ELECTROLYTE ANALYZER

OPERATOR AND SERVICE MANUAL

Electrolyte Analyzer 103AP V4 SB Electrolyte Analyzer 103AP V4 S+ Electrolyte Analyzer 103AP V4 A Electrolyte Analyzer 103AP V3 AUTOSAMPLER

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<u>1 – INTRODUCTION</u>

The Diestro analyzer is an in vitro diagnostic analyzer manufactured with state-of-the-art technology, precise, accurate and designed to be easy to use and maintain.

Intended Use

The Diestro 103AP V3 and 103AP V4 Electrolyte analyzer is an In Vitro Medical Device that allows the measurement of electrolytes in whole blood, serum, plasma and urine samples. It is capable to measure up to 5 electrolytes simultaneously between: sodium, potassium, chloride, calcium, lithium, and pH.

The health professionals use the obtained data for diagnosis purposes. They are responsible for the use and interpretation of the data obtained with the Diestro Electrolyte analyzer.

All configured electrolytes can be measured simultaneously on the same sample. Each model of the Diestro 103AP V3 and 103AP V4 is expandable in the number of ions to be measured.



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JS Medicina Electrónica reserves the right to modify the content of the manual or the specifications of the analyzer without prior notice.

JS Medicina Electrónica is not responsible for loss or damage caused directly or indirectly to the user or third parties due to the use of the analyzer or the interpretation of the results.

JS Medicina Electrónica SRL Manufactures under ISO 9001/ISO 13485 Standards

JS Medicina Electrónica SRL Manufactures under GMP Standard in accordance with ANMAT regulations (National Administration of Medicines, Food and Medical Technology of the Argentine Republic -MERCOSUR).

2 – SAFETY PRECAUTIONS

1. Important Safety Instructions

DANGER – Misuse of electrical analyzer can cause electrocution, burns, fire and other HAZARDS.

Basic safety precautions should always be followed, including those listed below.

READ THESE WARNINGS BEFORE USING THE ANALYZER

- Check that the supply voltage matches the available mains voltage.
 - Connection to Main Supply: Plug the equipment into a supply outlet which has a grounding connection.
 - Do not place the equipment where it could get wet, or where liquid may be spilled. In case the equipment gets wet, unplug it without touching it.
 - Use the equipment only for the purpose described in the instructions for use.
 - Do not use accessories which are not supplied or recommended by the manufacturer.
 - Do not use the equipment if it is not working properly, or if it has suffered any damaged. Examples:
 - Damage to the flexible supply cord or its plug;
 - Fall damage;
 - Water damage; Any other type of anomaly.
- Do not allow the analyzer or its flexible power cord to come into contact with surfaces that are too hot to touch.
- Do not place anything on top of the analyzer.
- Do not drop or place anything into any openings on the analyzer, or onto any hose or coupling.
- Do not use the analyzer outdoors.
- The power base (socket) where the power supply of the analyzer is connected must be accessible at all times.
- Always use gloves.

ALL PERSONNEL USING THE ANALYZER MUST READ THE MANUAL CAREFULLY AND BE AUTHORIZED BY THE MANAGER OF THE LABORATORY

The operator's manual includes instructions and guidelines to be observed during the start-up, operation and maintenance of the analyzer. Therefore, the operator or anyone who handles the Diestro 103AP analyzer must read the manual carefully before starting to use the analyzer.

The purchaser of the analyzer is responsible for training and having each new operator read the manual. The results issued by the Analyzer must be interpreted by a health professional duly authorized for this purpose. Do not process samples without having performed a quality control and verified the correct operation of the Analyzer.

If the analyzer is not used as specified by the manufacturer, the protection provided by the analyzer may be impaired.

2. Symbology

Different safety instructions are given in each chapter of the manual and on the analyzer, to highlight aspects related to safe operation.



Note: Identifies references to information in other sections of the manual.



Press on touchscreen



DANGER. Damage may occur if the analyzer or its parts are handled carelessly. Consult manual and documentation before use.



Biological risk. There are parts of the analyzer, accessories or supplies that can cause damage and biological infections if they are not handled with due care. WEAR GLOVES WHENEVER WORKING WITH THE ANALYZER, ITS PARTS AND THE SAMPLES, SINCE THEY ARE POTENTIALLY INFECTIOUS.









Number Reference/Catalog Number



In Vitro Diagnostic Medical Device



Authorized Representative in the European Union



Read the manual before use.



For indoor use only



Do not dispose of the product as household waste. Failure to follow these instructions may have detrimental effects. The user must dispose of the product as special waste, complying with the applicable regulations in their jurisdiction.



Manufacturer Data Manufacture







Only Authorized Personnel

3. Models Table

REF	Model	Description*
EQ 0730	103AP V3 A	Diestro Electrolyte Analyzer 103AP V3 A
EQ 0740	103AP V4 SB	Diestro Electrolyte Analyzer 103AP V4 SB
EQ 0750	103AP V4 S+	Diestro Electrolyte Analyzer 103AP V4 S+
EQ 0760	103AP V4 A	Diestro Electrolyte Analyzer 103AP V4 A
SMP	Autosampler	To be used with 103AP V3 A or 103AP V4 A

*Each Analyzer can be configured with the desired parameters.

Note that the listed models could be referred in this manual as the following:

Reference in this	Complete model name	REF
103AP V3	Electrolyte Analyzer 103AP V3 A without	EQ 0730
AutoBasic	Autosampler	
103AP V3	Electrolyte Analyzer 103AP V3 A <i>with</i> Autosampler	EQ 0730 + SMP
AutoPlus		
103AP V4	Electrolyte Analyzer 103AP V4 SB	EQ 0740
SemiBasic		
103AP V4	Electrolyte Analyzer 103AP V4 S+	EQ 0750
SemiPlus		
103AP V4	Electrolyte Analyzer 103AP V4 A without	EQ 0760
AutoBasic	Autosampler	
103AP V4	Electrolyte Analyzer 103AP V4 A with Autosampler	EQ 0760 + SMP
AutoPlus		

-For more information about the analyzer, press the Info in the main menu. Information can be printed





V Down

Select

-Pressing ${f V}$ you can access the button to print the analyzer information

-To return to the main menu press Esc.

3 – INSTALLATION

1. Unpacking

Carefully unpack the two boxes and verify that the following items are found:

- 103AP V3 / 103AP V4 Diestro Analyzer.
- Autosampler for Diestro Analyzer 103AP V3 / 103AP V4. (Only AutoPlus model)
- ISE Calibration Pack (AutoBasic and AutoPlus models).
- ISE Calibration Kit (SemiBasic and SemiPlus models).
- ISE urine diluent.
- ISE Intensive Rinse.
- Sodium Conditioner.
- Diestro Fill Port Cleaner
- Diestro Trilevel.
- Diestro Control Ampoules. (Optional)
- Pack/kit connection kit.
- User manual (CD or download link)
- Quick Start Guide.
- 15V 4A power supply (depending on the model, consult the factory).
- Tubing for peristaltic pump.
- Tip for Fill Port capillary sampling.
- Capillary adapters.
- Ground wire
- Pack holder tray.



See the section "**Technical Specifications**" for more detailed information. See the "**Diagrams**" for more detailed information.

2. Installation Requirements

2.1. Supply voltage

100 - 240 V 🔨 50 / 60 Hz

The supply voltage and the plug must comply with local electrical regulations. A ground connection must be available to connect the analyzer ground.



See the "Power Supply Specifications for more detailed information.

The supply voltage must be free of noise and electrical variations. If necessary, it is recommended to install a stabilizer.

2.2. Installation environmental conditions.

Check the environmental operating conditions detailed in the "Technical Specifications"



See the "Technical Specifications" for more detailed information.

2.3 Installation place

The Analyzer must be installed on a horizontal, clean and solid surface, without vibration, allowing the technician the necessary place to operate it without any obstacles in the front and the sides.

Dimensions

<u>103AP V4</u> Height: 280 mm Width: 470 mm Depth: 210 mm / 470 mm with pack included (*Auto Basic and Auto Plus models*) Weight (analyzer): 4.3 kg. Weight (with autosampler): 6.5 Kg.

<u>103AP V3</u> Height: 420 mm Width: 320 mm Depth: 300 mm Weight: 13.5kg (with pack installed)

The outlet where the Analyzer power supply will be plugged in must be easily accessible for connection and disconnection at any time.



See the "Power Supply Specifications for more detailed information.

3. 103APV4 Connection



Before installation, see the "**Diagrams**" section to identify the parts and accessories of your analyzer.

Use the cables and accessories provided with the analyzer.

If any need to be replaced, use replacement parts provided or recommended by the manufacturer.

-Connect the ground cable to the ground connection terminal of the analyzer \pm and then to a ground connection duly verified by qualified personnel

-Connect the power supply to the connector of the analyzer.

15V <u>- - 3</u>37W



Do not connect the power supply to the outlet yet.



Rear view of the 103APV4 analyzer

-If the analyzer is connected to a PC or external printer, connect the RS232 serial cable.

For the serial connection with a PC use a Null-Modem or mini USB to USB cable. (SemiPlus, AutoBasic and AutoPlus models)



See section 24 - CABLES to see the characteristics of the null-modem cable.

103APV4

-For AutoBasic and AutoPlus models: Place the calibrating solutions pack in the Pack holder tray.

Pack holder tray: Pack



Pack Connection Pack

installation



View REF IN 0100





- For SemiBasic and SemiPlus models: Place the Calibrator Solutions Kit on the right side of the analyzer.



Placing the Kit Connecting the waste pipe







Connecting the uChip

- Connect the waste bottle tubing to the back of the analyzer and screw on the waste bottle holder.
- Connect and screw the uChip cable to the Kit and to the back of the analyzer.

-Connect the adapter cable to the uChip of the Pack/Kit and to the corresponding connector on the analyzer.

- For AutoBasic and AutoPlus models: Unscrew the caps, break the aluminum security seals and insert the special connection caps. Connect them to their corresponding fittings on the analyzer. Keep the lids to cover the bottles of the Pack at the time of discarding it.



Observe the color coding and the text on the analyzer and Pack



Pack connection kit



View of the connected Pack

- To open the front of the analyzer, turn the fastening button a quarter of a turn, and pull forward from the sides of the front.



Locking button



Opening the front (1)



Opening the front (2)



Opening the front (3)



Opening the front (4)

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-Connect the peristaltic tubing.

Remove one of the peristaltic tubing couplings from the bracket and wrap the tubing around the pump head so that it is in contact with the head rollers and insert the free coupling into the bracket.



Waste tubing

Peristaltic Pump Tubing

Peristaltic pump mount

Peristaltic Pump Tubing

Peristaltic Pump Head

Peristaltic pump view



For more information see the section "Change of the peristaltic pump tubing"

Open the Take Fill Port Cleaner transparent package and remove the security seal from the Fill Port Cleaner as indicated in the figure.



Opening the Fill Port Cleaner (1)



Opening the Fill Port Cleaner (2)

-Carefully lift the sampling capillary to the horizontal position. Put the Diestro Cleaning module to the front of the positioning guides, and gently push it until it stops against the bottom.



Make sure the Cleaning Module is in the correct position, with the "Frente/Front" label facing the operator.





Placing the wiper (1)

Placing the wiper (2)



For more details see the section "Installing / Replacing the Diestro Sampling Wiper"

- Return the sampling capillary to the rest position, close the front of the analyzer and turn the clamp button to lock it.

-Connect the power supply to the outlet. The unit will turn on and automatically perform a purge and calibration. (Only AutoBasic and AutoPlus models)



See section "Calibration" and "Purge"

When the calibration is complete, the analyzer displays the following screen:



-Check the date and time of the analyzer. They can be modified by the operator following the steps detailed in the "Clock" section (SemiBasic model only)



See section "Clock"

4. Connection 103APV3



Before installation see section "**Diagrams**" to identify the parts and accessories of your analyzer.

Use the cables and accessories provided with the analyzer.

If any need to be replaced, use replacement parts provided or recommended by the manufacturer.

- Connect the ground cable to the ground connection terminal of the analyzer _____ and then to a ground connection duly verified by qualified personnel.

