press "Y"

Aspirating
Please Wait...

Please Remove Cleaner
&
Close Sampler

CLEANING
Performing . . . .

PUMPING CAL A

CAL B MEASUREMENT

...3 cycles
Air, liquid
Air, liquid
Air, liquid

Na = _____ mV
K = _____ mV
iCa= _____ mV
Li = _____ mV
pH = _____ mV
Cl= _____ mV

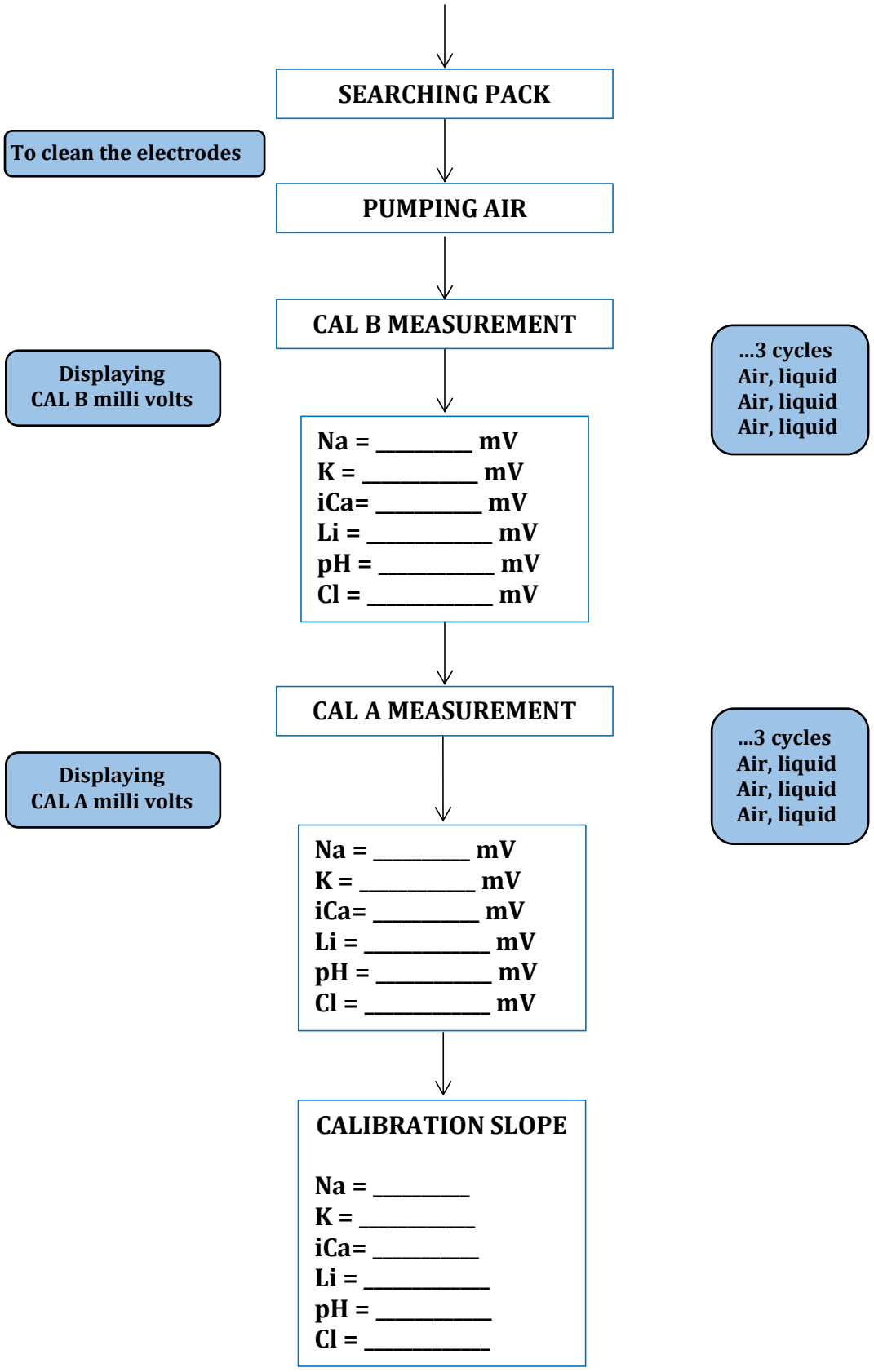
Displaying
CAL B milli volts

CAL A MEASUREMENT

...3 cycles
Air, liquid
Air, liquid
Air, liquid

Na = _____ mV
K = _____ mV
iCa= _____ mV
Li = _____ mV
pH = _____ mV
Cl = _____ mV

Displaying
CAL A milli volts

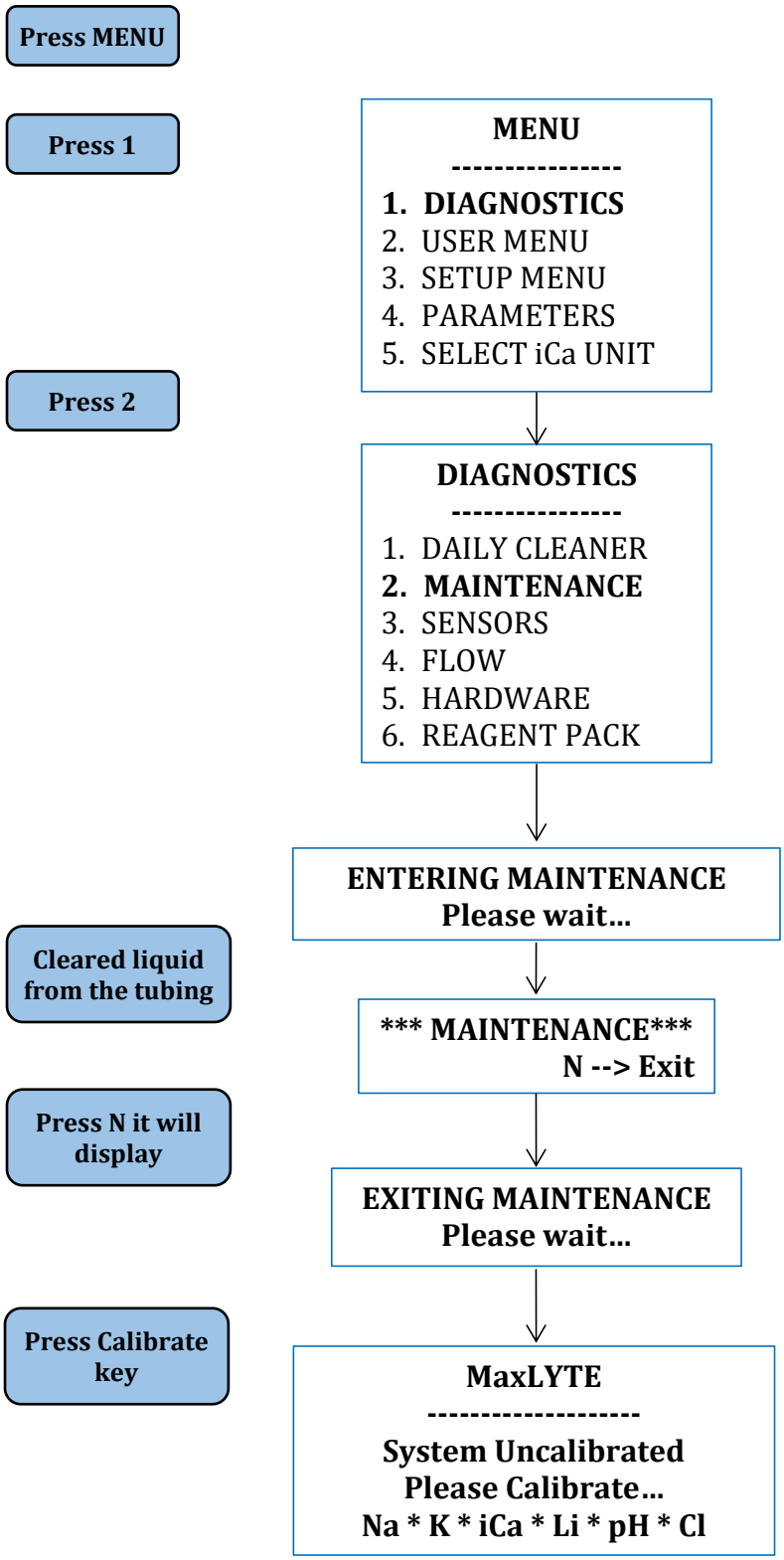


Finally displays Calibration Slope and instrument is ready for Analysis.

b) MAINTENANCE:

When the Operator wants to Switch off the instrument, then the operator should **activate maintenance** mode then can **switch off** instrument.

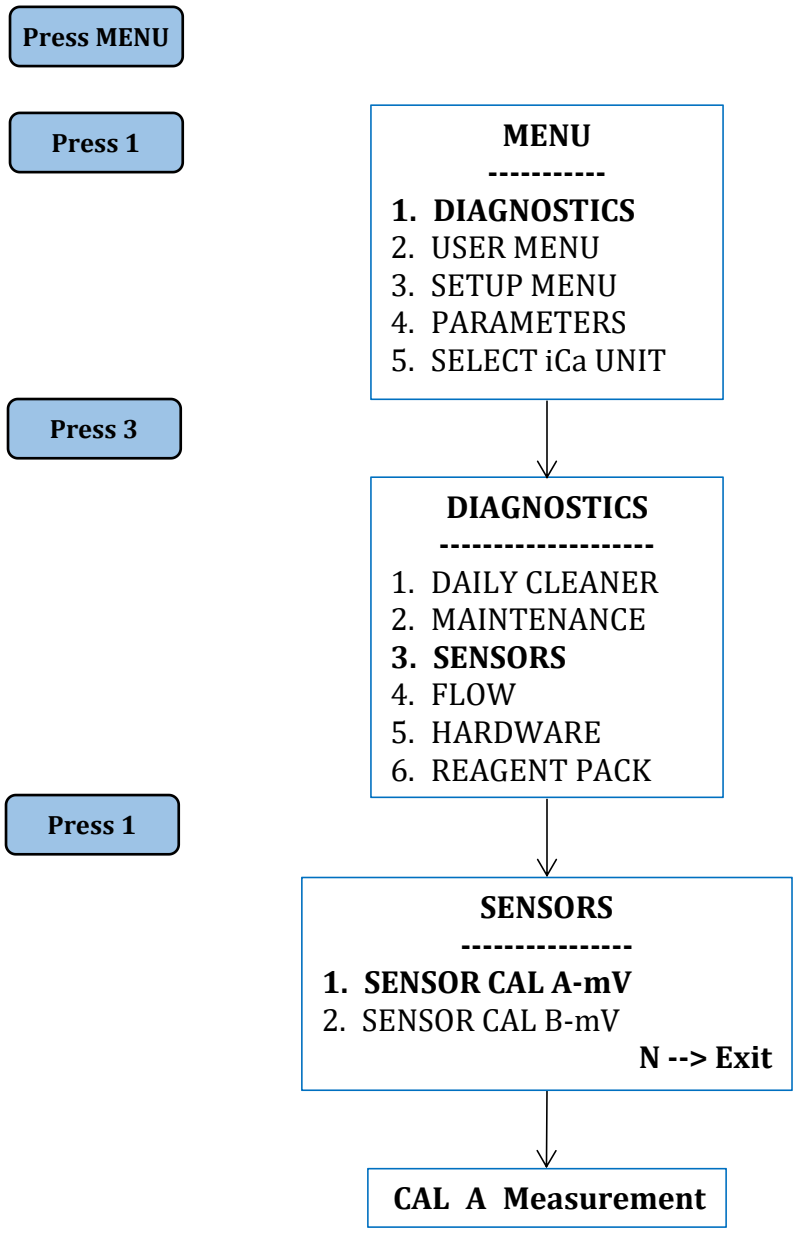
Following is the flow for Maintenance:



c) SENSORS:

Sensors option is used to check milli volts of the electrodes for each calibrant separately.

Following is the flow for Sensors:

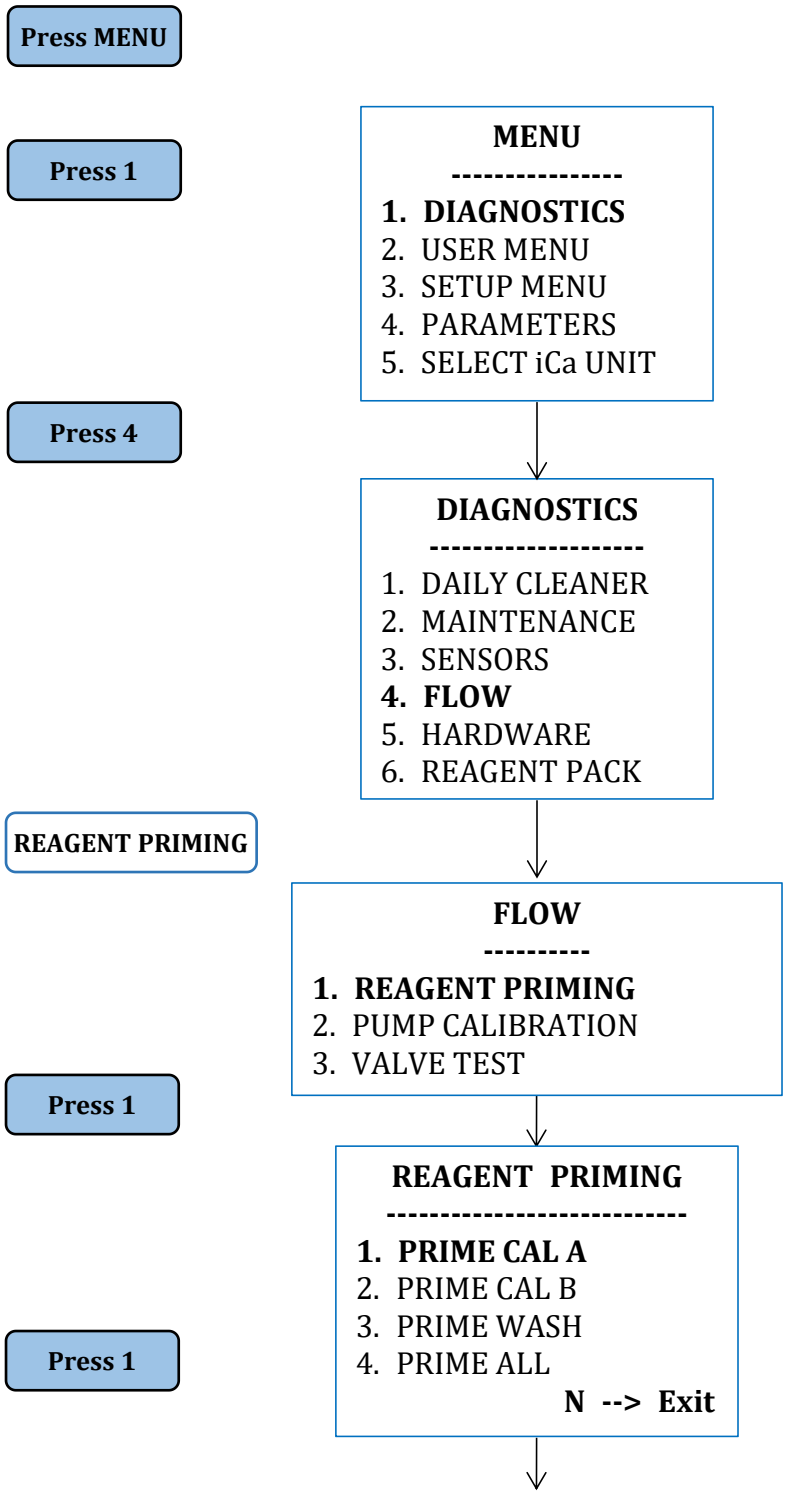


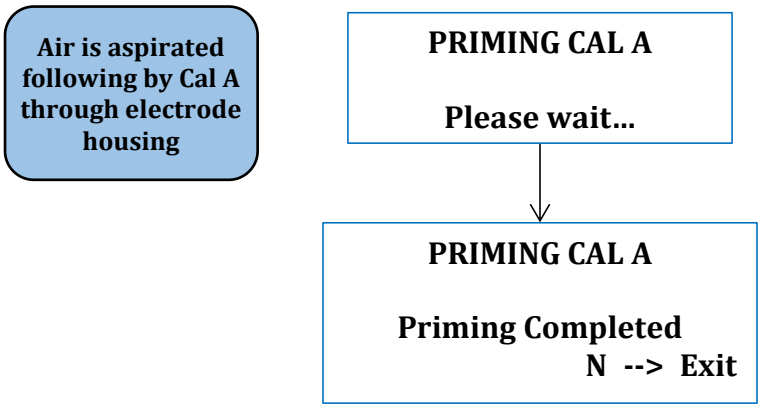
Similarly for Calibrant B

d) FLOW:

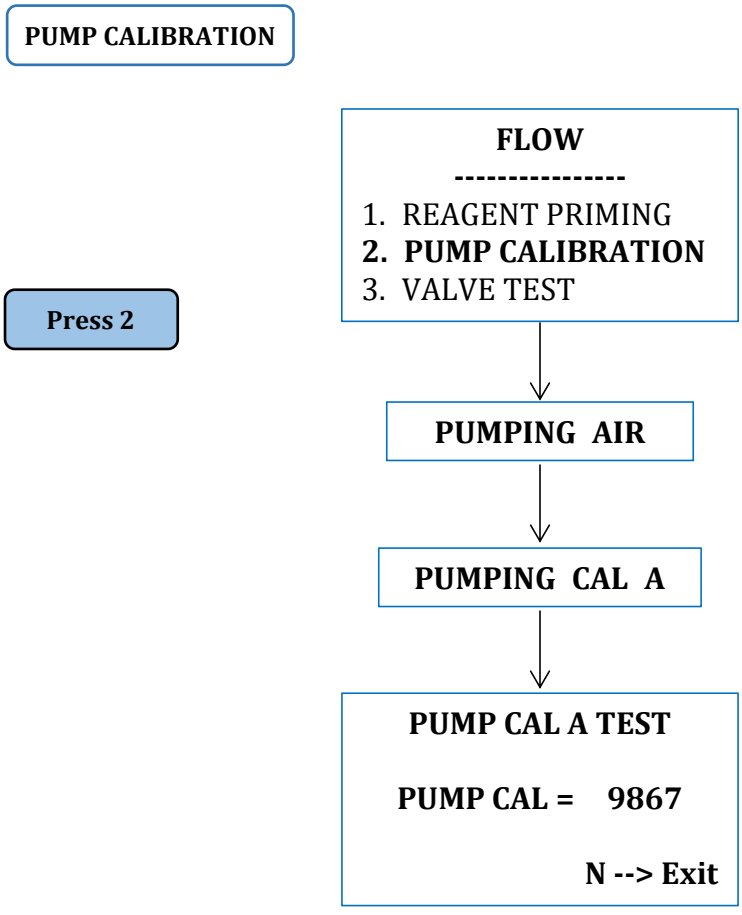
It will used when, inserting a new reagent pack or troubleshooting flow issues in the instrument by priming CAL A, CAL B, WASH & ALL.

Following is the flow for Flow:

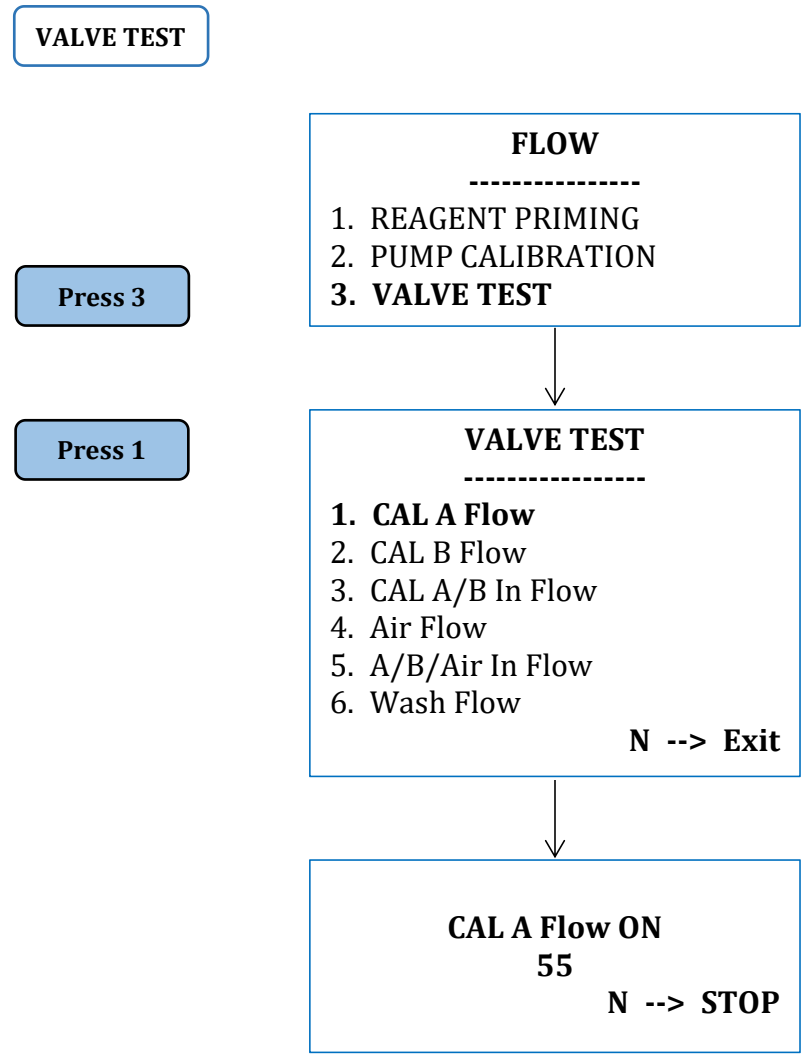




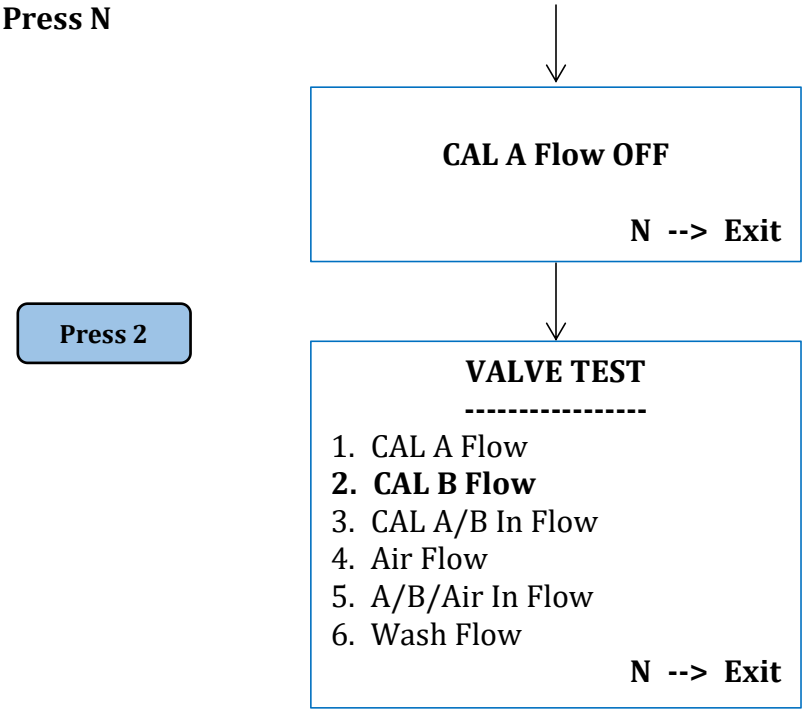
Similarly, we can perform for CAL B, Wash & PRIME ALL.

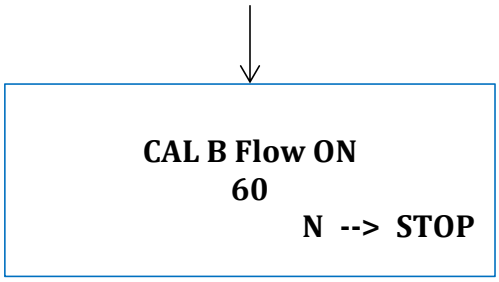


Instrument performs pump calibration using CAL A & displays the pump steps. If pump CAL is greater than 14000 then change the pump tube.



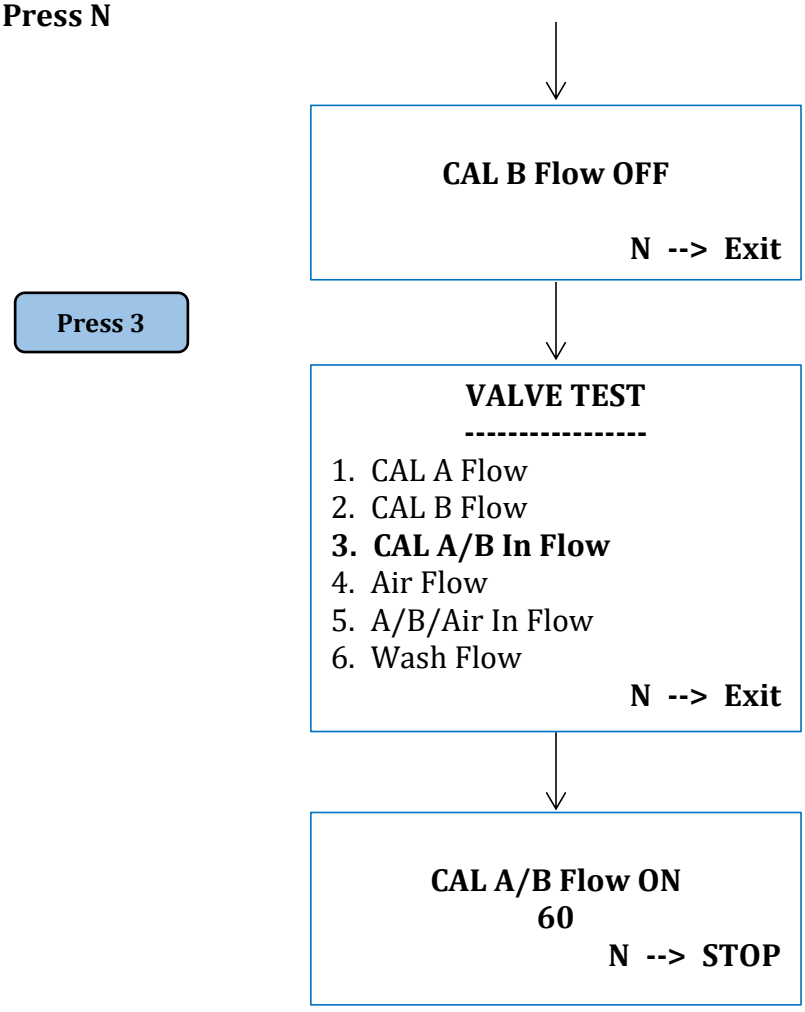
Clean the CAL A flow path of Valve 1 before counter reaches '0'.





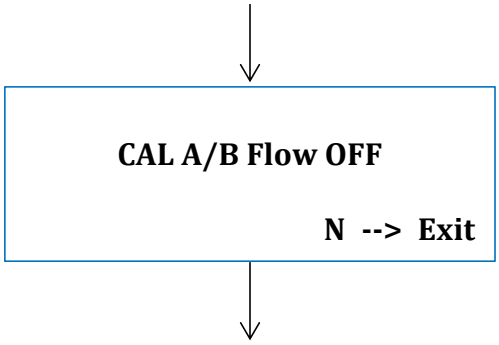
Clean the CAL B flow path of Valve 1 before counter reaches '0'.

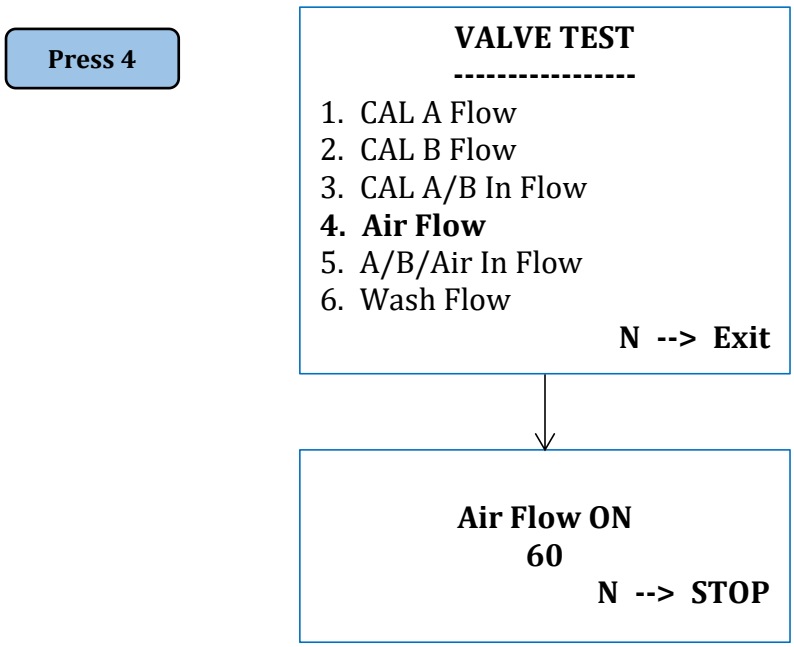
Press N



Clean the CAL A/B flow path of Valve 2 before counter reaches '0'.

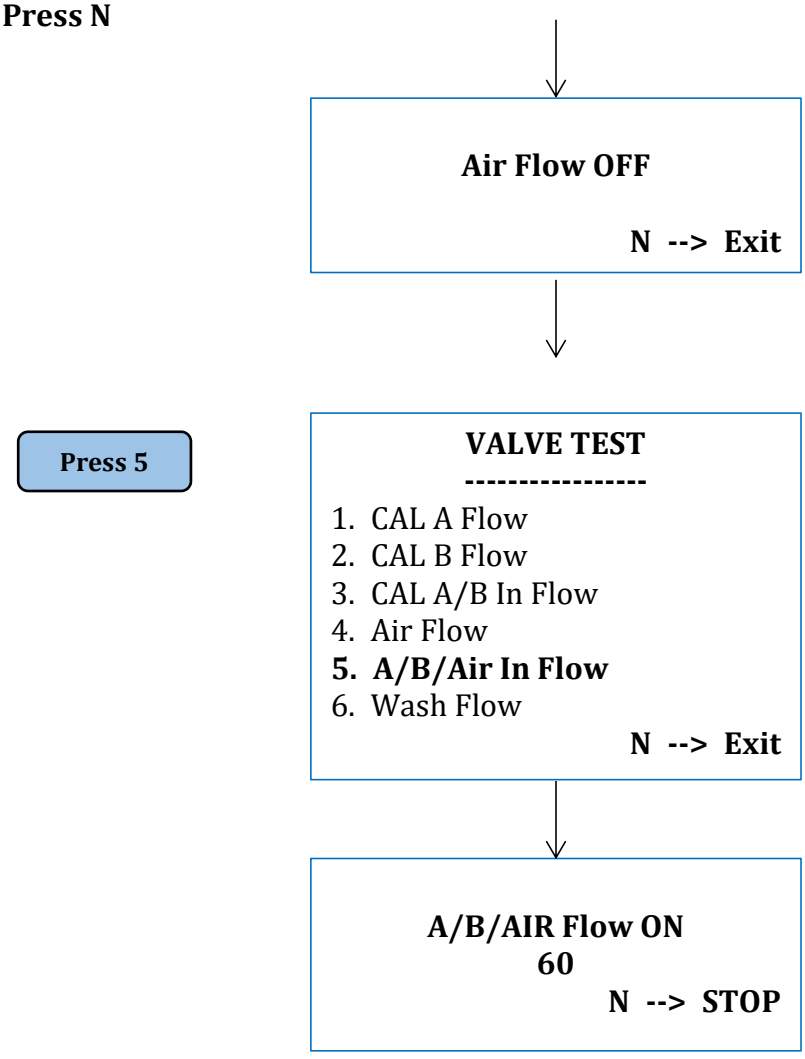
Press N





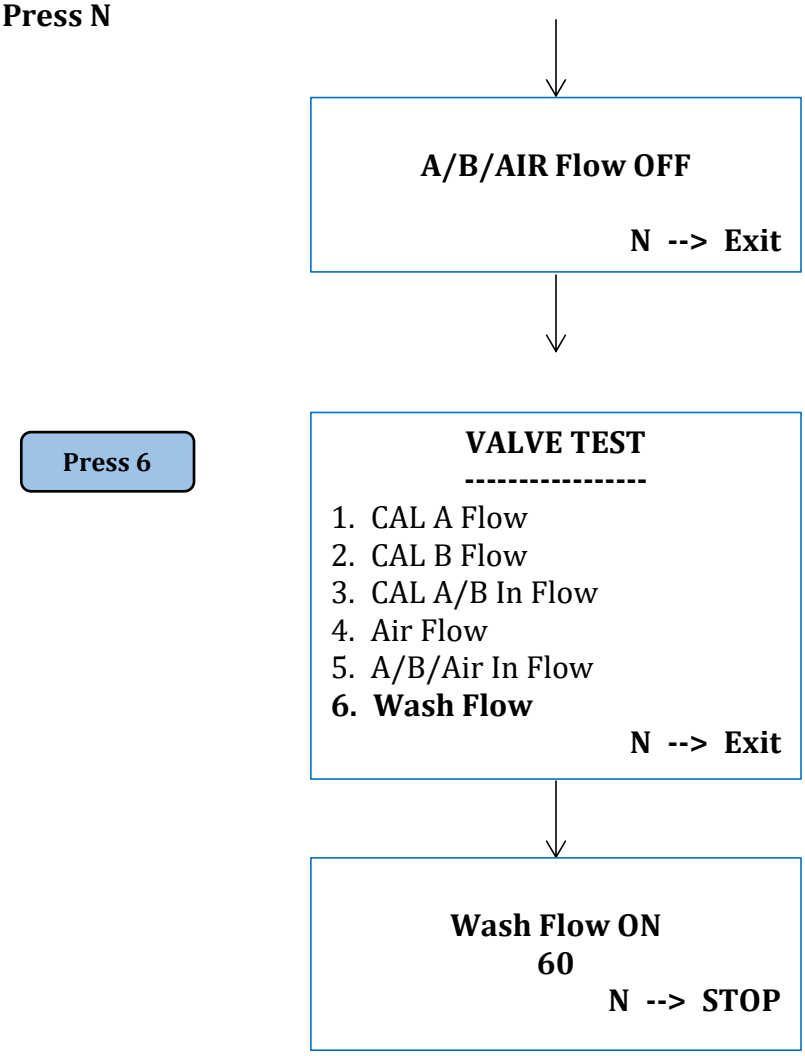
Clean the AIR flow path of Valve 2 before counter reaches '0'.

Press N



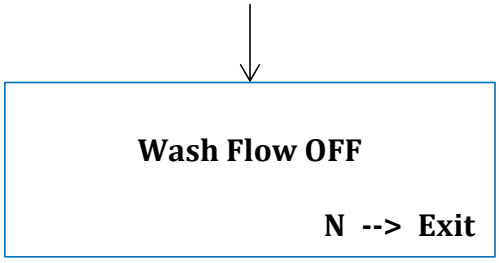
Clean the CAL A/B/AIR flow path of Valve 3 before counter reaches '0'.

Press N



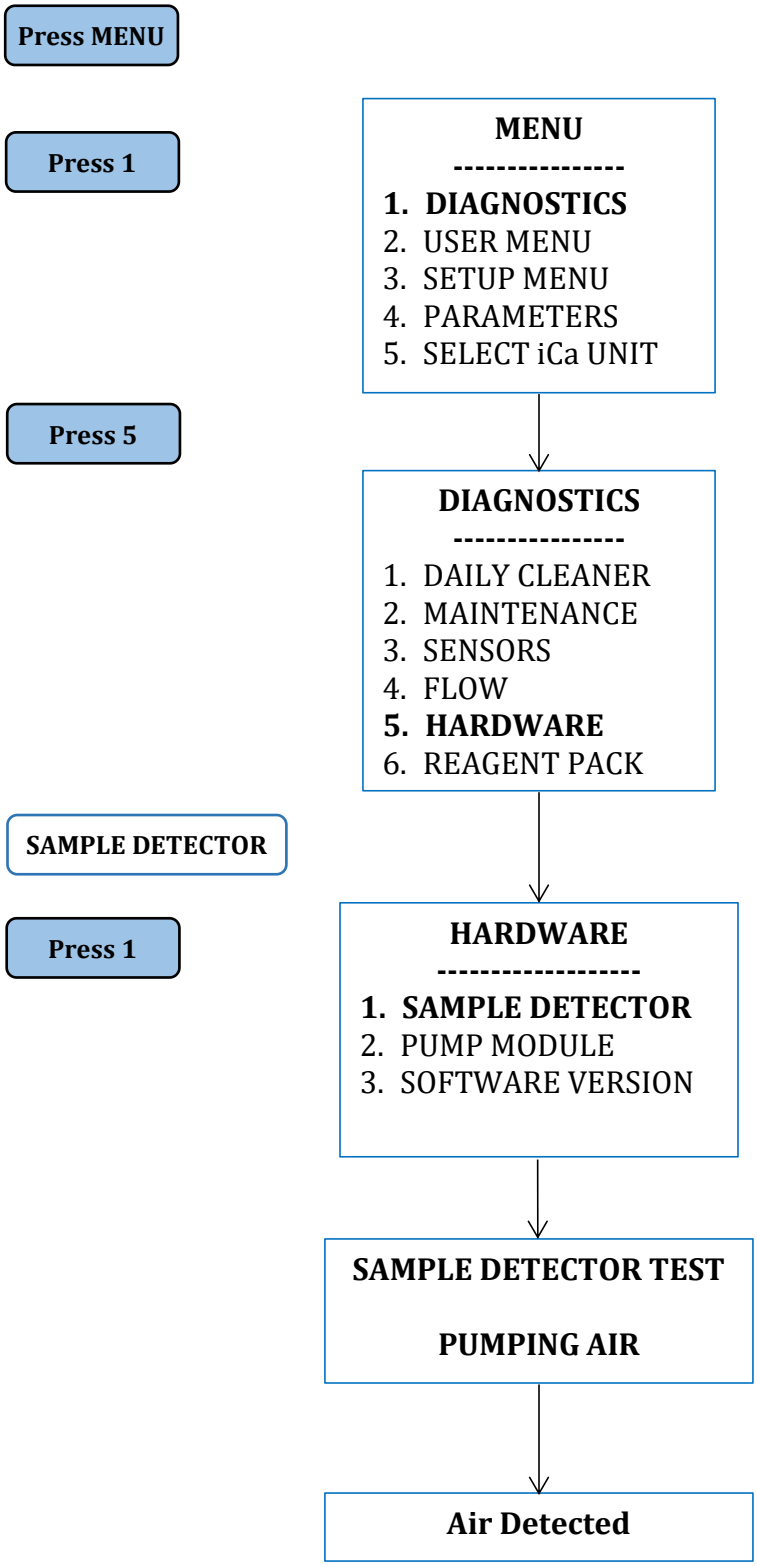
Clean the WASH flow path of Valve 3 before counter reaches '0'.

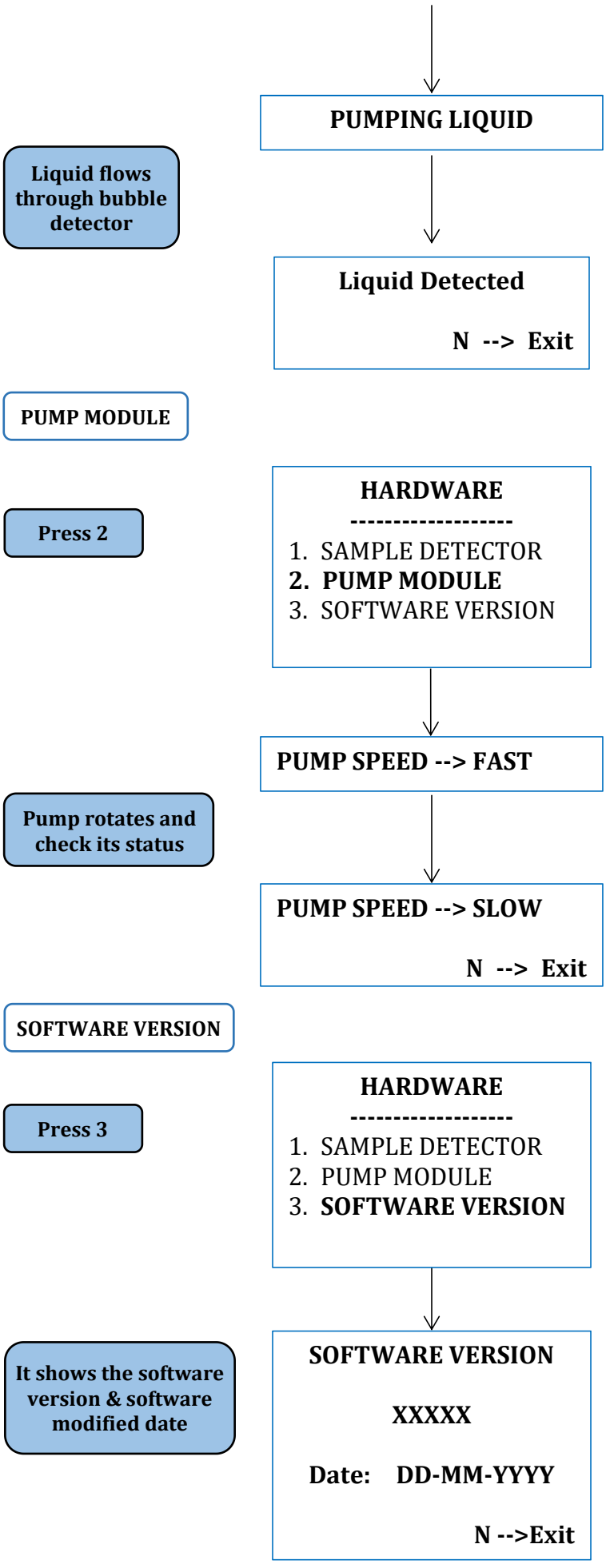
Press N



e) HARDWARE :

Following is the flow for HARDWARE:

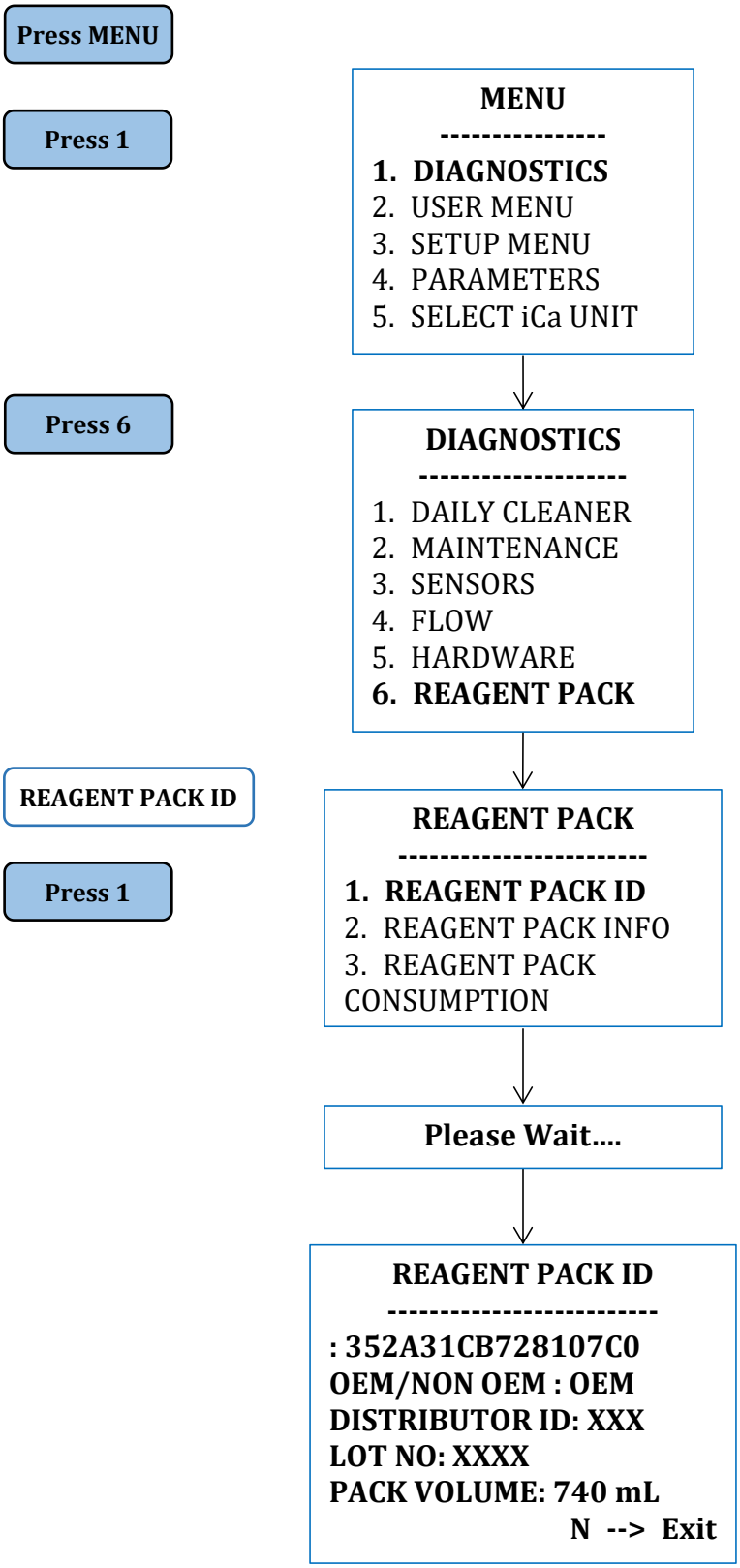


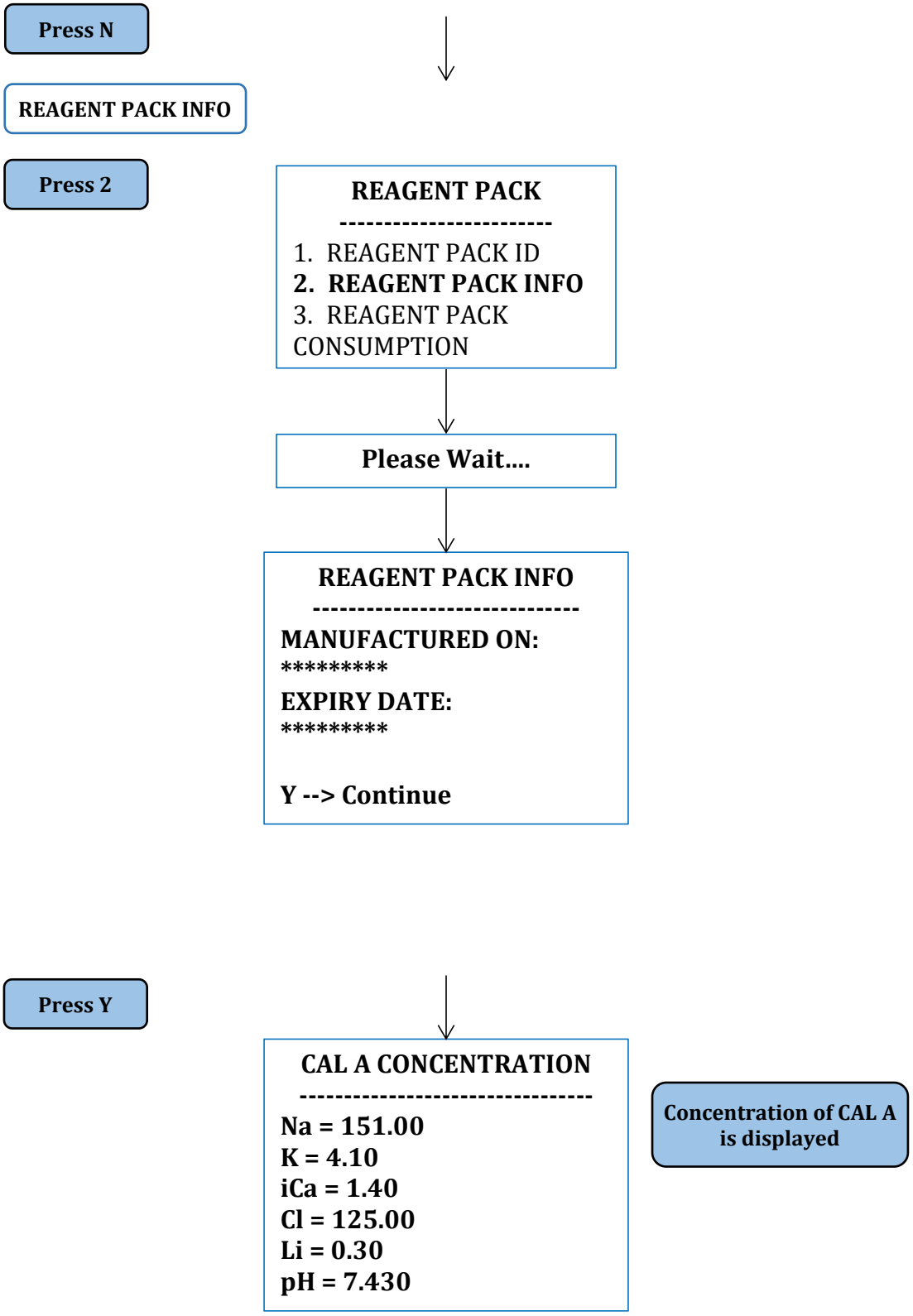

PUMPING LIQUID
Liquid flows through bubble detector
Liquid Detected
N --> Exit
PUMP MODULE
Press 2
HARDWARE
1. SAMPLE DETECTOR
2. PUMP MODULE
3. SOFTWARE VERSION
PUMP SPEED --> FAST
Pump rotates and check its status
PUMP SPEED --> SLOW
N --> Exit
SOFTWARE VERSION
Press 3
HARDWARE
1. SAMPLE DETECTOR
2. PUMP MODULE
3. SOFTWARE VERSION
It shows the software version & software modified date
SOFTWARE VERSION
XXXXX
Date: DD-MM-YYYY
N -->Exit

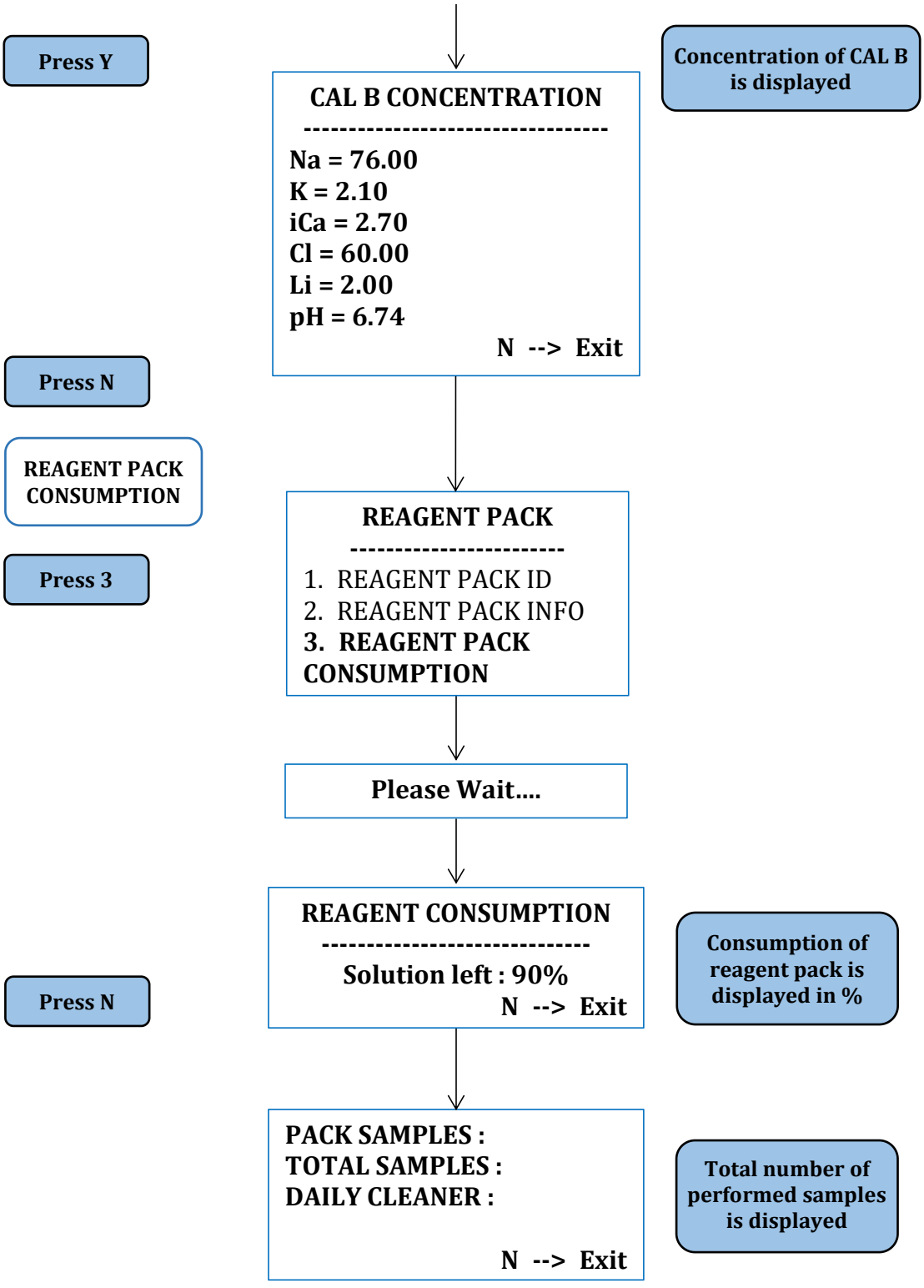
f) REAGENT PACK :

It will show the information of reagent pack like consumption, reagent pack lot number, pack volume and other information about CAL A & CAL B concentration.

Following is the flow for REAGENT PACK:




Press N
REAGENT PACK INFO
Press 2
REAGENT PACK
1. REAGENT PACK ID
2. REAGENT PACK INFO
3. REAGENT PACK CONSUMPTION
Please Wait....
REAGENT PACK INFO
MANUFACTURED ON:
****
EXPIRY DATE:
****
Y --> Continue
Press Y
CAL A CONCENTRATION
Na = 151.00
K = 4.10
iCa = 1.40
Cl = 125.00
Li = 0.30
pH = 7.430
Concentration of CAL A is displayed



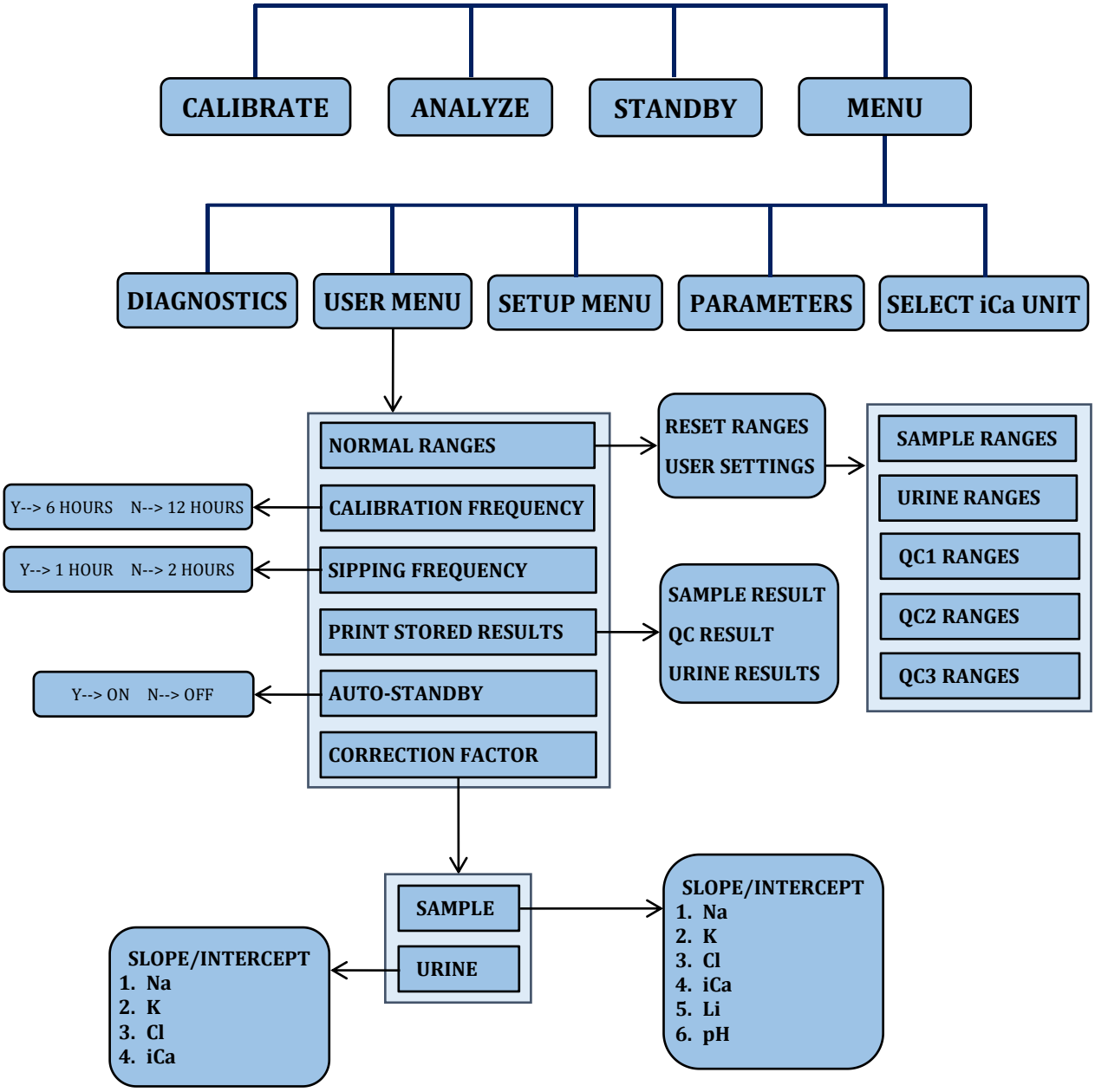
Notes:

Pack Samples : No. of samples performed with the current reagent pack.

Total Samples : Total number of samples performed in the analyzer since from the installation.

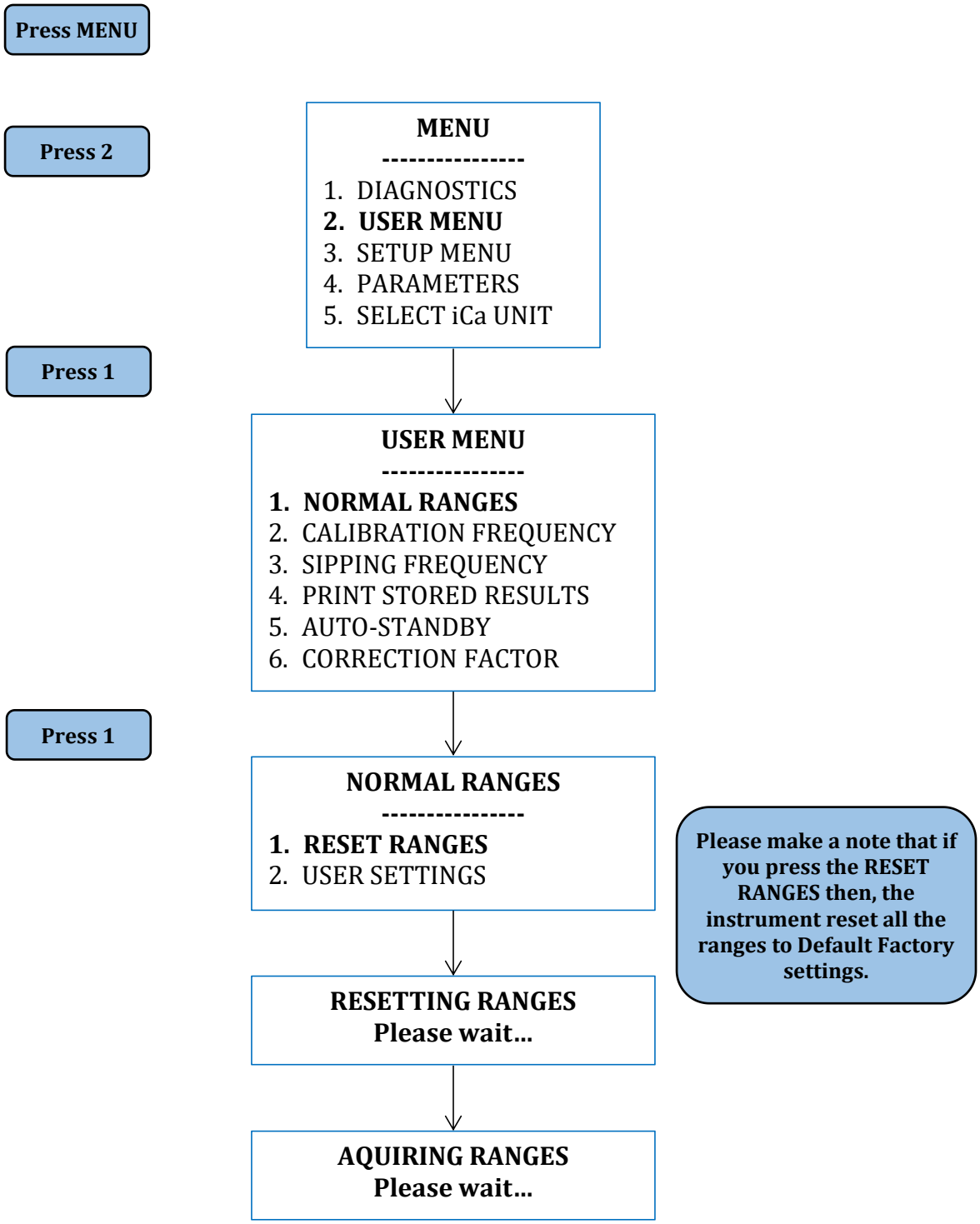
Daily Cleaner : No. of times daily cleaner performed with the current reagent pack.

3.4.2 User Menu: User Menu permits operator to check and test **key operating functions** of the MaxLYTE Electrolyte Analyzer.

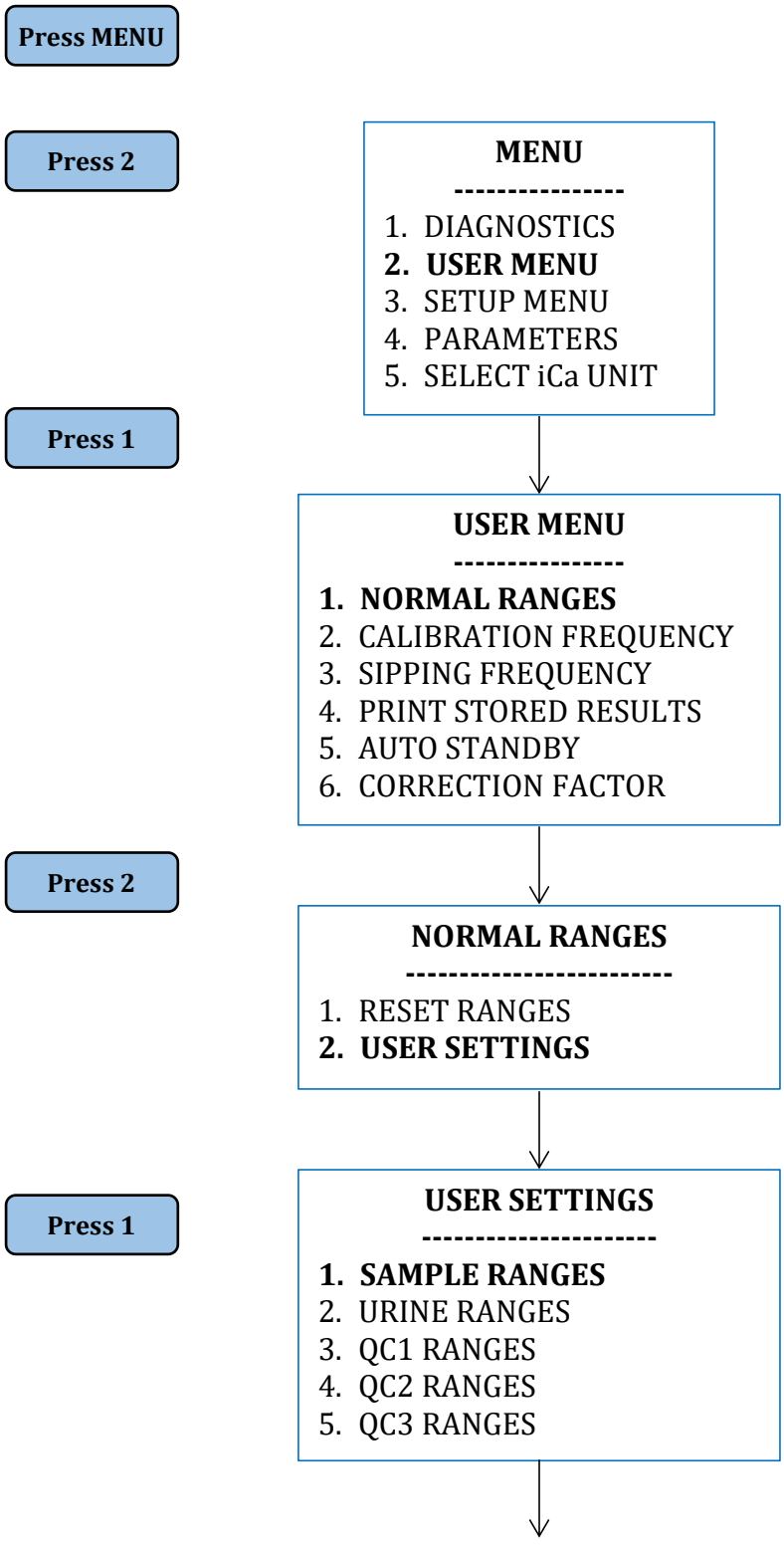


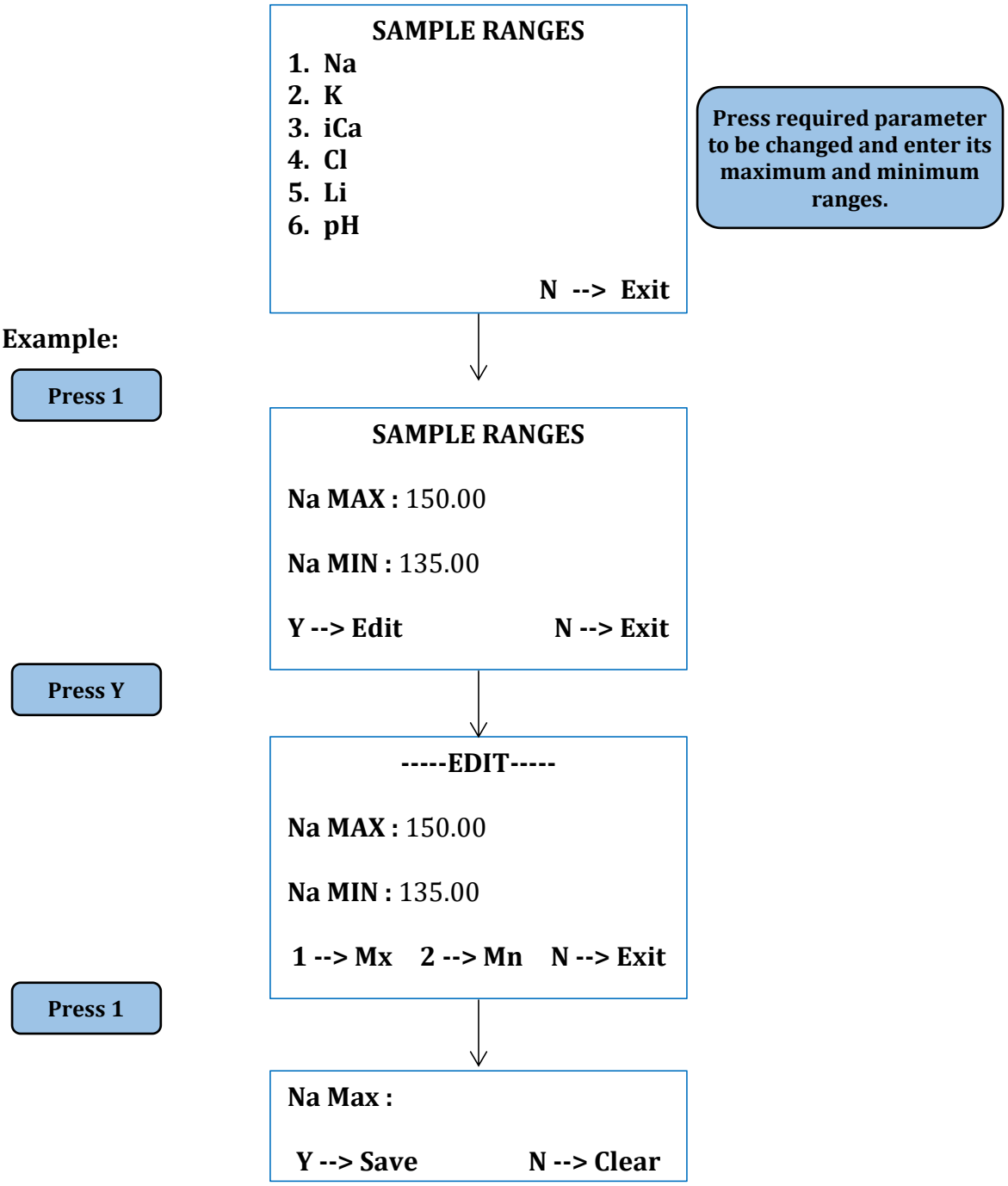
a) NORMAL RANGES:

Following is the flow for NORMAL RANGES:



NORMAL RANGES : USER SETTINGS



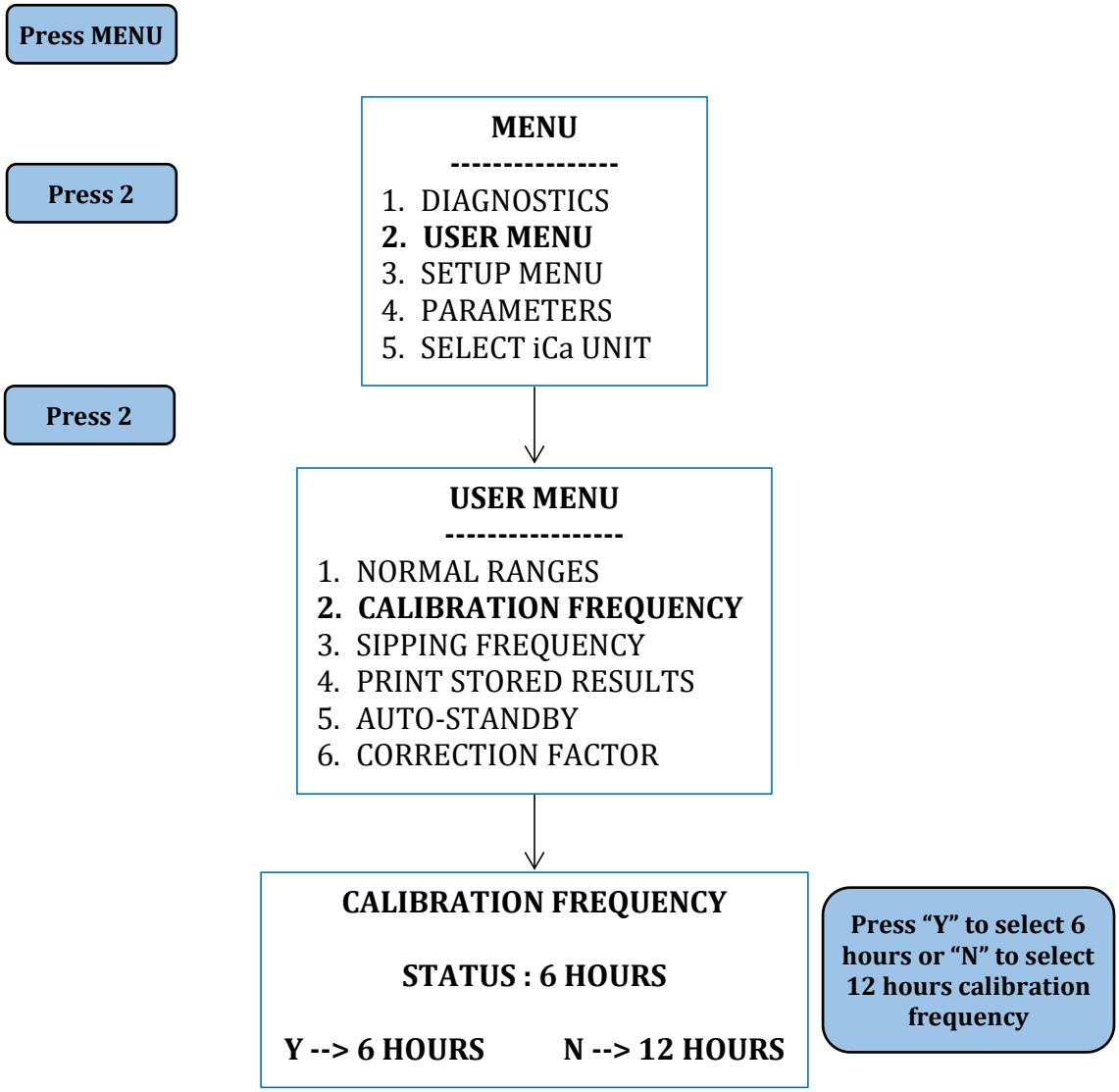


Enter the value and press "Y" to save and "N" to clear.

Similarly, perform the above process for all the parameters in Sample, Urine & QC Ranges.

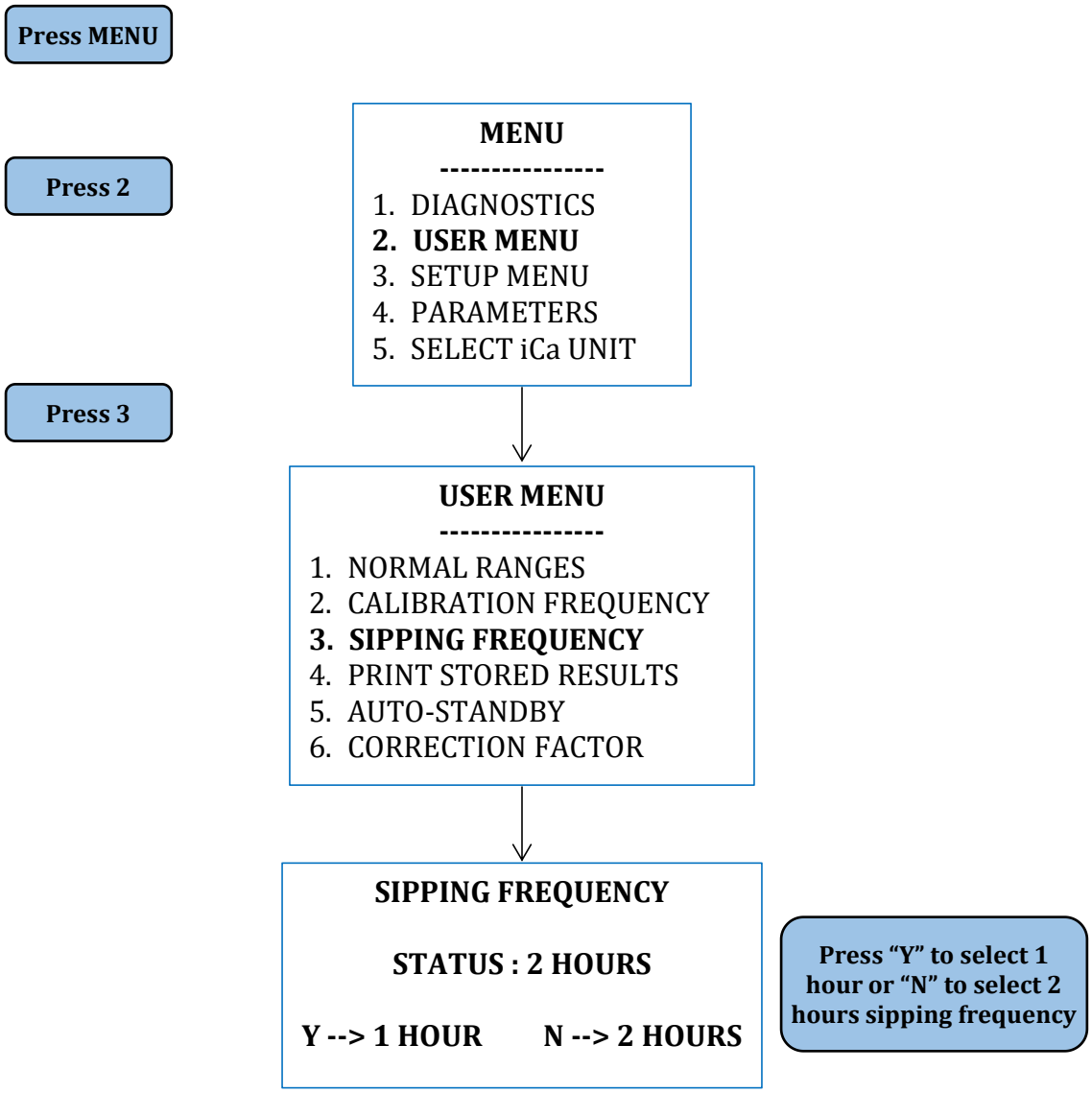
b) CALIBRATION FREQUENCY: Instrument will perform automatic calibration for every 6 hours / 12 hours for good performance of the instrument.

Following is the flow for CALIBRATION FREQUENCY:



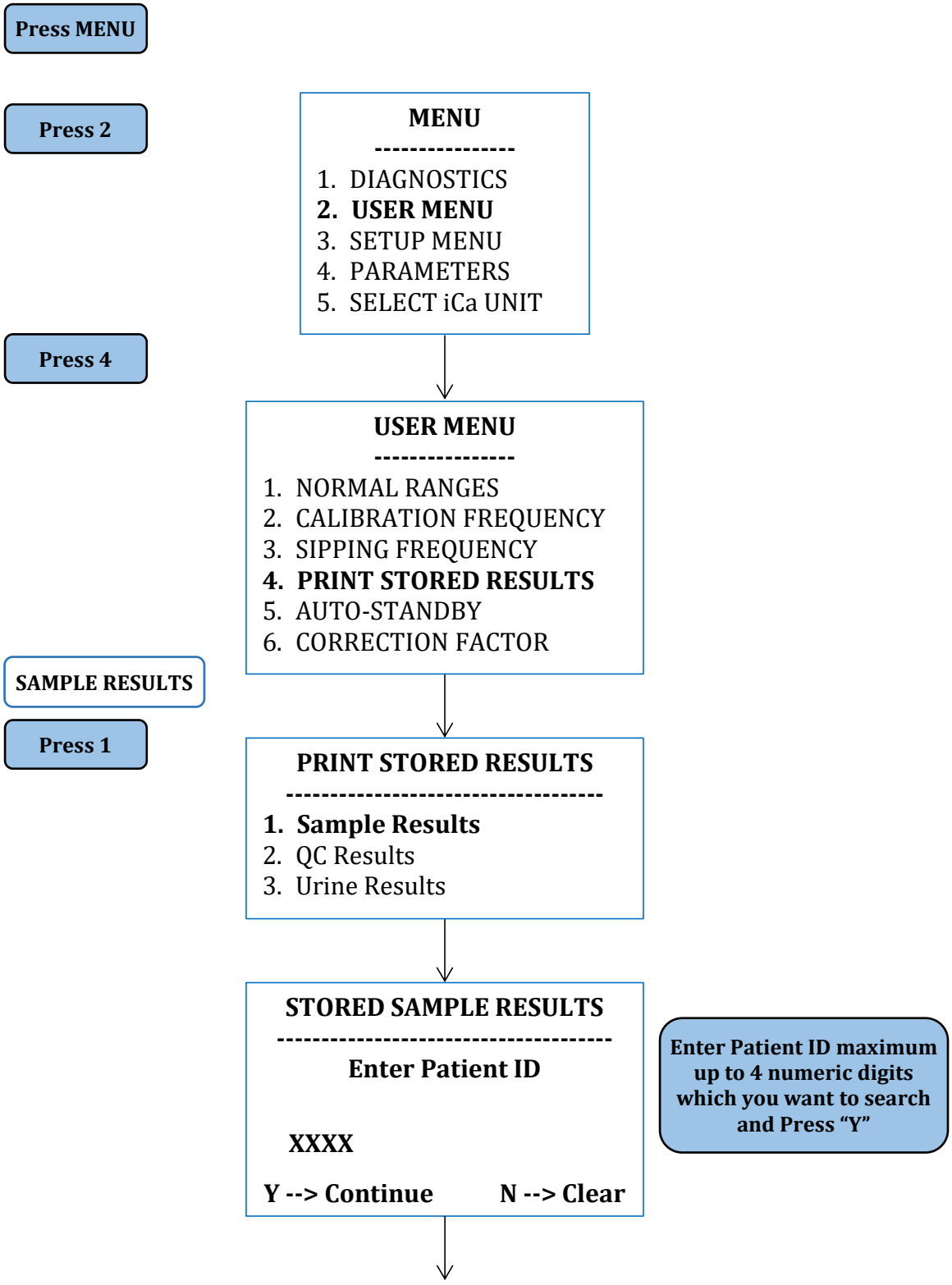
c) SIPPING FREQUENCY: For every 1 hour / 2 hours instrument takes liquid to make electrodes wet, this is called Sipping. Here we can select the sipping time frequency.

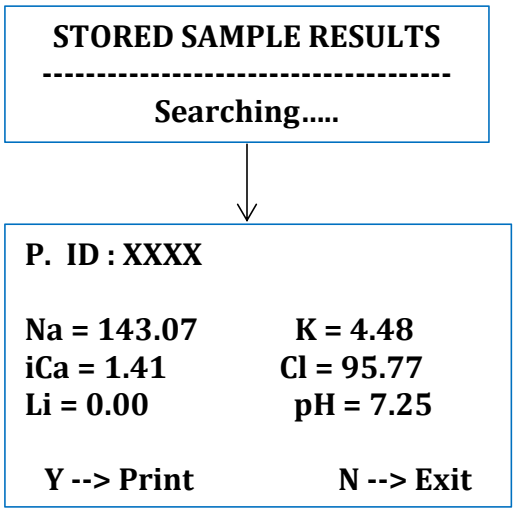
Following is the flow for SIPPING FREQUENCY:



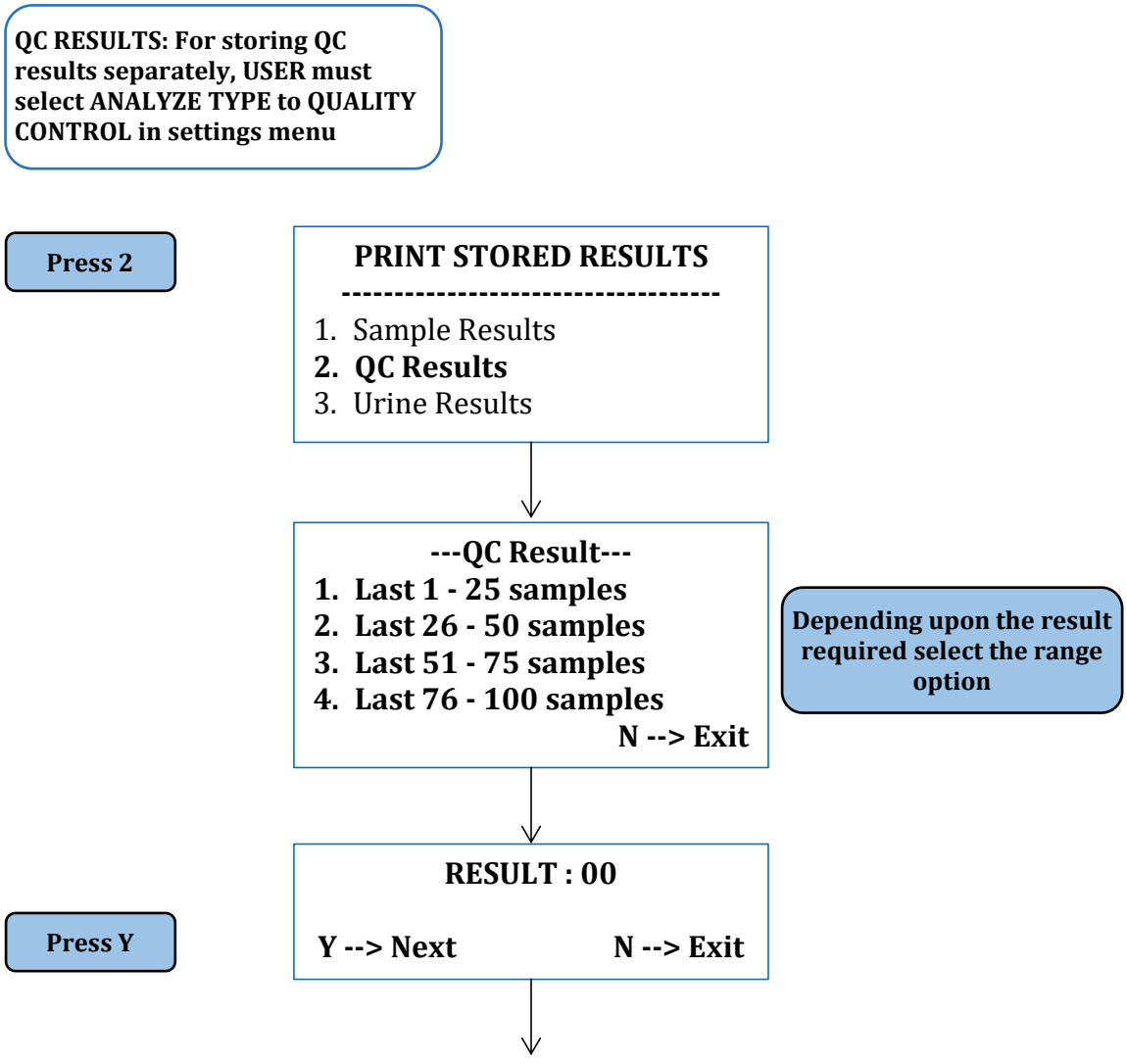
d) PRINT STORED RESULTS:

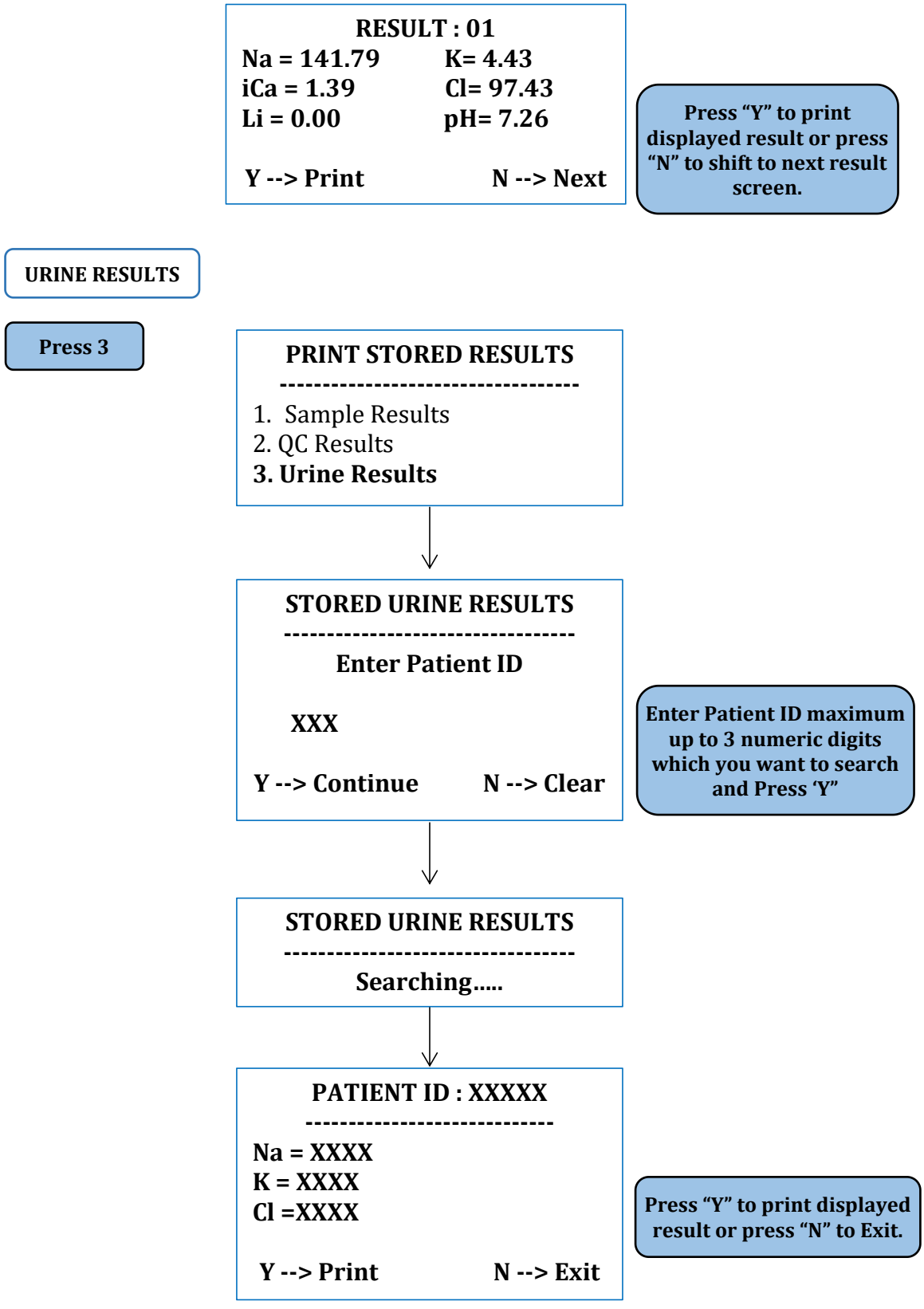
Following is the flow for PRINT STORED RESULTS:





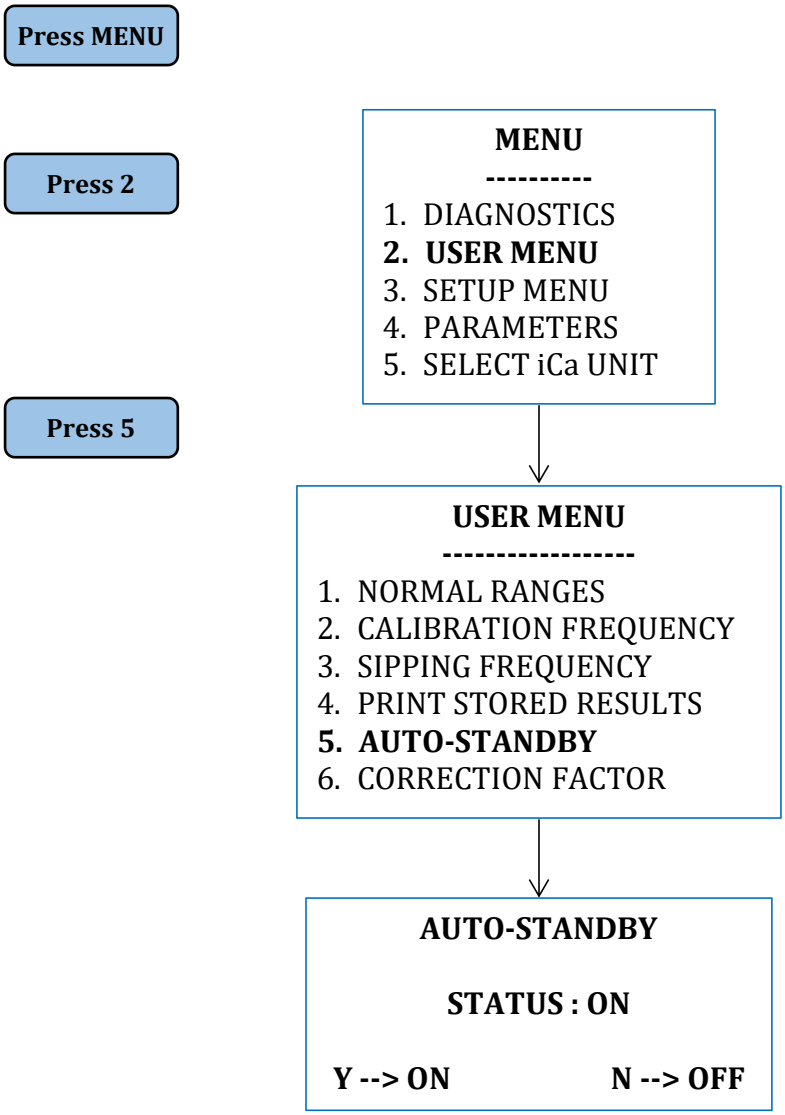
Press "Y" to print displayed results or press 'N" to Exit.




RESULT : 01
Na = 141.79 K= 4.43
iCa = 1.39 Cl= 97.43
Li = 0.00 pH= 7.26
Y --> Print N --> Next
Press "Y" to print displayed result or press "N" to shift to next result screen.
URINE RESULTS
Press 3
PRINT STORED RESULTS
1. Sample Results
2. QC Results
3. Urine Results
STORED URINE RESULTS
Enter Patient ID
XXX
Y --> Continue N --> Clear
Enter Patient ID maximum up to 3 numeric digits which you want to search and Press 'Y"
STORED URINE RESULTS
Searching.....
PATIENT ID : XXXXX
Na = XXXX
K = XXXX
Cl =XXXX
Y --> Print N --> Exit
Press "Y" to print displayed result or press "N" to Exit.

e) AUTO STANDBY: AUTO STANDBY option is used to ON the STANDBY mode automatically, which depends on Calibration Frequency. If Calibration Frequency is 6 hours, Calibration occurs after 6 hours from the previous Calibration after that analyzer automatically goes into STANDBY mode.

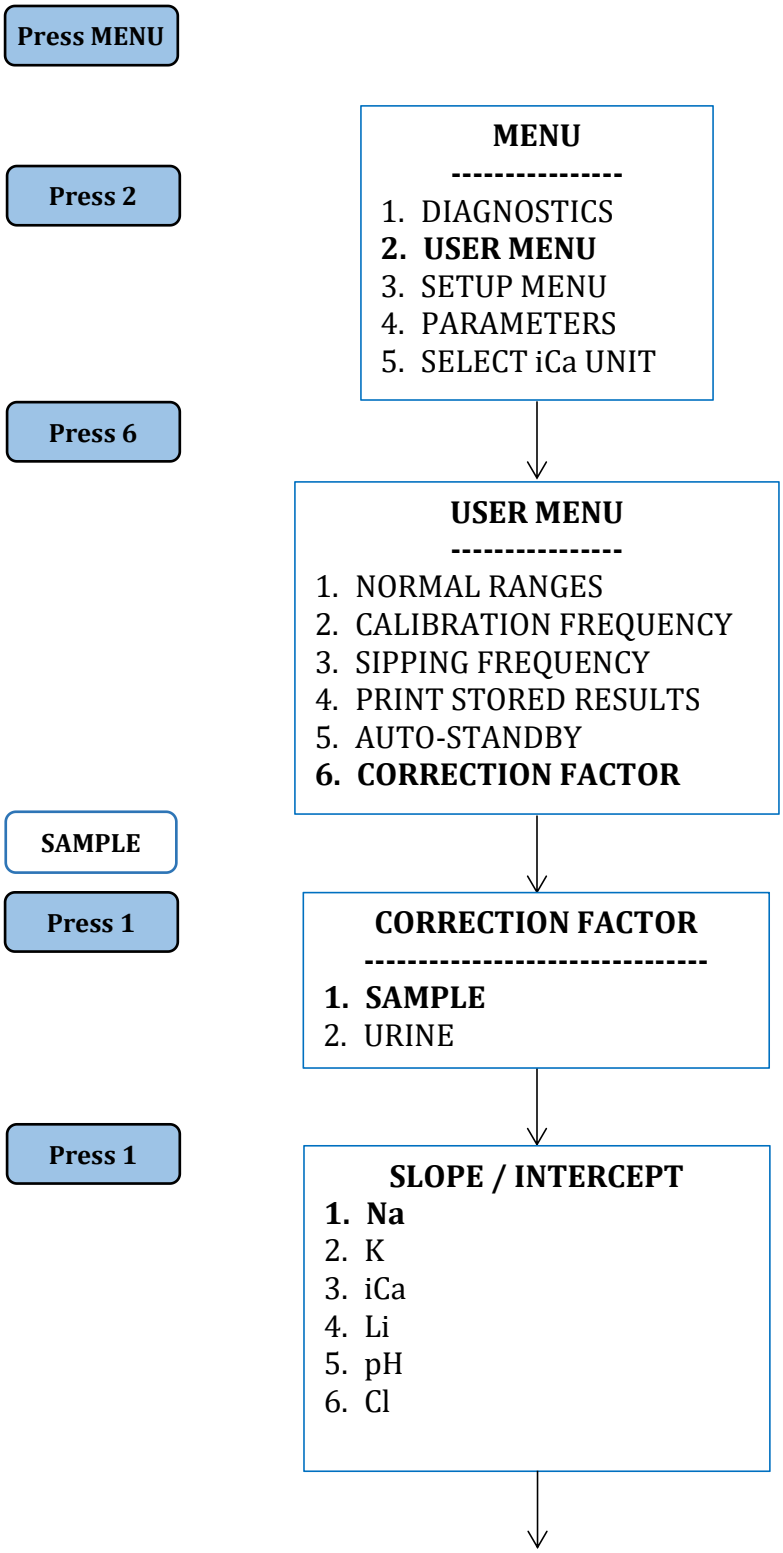
Following is the flow for AUTO STANDBY:

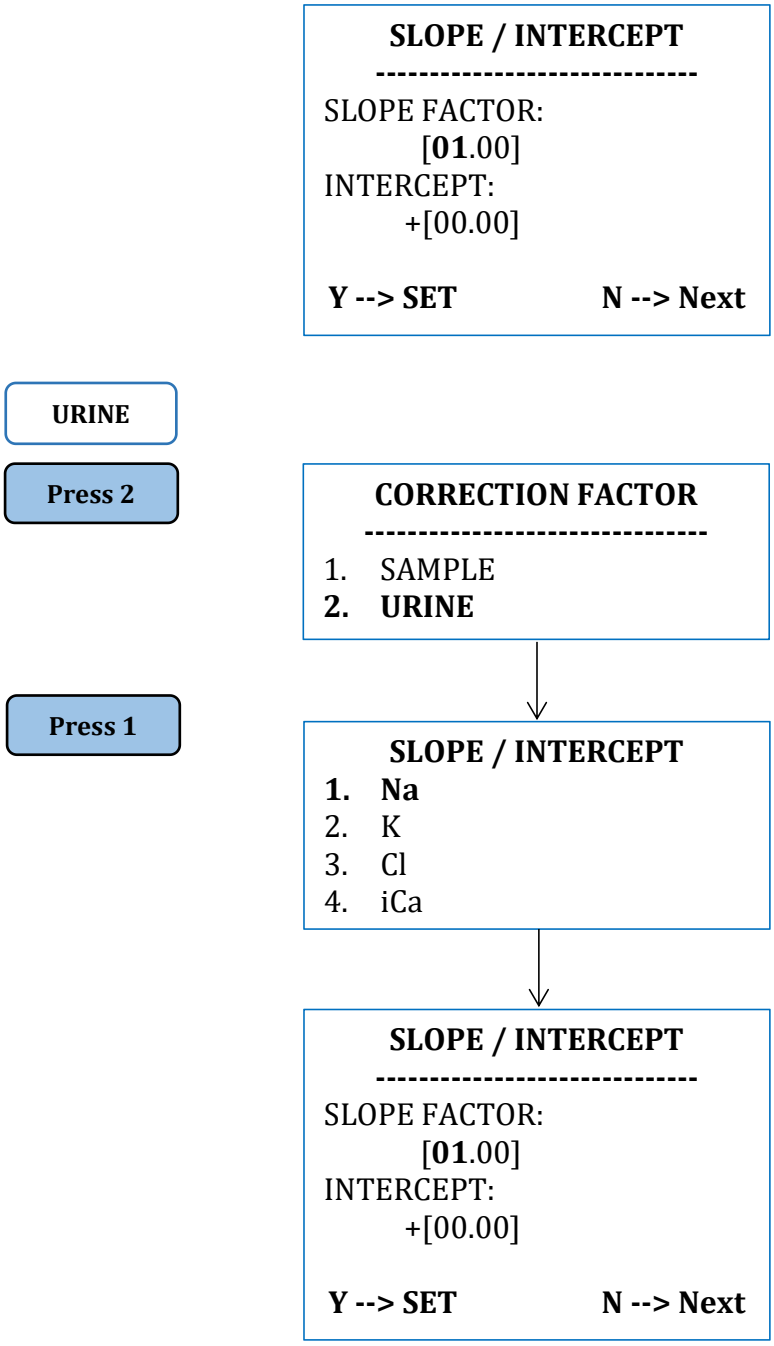


Press "Y" to ON and "N" to OFF

f) CORRECTION FACTOR:

Following is the flow for CORRECTION FACTOR:

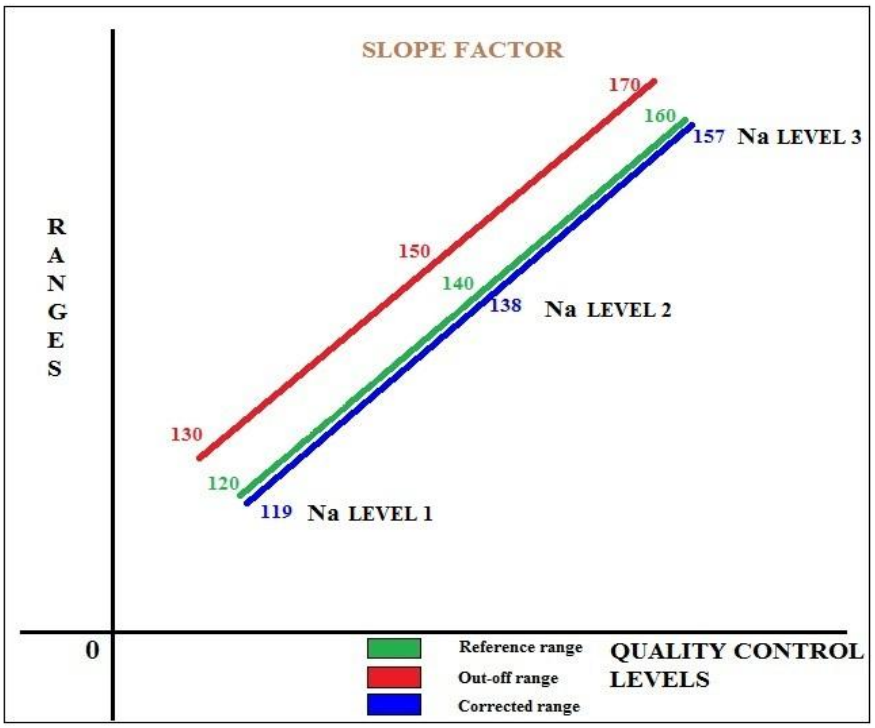




Note:
By default Slope Factor value is **01.00** & Intercept is **00.00** for both sample & Urine.

SLOPE FACTOR:

Slope factor is used for multiplying the factor with the result obtained.



In the above graph, green line indicates the normal/reference state (All the control levels lie with its range as per the Q.C sheet provided in the Q.C box), red line indicates the high/out-off state (Electrodes are reading higher) and blue line indicates the low/out-off state (Electrodes are reading either lower) than the target value range.

After running all the three controls only, we can confirm that whether slope factor/intercept should be added depending upon its readings.

In the above graph level-1, level-2 and level-3 of any parameter is reading on higher side. In this case we have to add slope factor between 0.5 to 1. So, that level-1, level 2 and level 3 results will be multiplied by that factor.

E. g.: In the above graph, when all the three Q.C levels are analyzed. We have got Na on higher side. In this case, we have to insert slope factor of 0.92. Now, 0.92 will be multiplied with the result of Na (e.g.: 130*0.92=119).

After adding slope factor we should run all the three controls and verify whether selected parameter (parameter which needed correction) lie within its range. Slope factor should be added and verified until the parameter lie in its range.

If level-1, level-2 and level-3 of Na is reading on lower side (i.e. reverse of above case). Then, we have to add slope factor between 1 to 1.5. So, that level-1, level 2 and level 3 results will be multiplied by that factor.

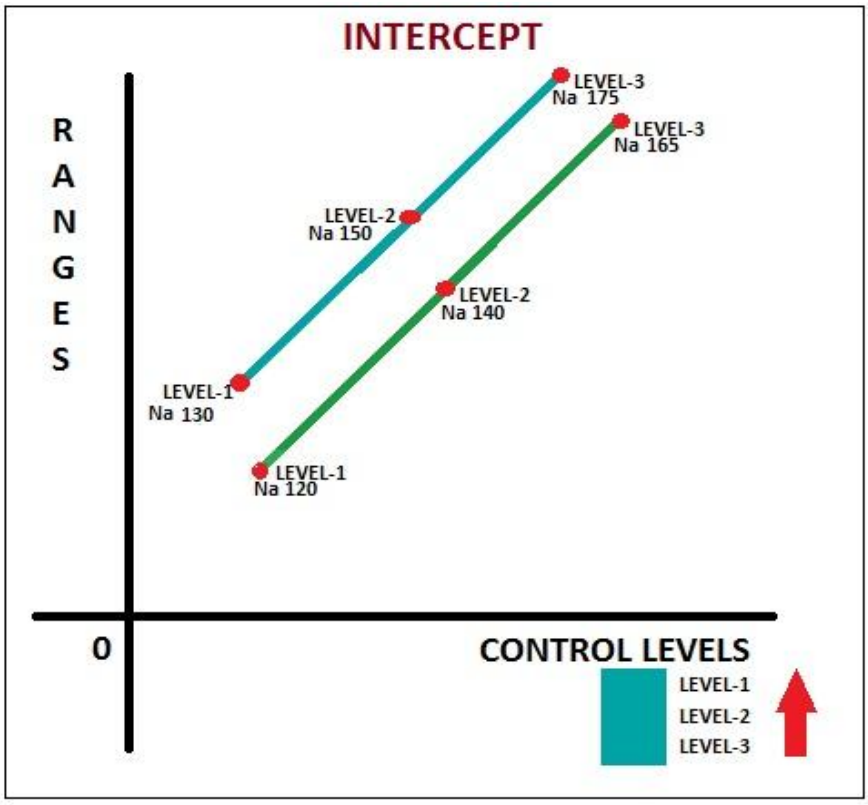
Y = m X + C

Where, m = slope. If we add slope factor from 0.5 to 1, then our output(Y) will be decreased. Since, slope factor will be multiplied with X (obtained result). Similarly, if we add slope factor from 1 to 1.5, then our output will be increased. Since, slope factor will be multiplied with X (obtained result).

Note: Slope factor acceptable range is from 0.50 to 1.50 for all (Na, K, iCa, Li, pH, Cl) parameters individually.

INTERCEPT:

Intercept is used if all the three control values read either higher or lower.

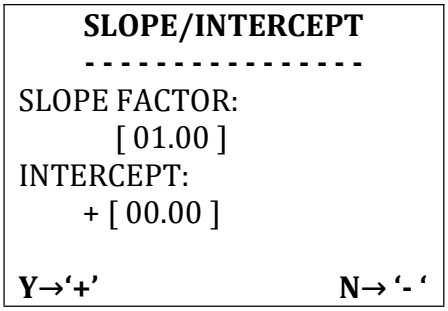


(i.e.) y = mx + c

Where m is the slope of the line and C is the y-intercept, which is the y-coordinate of the location where line crosses the y axis.

For increasing/decreasing all the control values to desired level we have to select + or -10 variation for Na, Cl & + or – 0.5 variation in K, iCa, Li & pH. In the above graph of intercept, Na is reading all the three control levels higher approximately by 10. In this case we have to subtract intercept as 10.00 and verify it by running all three controls. Similarly, for all the parameters intercept can be added according to their requirement and respectively intercept ranges.

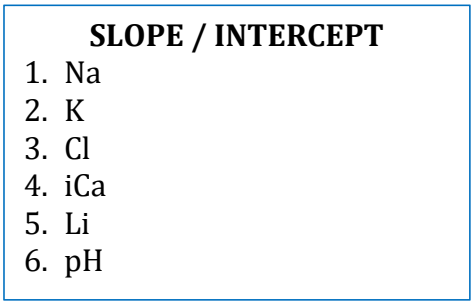
Note: - By default Slope factor value is 01.00 & Intercept is 00.00



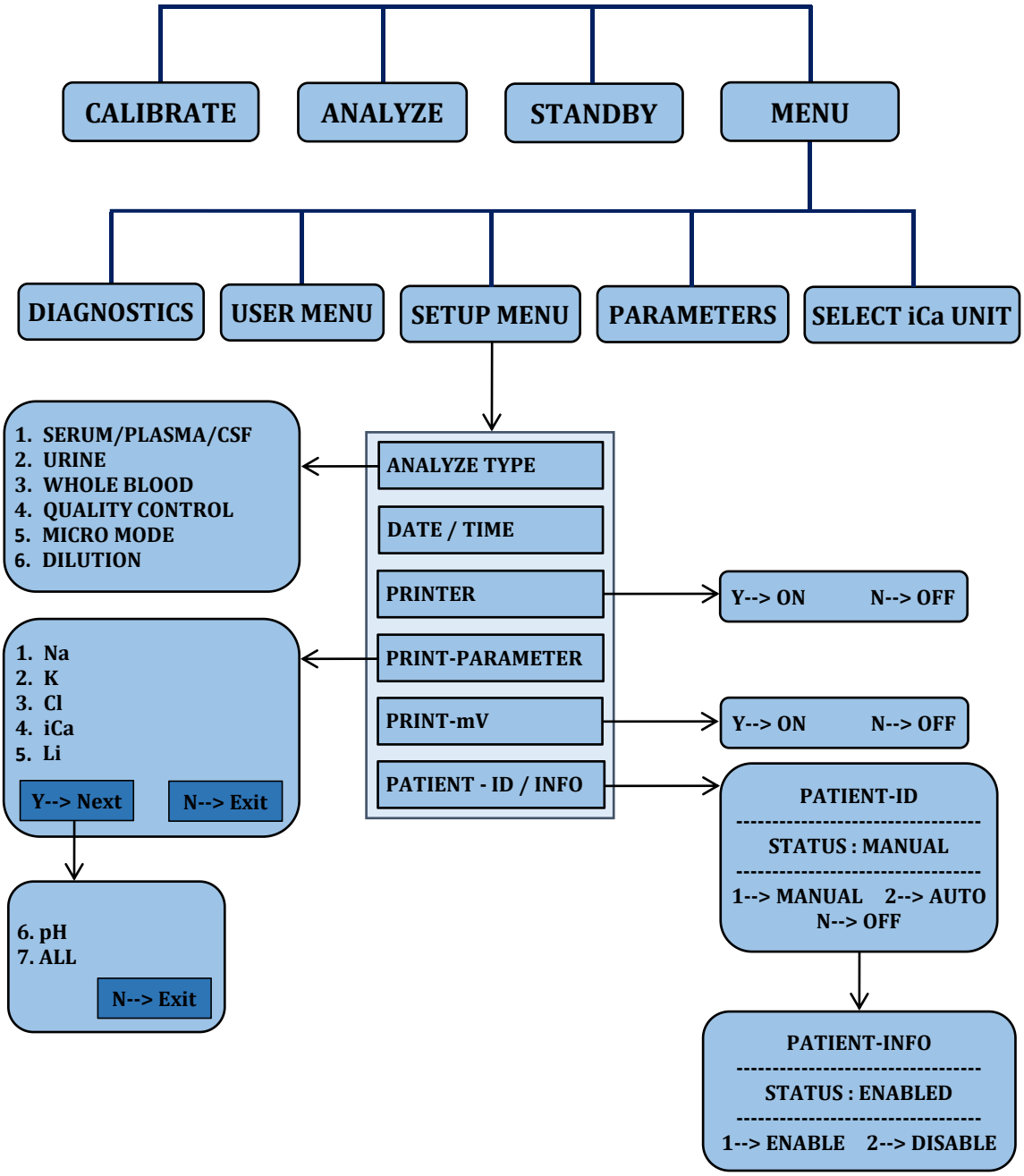
Note: Intercept acceptable range is -10.00 to +10.00 for Na, Cl parameters and -0.50 to +0.50 for K, iCa, Li & pH parameters individually.