- Connect the power supply plug to the analyzer receptacle.



Do not connect the power supply to the outlet yet.



Ground connection and power supply

- If the analyzer is connected to an external PC or printer, connect an RS232 serial cable.

For the serial connection with a PC use a Null-Modem cable.



See the "CABLES" to see the characteristics of the null-modem cable.

- Open the Pack container by gently pressing. Place the pack of calibrating solutions "Pack" on the base of the Pack



In case the pack container cannot be opened, press the drawer lock to unlock

it Once you have placed the pack inside the analyzer container. You can activate the container lock for added security.



See the section "CALIBRATOR SOLUTIONS PACK (PACK)"

- Connect the uChip adapter cable to the uchip of the Pack and to the corresponding connector in the container of the analyzer Pack. Screw the connector to the analyzer.

- Unscrew the caps, break the aluminum security seals and insert the special connection caps of the analyzer. Keep the lids that were removed to cover the jars of the Pack at the time of discarding it.

- Screw the 3 special Pack connection caps respecting the colors and texts. Connect the green, red and orange couplings of the pipes to their corresponding couplings in the Pack container.





Observe the color coding and the text on the analyzer and Pack



Piping kit for connection to the Pack

Special Connection Caps



Fig. 6 Connecting Pack

Connecting the Pack

- Remove the front of the analyzer by loosening the fastening screw, tilting the front slightly forward. Use the allen key provided with the analyzer.



- Connect the peristaltic tubing

Remove one of the peristaltic tubing couplings from the bracket and wrap the tubing around the peristaltic pump head, so that it makes contact with the head rollers and insert the free coupling into the support.



Peristaltic pump



For more information, see the section "CHANGING THE PERISTALTIC PUMP PIPE"

-Take the Cleaning Module, open the transparent packaging and remove the security seal from the Fill Port Cleaner as indicated in the figure.



Opening the cleaner

- Carefully lift the sampling capillary to a horizontal position, put the Diestro cleaning module in front of the positioning guides, and slide gently until it stops against the internal wall of the analyzer.



Make sure the Cleaning Module is in the correct position, with the "Front/Front" label facing the operator.





Placing the cleaner



For more details see the section "Installing / Replacing the Diestro Sampler Cleaner"

- Place the front of the analyzer.

- Connect the power supply to the outlet. The analyzer turns on and automatically performs a purge and calibration.

5. Touch screen calibration

If it is necessary to calibrate the touch screen due to a malfunction, perform the following sequence:

-Disconnect the power supply and wait a few seconds.

-Press the touch screen, and connect the power supply while holding it down.

- The following screens will be displayed. Press with your finger or a non-sharp plastic element where the arrows indicate.



-Then the analyzer will show the main menu, finishing the calibration of the touch screen.



6. Retractable Fill Port



Fill Port in rest position



Fill Port In position for Capillary



Fill Port In position for Tube or Syringe.



See Section "Retractable Fill Port"

5.1 Capillary Adapter



BIOLOGICAL RISK. Samples, capillaries, and adapters are potentially infectious. Handle with gloves.

After removing the sample, clean the sampling capillary with **ISE Intensive Rinse REF IN** 0400

It is specially made to adapt the analyzer's sampling needle to a Capillary:

- 1. Place the sampling capillary in
- 2. Connectposition to one end of the capillary that has the sample loaded.
- 3. Holdand the sample port end of the kit and connect the adapter with the capillary with sample press **load**___
- 4. Once the sample is loadedremove the capillary and adapter and press **ready**. Discardand capillary at the end of each measurement.



Capillary Adapter (1) Capillary Adapter (2)



BIOLOGICAL HAZARD. Samples, capillaries, and adapters are potentially infectious. Handle with gloves.

After removing the sample, clean the sample collection capillary with ISE REF IN 0400

4 – PACK/KIT OF CALIBRATING SOLUTIONS (PACK / KIT)

1. Pack REF IN 0100 (AutoBásico and AutoPlus models)

Diestro



View of the Pack and its connection pipes

2. REF IN 0200 (SemiBasic and SemiPlus Models).



View of the Kit

It is provided with:

A set of pipes for connecting the Pack. It consists of 3 special connection caps in green, orange and red colors with their corresponding couplings and tubing to

connect them to the analyzer.

These pipes are not disposable, they are reusable and are always connected to the analyzer.

There are different types of Pack/Kit according to the region where the analyzer is purchased. The type of Pack/Kit is independent of the model.

The type of Pack your analyzer requires can be identified on the Info :



The type of Pack your analyzer requires can be identified on the indicated screen. If the type of pack is not appropriate, the analyzer will display an error message: "Invalid Pack"



JS Medicina Electrónica recommends the simultaneous replacement of the Sample Collection Cleaner with the Diestro[®].



See the section "Error messages"

3. Microchip (uChip)



uChip Pack



uChip Kit

The uChip integrated in the Pack/Kit provides the analyzer with information about solution volumes, calibration values, content, type, lot and expiration date of the Pack.

4. Validity of the calibrating solutions Pack/Kit

Check the expiration date of the pack/kit to be connected.

In the event that the pack/kit is expired, the analyzer will display and print the message Expired Pack/Kit. Still, you can use the analyzer, under the sole responsibility of the operator.

5. Consumption of calibrating solutions

The analyzer electronically deducts "dose" from the uChip.

When the pack/kit is exhausted, the analyzer will display the message "Pack Exhausted"/"Kit Exhausted", and the analyzer will stop working with that pack/kit.

When the pack is exhausted, you must discard it and install a new one.



The red cap and associated tubing of the Analyzer may contain potentially infectious debris, exercise caution, always wear gloves, do not splash.

The exhausted pack contains potentially infectious waste. Discard the pack following the clarifications in "Disposal of supplies"



Take care not to contaminate the green and orange caps or tubes and their respective pipes, since they are used for the next pack.

In the exhausted pack, place the green, orange and red lids that the Pack brought to their respective jars before discarding to avoid losses.

6. Pack/Kit

Performance Pack/kit performance depends on how the analyzer is used and maintained.

Recommendations to optimize consumption:

* Measure the samples in batches, instead of doing them spaced (random): this saves calibrating solutions and improves the repeatability of the measurements.

* Perform maintenance as often as recommended in this manual.



See the "Maintenance" section

The pack/kit has been designed in such a way that the solutions are always sufficient for the doses calculated by the analyzer for the different amounts of installed ions, under various conditions of use. In this way, there may be a surplus of solutions in the Pack despite the "Pack exhausted" message appearing.

Do not open the pack. If you open it, you lose the Warranty and you run biological risks.



The consumption of Standard A and Standard B will never be the same. Therefore, there will always be a disproportionate surplus of both. The analyzer will display the message "Pack Exhausted" when one of the solutions is exhausted.



7. Pack Replacement in 103APV4 (AutoBasic and AutoPlus Models)



JS Medicina Electrónica recommends the simultaneous replacement of the Sample Collection Cleaner with the Diestro[®].

To replace the Pack:

- 7.1. Disconnect the power supply from the mains.
- 7.2. Disconnect the uChip adapter cable from the uChip and unscrew the connectors from the green, orange, and red caps. Note that the contents of the pipes will return to the inside of the pack.



The red cover of the Analyzer may contain potentially infectious residues, be careful, always wear gloves, do not splash.

The Exhausted Pack contains potentially infectious waste. Discard the Pack following the clarifications in the section "Disposal of supplies.



Take care not to contaminate the green or orange caps and their respective pipes, as they are used for the next pack.

In the exhausted Pack, place the green, orange and red lids that the Pack brought to their respective jars before discarding to avoid losses.



Closing the waste lid

- 7.3. Remove the Pack to be discarded and place the new Pack of calibrator solutions in the base of the Pack container.
- 7.4. Connect the uChip adapter cable to the uChip of the new Pack.
- 7.5. Unscrew the green and orange caps from the Pack and pierce the foil seals. Keep the lids, to close the jars of the Pack at the time of discarding it.

- 7.6. Unscrew the special connection caps of the old pack and screw them onto the new pack respecting the corresponding colors and place the original caps of the Pack to be discarded so that you do not lose liquid.
- 7.7. Screw the couplings of the special connection covers to the Analyzer respecting the corresponding colors and texts.



View of the Installed Pack

7.8. Reconnect the power supply to the electrical network. The analyzer automatically turns on and performs a purge and calibration.



See the section on "Calibration" and "Purge".

Once the calibration process is complete, the analyzer will display the following screen and is ready to measure.




8. Kit Replacement in 103APV4 (SemiBasic and SemiPlus models)



JS Medicina Electrónica recommends the simultaneous replacement of the Sample Collection Cleaner with the Diestro® Kit.

To replace the Kit, follow this sequence:

- Disconnect the power supply from the mains.
- Disconnect the uChip cable from the Kit.

The Analyzer's waste tank may contain potentially infectious waste, be careful, always wear gloves, do not splash.





Disconnecting the uChip

- Remove the Kit to be discarded and place the new one on the right side of the analyzer.
- Check the expiration date on the Kit box or vials. Do not use an expired Kit.
- Connect the uChip cable to the new Kit.



Installed Kit

- Reconnect the power supply to the electrical network after at least 15 seconds after being turned off. The analyzer turns on automatically and will ask to perform a calibration.



See the "Calibration" section

Once the calibration process is complete, the analyzer will display the following screen and is ready to measure.



9. Replacing the pack in 103APV3

To replace the Pack, follow these steps:

- Disconnect the power supply from the mains.

- Unlock the Pack container

- Open the Pack container by gently pressing, disconnect the uChip adapter cable from the uChip and unscrew the connectors from the green, orange and red caps. Note that the contents of the pipes will be purged into the Pack.



The red lid of the pack may contain potentially infectious waste. Always wear protective gloves and glasses, do not splash.

The exhausted Pack contains potentially infectious waste.



Take care not to contaminate the green or orange caps and their respective tubes, as they are not disposable.

In the exhausted Pack, place the green, orange and red lids that the Pack brought to their respective jars before discarding to avoid losses.



Closing the waste lid

- Remove the Pack to be discarded and place the new Pack of calibrator solutions in the base of the Pack container.

- Connect the uChip adapter cable to the uChip of the new Pack.

- Unscrew the green and orange caps of the Pack and pierce the aluminum seals. Keep the lids that were removed to cover the jars of the Pack at the time of discarding it.

- Unscrew the special connection caps and screw them into the new pack respecting the corresponding colors. Cover the exhausted pack, that is, the one that is going to be discarded to avoid loss of liquid.

- Screw the couplings of the special connection covers to the Analyzer respecting the corresponding colors and texts.

- Close the Pack container by gently pressing.

- Block the container of the Pack.

Reconnect the power supply to the electrical network. The analyzer automatically turns on and performs a purge and calibration.



See the section on "Calibration" and "Purge".

Once the calibration process is complete, the analyzer will display the following screen and is ready to measure.



5 – SERUM/ PLASMA/ WHOLE BLOOD MEASUREMENT

1. General Information

Diestro



Make sure that the analyzer works correctly by maintaining it correctly and performing a quality control.

See the "Maintenance" and "Quality control" sections.



The sample must be free of fibrins and clots.

It is recommended to centrifuge the samples and measure the serum.

Do not collate serum and urine samples.

2. Sample load in 103APV4



BIOHAZARD: Samples, capillaries, and adapters are potentially infectious. Handle with gloves.

After reomving the sample, clean the sample collection capillary with ISE Intensive Rinse Solution REF IN 0400

The sample can be loaded from a tube, syringe or from a capillary (With an adapter)





Load from a capillary

Load from a tube

When loading from a capillary, insert the capillary with the adapter into the needle.



-Press Load to start loading



3. Sample loading on 103APV3

The sample can be loaded from a tube, syringe or from a capillary (with an adapter).

- Press "**Serum**" to measure from a tube or "**Cap**" to measure from a capillary. The needle will rise automatically



Loading from a capillary

Loading from a tube

When loading from a capillary, place the adapter on the needle.

4. Measurement on 103APV4



Pressing Esc. at any time during the measurement will abort.