Select variation according to the necessity for result.

Press N

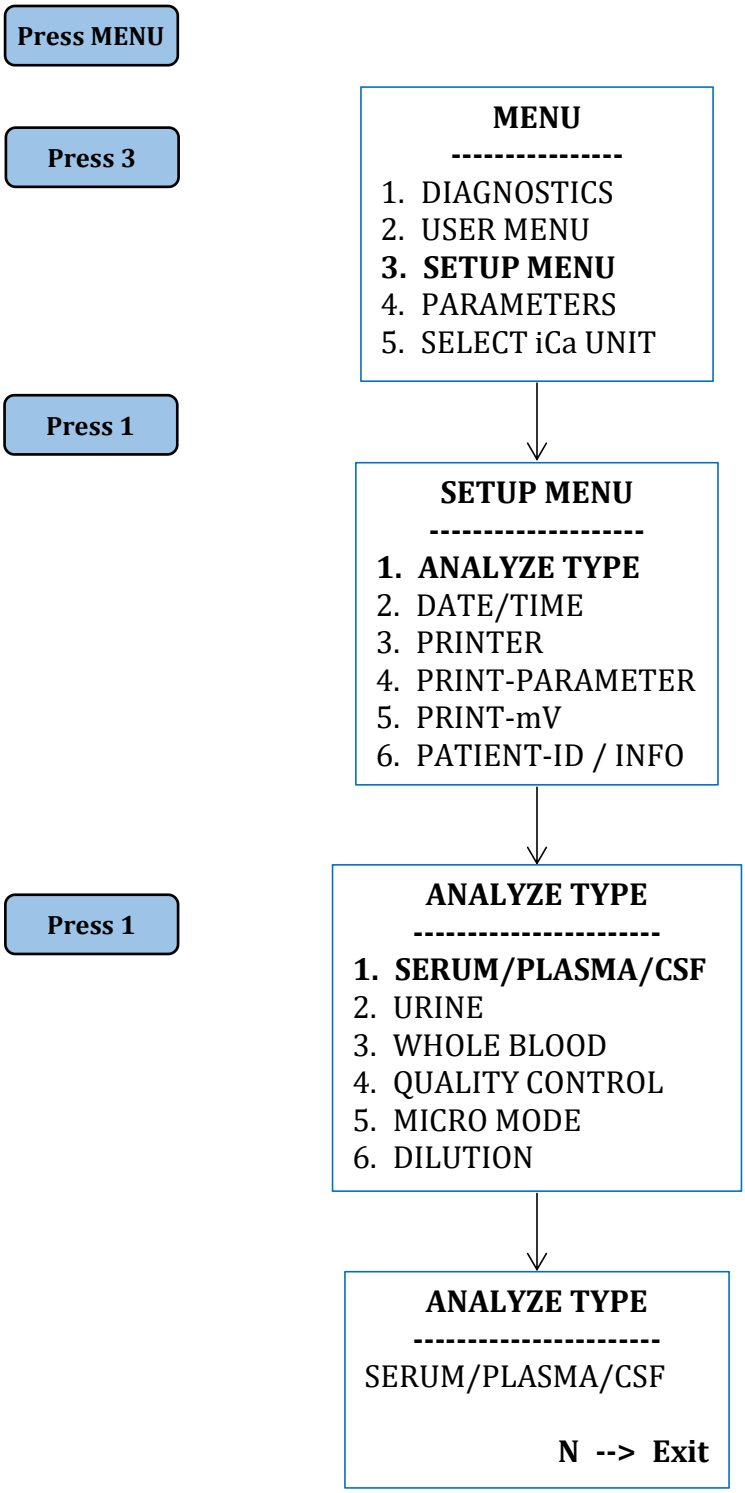


3.4.3 Setup Menu



a) ANALYZE TYPE: By using this option, User can select different modes of analyze sample as per requirement.

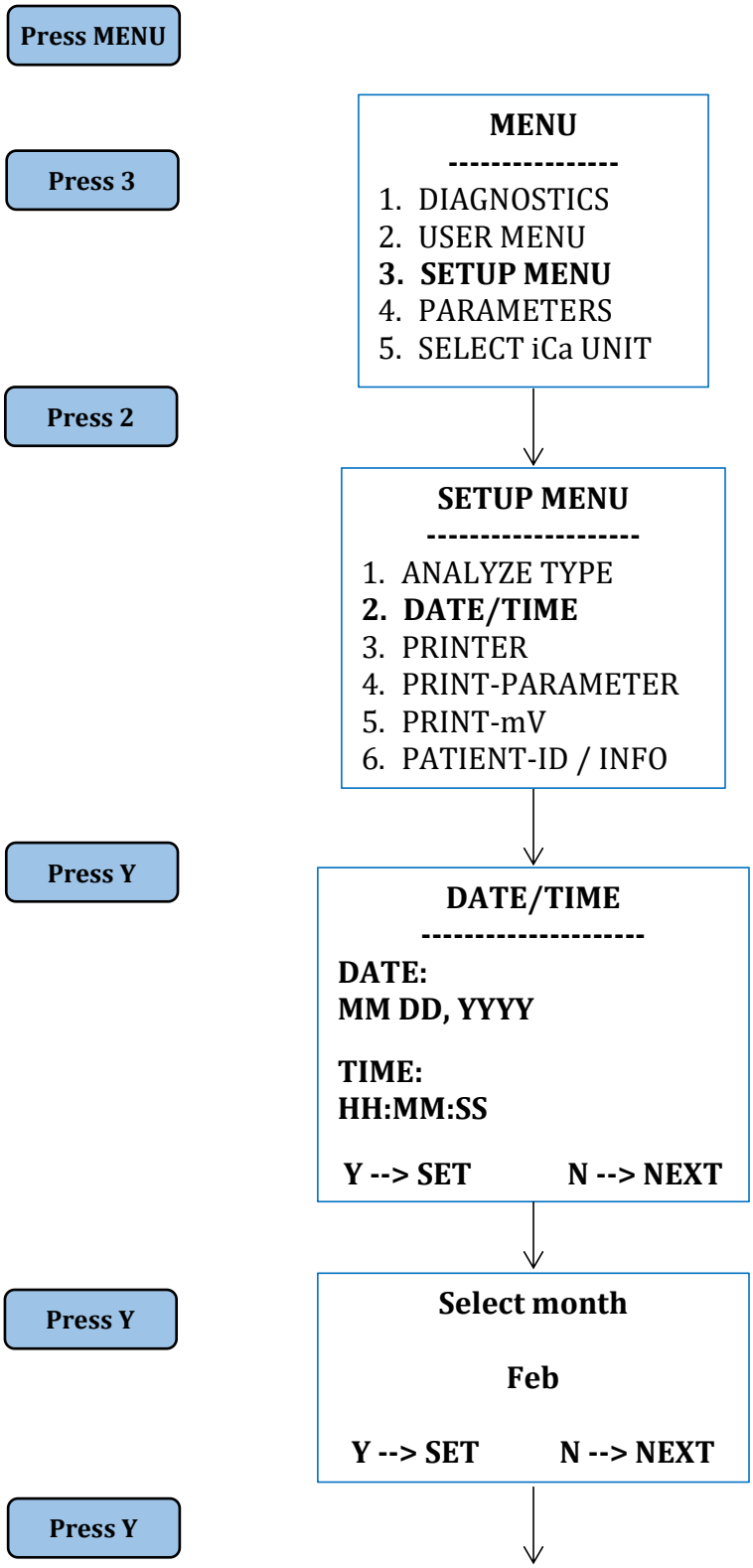
Following is the flow for ANALYZE TYPE:

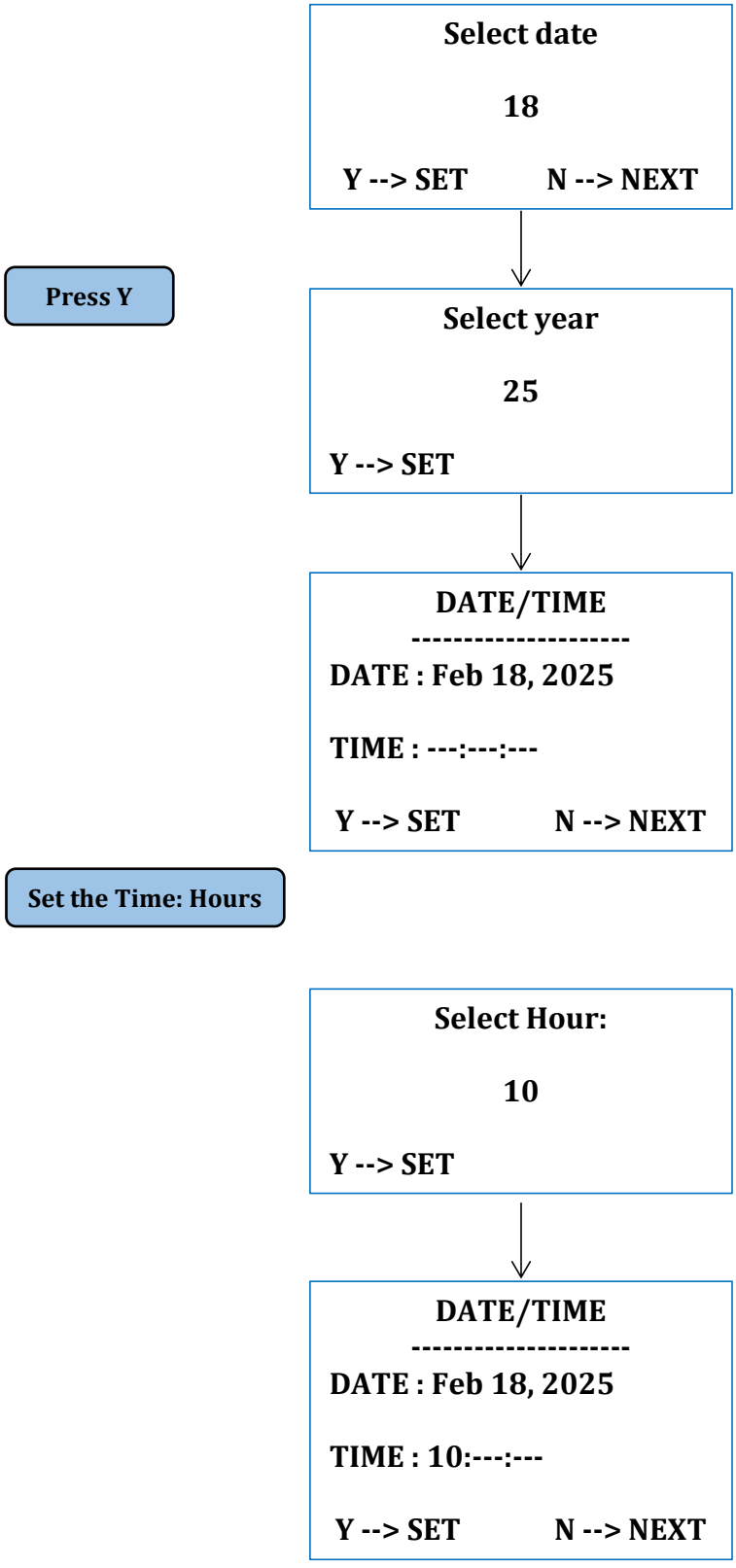


Similarly, perform the above steps for selecting the Urine, Whole Blood, Quality Control, Micro Mode and Dilution Analyze Sample Types.

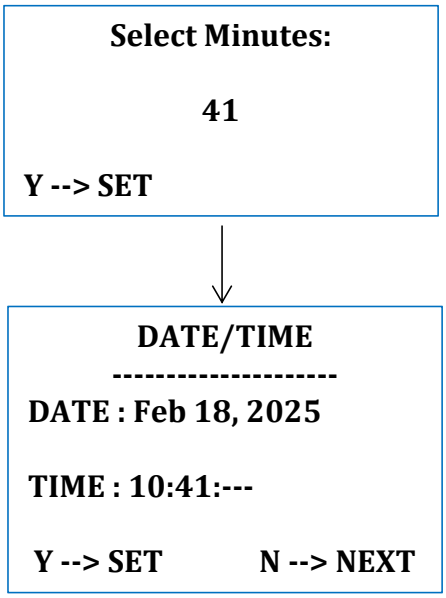
b) DATE/TIME: By using this option, User can change the Date & Time of the instrument. By using "Y" button, user can select the field which we want to change and by using "N" button, user can change the field.

Following is the flow for DATE/TIME:

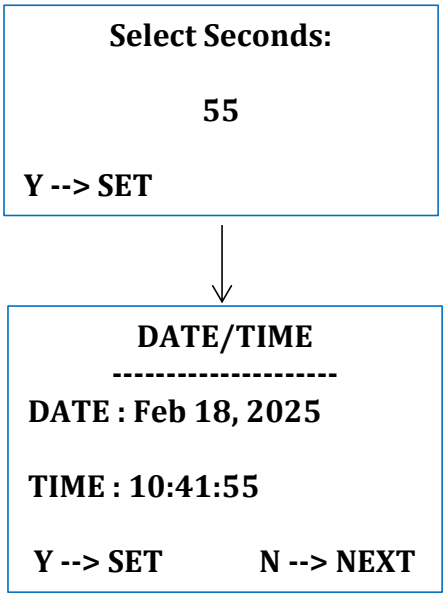



Select date
18
Y --> SET
N --> NEXT
Press Y
Select year
25
Y --> SET
DATE/TIME
DATE : Feb 18, 2025
TIME : ---:---:---
Y --> SET
N --> NEXT
Set the Time: Hours
Select Hour:
10
Y --> SET
DATE/TIME
DATE : Feb 18, 2025
TIME : 10:---:---
Y --> SET
N --> NEXT

Set the Time: Minutes



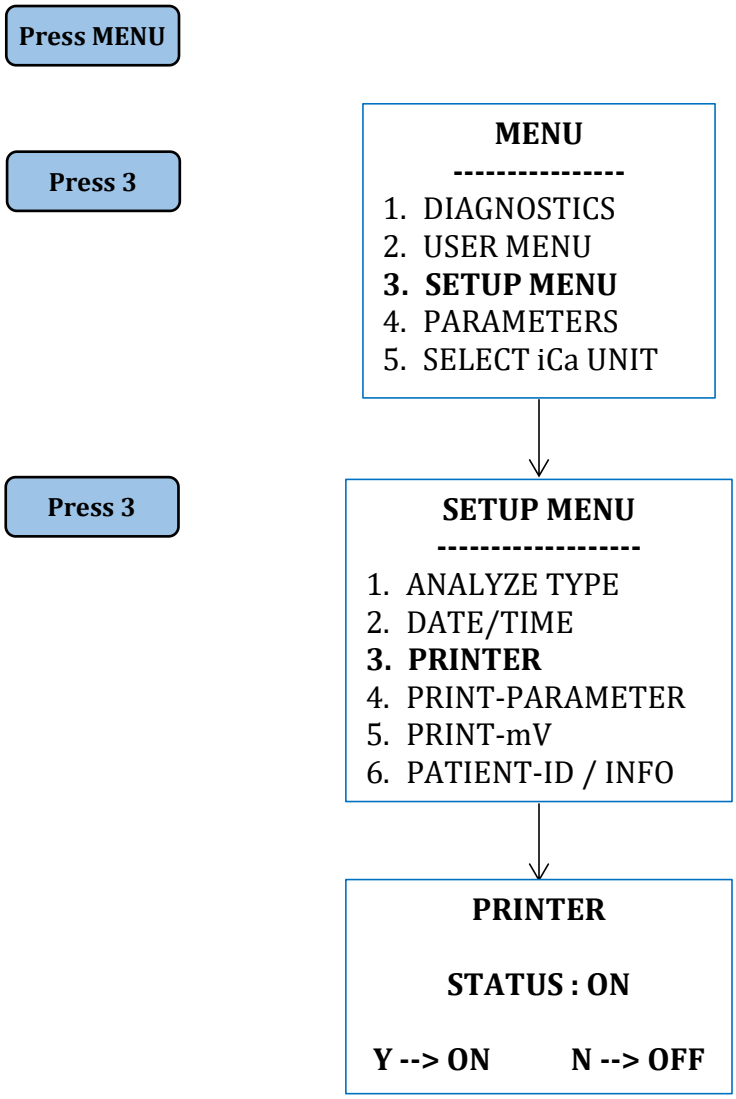
Set the Time: Seconds



Press N and the Date and Time has been SET.

c) PRINTER: USER can Switch OFF the printer.

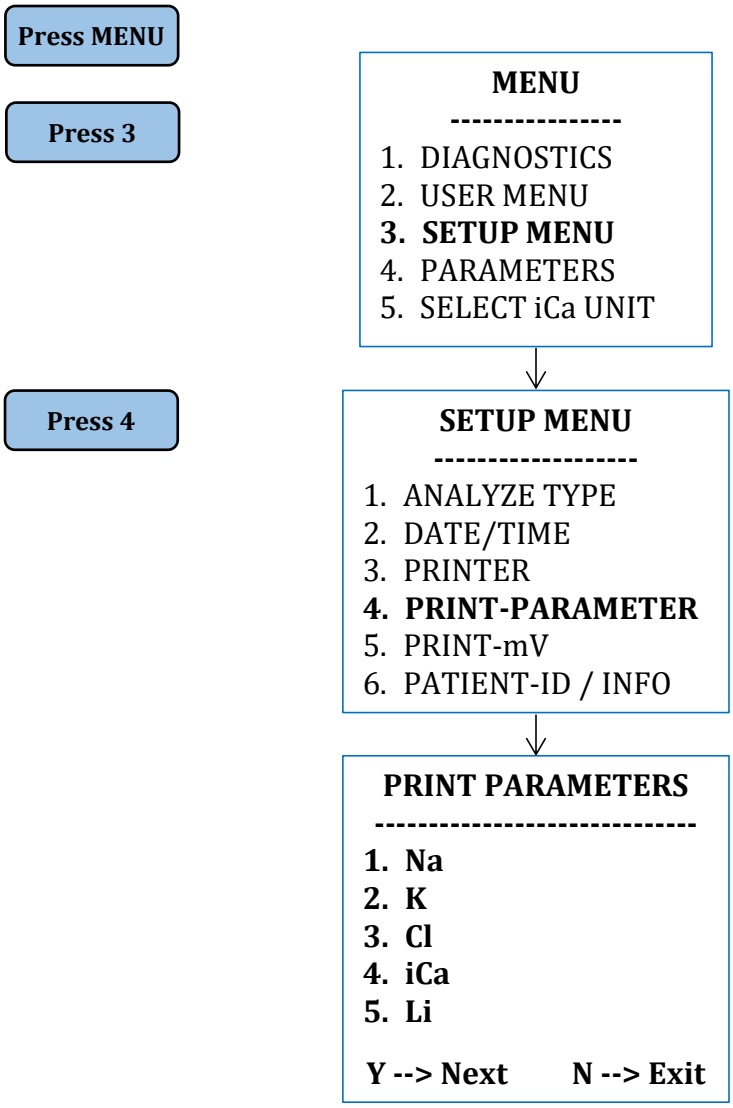
Following is the flow for PRINTER:



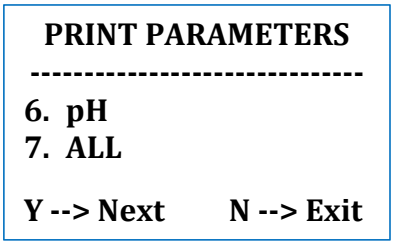
Press “Y” to ON, press “N” to OFF the printer status.

d) PRINT-PARAMETERS:

Following is the flow for PRINT-PARAMETERS:



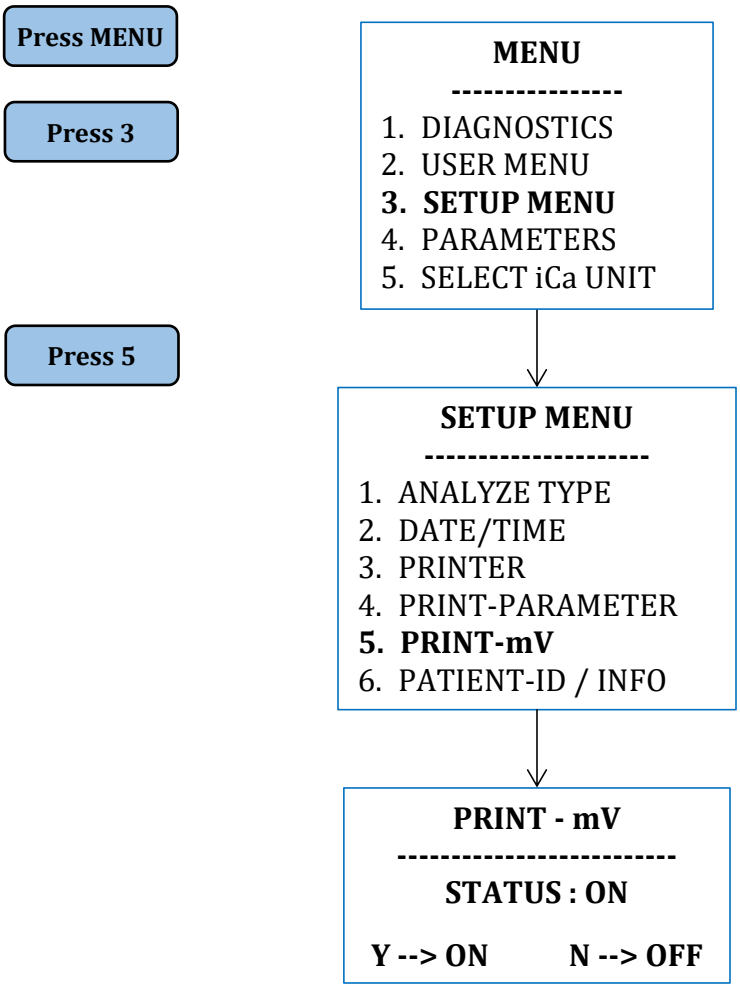
If your required parameter is present in this screen, then select the parameter by pressing appropriate number, if not then press "Y" button to see more parameters.



Press corresponding number for parameters details which to be analyzes and printed. Press "N" to Exit.

e) PRINT-mV : If USER doesn't want to print milli volts (mV) of CAL A, CAL B, but only wants results to, then the USER can adjust it to off in the Print-mV.

Following is the flow for PRINT-mV:

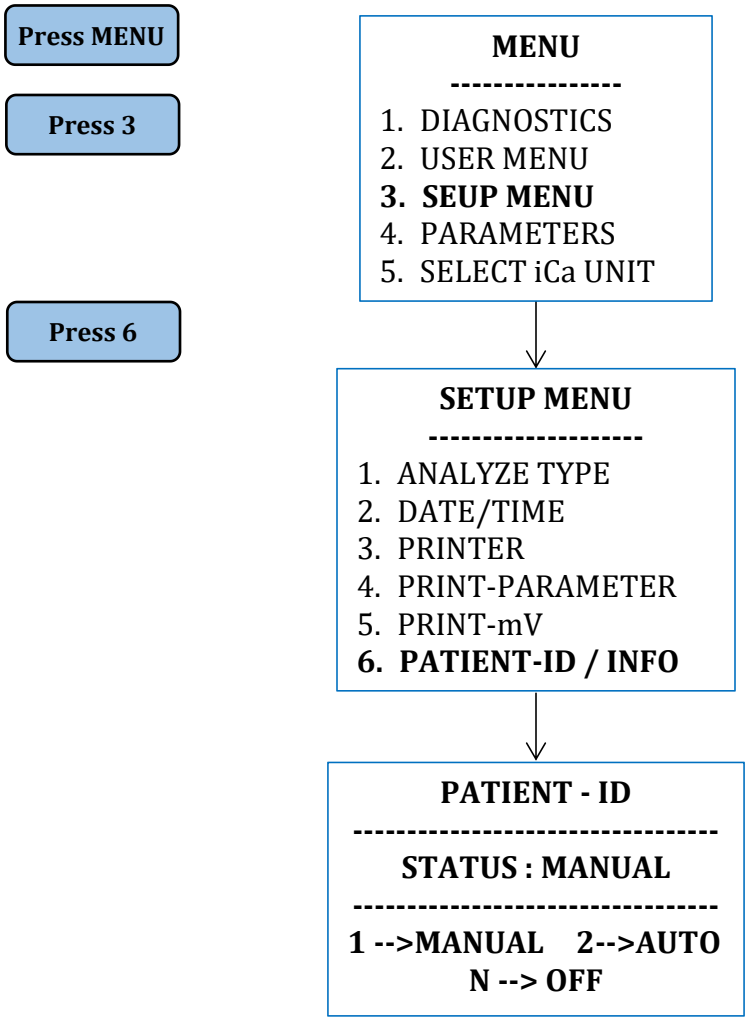


Press "Y" to ON, press "N" to OFF the PRINT - mV Status.

f) PATIENT-ID/INFO :

Patient-ID: Patient-ID should be ON to get previous stored results. If patient-ID option is not selected, then instrument will not ask to enter Patient-ID while analyzing.

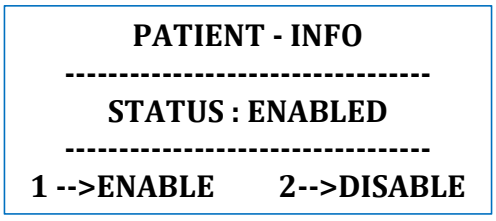
Following is the flow for PATIENT-ID/INFO :



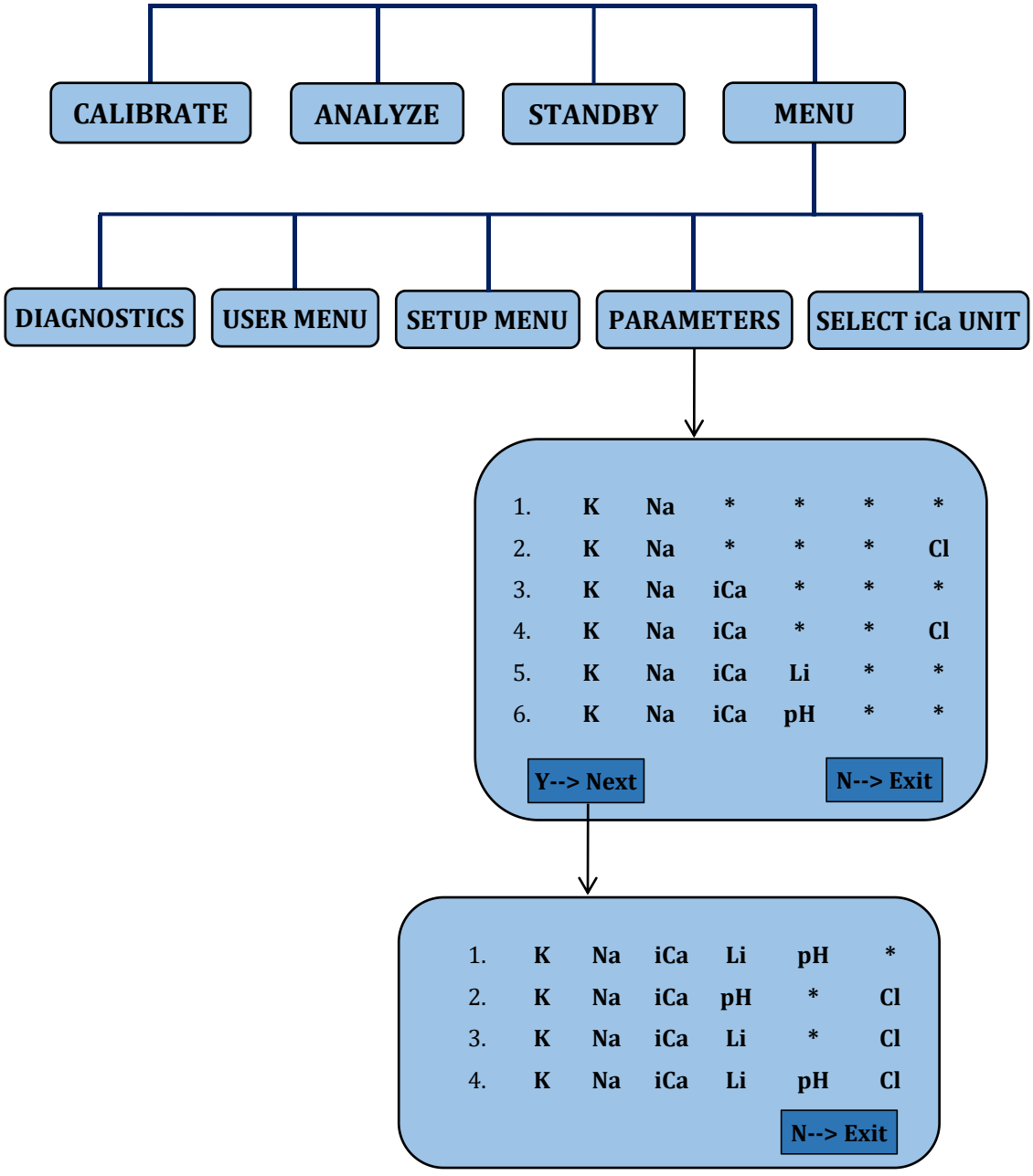
- User can set manual or auto status for PATIENT-ID (i.e.,) press 1 for AUTO status, it takes the PATIENT-ID inbuilt in serial wise for each sample without giving PATIENT-ID.
- In MANUAL status (i.e.,) the USER need to provide PATIENT-ID for each sample as per requirement.

Patient-Info:

- User can set Enable or Disable status for PATIENT-INFO. If user press 1 for ENABLE, then user need to provide the Patient-Info (i.e; Patient Name, Age & Gender) for each sample as per requirement.
- If user press 2 for DISABLE, then analyzer cannot ask for the Patient-Info details.



3.4.4 Parameters

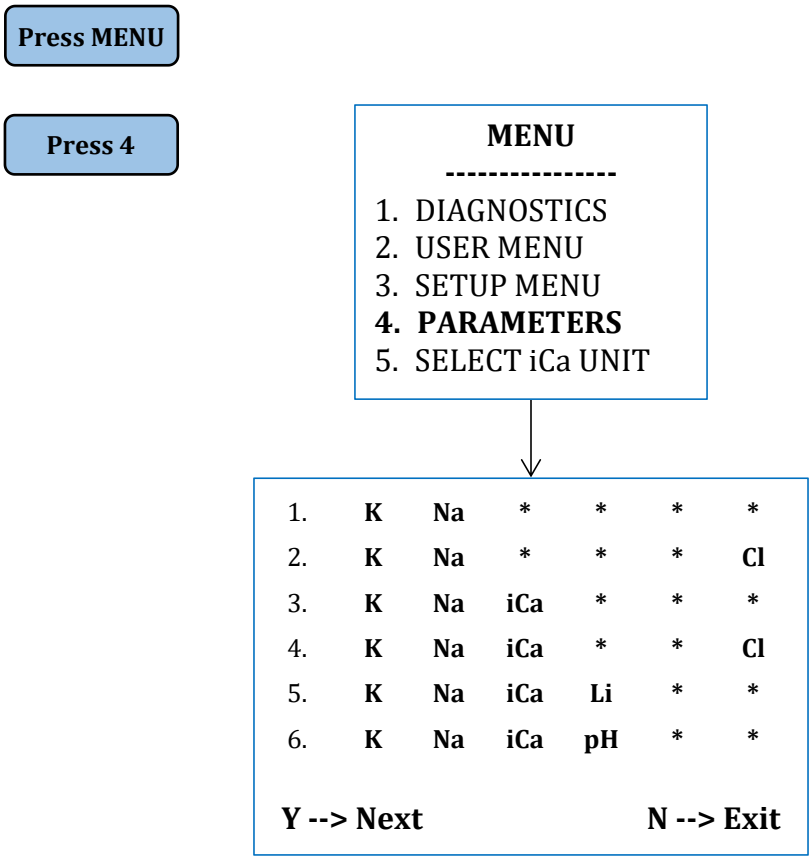


Note: Star (*) indicates Blank

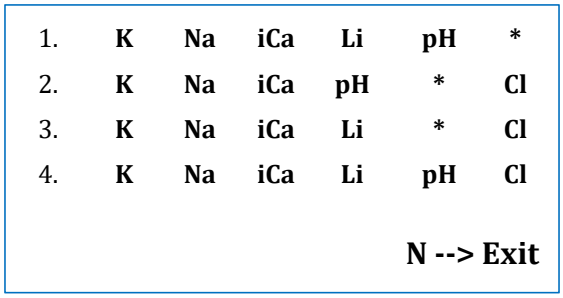
Parameters: Depending upon requirement change model of the analyzer, ensure that the electrode stacking should be done according to the order in Parameter Option.

Where (*) indicates Blank Electrode

Following is the flow for PARAMETERS:



If your required model is present in the screen, then select the model by pressing the appropriate number, if not then press "Y" button to see more models.

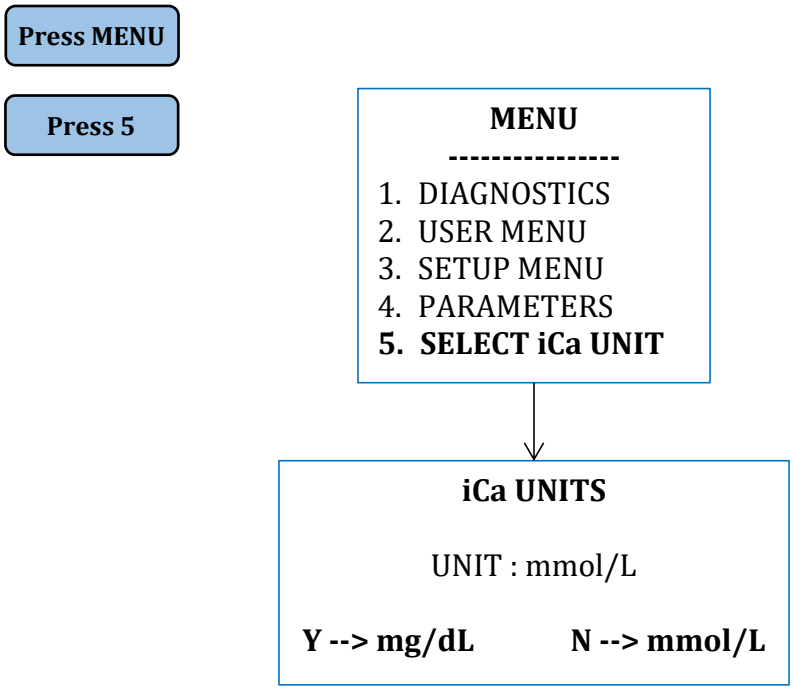


Depending upon the requirement select the model & arrange the electrodes as mentioned above.

3.4.5 Select iCa Unit :

Depending upon requirement, user can select iCa measuring units to mg/dL or mmol/L. By default it is in mmol/L.

Following is the flow for Select iCa UNIT:



4. Handling and Collection

Sample Handling and Collection:

Caution:

- Make sure there are no small air bubbles trapped in the collected sample. Small bubbles in the sample can affect the results.
- Do not use liquid anticoagulants as they can dilute the sample and affect the results.
- Hemolysis at any stage of sample preparation may cause erroneously high potassium results.
- If blood is not mixed completely with anticoagulant, blood clots can be partially formed in the sample. Samples containing clots must not be used as clots will cause sampling failure in the cartridge.
- Samples in which hemolysis is present or suspected and samples collected more than one hour before analysis must not be used.

4.1 WHOLE BLOOD:

- Use heparinized vacuum blood collection tubes for whole blood.
- Collect blood up to fill indicator on the tube label.
- Immediately after collecting blood, roll the tube between palms or gently shake up and down 8 to 10 times to thoroughly mix the blood and anticoagulant.

4.2 SERUM:

- Use non-heparinized, plain vacuum blood collection tubes for serum separation.
- Collect blood up to the fill indicator on the tube label.
- After collection, gently shake the tube slowly up and down five times.
- Allow the blood collection tube to stand vertically for about 30 minutes to fully clot before centrifugation.
- Centrifuge the blood sample, then collect and transfer the serum (liquid component separated from solid components of blood) to another clean container.

4.3 PLASMA:

- Use heparinized vacuum blood collection tubes for plasma separation.
- Collect blood up to the fill indicator on the label.
- Roll the tube between palms or gently shake the tube slowly up and down 8 to 10 times.
- Centrifuge the tube immediately after collection.
- Collect and transfer the plasma (liquid component separated from solid components of blood) to another clean container.

4.4 URINE:

For complete sample preparation and storage information, the user should refer to the standard clinical chemistry procedures published by NCCLS.

- Follow standard clinical procedures for collection of random and 24-hour urine specimens.
- Refrigerate Urine specimens until time of analysis.
- Centrifuge Urine specimens to remove cellular matter etc.
- Dilute the Urine specimen with one part of the supernatant to 5 parts of Urine Diluent. Urine must be diluted.

Note: Do not attempt to analyze Undiluted Urine.

5. Maintenance

5.1 Maintenance Information:

- The analyzer requires very little operator maintenance. The only maintenance required is to run the Daily Cleaner solution after every 25 samples of the day.
- All other maintenance is performed by replacing the components as described in the schedule below:
- When you wish to perform routine or any other maintenance function, Go to the **MENU → Diagnostics → Maintenance.**
- The instrument removes all the liquid present in the tubing's by performing air priming.

5.2 Cleaning:

Caution:

- Wear appropriate personal protective clothing to prevent infection when cleaning.
- Do not spray cleaning solution directly onto the analyzer.
- Do not allow cleaning solution to enter the analyzer.
- Do not use force to wipe the screen.
- Dispose of all waste after cleaning in accordance with the laboratory's established procedures for disposing of bio-hazardous materials.

Cleaning Analyzer:

- Use 0.5% hypochlorite cleaning solution.
- Dampen a soft cloth with the cleaning solution.
- Using a dampened soft cloth, wipe sampler cover, screen, and other contaminated areas on the analyzer.
- Allow to air-dry for about 10 minutes.
- Use a soft cloth dampened with water, wipe the analyzer.
- Use a dry cloth, dry the surface of the analyzer.

Cleaning the Sampler Probe:

Examine the probe outer and inner surface daily for dirt or contamination. Clean the probe surface using a swab moistened with isopropyl alcohol or a 10% bleach solution. The inner surface of the probe can be cleaned with spring needle if any blockage. Allow the probe to completely dry before testing.

Cleaning the pinch valve flow path:

If any valve is blocked you can identify this by:

Go to Menu > Diagnostics > Flow > Valve Test

Flush the flow path with deionized water and re-calibrate the analyzer. Flushing the flow path removes the clots or other debris that may have been aspirated into the system.

6. Troubleshooting

6.1 Troubleshooting

This section describes the recommended troubleshooting procedures for use with MaxLYTE Electrolyte Analyzer. The procedures use the most logical and direct steps to resolve each problem and are written to minimize the replacement of any unnecessary parts.

Guideline:

- If the problems described below are encountered during installation and/or operation of the analyzer, try the Suggested solutions as described in this manual.
- If the problem persists, please call a service engineer for further assistance.
- To enhance trouble-free operation, it is imperative to follow the maintenance schedule. When any error messages appear in the display, then refer to the list of "typical error messages" to locate the problem area and proceed to the appropriate section for troubleshooting instructions.
- *When performing troubleshooting procedures, put the analyzer in* ***MAINTAINANCE*** *mode.*

Power:

If one of following situations applies:

- ✓ *The analyzer has turned off.*
- ✓ *The analyzer does not turn on.*
- If not already done, turn off the power switch of the analyzer.
- Check for loose power connections between the analyzer and the outlet.
- Tighten any loose power connections.
- Turn on the power switch of the analyzer.
- If the analyzer does not turn on, turn off the power switch of the analyzer.
- Turn on the power switch of the analyzer again.

If problem persists, restart the instrument or please call a service engineer for further assistance.

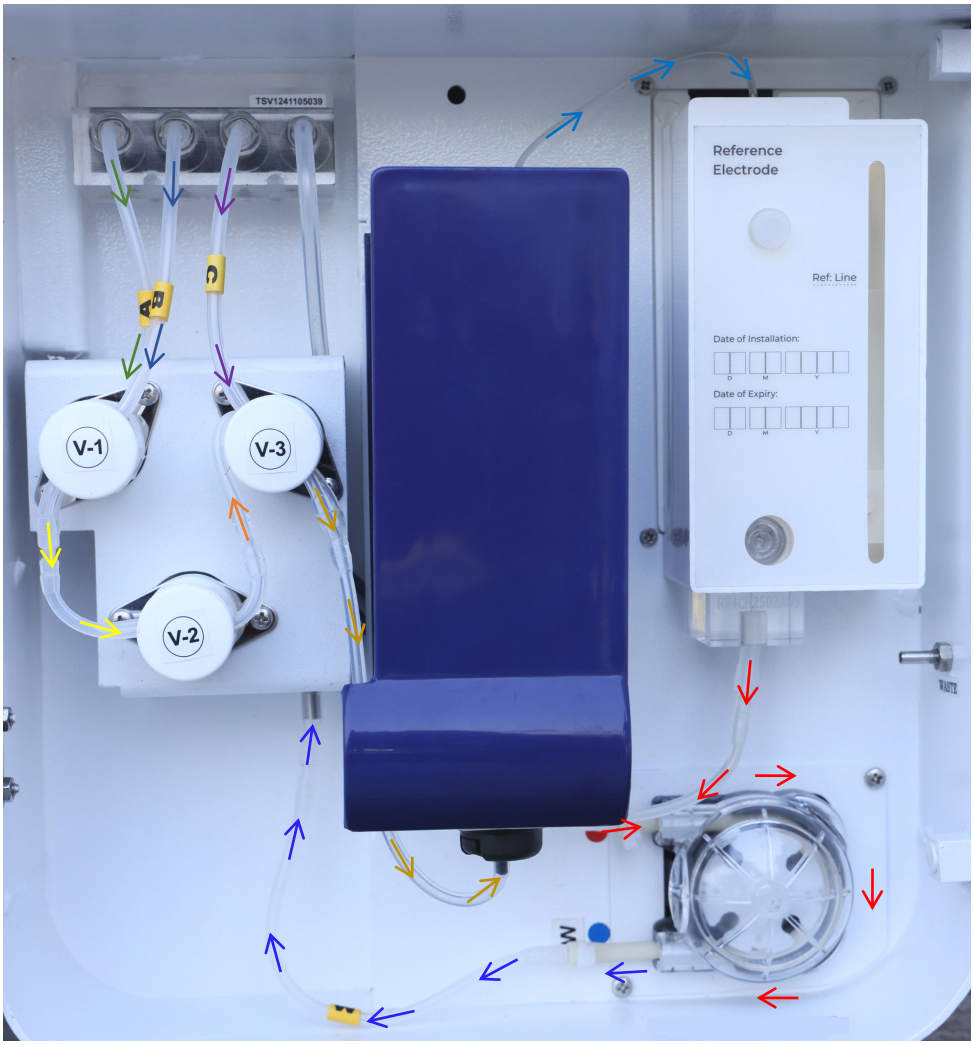
Troubleshooting Kit:

Tools to help diagnose and correct problems.