The Analyzer must be calibrated in order to measure.

4.1. From the initial menu press **Measure** (if the analyzer is on the main screen go to step 3.3)



4.2. In the measurement menu press **Meas.** (the sampler option will be visible only for the AutoPlus model).



4.3. From this step, the actual measurement process begins, from the main screen:





After 10 minutes of inactivity, the analyzer will request a rinse before performing the measurement.

-For samples in a tube or syringe simply move the lever to the first position (45°). For samples from a capillary move the lever to the second position (horizontal). -Put the sample and press "Load".





BIOLOGICAL RISK. Samples, capillaries, and adapters are potentially infectious. Handle with gloves.



The operator can enter the sample manually in case it cannot be detected (a low conductivity sample) by pressing Sens. See the section "Samples not detectable". The analyzer emits a sound signal that indicates that it has already loaded the minimum amount necessary to be able to measure. If little sample is available, you can remove the tube at this time.



You can enter sample information by pressing Info. See the section "Entering sample data".

-During loading, the analyzer will show the following screen: -Once loading is complete, the analyzer will emit a sound and will show the following screen:



-Remove the sample

-Move the lever to the rest position.



If the lever is not returned to the home position, the analyzer will not continue with the measurement.

-The analyzer automatically positions the sample in the measurement chamber and performs the measurement.



-Then the analyzer automatically loads (AutoBasic and AutoPlus models), or will ask to load (SemiBasic and SemiPlus models) a dose of StdA to rinse and calibrate at one point.



If the analyzer cannot successfully load the StdA, it will display the error "Not Filled" and the measurement will not complete. "Error Messages"



-When the measurement is complete, the analyzer displays the result on the screen:





If the Sodium result is lower than expected, perform a rinse with Sodium conditioner. See section "Sodium Conditioner"

5. Measurement in 103APV3



Pressing Esc. at any time during the measurement will abort.

The Analyzer must be calibrated in order to measure.

- From the initial menu, press Measure (if the analyzer is on the main screen skip the next two steps)



- In the measurement menu, press "Measure".





After 10 minutes of inactivity, the analyzer will request a rinse before taking the measurement.

- From this step, the actual measurement process begins, from the main screen:



- To start the measurement process from a tube or syringe, press Serum. For samples from a capillary press Cap.



- Place the sample and press Fill.





BIOLOGICAL RISK. Samples, capillaries, and adapters are potentially infectious. Handle with gloves.



In the case that the sample cannot be detected, the operator can position it manually, by pressing **Sens**. See "**Non detectable Samples**" section for more information. The analyzer signals the minimum sample volume has been loaded with a beep. Once heard, you can remove the tube.



You can input the sample information by pressing Info. See the section "Entering sample data".

- During loading, the analyzer will show the following screen:



- Once the loading is complete, the analyzer will emit a sound and will show the following screen:



The symbol **indicates** indicates that the measurement chamber was filled correctly with the sample.

- Press ready and the sampling needle will return to its initial position.

Measure	
Stabilizing	
Wait	Esc.



You must press **Ready** for the analyzer to continue with the measurement.

- The analyzer automatically positions the sample in the chamber and performs the measurement.
- Then, the analyzer will automatically load a dose of StdA to rinse and performs a one-point calibration.

If the analyzer cannot successfully load the StdA, it will display the error "Not filled" and the measurement will not complete. See "Error Messages" section for more information.

- When the measurement is complete, the analyzer displays the result on the screen:





Diestro

If the Sodium result is lower than expected, perform a rinse with Sodium conditioner. See section "Sodium Conditioner"



After 10 minutes of inactivity, the analyzer will request a rinse before performing the measurement.

6. Printed Electrolyte Report (Optional)

(SemiPlus, Autobasic and AutoPlus models)



Printed electrolyte

The result is stored in memory and can be viewed and printed at any time. The analyzer can save the last 1000 measurements.



See "Electrodes" section

See "Data Storage" Section

7. Sample Data Entry (Optional)

(Semi Plus, Basic Auto and Auto Plus Models)

The operator can enter sample information (Patient No.) with the following sequence:

-Pressing info. Before placing the sample, you have access to the information screen of the sample to be processed:



-The sample number is incremental and is not editable,



<==>	Selects the digit to edit
٨	Increases the selected digit
V	Decrements the selected Digit

Once patient number has been entered, press "Esc" to continue with the measurement sequence.

8. Measurement of Ca corrected by pH

(Only analyzers with installed and enabled Ca and pH electrodes)

The analyzer can measure pH to correct the value of ionized calcium to pH=7.40, and thus obtain the standardized Ionic Calcium.

When a pH measurement is made, it is done at room temperature and the gain is corrected for temperature, using a temperature sensor included in the electrode plate.

Results can be displayed at room temperature or corrected to 37°C (user selectable).

6.1 Important considerations:

It is recommended to carry out the pH measurements at room temperature (close to 25°C), without abrupt changes in temperature.

Calibration solutions and samples must be at the same temperature as the instrument. Do not use control solutions or samples fresh from the refrigerator, allow to stabilize at room temperature first.

The remaining lons are measured simultaneously with the corrected Ca and pH, up to a maximum of 5 measured parameters.



Always handle the sample anaerobically



BIOLOGICAL RISK. Samples, capillaries, and adapters are potentially infectious. Handle with gloves.

After removing the sample, clean the sampling capillary with ISE REF IN 0400 Intensive cleaning Solution.

6.2 Ionic Calcium Correction Equation:

For pH correction, the following equation is used

Ca++ (@pH=7.4)= Ca++ x 10^[0.178 x (pHm - 7.4)]

Ca++m = Measured Ca++ concentration of the sample

pHm = Measured pH of the sample.

6.3 Temperature configuration:

For pH display temperature configuration, go to calibration options:



In calibration options press "ION" and then "Settings"

In this window, pressing on "pH " toggles between room temperature and 37°C



6.4 Sample measurement:

Measurement is performed in the same way as any other ion.

Example of a measurement ticket, with pH corrected at 37°C

Diestro	
103ApV4	
Analyzer Auto Plus V 4,26 D/D NS 9999	
"Na *K *Ca *Li *pH	
Laboratory JS-Med.	
	=
Electrolyte Report	
2016/02/25 10:48:27	
Mem: 336	
Patient:	
t Amb= 23.7°C	
Na = 138.4 mmol	
K = 4.23 mmol	
Ca = 1.08 mmol	
Li = 0.96 mmol	
pH= 7.34 @37°C	
Ca = 1.05 mmol @pH 7.40	

Example of a measurement ticket, with pH corrected at room temperature

Diestro
103ApV4
Analyzer Auto Plus
V 4.26 D/D NS 9999
*Na *K *Ca *Li *pH
Laboratory JS-Med.
Electrolyte Report
2016/02/25 10:45:11
Mem: 336
Patient:
t Amb= 25.3°C
Na = 138.4 mmol
K = 4.23 mmol
Ca = 1.02 mmol
Li = 0.96 mmol
pH= 7.59 @ tAmb
Ca =1.10 mmol @pH 7.40



For more details, see "Measurement of Serum/Plasma/Whole Blood" section



6.5 Quality control:

Samples measured from the quality control menu are always reported at 37°C. Ca Quality control is carried out in the same way as the other lons



For more details, see "Quality Control" section

6 – URINE MEASUREMENT

1. General Information



Make sure that the analyzer works correctly by maintaining it correctly and performing a quality control.

See the section "Quality control" and "Maintenance".



Always dilute urine samples. The default dilution is 1 part urine to 4 parts diluent (1:5). The analyzer only measures Na, K and CI in Urine samples. Use Urine Diluent ISE REF IN 0300.

2. Sample Load



BIOLOGICAL RISK. Samples, capillaries, and adapters are potentially infectious. Use gloves. After withdrawing the sample, thoroughly clean the sampling capillary with ISE REF IN 0400 Intensive Rinse Solution.

Always load urine samples from a tube. Always DILUTE with the urine diluent provided with the analyzer.

3. Measurement



Pressing Esc. at any time to abort the measurement.

3.1. The measurement can be started from the main screen by pressing Urine:



3.2. Enter the dilution



∧ Increase the parts of the dilution

V Decrease the parts of the dilution <==> Enter the selected proportion

3.3. Press **Esc** and move the lever to tube position to start the measurement.





After 10 minutes of inactivity, the analyzer will need a rinse before the measurement.

3.4. Insert the tube so that the needle is immersed in the sample and press "Load".





BIOLOGICAL RISK. Samples, capillaries, and adapters are potentially infectious. Handle with gloves.



The operator can enter sample information by pressing Info. See the section "Entering sample data" and "Sample data entry (Optional).





The operator can enter the sample manually in case the analyzer does not detect it (a low conductivity sample) by pressing **sens**. See the section "Samples not detectable".

3.5. During loading, the analyzer will display the following screen:



3.6. Once loading is complete, the analyzer will emit a sound and display the following screen:



3.7. Remove the sample



Clean the needle with a gauze moistened with ISE REF IN 0400 Intensive Rinse Solution after removing the sample.

3.8. Lower the lever.



If the lever is not completely lowered, the analyzer will not continue with the measurement.

3.9. The analyzer automatically positions the sample in the measurement chamber and performs the measurement.





3.10. The analyzer then automatically loads a dose of StdA to rinse and calibrate at one point.



If the analyzer does not load Std. A it will display a "Not filled" error and the measurement will not be performed. See "Error messages".

3.11. Once the measurement has finished, the analyzer will show the result on the display ("O" = Urine)



If the Sodium result is lower than expected, perform a rinse. See section "Sodium Conditioner".

4. Result



Urine result ticket



See "Reference Values" section for more details about normal and critical serum electrolyte values.

See "Electrode Gain Range" section.

The measurement result is stored in memory and can be retrieved and printed. The analyzer can save the last 1000 measurements.



See the section "Data storage".

5. Sample data entry (Optional)

(Semi Plus, Basic Auto and Auto Plus models)

The operator can enter sample information (Patient number) with the following sequence:

5.1 Pressing info. you have access to the information screen of the sample to be processed:



5.2 The sample number (**M#**) is incremental and not editable. It is set by the analyzer.



5.3 Once the patient number is entered, press "Esc" to continue with the measurement sequence.



Go to step 3.4 of this same section.

Diestro 7 - CALIBRATION

1. General Information

The analyzer performs two types of calibration

1-Point Calibration

2-Point Calibration



Make sure that the analyzer is working properly by maintaining it properly and performing a quality control.

See the section "Quality control" and "Maintenance".

2. 1-point calibration

For AutoBasic and AutoPlus models: It is performed automatically by the analyzer during the measurement of a sample and is inaccessible to the operator.

For SemiBasic and SemiPlus models: It must be done manually in each measurement.

During the measurement, after stabilizing the sample, the analyzer loads StdA to perform a 1-point calibration.

3. 2-Point Calibration

3.1. Automatic Calibration (AutoBasic and AutoPlus models)

Is performed when the analyzer is turned on, or depending on the configured calibration frequency.



The calibration frequency is 8 hours

For SemiBásic and SemiPlus this calibration is done manually.

3.2. On Demand Calibration

Diestro

3.2.1 It can be done at the request of the operator through the following sequence, starting at the main screen and pressing **Menu**:





After 10 minutes of inactivity, the analyzer will request a rinse. It is recommended to do it before calibration.

3.2.2 In the initial menu press Cal.



3.2.3 Press Cal2 to start the 2 point calibration.



For AutoBasic and AutoPlus models:

When the 2-point calibration begins, the analyzer loads and stabilizes two doses for each calibrator solution automatically Starting with the StdB and then with the StdA.

For SemiBasic and SemiPlus models:

-The analyzer will request 2 StdB loads.

- Remove the sampling capillary
- Place the tube with the corresponding calibrator
- Press load
- Wait for the "Ready" message to remove the tube
- Move the Fill Port to the rest position.
- Repeat the process for the second dose of StdB

- The analyzer will then request two doses of StdA.

• Repeat the above procedure, but with the new reagent tube.



If the analyzer fails to complete the StdA or StdB load it will display a "Not filled" error and calibration will not be performed. See errors in maintenance section.

4. Calibration Result

4.1 When the calibration process ends, the analyzer will show the results on the screen and they will also be printed, showing each electrode with its gain and status:



4.2 By pressing the Next Ion name you have access the rest of the electrodes.

4.3 By pressing the Previous ion Name key

you can see again the first three electrodes.





The legend "Calibrated" indicates that the electrode is ready to measure.

See "Electrode Gain" section for gain ranges.



If the sodium gain is less than expected, it might need a rinse. See section "Sodium Conditioner".

4.4 In case one of the electrodes does not calibrate, the analyzer will show it in the report.





The legend "NO CALIB" indicates that the electrode is not ready to measure. The corresponding electrolyte will not be measured.

See the "Error messages" section.

5. Calibration Result printing

The printed result includes the following information



Printed Calibration Result

When all the ions have been correctly calibrated, and returns to the initial menu. Note that each ion is preceded by an "asterisk". This means that the electrode is calibrated correctly.



If the analyzer is out of calibration, each ion is preceded by an "X" symbol.

If the type of electrode (you can find out which one corresponds to your analyzer, from the **Info**, from the electrode/pack history menu or in any ticket that the analyzer gives you such as calibration and measurement) is not the appropriate one for the analyzer, each installed ion is crossed out.

6. Saved results

6.1 The result of the last calibration can be viewed by the operator with the following sequence, starting from the main screen by pressing menu:



6.2 Enter the calibration menu by pressing Cal



6.3 Select Hist. to see the last calibration



6.4 The results are shown on the screen



7. Calibration Options

All calibration options start from the calibration menu, to access this menu, from the main screen press **Menu**



and then Cal.



This is the calibration menu:

Calibration			Pack Hist
Cal2	Hist	Opt	Esc

For AutoBasic and AutoPlus models: press Cal2 and the analyzer will start the calibration automatically.

For SemiBasic and SemiPlus models, the drawing of the lever is shown below the Cal2:

- 1- Raise the lever
- 2- Place the StdB tube
- 3- Press load
- 4- Remove the tube when the ready message is displayed on the screen
- 5- Lower the lever
- 6- Repeat the process for once more of stdB and twice of stdA.

7.1 Enabling / Disabling Electrodes

The electrodes present in the analyzer can be enabled or disabled.



Disabling an electrode implies that its calibration or measurement will not be informed, but it does not influence the consumption of sample or reagent.

7.1.1 To enable or disable lons, go to: Menu \rightarrow Cal \rightarrow Opt \rightarrow Ion \rightarrow En

From the calibration menu:



7.1.2 Press Ion



JS Medicina Electrónica
7.1.3 Press Enable.



*

7.1.4 On this screen you can enable or disable all electrolytes (up to 5 simultaneously)

Na	K	CI	Ca
*	*	*	*
Li *			Esc

Press on each Electrode to enable/disable

Electrode Enabled Electrode Disabled

7.2 Modification of units

Only applies to Calcium electrolyte.

Possible units: [mmol/l], [meq/l] or [mgr%]

1 mmol/l = 2 meq/l = 4 mgr%

7.2.1 To modify the Calcium unit, go to: Menu \rightarrow Cal \rightarrow Opt \rightarrow Ion \rightarrow Hab



7.2.2 Press Ion



7.2.3 Press Set.



JS Medicina Electrónica



7.2.4 Select the desired unit



7.3 Delta correction configuration

Delta correction allows you to correct the values obtained by the analyzer, so that they coincide or are level with those obtained with other analyzer, internal or external quality controls or with the Standard wanted.



Before using Deltas, verify the correct operation of the analyzer and perform a quality control because there may be a hidden problem. Never apply Deltas if the analyzer is not accurate, in other words if it does not repeat a sample correctly.

See the section "Delta Correction" and "Quality Control"

7.3.1 The sequence of modification of the Delta values is as detailed below, in the calibration menu, press **Opc**.



7.3.2 In the calibration options press Delta



7.3.3 Now you can change the Delta value. Each electrode has a delta for each type of sample.



Press \Lambda or 🔽 to access serum/urine delta



Select electrode to edit value

<==> Press to select digit of delta value corresponding to selected electrode

- A Increases delta Value
- v Decreases delta value

7.3.4 Pressing Esc. will exit to the calibration options menu



7.4 Delta Correction Ranges

The analyzer allows the following delta values according to the sample tube.

Serum	Range	Resolution
Na	-9.9 to 9.9	0.1
K	-0.99 to 0.99	0.01
CI	-9.9 to 9.9	0.1
Ca	-0.99 to 0.99	0.01
Li	-0.99 to 0.99	0, 01

Urine	Range	Resolution
NaO	-99.9 to 99.9	0.1
KO	-9.9 to 9.9	0.01
CIO	-99.9 to 99.9	0.1



Before using high value deltas, make sure that the pattern and its use are correct and/or that the analyzer is working correctly.

8. Electrode History

General information:

This menu contains all the data related to the installed electrodes, such as:

- -Serial number.
- -Date of manufacture.
- -Date until which it can be in stock without being installed.
- -Date on which it was installed.
- -Type of electrode.
- -Gain of the last calibration
- -Initial gain with which the electrode was approved

Quantities of:

-0n.

- -Calibrations.
- -Serum measurements.
- -Urine measurements.
- -Intensive rinses.
- -Normal rinses.
- -Sodium rinses.

This way you can check the condition of the electrodes.

8.1 To access this menu press Cal from the initial menu.



8.2 Then Opt and Ion.



8.3 Finally Elect.



8.4 This is the Electrode History menu.

Ref.	Na	K	Cl
Ca	Li		Esc

91

18

B1

2

0

Esc

8.5 To access the history of an electrode, press the desired parameter:



8.6 This is the history of K.



Page 1 Page 2



Page 3

-To change the page press "V".

-To print the electrode history press "V" 2 times, until the same button shows Print. Press Print. to print the history (only for devices with a printer)

-To return to the Electrode History menu, press Esc.

9. History of the Pack/Kit installed

General information:

This menu contains all the data related to the use of the pack:

-Type of the Pack/Kit

-The remaining percentage of Std A and Std B.

-Date of installation of the Pack/kit

Date Pack / kit expiration date

Quantities of:

- -Analyzer power-ups.
- -Purges carried out.
- -Calibrations performed.
- -Wets of Std A and B
- -Samples in Batch mode.
- -Samples in random mode.
- -Normal rinsees.
- -Wets of Std A.
- -Errors "not empty"
- -Errors "not filled"

In this way you can view the usage statistics of the analyzer.

9.1 Press Cal from the Main Menu.



9.2 Press Pack Hist / Kit Hist.



9.3 This is the pack / kit history menu.

Pack: D 97 69% Exp: 2016/03/06 Inst: 2014/03/06	•	Wet A&B: Batch: Random:	284 4543 10	•
Turned on: 27 Purge: 1 Cal: 832	Esc	Rinse: Clean:	318 1	Esc
Page 1		Page 2		
Purge: 2 Not empy: 5	Impr			
Not Filled. 8	Esc			
Page 3				

-To change the page press "V".

-To print the electrode history press "v" 2 times, until the same button shows **Print**. Press **Print**. to print the history (only for devices with a printer)

10. Standby Function

After 10 minutes of inactivity, the analyzer automatically goes into standby and displays the following screen:



While in this mode, the automatic calibration and rinsing operations are suspended (models AutoBasic and AutoPlus)

Two types of operations will be executed in this mode (AutoBasic and AutoPlus models):

-A&B humidification: performed every 8 hours after the last calibration

-A Humidification: performed every 3 hours after the last calibration.

In this way, the performance of the pack is improved without losing the benefit of maintenance of electrodes, valves and pipes.

It is recommended to keep the analyzer always on.

Screen saver

While the analyzer is in standby, if the operator presses the screen and instead of executing the function that appears on the reassignable key on the left, presses menu and navigates through the analyzer, after 5 minutes of inactivity, the analyzer it will go to the standby screen automatically.

Diestro 8 – RINSE AND CLEANING

1. General Information

While the analyzer measures or calibrates, you will need to rinse the electrodes. The rinse renews the StdA in the electrodes preventing the mixture of different substances, it also cleans the liquid circuit removing bubbles, clots, dirt or other substance that can change the result of the measurement or calibration.

2. Automatic Rinse

AutoBasic and AutoPlus Models: Is performed automatically between Std. B and Std. A during calibration or between a sample and Std. A during measurement. Also when the analyzer is 10 minutes without use.

SemiBasic and SemiPlus models: you will be asked to do them manually.

3. On demand Rinse

3.1 Can be performed on operator demand by the following sequence, starting from the main screen and pressing menu:



3.2 Press Measure to enter the measurement menu



3.3 Press **RINSE** to enter the rinse menu (the sampler options will be visible only for the AutoPlus model).



3.4 Press Rinse and it will automatically start normal rinsing.



For AutoBasic and AutoPlus analyzer, follow the next sequence

3.5 The rinse will start: the analyzer will load and rinse several times with Std. A.

3.6 When the process is complete, the analyzer will show the following screen:



For SemiBasic and SemiPlus analyzer, follow the next sequence

3.5 Press Norm. and lift the FillPort lever



3.5 Place the StdA tube

3.6 Press "Fill"

3.7 Wait for the message "ready to remove the tube"

3.8 Move the FillPort to rest position. At this time the analyzer will flush the analyzer tubing.

4. Automatic Clean

4.1 The analyzer needs an intensive rinse every 24 hours (only when a sample has been measured). After this time, the analyzer will show this screen. Dose Intensive cleaning Solution in a tube and then press **L. Int.**

Diestro			10	3 ApV4
V 4.0		D/D	NS	: 10000
*Na	*K	*Cl	*Ca	a *Li
Clean				
				Menu

4.2 Open the Fill Port, put the Intensive cleaning solution and press Load



4.3 When finished, the analyzer will emit a sound. Pull out the tube and move the lever to rest position.



4.4 The analyzer will continue with the intensive rinse.



The rinsing process ends with the loading of StdA.

For SemiBasic and SemiPlus models

You will need to load StdA manually.

4.5 After the intensive rinse is finished, the analyzer will need a 2-point calibration and will display it on the screen. If no button is pressed for 1 minute, it will automatically start to calibrate (AutoBasic and AutoPlus models). For SemiBasic and SemiPlus Models, the analyzer will remain with the calibration message until it is done manually.



4.6 When the calibration is finished, the analyzer is ready to measure.

5. On Demand Clean

5.1 It can be performed by operator need, through the sequence that begins on the main screen, pressing menu:



5.2 Press Measure to enter the measurement menu





5.3 Press **Rinse** to enter the rinseing menu.



5.4 Press Clean and pull out the lever to start the Clean.



Repeat the procedure described in point 8.4

6. Sodium Conditioner

The analyzer will request once a week a rinse with the sodium conditioner. It is recommended to dose the sodium conditioning solution in an eppendorf tube.

6.1 Automatic Sodium Conditioner Clean (AutoBasic and AutoPlus models)

Every 7 days, the analyzer will require a Rinse with Sodium Conditioner.

Repeat the indicated Clean procedure (both for automatic and semi-automatic analyzer).



See Section "Rinsing and Cleaning".

6.2 On Demand Sodium Conditioner

Repeat the procedure indicated for On Demand Clean

- Press Clean, the legend will change to Na Cln
- pull out the lever to start the Sodium Conditioner Rinse.



9 – PURGE (AutoBasic and AutoPlus Models)

1. General Information

Diestro

During this process, the pack and analyzer pipes are filled with both calibration solutions.

Note: this option is available only for Automatic Basic and Automatic Plus

2. Automatic Purge

It is carried out automatically when a new Pack is installed in the analyzer.

The screen will display the following sequence:



The analyzer will first purge the reagent from the stdB bottle and then the reagent from the stdA bottle.

When the process is complete, a calibration will automatically start.

If **Esc** is pressed, the purge is aborted.

Note: The computer must detect that the purge action has been completed (when installing the pack). Therefore, if the purge is aborted, the analyzer will continue to attempt to purge, until the action is complete. This implies consumption of reagents.