Component	Quantity
Needle Cap	10
Syringe - 10 mL	1
ISE Body Seal	2
ISE Body Seal - Mini - Blue	2
Fuse - 2 Amp	1
Fuse - 5 Amp	1
Pump Motor Tube	1
Sampler Probe - Reference Electrode Tube (14.5 cm)	1
Silicon Gel Grease Pack	1
Blunt Dispensing Tip - 1.3mm	2
Blunt Dispensing Tip - 0.8mm	1

a) Flow Path System:

All reagents and samples flow in one direction through the entire flow path system as shown. The flow path is a closed loop which ensures that the electrodes will always be kept wet, an important requirement of ISE's. All flow path connections are simple push-on, air tight connections, which requires no special tools.



- If removal of MaxLYTE Electrolyte Analyzer components are required during Troubleshooting, the component removal order should be as follows:
  - ✓ Electrode Housing
  - ✓ Sampler Probe
  - ✓ Valve Module Flow Connections

- For example, if any electrode block requires replacement, it is necessary to go to **MAINTENANCE MENU** for disconnecting the bubble detector tube from sampler and pump tube from the electrode housing. Then carefully remove the electrode housing.
- If the solutions valve requires cleaning, the operator must remove all of the items in the above list, before removing the solutions valve.
- To install components on the MaxLYTE, follow the installation order outlined under installation and replacement.
- Troubleshooting is covered in the order that problems are most likely to occur. Approach Troubleshooting as a logical sequence of events. Isolate the problematic area to avoid unnecessary component replacement and/or excessive downtime.

FLOW ERRORS	AIR IN CAL A, AIR IN CAL B, AIR IN SAMPLE, AIR IN CLEANER & DRIFT
ELECTRODES	HIGH, LOW, DRIFT, BUBBLE, ERROR, UNCALIBRATED
REAGENT PACKS	AIR IN CAL A, AIR IN CAL B, INSUFFICIENT PACK PLEASE REPLACE, PACK EXPIRED, PLEASE INSERT PACK.
SAMPLE/BUBBLE DETECTOR	AIR/LIQUID DETECTED AIR/LIQUID NOT-DETECTED AIR IN SAMPLE
RFID	CONNECTION ERROR, PLEASE INSERT PACK, INCOMPATIBLE PACK, PACK EXPIRED

b) Flow Errors:

- Obstructions or air leaks in the flow path will result in error messages such as AIR IN CAL A, AIR IN CAL B, AIR IN SAMPLE & DRIFT. These messages indicate flow problems. A low or empty reagent pack may also cause AIR IN CAL A or AIR IN CAL B messages. If this problem exists, based on usage since the last reagent pack installation refer to reagent pack Consumption in Diagnostics Menu and troubleshoot before proceeding.
- If AIR IN CAL B or LIQUID NOT DETECTED! message appears during a SOLUTION PRIMING or calibration, and reassembled, check to make sure that the electrode blocks are installed right side up and that all electrode connectors are properly installed. Performing this function twice may eliminate the error.
- FLOW ERROR (Valve fluidic error or fluid path error): Flow error depends on following points.
    - ✓ Electrode Housing
    - ✓ Valves
    - ✓ Reagent Pack

i) Solution for Electrode Housing: Remove the sample detector tube from probe and attach it directly to pump tube which is connected at the bottom of reference housing and check liquid flows.

Menu → Diagnostics → Flow → Reagent Priming → Prime Cal A

Now, the pump rotates and liquid is aspirated through the tube. If **liquid is aspirated properly** follow the **STEP 2 SAMPLER.**

OR

If it does not aspirate properly, enter **maintenance mode** and remove the electrode housing. Clean deposited protein from electrode blocks with distilled water and reassembled electrode housing carefully.

After cleaning, stack the electrodes blocks set with seals properly including sample/bubble detector and gently flush the total stack assembled with DI water. So that, if there is any blockage or air leakage in the flow can be identified.

Reinsert the reference housing stack and check the flow. If problem gets resolved you an proceed with regular operation. Else please contact your concern service engineer.

Press "N" to **maintenance exit**. The pump rotates. The liquid is aspirated through the sample detector tube to check either liquid is flowing properly or not. If liquid is not flowing properly, then check PUMP TUBE as follows:

Menu → Diagnostics → Maintenance

The pump rotates and the liquid is aspirated through the pump tube which is removed from electrode housing and check whether liquid is flowing properly or not. If not, replace pump tubing.

ii) Solution for Valve Test: To clean the flow path in valves, use VALVE TEST option.

Menu → Diagnostics → Flow → Valve Test

Check the valve system functionality individually as per its respective operation and check the liquid flow through both VALVE 1 and VALVE 2 by flush tubing with DI water to clear the path.

iii) Solution for Reagent Pack: The problem might be with reagent pack or valve system or probe seal or probe or pump tubing.

Menu → Diagnostics → Reagent Pack → Reagent Pack Consumption.

Check the reagent pack consumption. If it is above 20%, then remove the reagent pack and aspirate the liquid using syringe attached with tygon tube. If there is no flow observed, then replace the reagent pack and recheck the above **STEP (i).** Else if the flow is proper, then look into the valve functionality and tubing's.

Then finally, perform reagent priming test and then go for sample analysis or repeat calibration.

c) Electrode Assembly Errors:

The electrode assembly should be replaced after 6 months of use. MaxLYTE guarantees this item's performance for 1 month of use, but the frequency of replacement may depend on your sample volume or sample type (volume of

lipemic high protein samples may necessitate more frequent changes of the electrode assembly). MaxLYTE customers testing 100 or more patient samples per week should replace the electrode assembly after 6 months of use.

The electrode assembly should be checked to prevent any leakage. At the same time, the electrode block pins and pogo pins should be inspected to make sure they are dry and clean, including the reference electrode pin and Female connector, if low or erratic readings occur.

Electrodes with low calibration values (below 35 for Na/K, below 30 for Li/Cl/pH & below 15 for iCa), Drift or Noise messages may indicate electrode failure. Electrodes with HIGH calibration values messages most often indicate an electrode assembly/disposable reference electrode failure.

Check the **Calibration Slope**. If they are within the following ranges:

Na^+	:	Should be between 35 to 100
K^+	:	Should be between 35 to 100
iCa^{++}	:	Should be between 15 to 50
Cl^-	:	Should be between 30 to 100
Li^+	:	Should be between 30 to 100
pH	:	Should be between 30 to 100

Then go for sample analysis or repeat calibration. After multiple calibration failure, replace the faulty electrode block.

When electrode housing is removed for electrode block replacement, maintenance, Troubleshooting, etc., wait for 10 minutes after re-installation to ensure proper electrode temperature.

- Calibration values (Slopes) of the electrodes should fall within a range of 35 to 100 for Na/K, 15 to 50 for iCa & 30 to 100 for Cl/Li/pH. If they fall outside of this range, the out-of-range values **** for “Na”, “K”, “iCa”, “Cl”, “Li”, “pH”, will be flagged. The analyzer should be re-calibrated. At the end of the

calibration cycle, the slope values will be displayed for each electrode. The MaxLYTE will permit sample analysis only for the electrodes that are calibrated successfully.

If Na or iCa or both Na and iCa not calibrated, Li won't analyzed, because Li Electrode depends on Na and iCa Electrodes.

- A **LOW, DRIFT** message indicates that an additional Prime cycle may be necessary to condition the electrode. Perform a daily cleaning cycle, as described under **DAILY CLEANER**. Next, perform a calibration. If the calibration value remains low, replace the electrode block.
- If all electrode parameters have low or high calibration values, the problem is most likely with the electrode block assembly or the reference electrode (on the Na/K/iCa/Li/pH/Cl analyzer, the problem may be the reference electrode). It is also possible that an incorrect reagent pack is being used, the MaxLYTE will not calibrate successfully.
- If drift messages appear for all electrode parameters, there is most likely a flow problem (refer to flow problems) or electrode block assembly problem (refer to electrode block assembly). Also, inspect the electrode pins, including the reference electrode pin, to ensure that they are dry and clean. After reassembly, the analyzer should be primed and calibrated.

  Do not perform the cleaning procedure described in below as a preventative measure. Do not clean the electrode blocks, as described, if their calibration values are within the acceptable range.

d) REAGENT PACK:

AIR IN CAL A, AIR IN CAL B, AIR IN WASH and REAGENT PACK LOW messages may indicate that the reagent pack is empty or low.

The MaxLYTE has an RFID (Radio Frequency Identification System) which keeps track of the reagent pack usage. The MaxLYTE will indicate the availability of reagents in a decreasing manner i.e., 100% to 0% at every analysis.

When 15% of the reagent pack has remained in the reagent pack, instrument will indicate the message 'Insufficient Pack please replace' till it reaches 4%. Below 4% the instrument will displays 'Empty pack Please Replace' and there is no possibility for Calibration and Analysis.

e) BUBBLE DETECTOR:

The bubble detector detects the difference between liquid and air, which is important for proper sample positioning in the MaxLYTE. To verify performance, press > DIAGNOSTICS > HARDWARE > SAMPLE DETECTOR.

In sample detector test, if liquid or air is not detected, clean Bubble Detector flow path with Sodium Hypo Chloride and DI water and perform sample detector test again. Then also if it is not detecting air or liquid replace the bubble detector.

Finally install that bubble detector in instrument and perform sample detector test, it will work.

f) PRINTER:

If the MaxLYTE printer fails to print, attempt the following procedures:

- To verify that the printer is turned on, enter the **SETUP MENU** and check **PRINTER ON/OFF.**
- Check the printer mechanism for any paper obstructions in the printer head area. Remove any obstructions if possible, without damaging the printer assembly or paper tear bar.
- Press the paper play button. The printer head should move across the paper and the paper should advance forward.
- If the printer continues to function abnormally, contact your Service Engineer.

6.2 Display Messages

ANALYZE SAMPLE	: Perform Whole heparin blood, serum, CSF Sample analysis.
ANALYZE URINE	: Perform diluted urine Sample analysis.
ANALYZE QC	: Perform QC sample analysis.
AIR DETECTED	: Air detected in Sampler detector test.
AIR NOT DETECTED	: Air not detected in Sampler detector test.
AIR IN CLEANER	: Cleaning solution not detected correctly.
AIR IN SAMPLE	: Insufficient sample.
AIR IN CAL A	: Cal A not detected correctly.
AIR IN CAL B	: Cal B not detected correctly.
AIR IN WASH	: WASH is not detected correctly.
ASPIRATING	: Sample is being drawn into probe.
AUTO STANDBY	: Auto standby on/off
CALIBRATION FREQUENCY	: Set auto-calibration time.
SIPPING FREQUENCY	: Set auto-sipping time.
CALIBRATION SLOPE	: Display calibration values.
CALIBRATE	: Allows operator to calibrate analyzer.
CALIBRATING	: Analyzer is calibrating.
CAL A CONCENTRATION	: CAL A concentration values will be displayed.
CAL B CONCENTRATION	: CAL B concentration values will be displayed.
SOLUTION LEFT	: Percentage reagent left in Reagent pack.
INCOMPATIBLE PACK	: Pack is not suitable for the instrument.
CLEANING…	: Analyzer is performing daily cleaning
SYSTEM UNCALIBRATED PLEASE CALIBRATE	: Instrument is not calibrated. Please Calibrate.

Display Messages *Continued,*

HIGH	: Result obtained are on the higher side.
LOW	: Result obtained are on the lower side.
DRIFT	: Result obtained are inappropriate due to mV variation as per standards.
ERROR	: Result obtained out of measuring ranges.
BUBBLE	: Result obtained is fault due to presence of air bubble in sample. Re-aspirate it.
DATE/TIME	: Allows operator to change date and time
DAILY CLEANER	: Allows operator to perform daily cleaning
DIAGNOSTICS	: Allows operator to check key analyzer functions.
DISTRIBUTOR ID	: Allows the operator to check distributors ID.
ENTERING STANDBY	: Analyzer will go into standby mode. Where only sipping is performed.
AIR IN SAMPLE	: Insufficient sample or Sample aspirated is not detected by sensor.
EXIT	: To clear the process or return to previous/idle screen.
PACK EXPIRED	: Check the expiry date of reagent pack and also check the date in instrument
MANUFACTURED ON	: Allows user to know the manufacturing date.
QC LEVEL 1 QC LEVEL 2 QC LEVEL 3	: Quality control analyze mode.
LIQUID DETECTED	: Message will appear when the liquid is detected in sample detector test
LIQUID NOT DETECTED	: Message will appear when the liquid is not detected in sample detector test
LOT NO.	: Allows the operator to check lot number
MENU	: Menu selection

Display Messages *Continued,*

MAINTENANCE…	: Instrument is in maintenance mode.
POSITIONING SAMPLE	: Message will appear during sample positioning.
PROBE IN SAMPLE?	: Request operator to confirm whether probe is in sample.
PLEASE INSERT PACK	: Message will appear when the system has not detected reagent pack.
PRIMING CAL A	: Cal A fluid is being primed.
PRIMING CAL B	: Cal B fluid is being primed.
PRIMING WASH	: Cal C fluid is being primed.
PRIME ALL	: Cal B, Wash and Cal A fluids/calibrant's are primed.
PRINTER	: Allows user to on the printer or of the printer.
PRINT-mV	: Allows user to print the results with mV.
PRINT REFERENCE RANGES	: Allows user to print the reference ranges.
PROBE IN CLEANER	: Requests operator to confirm that probe is in Daily Cleaning Solution
PUMPING AIR	: Message will appear when air pumps
PUMPING CAL A	: Message will appear when CAL A reagent gets pumped
PUMPING CAL B	: Message will appear when CAL B reagent gets pumped.
PUMPING WASH	: Message will appear when WASH reagent gets pumped.
PUMP CAL 0	: Failure of Pump cal Test.
PUMPING LIQUID	: Message will appear when liquid is pumped.
PUMP SPEED : FAST	: Allows the operator to set the pumping speed fast
PUMP SPEED : SLOW	: Allows the operator to set the pumping speed slow
REAGENT CONSUMPTION	: Allows the operator to check the quantity of the reagent solution consumed
REAGENT PACK	: Allows operator to check the reagent pack details.

Display Messages *Continued,*

REAGENT PACK CONSUMPTION	: Allows operator to display % pack expended
REGEANT PACK ID	: Allows the operator to check the pack ID
REAGENT PACK INFO	: Allows the operator to check the pack information
REMOVE SAMPLE FROM PROBE	: Requests operator to remove sample from probe.
SAMPLE DETECTOR TEST	: Message will appear during sample detect test
NORMAL RANGES	: Used to set the Na/K/iCa/Cl/Li/pH sample limits
ANALYZE TYPE	: Allows operator to select the sample type. Eg: Serum-Plasma, Urine, Whole Blood, QC, Micro mode & Dilution.
SENSOR CAL A - mV	: Allows the operator to display the mV readings of CAL A reagent selected.
SENSOR CAL B - mV	: Allows the operator to display the mV readings of CAL B reagent selected.
Standby	: Appears when Analyzer is in Standby mode.
NO OF SAMPLES	: Allows the operator to check the total samples performed with the pack.
TOTAL SAMPLES	: Allows the operator to check the total samples performed in the instrument.

7. Specifications

7.1 Operating Specifications

Measured Parameters

- Measured Parameters Ranges Resolution

Serum/Whole Blood:

Parameter	Measurement Range	Reproducibility (CV%)
Na^+	20.0 - 200.0 mmol/L	< 1.0%
K^+	0.2 - 40.0 mmol/ L	< 2.0%
Cl^-	25.0 - 200.0 mmol/L	< 1.0%
iCa^{++}	0.1 - 6.0 mmol/L	< 2.0%
Li^+	0.2 - 5.0 mmol/L	< 2.0%
pH	6.5 - 8.0	± 0.03

Urine :

Parameter	Measurement Range	Reproducibility (CV%)
Na^+	25 - 1000 mmol/L	< 5.0%
K^+	1.0 - 500 mmol/ L	< 5.0%
Cl^-	25 - 500 mmol/L	< 5.0%

- Sample types: Whole Blood, Serum, Plasma, CSF and Diluted Urine
- Sample volume: 120 µL for Whole blood, Serum, Plasma & CSF
  500 µL for diluted urine
- Sample introduction method: Aspiration
- Sample analysis time: 55 seconds
- Measuring principle: Direct measurement with Ion Selective Electrode (ISE).
- Calibration : Automatic or manual

Environmental Conditions

- Operating location: Indoors on a flat surface
- Operating temperature: 5°C to 40°C (41°F to 104°F)
- Relative Humidity: 10% to 90%
- Power supply: 100 - 240V AC, 50/60 Hz, 1.4A

7.2 Instrument Specifications

Instrument Specifications

- Alphanumeric Keypad
- Printer: 2" thermal printer (internal printer)
- Printer paper: Thermal (2" inch 24 column)
- Port: Serial (LIS)
- Power adapter:
  - AC-DC power supplies
  - Input: 100-240V AC, 50/60Hz, 1.4A
  - Output: 12V ⎓ 5.0A, 60W Max
- Storage temperature: 5°C to 40°C (41°F to 104°F)
- Size: 9” W x 15.7” H x 12.6” D
- Weight: 5.4 kg (without reagent pack)

7.3 Reagent Pack Specifications

Reagent Pack

- Unit: 1 Reagent Pack
- Shelf life: 18 months from manufactured date
- Storage temperature: 18 - 25 °C
- Components:
  - Waste bag (Biohazard after use)
  - Cal A solution, approx. 450 mL
  - Cal B solution, approx. 200 mL
  - Wash solution, approx. 140 mL

- Composition of calibration solutions

CAL A : Electrolytes, Buffer and Preservatives

CAL B : Electrolytes, Buffer and Preservatives

WASH : Electrolytes, Buffer and Preservatives

7.4 Performance Specifications

7.4.1 Introduction

The results obtained during evaluation of MaxLYTE Electrolyte Analyzers are shown below to demonstrate the typical performance characteristics of the analyzer.

7.4.2 QC Precision

Precision of an MaxLYTE Electrolyte Analyzer were obtained using QC levels and Bio-rad serum Samples.

QC Level 1						
Parameters	**Na^+**	**K^+**	**iCa^{++}**	**Li^+**	**pH**	**Cl^-**
1	121.8	2.11	1.77	0. 48	6.995	81.1
2	123	2.13	1.76	0.48	6.995	80.3
3	122.6	2.12	1.76	0.48	7.00	82.2
Mean	122.47	2.12	1.76	0.48	6.997	81.20
STD	0.61	0.01	0.01	0.00	0.00	0.95
CV	0.50	0.47	0.33	0.00	0.04	1.17

QC Level 2						
Parameters	**Na^+**	**K^+**	**iCa^{++}**	**Li^+**	**pH**	**Cl^-**
1	140.6	4	1.19	1.5	7.242	101.6
2	141.5	4	1.2	1.5	7.238	101.8
3	141.1	3.96	1.19	1.5	7.238	102.3
Mean	141.07	3.99	1.19	1.50	7.239	101.90
STD	0.45	0.02	0.01	0.00	0.00	0.36
CV	0.32	0.58	0.48	0.00	0.03	0.35

QC Level 3						
Parameters	**Na^+**	**K^+**	**iCa^{++}**	**Li^+**	**pH**	**Cl^-**
1	159	5.91	0.81	2.22	7.403	121.1
2	159.3	5.94	0.8	2.21	7.408	121.2
3	159.6	5.92	0.78	2.2	7.403	121.3
Mean	159.30	5.92	0.80	2.21	7.405	121.20
STD	0.300	0.015	0.015	0.010	0.003	0.100
CV	0.188	0.258	1.917	0.452	0.039	0.083

Bio-rad Level 1						
Parameters	**Na^+**	**K^+**	**iCa^{++}**	**Li^+**	**pH**	**Cl^-**
1	148.2	4.03	0.86	0.7	NA	97.2
2	147.7	4.04	0.87	0.7		96.7
3	148.8	4.09	0.87	0.72		96.9
Mean	148.23	4.05	0.87	0.71		96.93
STD	0.551	0.032	0.006	0.012		0.252
CV	0.372	0.793	0.666	1.634		0.260

Bio-rad Level 2						
Parameters	**Na^+**	**K^+**	**iCa^{++}**	**Li^+**	**pH**	**Cl^-**
1	127.1	5.92	1.09	1.49	NA	84
2	128.3	5.92	1.12	1.48		82.7
3	128.9	5.93	1.13	1.47		84.9
Mean	128.10	5.92	1.11	1.48		83.87
STD	0.92	0.01	0.02	0.01		1.11
CV	0.72	0.10	1.87	0.68		1.32

7.5 Measuring Principles

7.5.1 Measuring Principles

The measurement of Sodium (Na^+), Potassium (K^+), Ionized Calcium (iCa^{++}), Lithium (Li^+), pH, Chloride (Cl^-) by the MaxLYTE Electrolyte Analyzer is based on the principle of Ion-Selective Electrode (ISE).

Principle of Measurement

In an Ion-Selective Electrode, an electrical potential is established across a membrane that is selective to a specific ion. Such electric potential of the Ion-Selective Electrode is measured against a reference electrode and it is used to determine the activity (a) or effective concentration (c) of the ion of interest in a sample.

The electrical potential (E) of the ion-selective electrode measured against the reference electrode can be described by the following Nernst equation.

$$E = E^{\circ} \pm \frac{RT}{nF}\ln(a)$$

Equation 1

where, (+) for cation, (-) for anion

E: monitored potential

E^o: potential at a = 1

R: gas constant

T: temperature in Kelvin scale

n: valence of ion

F: Faraday constant

a: activity of the target ion

7.5.1 Calculated Parameters

nCa = Normalized Calcium

Formulae used to calculate nCa is given below

nCa = (iCa Result) x 10^(- 0.24 x (7.40 - pH Result))

TCa = Total Calcium

Formulae used to calculate TCa is given below

TCa = (nCa result) x 2

8.1 Warranty

The Product warranty for the analyzer will be free of defects in material and workmanship for a period of twelve months from the date of purchase, except for those parts or materials which are consumed or expended in normal use.

In the case of consumables or expendables, the warranty time period shall be used within the time prescribed providing such consumable or expendable is used prior to any “install by” or “expiration date”.

The warranty is only applicable for MaxLYTE Electrolyte Analyzer under normal operating conditions and maintained in accordance with the instructions in the operator’s manual and when not having been subjected to accident, alteration, or misuse.

In the event of failure within the warranty period, Avecon Healthcare will repair or replace any Analyzer returned. Avecon Healthcare reserves the right to ask for proof of date of purchase, such as original invoice and / or maintenance records.

Representations and warranties made by any person including dealers, representatives and employees, which are inconsistent or in conflict with, or in addition to, the terms of this warranty shall not be binding upon Avecon Healthcare unless in writing and signed by one of its officers.

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Transforming Research into Innovations

Avecon Healthcare Pvt. Ltd.

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