Avoid purging if the analyzer shows "Not filled" or "Not Empty" errors, as it will consume reagents without solving the problem.



See the "Calibration" Section.



If the pipes of the Pack are disconnected, it will be necessary to perform a manual purge. Otherwise, the parser will give "Not filled" errors.

3. Purge on demand (Manual)

Diestro

3.1 It can be done when the operator requires it. Using the following sequence, on the main screen press **Menu**:



3.2 Press Measure to enter the measurement menu



3.3 Press Rinse to enter the rinse menu



3.4 Press Purge to start the purge



3.5 When the purge starts the analykzer shows this sequence:



3.6 When the process is completed, the analyzer will display the rinse screen:

10 – QUALITY CONTROL (V3/V4 AutoBasic or AutoPlus Models)

1. General Information

Diestro

The Diestro Analyzer has the possibility of performing statistical calculations to assist the operator in the quality control of his analyzer.

Diestro Control and Diestro Trilevel control ampoules come in 3 levels, low, medium (the normal value) and high.

Do not use the calibrator solutions as controls.

Do not use calibrator solutions or flame photometer controls.

Use controls for direct ISE

Contact the manufacturer, distributor or technical service to ensure which controls are the most suitable and how to interpret the results obtained



If serum controls are used, use gloves

The greater the number of control samples measured, the more accurate the analysis will be.

The analyzer allows you to store up to 20 samples of each level in its internal memory.

The statistics will be made with 5 samples per level or more (up to 20); with fewer samples it will not give statistical results, although it will store the results.

If you want to verify the specifications of the analyzer, you must perform the 20 measurements and have the analyzer in optimal maintenance conditions.

Statistical calculations are:

Mean value, Standard Deviation and Percentage Variability Coefficient

2. Quality Control Performance

From the Start menu press CC



Select the level to measure:

Note: If you are going to make more than one measurement, group them by level.



The analyzer allows identifying the quality control that is being used, name and batch number, by pressing the **Brand**.

Press CC1, CC2 or CC3, to access the measurement menu of the corresponding control.

The analyzer allows you to load the acceptance ranges for each ion from the Value

If you press **Measure**, you can choose to load from tube or capillary. From here the process is similar to any measurement.



Pressing Clear will clear or all the results stored in the result memory for that control level



3. QC Results From the QC Menu

Press Mem.



The result will be displayed:

Na= 121.3 K = 8.19 Cl= 129.4		Ca= 1. Li= 1	.80 .12
#: 18 *	•	•	Esc

With the arrows you can explore the memory; the number that you see between the arrows is the sample number within the 22 possible within the selected level.

If the sample position number is identified with an asterisk (*), it means that the sample is considered for the statistics, otherwise that result will not be included.

If you want to exclude a sample from the statistics of this level, you must remove the asterisk (*)by pressing the **#** button.

By default, the analyzer excludes the first 2 samples. If you want to include them, find the sample in memory and enable it by pressing the **#** so that the asterisk is visible.

Press **Status**. to access the stats for that level.



One screen is displayed for each electrolyte.

Change the parameter using the arrows.

N is the number of quality control samples in memory enabled with (*).

Press **Print**. to print a ticket with all included measurements and statistical values.

JS Die An V 2 *N La	Diestro JS Medicina Electronica Diestro 103ApV4 Analizador Auto Plus V 4.00 D/D NS 9999 *Na *K *CI *Ca *Li						
Co	ontrol d	e Calida	ad	2013/1	2/30		
Ν	Na+	K +	CI-	Ca++	Li+		
1	118.0	2.10	80.2	7.96	0.20		
2	118.4	2.12	80.4	7.92	0.21		
3	117.6	2.11	80.4	7.96	0.21		
4	117.6	2.13	80.5	7.92	0.21		
5	118.0	2.12	80.2	8.00	0.21		
M	117.9	2.11	80.3	7.95	0.20		
DS	6 0.34	0.012	0.14	0.032	0.005		
C١	/ 0.2	0.5	0.1	0.4	2.4		
==	=====						

Printed quality control result

To exit the Quality Control menu press **Esc**. from the main menu screen.



<u>11 – CLOCK</u>

1. General Information

The analyzer is capable of keeping the date and time updated despite being turned off. (SemiPlus, AutoBasic and AutoPlus models)

2. Clock adjustment

2.1 To adjust the clock, first enter the menu:



2.2 In the initial menu press Serv and Conf.



2.3 Press Clock



2.4 Now you can change the date and time of the analyzer



<==>	Select between year, month, day, hour and
	minute

- Increase the selected value
- Decrease the selected value

2.5 Press Esc. and then Done to save changes and return to the setup menu.

Diestro 12 – RESULTS STORAGE

1. General Information

Allows the operator to access the results of the last measurements, sorted by sample number. The analyzer can save the last 1000 measurements. (SemiPlus, AutoBasic and AutoPlus models only)

2. Measurement Results

2.1 Start by pressing Menu



2.2 Press Meas.



2.3 Press Mem to enter results memory



2.4 Select the sample number using the arrows and press **Res** to see the result of the selected measurement.



2.5 The selected result is displayed on the screen



2.6 By pressing Info, you return to the previous window to select the sample number and view the measurement date and time

Press Print to print the measurement result

Press **Esc** to exit the results memory and go to the main screen.

13 – NON-DETECTABLE SAMPLES

1. General Information

It may happen that a sample (Serum, Whole Blood or Urine) with low conductivity is not detected or its volume is insufficient to measure all the configured ions and an error occurs in the analyzer (Error: Not filled).

If the operator is sure that the sample was loaded correctly, he can disable the sample detector, to make the measurement without the risk of losing the sample.

Disabling the sample detector involves visual and manual positioning of the sample in the electrode chamber.

2. Disabling the sample detector

2.1 Facing a "Not Filled" error the analyzer shows:



If you press **Rinse**, the analyzer will rinse and the sample will be lost. After the rinse, the analyzer will be ready to measure again

is pressed Esc. the sample can be saved

2.2 Open the front of the analyzer to have a view on the electrode chamber.

2.3 When you press Esc. The analyzer will go to the initial menu, press Meas.





2.4 Press Meas. again



2.5 Select the type of sample to be measured and move the lever to its respective position (Tube or capillary).



2.6 Press Sens. To load the sample manually



2.7 At this point, while holding down the clockwise button , the sample will move forward, (to the

right inside the measurement chamber). While holding down the counterclockwise button ^(C) the sample will move backwards (to the left inside the chamber).



If the sample was loaded before entering this option (case of the "Not filled" error) the operator only has to hold down the counterclockwise button in the measurement chamber is completely full

2.8 Once the chamber is completely full with the sample and no bubbles, move the lever to its rest position.

2.9 Measurement will continue normally





The operator is responsible for how the sample is positioned. Position it from the reference electrode covering as many electrodes as possible with the amount of sample you have. Remember that the sample has to be in contact with the reference electrode. Results from electrodes not in contact with the sample will be incorrect. It is the operator's responsibility to disregard the results of such electrodes.

14 – PRINTER, SERIAL OUTPUT, LANGUAGE AND INSTITUTION DATA CONFIGURATION (V3/V4 SemiPlus, Autobásico and AutoPlus Models)

1. General Information

Diestro

The analyzer allows you to configure: Printer, serial output and choose language.

Both the serial output (RS232) and the USB port allow the analyzer to be connected to a printer or other type of device (for example, a PC or a data network).

2. Printer configuration, serial output, language and institution data

2.1 To configure, enter the menu by pressing Menu



2.2 In the initial menu, press Serv and then Conf





2.3 Press Sal



2.4 In this screen you can enable or disable the printer, output series, language and institution details on the ticket.

Print *	Out RS232 No	Valid No	Bip
Disp. Time s: 2	Eng.	Lab.	Esc

When you press "**Print**", an asterisk (*) will be displayed, which means that it is enabled. If we press again, the asterisk disappears, deactivating the printer.

Print *	Out RS232 No	Valid No	Bip
Disp. Time s: 2	Eng.	Lab.	Esc
$\left \right\rangle$			

Pressing the language sequentially cycles through the available languages.



To deactivate or activate the audible warning, press **Beep**.

Print *	Out RS232 No	Valid No	Bip
Disp. Time s: 2	Eng.	Lab.	Esc
			$\left(\begin{array}{c} -\end{array}\right)$

To modify the time for displaying the results on the screen, press View Time.

Print *	Out RS232 No	Valid No	Bip
Disp. Time s: 2	Eng.	Lab.	Esc
$\left(\begin{array}{c} \\ \end{array}\right)$			


To edit this data:

<==> Select the digit

 ΛV Choose the letter or number

To change the data of the institution, press Lab.





To edit this data:

<==> Select the character.

 ΛV Choose the letter or number.

Example of a Ticket with Institution



Data Institution data on ticket

2.5 If the serial output was not enabled, pressing **Esc**. returns to the initial menu. If serial output was enabled, pressing **Esc**. the "Serial Output Options Menu" will be displayed.

Serial output: No

Print *	Out RS232 No	Valid No	Bip
Disp. Time s: 2	Eng.	Lab.	Esc
			\bigcirc

Serial output: Net (AutoBasic and AutoPlus Models)



Serial output: Print

(SemiPlis, AutoBasic and AutoPlus models)

Print *	Out RS232 Print	Valid No	Bip
Disp. Time s: 2	Eng.	Lab.	Esc

Press Esc to return to Main Menu

Root Menu

Press **Esc** and this screen will be displayed



Baud: (Baud rate) It is the data transfer speed of the serial output.

Xon – Xoff: It is an option of the serial communication protocol.

<CR>+<LF>: Some printers or interfaces require this option.

Serial communication is: (8N1)

- 8 data bits 1 bit Stop
- No Parity

103APV4 *Na *K *Cl *Li Cal Meas QC Serv

15 – LIS INTERFACE CONFIGURATION

(SemiPlus, AutoBasic and AutoPlus Models).

The analyzer has the option to send data according to the "LIS" communication protocol. In other words, if you work with this communication standard, you can integrate the analyzer to your network.

Connection cable (AutoBasic and AutoPlus Models)

DB9 Female Pins Analyzer	DB9 Female Pins PC
1	1
2	3
3	2
4	6
5	5
6	4
7	8
8	7
9	9

For SemiBasic Model, follow instructions in section 14.2. and configure the RS232 output for printer. Results will be sent to RS232 serial port with format equal to the printed ticket

Serial output configuration:

To enable serial communication, modify the **"Serial Output"** parameter found in the menu **Serv->Conf-**>**Outputs**.

The "RS232 includes the following options:

- No: serial output disabled.
- Print: transmits through the RS232 and/or USB output the calibrations and measurements data carried out by the analyzer in printer ticket format (the same as what is printed on a calibration or measurement ticket).
- >Net (AutoBasic and AutoPlus Models): sends the measurement data in a data string with the following format:

Sample Number;& Patient;Date Time;Na measurement result;K measurement result;Cl measurement result; Ca measurement;Li;CR measurement result

Field Name Field	Format	Remarks
Sample Number	#XXXXX	Increments from 1 to 65535. Not editable by the user.
Patient ID	&XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX	Allows up to 20 alphanumeric characters entered by keyboard, barcode or embedded computer keyboard
Date and Time	YYYY/MM/DD HH:MM:SS	There are 2 spaces between Date and Time.
Na measurement result in serum	Na= XX.X mmol v^ Error:Z	
Serum K measurement result	K = X.XXmmol v^ Error:Z	
Serum Cl measurement result	CI=XXX.X mmol v^ Error:Z	
Serum Ca measurement result	Ca = X.XX mmol v^ Error:Z	2: Measurement Error Flag (/?SCLQuU) v^: Result outside the established normal range
Serum Li measurement result	Li= X.XXmmol v^ Error:Z	Calcium units can be mmol , mgr % or meq/l
Urine Na measurement	NaO=XXX.X mmol v^ Error:Z	
resultUrine K measurement	KO= XX.XX mmol v^ Error:Z	
Urine CI measurement result	CIO=XXX.X mmol v^ Error:Z	
CR		Carriage return (End of string)

Note 1: In this mode calibration or quality control data will not be sent through the serial port, only the measurements of the samples will be sent to the network.

Note 2: ">Network" This option is available only in AutoBasic and AutoPlus models.

Example of Strings sent by Network:

Serum measurements

Analyzer with Na-K-CI-Ca-Li configuration Sample number: 7 Patient Juan Perez1234 Measurement with errors ?CI, K Measurement with errors ?Q, CI Measurements OK, Ca below normal value and Li above normal value.

All ions are in units of mmol.

7;&Juan Perez1234 ;2020/11/09 11:09:39;Na=145.3mmol/E:u ;K = 4.16mmol/E:Q ;Cl=105.7mmol ;Ca= 0.85mmolv ;Li= 0.51mmol^ ;;;

Urine measurements

Analyzerwith Na-K-Cl-Ca-Li configuration Error-free urine measurements, no patient ID

All ion units are in mmol/L.

8;&;2012/10/13 16:39:57;NaO=251.0 mmol/l;KO= 21.20 mmol/l;CIO=251.0 mmol/l;;;

Note: In urine measurements, a letter "O" is added after the measured ion.reported.Only Sodium, Potassium and Chlorine areThe other fields remain empty.

Baud rate, flow control, carriage return and line feed settings.

Pressing Esc in the Serv-> Conf-> Output and having Serial will be displayed A screen with options Baud Button: (Baud Rate) The data transfer rate of the port.

Xon – Xoff button: It is an option of the serial communication protocol.

Serial communication is: (8N1)

8 data bits

1 sop bit

No parity

<CR>+<LF>: Some printers or interfaces need this option. (Appears only when the serial output is configured as a ticket)

Sending results to the Network from memory

To send a result to the Network from memory, go to: Measure->Mem and search for measurements using "v" and " $^{"}$ until you find the desired measurement.

Note: In the search screen you will find the data Patient Name, Sample Number, Date and Time. Once found, press "**Result**" to display them.

By pressing ">Network" the measurement data will be sentviaRS232.

Validation of sample measurements before saving them in memory or sending them to the network.

The "Valid" parameter found in Serv-> Conf-> Output specifies whether the measurement should be manually validated before sending it and what happens in the event of an error.

Choose from the following options:

Yes: Every time a measurement is finished, the operator press **OK** (by pressing ">Network" on the screen) to send the data through the RS232 output or press "**ESC**" to cancel the sending.

- No: Every time a measurement is finished, it will be automatically sent through RS232
- Error: Every time When the measurement ends and there is an error, the operator must give OK (by pressing "> Network") so that it is sent through RS232 or "ESC" to cancel the sending.Measurements without errors are sent to the network, without validation by the operator.

16 – BARCODE READER AND/OR EXTERNAL KEYBOARD INSTALLATION (OPTIONAL)

(SemiPlus, AutoBasic and AutoPlus Models)

1. Plug the barcode reader or external keyboard into the connector located on the back of the analyzer.



2. Entering the information in the measurement process. (See section 5.3 and 6.3 of the user manual)

2.1. When the analyzer asks to load the sample, the following screen will be displayed. Press Info.



Enter the patient's name on the keyboard and press "**Enter**" or scan the barcode with the barcode reader.

Note: The patient's name will be displayed on the measurement screen.



The patient's name can be re-entered by repeating this step.

2.3 To continue with the normal measurement procedure, press **Load** and follow the steps described in the manual.

Example of patient name on a report ticket



Patient name on ticket

17 – QUADRATIC CORRECTION EQUATION FOR SERUM AND URINE MEASUREMENTS.

1. General Information

Diestro

Depending on the needs of each user, the Diestro Ion Analyzer has the option of applying a quadratic correction equation:

 $y = ax^2 + bx + c$

a= Quadratic factor.

b= Linear factor.

c = Constant factor (Delta)



For more information about the quadratic equation and how to calculate its parameters, contact the Technical Service.

2. Delta Correction Delta

correction allows the results obtained by the analyzer to be corrected, in such a way that the results can coincide or increase with those obtained by other measurement analyzer, internal or external quality controls or desired standards.

Before using Deltas, verify the correct operation of your analyzer by performing a quality control. Never apply Deltas if your analyzer is not accurate, in other words, if the analyzer does not repeat the measurement correctly.

1.In the calibration menu press Opt.



2.In the calibration options press **Delta**.



3. In this screen you can edit the Delta value of the different ions for both serum and urine. Select the ION you want to edit.

4. Edit the Delta value digit by digit starting with the sign.



- A Digit increment
- v decrement

==> Press to select the digit. Once edited press again to accept the changes.

5. Once the changes are accepted press **Esc** to return to the calibration options.

3. Quadratic Correction

1. In the calibration menu press Opt.



2. In the calibration options menu press Corr. to apply quadratic corrections.



3. In this screen you can change the quadratic (**Sqr**) and linear (**Lin**) factors of each electrode. Select the type of factor and ION you want to edit.

4. Edit the factor digit by digit starting with the sign.



- Increase digit
- Decrease digit

==> Press to select the digit to modify. Once edited press again to accept the changes.

5. Once the changes are accepted press **Esc** to return to the calibration options.

18 – NORMAL RANGE CONFIGURATION

Diestro

The Normal Range is specific to each laboratory. Setting this value will cause samples outside of this range to be marked with an arrow.

1. To edit the normal ranges for serum and urine, press **Menu** to enter the initial menu.



3. Edit the value ranges.

Na	K	Cl	
Max	Max	Max	
148	5.30	107	
Na	K	Cl	
Min	Min	Min	Esc
135	3.50	98	

Serum

Nao	Ко	Clo	
Max	Max	Max	
80.0	30.0	250.0	
Nao	Ко	Clo	
Min	Min	Min	Esc
40.0	25.0	110	

Urine

Navigate between available ions and serum/urine by pressing the arrow.

Click on the parameter you want to modify.



- Increase digit
- Decrease digit

==> Press to select the digit to modify. Once edited press again to accept the changes.

5. Once the changes are accepted press **Esc** to return to the calibration options.

lonogram report with values out of range



Report out of range

19 – DISPLAY TIME SETTING (V3/V4 SemiPlus, AutoBasic and AutoPlus Models)

1. Press Menu to enter the initial menu.

Diestro



3. Press Out.







Press on each button to activate, deactivate or modify outputs.



View Time: It is the display time (in seconds) of the results of the calibrations and measurements.

Beep: Yes (sound alerts activated)

No (Silent mode)

"*" = Output activated

20 – ERROR MESSAGES

These errors may appear during the rinseing, calibration, measurement, standby, etc. processes. They are informed to the user through the display and printed ticket as follows:

Error	Description	Possible Cause	Effect	Action
No CALIB	Electrode not calibrated	Check the gain and the symbols behind the phrase "No CALIB"	The electrolyte will not be measured.	Analyze the error symbol behind the phrase "No CALIB" or proceed as if it were a "Not Filled Error"
1	The measurement of the Standard in the calibration or the sample in the measurement is not stable.	Bubbles in the liquid circuit. Interference during stabilization. Electrode failure. Fault in the measurement channel. Unstable sign.	In calibration: The electrolyte will not be measured. In measurement: The result will not be valid.	In the measurement, test with different samples. Repeat calibration. Check plugs in pipes and electrodes.
?	ADC out of range.	Bubbles in the liquid circuit. Interference during stabilization. Electrode failure. Fault in the measurement channel.	In calibration: The electrolyte will not be measured. In the measurement: The result will be invalid.	Eliminate any possible sources of interference. Check valves and peristaltic tubing. In the case of the sodium electrode, pass sodium conditioner. Possible electronic failure.
S	Low or High Gain.	Bubbles in the liquid circuit. Interference during stabilization. Electrode failure. Fault in the measurement channel.	The electrolyte will not be measured.	Change electrode. If the problem persists, call the technical service.

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Diestro

!	The calibration slope is inverted.	Calibrator solutions are changed or contaminated.	Electrolytes will not be able to be measured.	Verify the correct connection of the Pack. Purge and calibrate. Change for a new Pack.
Not Filled	The sample or calibrator solution could not be loaded normally.	Insufficient sample. Sample with clots, fibrins or bubbles. Operator error. Electrodes or piping circuit clogged. Faulty peristaltic tubing or valves.	The current operation is aborted.	Check the sample Check the loading process. Obstruction in the pipes, electrodes or peristaltic pipe, Check valves. Change peristaltic
Not empty	The measuring chamber cannot be emptied.	Electrodes or piping circuit clogged. Faulty peristaltic tubing or valves.	The current operation is aborted.	tubing. Change clogged electrode or contact technical service.
Missing Pack	Does not recognize the uChip.	uChip not connected. Electrical discharge to the analyzer.	Does not calibrate. It doesn't measure. does not rinse	(*) Connect a uChip. (*) Turn off and turn on again. Contact the technical service.
Error	Description	Cause Possible	Effect	Action
Pack Expired	Pack Expired.	Pack out of date. Wrong date on the computer. Electrical discharge to the analyzer.	Print legend "Pack Expired" on the screen and on the printer when calibrating.	 (*) See Calibration Pack. (*) Turn off and turn on again. Set the date. Change for a new Pack. Contact the Technical Service.
Exhauste d Pack	The Pack is exhausted.	Some of the calibrating solutions appear	Does not calibrate.	(*) Change for a new Pack.

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		on the uChip as exhausted.	It doesn't measure.	(*) Turn off and turn on again.
		Electrical discharge to the analyzer.	does not rinse	Contact the Technical Service.
С	Balance during 1 Point Calibration differs from last 2 Point Calibration.	External interference during measurement. Bubbles in the liquid		Repeat measurement or calibration Check for blockages or leaks in pipes and
L	The balance during 1-point calibration differs from the last 1- point calibration.	circuit. Electrode failure. Fault in the measurement	The result is not valid.	Check valves and peristaltic tubing. Change electrodes.
Q	Sudden differences during the measurement process.	Bad ground connection. Noisy power line.		interference from other analyzer or appliances. Contact technical service.
U	Sudden differences during sample stabilization.			
	Measures low	sodium Dirty sodium electrode	Low sodium electrolyte measurement values	Pass sodium conditioner

(*) When turning off the analyzer, wait 1 minute before turning it on again to avoid a Pack error.

In addition to being printed on the ticket, errors are indicated on the main screen with an exclamation point as shown in the following image:



Press the exclamation point to see the errors.

21 – MAINTENANCE

1. Daily Maintenance

1.1 Decontamination of the analyzer



BIOLOGICAL RISK. Samples, capillaries, and adapters are potentially infectious. Handle with gloves.

1.1.1 Keep the work table and the surfaces of the analyzer in hygienic conditions.

1.1.2 Clean all exterior surfaces of the analyzer with a cloth lightly moistened with a 1:10 solution of sodium hypochlorite.

1.1.2 Decontaminate the Fill Port with ISE REF IN 0400.

1.2 Cleaning

To protect the analyzer from possible contamination and from obstructions and blockages, do this Rinse daily.

It is recommended to carry out the Clean at the end of the work day, to remove possible residues from the liquid circuit.



If the intensive rinse is not performed daily, the analyzer will not allow to continue working until an intensive rinse is completed.



See the section "Rinse and intensive rinse".

2. Weekly Maintenance

2.1 Sodium Conditioning Solution

Perform a Clean with Sodium conditioner once a week.



See the "Sodium Conditioner" section.

2.2 Internal cleaning of the analyzer

Clean the internal surfaces of any spillage of substances with a cloth moistened with a 1:10 dilution of sodium hypochlorite.



3. Other maintenance and replacement of parts or components



Buy only original parts.

The indicated frequencies are recommended, but they are only preventive. These frequencies can be modified depending on the number of samples processed and according to the needs.

In the following table you will find instructions, recommended frequencies and who can make the changes:



BIOLOGICAL HAZARD. Potentially infectious elements, discard according to the laws of your country for the treatment of pathological waste. Use gloves.

Spare part / Component	Recommended Frequency	Authorized Person
		Trained operator
Tubing for peristaltic	3 months (up to100 samples/day)	Distributor
pump	6 months (more than 100 samples/day)	Technical Service
		Manufacturer
		Trained operator
Floctrodos	As Needed, (estimated lifetime: one	Distributor
Electiodes	year)	Technical Service
		Manufacturer
		Trained operator
Sampling Capillany	Eveny 6 months	Distributor
Sampling Capillary		Technical Service
		Manufacturer
Standard and valvo		Distributor
nines	Every 1 year	Technical Service
pipes		Manufacturer
		Distributor
Clock Battery	As Needed	Technical Service
		Manufacturer
		Trained operator
Fill Port	As Needed	Distributor
	As needed	Technical Service
		Manufacturer
		Trained operator
Fill Port Cleaner	Simultaneous with Diestro Pack/Kit	Distributor
		Technical Service
		Manufacturer
		Trained operator
Gel battery	Every 5 years	Distributor
		Technical Service
		Manufacturer

4. Open the front

4.1 Loosen the locking button.

4.2 Open the front forward.

5. Assemble the front

5.1 Close the front.

5.2 Lock the locking button.





Front locking button

Front opening



Upper lock

6. Installation / Replacement of the Diestro Fill Port Cleaner (REF IN 0050)



Fill Port cleaner



Biological Hazard: Use gloves in all cases.

The Fill Port Cleaner lifetime is 800 samples (100 samples per day) or 3 months (10 samples per day).

JS Medicina Electrónica recommends the simultaneous replacement of the Sample Collection Cleaner with the Diestro® Pack.

Take into account that if a rinse is carried out without the Fill Port Cleaner, the analyzer will drip on the area under the sample taking

Keep in mind that, if whole blood is measured, the effectiveness of the rinseing may be reduced due to the presence of clots or fibrins in the cleansing dressing.

6.1 Disconnect the analyzer from power and open the front.

6.2 Carefully lift the sampling capillary to a horizontal position. Remove the used Fill Port Cleaner and dispose of it according to current regulations related to potentially infectious biological waste.6.3 Clean the needle with a disposable cloth or towel moistened with Diestro intensive cleaning solution.



The needle and used Sample Collection Cleaner may contain potentially infectious residue. Wear gloves.

Discard the cloth or towel and the used Fill Port Cleaner following the clarifications in the "Disposal of supplies" section.

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6.4 Open the transparent packaging and remove the security seal from the new Sampler Cleaner as indicated in the figure.





6.5 Present the Diestro cleaning module to the front of the positioning guides, and gently push until it bottoms against the bottom.



Make sure the Cleaning Module is in the correct position, with the "Front/Front" label facing the operator.





6.6 Move the FillPort to rest position.

6.7 Close the front of the analyzer, turn it on and continue to use it normally.

7. Transporting the analyzer

Perform a Clean and, if necessary, clean and decontaminate all the necessary surfaces of the analyzer.



Use gloves in all cases.



Avoid damage to the power cord during transportation or storage of the analyzer. In case of damage, replace it with a new one.

7.1 Transport within the laboratory environment

If the transport does not imply important movements, it will be enough to verify that the fastening screws of the Pack container base are properly tightened and carry out the transport carefully, without tilting or hitting the analyzer.

7.2 Transfer outside the laboratory area

Reinstallation within 24 hours

- 1. Disconnect StdA, StdB and the waste.
- 2. Disconnect the analyzer from the power supply.
- 3. Completely close the jars of the Pack.
- 4. Never tilt the analyzer.

5. If it is necessary to pack it for transport, use the box in which the analyzer was delivered together with the parts that prevent knocks and movements. If such a box is not available, use one of similar size and fill the sides of the analyzer well.

6. Install by following the installation steps.

Reinstallation after 24 hours have elapsed

- 1. Disconnect StdA and StdB caps.
- 2. Empty the pipes from the analyzer.

a. In the valves menu, open valve A and in manual movement press **CW** until no more liquid flows through the waste line.

- b. Repeat step a) opening only valve B.
- c. Repeat step a) opening only valve M.
- d. Repeat step a) opening only valve S.



See section "Manual positioning".

3. Connect immerse a tube to the Standard A and B fittings of the analyzer and them in distilled water, then proceed in step 2 to rinse the entire circuit.

- 4. Repeat step 2, previously removing the pipes from the distilled water, until the entire circuit is dry.
- 5. Disconnect waste bottle.
- 6. Disconnect analyzer.

7.Completely close the jars of the Pack.

8. Do not tilt the analyzer.

9. If it is necessary to pack it for transportation, use the box in which the analyzer was delivered together with the parts that prevent knocks and movements. If such a box is not available, use one of similar size and fill the sides of the analyzer well.

10. Install by following the installation steps.

8. Disposal of supplies

Use gloves in all cases.

For the final disposal of supplies, you should seek advice from your Safety and Hygiene service and/or with the Secretary of the Environment of the place where your Laboratory is located.

As an orientation we suggest:

- Close the Pack bottles well and consider them as pathological waste.
- Close any bottle of solutions well and consider them as special waste.
- Consider the used spare parts that probably had contact with biological samples and were not properly disinfected as pathological waste.

9. Final analyzer disposal

For the final disposal of the analyzer, you must consult with your Safety and Hygiene service and/or with the Secretary of the Environment of the place where your Laboratory is located.

As an orientation we suggest:

Separate

• **potentially infectious waste**, such as remains of patient samples, pack, and all those parts that had contact with biological samples and were not properly disinfected. (Piping, electrodes, sampling capillary, etc.)

• **Special waste**, such as liquid supplies and elements used in cleaning it, without having infectious potential.

• **The rest**, which is the analyzer itself, completely disinfected.

With each of these groups identified, contact the corresponding company(ies) duly authorized by the Secretary of the Environment of your Jurisdiction so that they proceed to discard them

1. General Information

This is a feature of the analyzer software that allows the technician, operator trained by the manufacturer and the authorized dealer to check and evaluate the liquid circuit and the condition of the electrodes.

The liquid circuit of the analyzer is explained in the following diagram:



diagram Hydraulic of the analyzer

- 2. Access to the service menu
- 2.1 Press Menu.



2.2 In the initial menu press Serv and Serv.



2.3 This is the service menu. (Sampler button only available in the AutoPlus model)



3. Evaluation of the electrodes Status

The solution present in the measurement chamber allows the measurement of an electrical voltage (mV) in its corresponding channel, proportional to the concentration of each electrolyte.

The observed voltage allows the operator to evaluate:

- Electrode Stability: Voltage without significant variations implies stable electrodes.
- Electrode Gain: Differences between the voltages generated by the StdA and the StdB.

Also, in some cases it can be useful to determine the voltage generated by certain samples in the measurement chamber.

The positioning of each calibrator solution or of the sample in the measurement chamber can be done both manually and automatically in automatic models, and in semi-automatic models only manually.



3.1. Manual Positioning

3.1.1. Before manual positioning, it is necessary to open the valves. Press mV.



3.1.2 Press Valv (AutoBasic and AutoPlus models only)





3.1.3 Pressing any of the options opens the corresponding valve. (Only AutoBasic and AutoPlus models)



- A: Opens / Closes valve Std. A.
- **B**: Opens / Closes valve Std. B.
- M: Opens / Closes valve Sample.
- S: Open / Close Autosampler valve.

3.1.4 Open valves are indicated with an Asterisk (*)

For Example: Pressing A opens the Std valve.

Pressing A again closes the valve (the asterisk disappears) (Only AutoBasic and AutoPlus models).



3.1.5 Press Esc. to continue the movements. (Only AutoBasic and AutoPlus models)



If you want to load air, open valve M and carry out the movement without introducing liquids.

It is not recommended that you open more than one valve at the same time because air can enter the liquid circuit. If necessary, purge the analyzer after the test.

Do not keep the valves open for too long.

Press **Esc**. does not close open valves.

3.1.6 Now press Man.



3.1.7 In this screen you can move liquids, see the conductivity and the voltage measured by the electrodes:



While this button is held down, the peristaltic rotates clockwise, loading the electrode chamber with Std. A, Std. B, sample or air. It causes the solution loaded in the electrode chamber to go to the waste.

While this button is held down, the peristaltic rotates counterclockwise. Discharging the electrode chamber with Std. A, Std. B, sample or air. It causes the solution leaving the electrode chamber to go to the open valve.

When the peristaltic is moving and 5 seconds after it stops rotating, it will display the value measured by the sample detector. A symbol also appears and indicates the status of the measurement chamber:

Chamber empty

Chamber full

3.1.8 Position the solution or sample by pressing continuously. The metering chamber status indicator changes from empty () to full () when charging is complete. Once the "full"

message appears, release the button

In case it is necessary to move back the solution in the measuring chamber. YOU MUST ENABLE THE VALVE CORRESPONDING TO THE SAMPLE (AutoBasic and AutoPlus models). See steps 3.1.1 to 3.1.5

Later you can press until the solution is properly positioned in the measurement chamber,

Five seconds after the peristaltic pump stops, the display shows the voltage generated by the calibrator solution or the entered sample. Allow to stabilize for 30 seconds so that significant variations are not perceived.



Voltages (mV) generated by the entered sample.

3.1.8 Press **Esc**. to return to the service menu. All open valves will be closed (Only AutoBasic and AutoPlus models)

3.2. Automatic Positioning (AutoBasic and AutoPlus models only)

A dose of Std. A, Std. B or the sample can be loaded automatically by doing the following sequence:

3.2.1 Press mV (Autosampler button only available in AutoPlus models)



3.2.2 Press Auto





3.2.3 In this screen you can load Std. A, Std. B or a sample.

Na= 8	2.61	Ca = 4	9.19
K = 5	1.04	Li = 8	0.03
CI = 3	7.33		
StdA	StdB	$\langle \boldsymbol{x} \rangle$	Esc

Press StdA to load a dose of Standard A or StdB to load a dose of Standard B.

Move lever to tube position to load a sample.

The voltage generated by the calibrator solution or sample loaded in the analyzer will be displayed. Let stabilize for 30 seconds so that the variations are not significant.



Voltage generated by the loaded calibrator solution or sample. Consider only the voltages corresponding to the electrodes installed in the analyzer.

3.3. Interpretation of the results obtained

The result obtained for Std. A and Std. B, allows verifying the gain of each electrode in mV.



See section "Electrode gain".

4. Threshold Options

The "threshold option" allows you to modify the conductivity value at which the analyzer detects StdA, StdB, Serum and Urine



For use by trained technicians only. This parameter will affect the circulation of liquids if it is improperly modified.

4.1 To access this feature, in the service menu press **Umbr**. (AutoSampler button only available on Auto Plus models)



4.2 Edit threshold values

Std. A	Suero	L. Int	
42	42	0	
Std. B	Orina	LavNa	Esc
32	32	88	

Select the value to edit (Std. A, Std. B, Serum and Urine)

- ==> Press once to select the digit to edit.
- Λ V Increase / Decrease the value
- ==> Press to save the edited value.

4.3 Pressing **Esc**. back to the service menu



5. Retractable Fill Port



See sections "Retractable sampler" and "Capillary adapter".

For use by trained technicians only. This parameter will affect the circulation of liquids if it is improperly modified.

5.1 Access to the needle configuration is detailed in the following steps, press **Needle**. (Autosampler button only available in AutoPlus models)



JS Medicina Electrónica

5.2 In this menu you can configure the needle rinse and the Sample BIP (sound alert that indicates the minimum amount of sample necessary for the analyzer to measure correctly). When the analyzer rinsees, it makes a return of the liquid so that it rinsees the inside of the needle, dripping on the Sample Collection Cleaner to clean serum residues and possible obstructions. By increasing the number of steps, the liquid will go back further and the dripping will be increased.



Note: A high rinse value will reduce the Fill Port Cleaner lifetime.





- Increase digit
- Decrease digit

==> Press to select the digit to modify. Once edited press again to accept the changes.

5.5 Pressing Esc. returns to the configuration menu.
23 – REPLACING THE ELECTRODES

1. REPLACING ELECTRODES Buy original spare parts from the manufacturer and authorized seller. To replace an electrode, perform the following sequence:

1.1. Disconnect the power supply from the mains.

1.2. Open the front of the analyzer and electrode cover to access the electrodes, remove the stop screw from the right, and open the electrode cover.

1.3. Remove the electrode lock by loosening the screw on its back.

1.4. Unplug the connector from the electrode to be replaced.

1.5. Loosen the terminal(s) of all the electrodes to the right of the one to be changed, move them all a little to the right, the electrodes are joined with silicone couplings that join them under pressure.

1.6. Remove the defective electrode.

1.7. Place the new electrode with the couplings and attach them to those that correspond.

1.8. Replace the electrode lock.

Diestro

1.9. Plug the electrode connectors back to the corresponding terminals.

1.10. Replace the electrode cover and close the front of the analyzer.

1.11. Connect the power supply, turn on the analyzer and verify that calibrates correctly.





Opening the electrode protector and taking out the



Taking out the defective electrode

24 – ELECTROLYTE EXPANSION

1. General Information

Diestro

One of the advantages of the Diestro analyzer is that it is a device with expandable electrolytes,

allowing the addition of electrodes up to a maximum of 5 simultaneous electrolytes: Na, K, Cl, Ca and Li. The addition of new electrodes, called Expansion, can be done remotely and consists of the following steps:

2. Installation of electrode(s) and accessories that make up the expansion

It can be done by the User, following the instructions provided by the manufacturer with the new electrode.

2.1 Enabling expansion in software

This consists of entering a code, (a combination of 16 alphanumeric digits 0, 1, 2, 3, 4, 5, 6, 7, 8, 9, A, B, C, D, E, F) provided by the manufacturer from the code generated by the analyzer.

2.1.1 Generate a code in the analyzer following the sequence:

Enter the menu by pressing menu



2.1.2 Enter the configuration menu by pressing Serv and Conf.



2.1.3 Press Ena. to generate the code



2.1.4 Press Gen. and then Ready to generate the new code.



2.2 Contact the manufacturer. The generated code will be requested

2.2.1 In this step, the manufacturer will provide you with a new code. Enter it by pressing **Mod**.:



2.2.2 Edit each character to enter the new code



2.2.3 Once the code is entered, press Ent.



2.3 Enabling the New Electrode

2.3.1 Once the expansion is done, it is necessary to enable the new electrode. This step also verifies that the code was entered correctly.

Enabled ions are shown with an asterisk.

If it is not enabled the Ion is displayed without the asterisk, press the Ion to enable it.



2.3.2 Then perform a 2-point calibration.



See the "Calibration" section.

25 – CHANGING THE PRINTER PAPER

(SemiPlus, AutoBasic and AutoPlus Models Only)

To replace the thermal paper roll, carry out the following sequence:

1. Open the roll holder cover, gently forcing from the slot outwards.



Opening the roll holder

1. Replace the roll and remove the end of the paper as described in the image.



Changing the paper roll

3. Close the roll holder cover.



Closed roll holder

26 – PERISTALTIC PUMP TUBING REPLACEMENT

- 1. Open the front of the analyzer to gain access to the peristaltic pump.
- **2.** Remove the peristaltic tubing couplings from the bracket.

Diestro



Peristaltic pump

- 3. Disconnect the waste tubing from both fittings.
- 4. Connect the waste tubing to the fittings on the new peristaltic pump tubing.

5. Place one of the peristaltic pump couplings in the bracket. Wrap the tubing around the peristaltic pump head so that it makes contact with the head rollers and insert the free coupling into the bracket.

6. Close the front of the analyzer.

27 – FILL PORT REPLACEMENT

Diestro



Retractable sampling system

Parts

REF RE 0200 Sampling capillary

REF RE 0202 Fill Port: Stainless steel capillary + Sampling capillary

1. Changing the sampling capillary

- **1.1** Open the front to access the sample collection.
- **1.2** Remove the tip that surrounds the stainless steel capillary.
- 1.3 Place the new tip.
- **1.4** Close the front.

2. Change of sampling needle

- 2.1 Open the front of the analyzer.
- 2.2 Pull out the stainless steel capillary tubing.
- 2.3 Loosen without removing the clamping screw and remove the stainless steel capillary.
- 2.4 Loosen the screw until the Fill Port can be removed.

2.5 Insert the tip into the tip of the capillarystainless leaving it protruding 1.5 cm.

2.6 Place the stainless steel capillary, checking that it coincides with the groove of the Teflon support and tighten the screw so that it is fixed.

2.7 Check that the stainless steel capillary is aligned and does not collide with the edges of the front slot.

2.8 Reconnect the tubing to the stainless-steel capillary. See Figure:





Fill Port Pipe connection

28 – BATTERY REPLACEMENT (optional)

- 1. Disconnect the power supply
- 2. Disconnect the three pipes from the pack and remove it from the tray.
- 3. If you have the autosampler, disconnect it
- 4. Tilt the analyzer towards one of its sides
- 5. Using the Allen key provided, remove the two battery supports from the bottom of the analyzer.
- 6. Open the front of the analyzer
- 7. Place the lever in the capillary position (horizontal position)
- 8. Remove the sample intake cleaner
- 9. Disconnect the battery cables
- 10. Remove the supports and then the battery carefully.
- 11. Replace the battery with a new one
- 12. Perform steps 10 to 1 in reverse.

Precautions:

-Once the battery is replaced. Connect the power source and leave the battery charging for 8 hours.

During this period of time, you will not be able to measure with the analyzer.

-Before you start taking measurements, perform a purge and calibration. See section 9 and 7 respectively.

-The battery is a sealed and maintenance-free unit.

-Follow the instructions printed on the battery for disposal.

29 - AUTOSAMPLER (AutoPlus model only)



1. General Information

Diestro

The Autosampler allows to measure up to 40 samples automatically. By having the internal barcode reader option, it allows the automatic identification of samples.

Samples can be taken from a primary tube, pediatric primary tube, or sample cups.

There are different applications, although the maximum number of samples is 40, keep in mind:

-When using the Normal Rinse (recommended), the positions are reduced to 39. The solution used for the Normal Rinse is physiological solution and the tube is filled almost flush.

-If a Clean is performed at the end of the Measuring, they come down to 38 positions-

-By using Prime I also reduce one position, leaving 37 positions.

-If a Quality Control is carried out, depending on whether it runs 1, 2 or 3 levels, the positions will be reduced to 36, 35 or 34.

-Using the Autosampler to run only a Quality Control will require the 3 Control positions and a normal Rinse.



Caution with Ca measurements. Exposure of samples to air lowers the calcium value due to the generation of calcium carbonate.

2. Installation

- 1. The AutoSampler is shipped in a separate box from the one containing the analyzer. Unpack the AutoSampler so you can connect it to the analyzer.
- 2. Unscrew the needle cover to expose the needle, using the Allen key provided.



3. Connect the flat cable from the Sampler to its corresponding connector on the side of the analyzer. Also connect the pipe.



4. Screw the sampler connector (white plastic part) to the analyzer.







5. Move the sampler closer to the analyzer. Align the analyzer tubing connector to the sampler as shown in the photos. Screw in with the Allen key.



6. Attach the needle guard.





View of a 103APV4 with AutoSampler



View of a 103APV4 with AutoSampler

7. Connect to power supply.

3. Autosampler Settings

- To access the Autosampler Settings menu press Serv. from the initial menu and then Conf.



- Press **Sampler.** The Autosampler Settings menu will be displayed.



3.1 Origin



To perform only by trained and authorized personnel..



Origin

This command is used to center the sampler needle relative to the tube it will sample from.

Press **Orig** and the sampler will start to rotate looking for position 40, which corresponds to the normal rinse. Finding the home position will display the "CW" and "CCW" buttons.



3.2 CW and CCW

Once located at position 40, the CW and CCW buttons will be displayed with which the sampler needle can be centered with respect to the tube.



Keep in mind that the settings made in this menu will be configured and will change the position of the needle in relation to the sampler's tube holder disc. If it is not set correctly, there is a danger that the needle will not be able to go down and will hit the tube holder disc.

3.2.1 In the Autosampler Setup menu press **CW** to rotate the sampler tube holder disk clockwise a small angle. When using "**CW**" and/or "**CCW**" the "**Needle Sens**" button will display "**Set**".





3.2.2 To slightly rotate the sampler tube holder disk counterclockwise, press **CCW**.

	Print Test	Needle Sens *	Needle Clean 2000
CW	CCW	Orig	Esc
(-)			



3.2.3 When the needle is correctly centered, press "Set" to save the setting.







Needle not correctly centered.

Centered Needle.

3.3 Rinseing of the Autosampler sampling capillary

It consists of a backward movement of Std. A to clean the remains of serum, urine or blood inside the sampling capillary.

A value must be set that allows the StdA to reach the end of the sampling capillary. Over time, the performance of the peristaltic pump changes, so this value must be corrected, if this is not done, it may happen that the liquid does not reach the end, increasing the risk of clogging.



Press the value to edit.

<==> During value editing: Press to select the digit. Positioned on the last digit, press again to save the value.

 $\wedge V$ Edit the selected digit.

Press **Esc** to return to the Autosampler Setup menu.

4. Sample Loading Modes

The sample can be loaded from a sample tube or sample cup.

To load from a sample cup, first place an empty primary tube, then place the sample cup into the tube.



Loading a tube into the sampler

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Loading from sample cup







BIOLOGICAL HAZARD. Samples, capillaries, and adapters are potentially infectious. Handle with gloves.

After removing the sample, clean the sample collection capillary with ISE REF IN 0400 Cleaning Solution.

4.1 Loading Mode

This loading mode allows you to manually load the samples one by one into the sampler and allows you to measure serum and urine in the same run.

A high number of samples in this mode is not recommended.

Patient data can be entered in 3 different ways: from the analyzer screen (numeric only), external keyboard (accessory, alphanumeric), or with an external scanner (accessory, alphanumeric).



Pres **Esc**. at any time to cancel de measurement

4.1.1 From the start menu press Measure.



4.1.2 In the measurement menu press Sampler.



4.1.3 This is the Autosampler menu.





4.1.4 Press Load to start loading samples.



4.1.5 The first sample that appears is the Normal Rinse, which is made up of physiological solution and is located in slot 40. This will be used to rinse the needle. Press **CO** to activate it.





Placement of the Normal Rinse tube

4.1.6 After placing the tube with the Normal Rinse press **Next**. to load the first sample.



4.1.7 Place the first tube/cup in position 1 of the sampler's tube disk and select **serum** or **urine** depending on what you want to measure.

If you are going to perform serum and urine measurements, place all the serums in a row and all the urines in a row, without inserting them.







4.1.8 Enter the patient data. You can do this in 3 different ways: from the analyzer screen (numeric only), external keyboard (accessory, alphanumeric), or with an external scanner (accessory, alphanumeric).

If you have an internal scanner, the sampler will automatically take the patient data (skip this step and go to step 4.1.9).

To use the internal laser scanner, the barcode must be clean and positioned correctly.



4.1.9 Patient data upload can be dispensed with. The analyzer always numbers ascending from 1 to 39. Press **Measure** to continue with the next sample.



4.1.10 Press **Next** and load the next sample. Continue this process until you have loaded the number of samples you want to measure.



-If it is necessary to delete all the information already entered from the tubes and start the data loading process again, press **Reset**. This function will erase all uploaded data.

Prev.	Autosa T#: LN	mpler	Reset
Sig.	LN		Esc
			$\left(\begin{array}{c} \\ \\ \\ \\ \end{array}\right)$

4.1.11 When you want to finish the upload press **Esc**. The following screen will be displayed, where you can see a graph with the loaded samples.



4.1.12 Press Measure to start the measurement process.



4.1.13 The Autosampler will start to measure. At the end of each sample, it will print the corresponding result.

4.2 Easy Load Mode

In this mode, the sampler will take data from the tubes automatically. To do this, the barcodes must be clean and correctly placed.

This loading mode allows measurements of only serum or only urine, and not both in the same process.



Press **Esc**. at any time to cancel the measurement



4.2.1 Press Measure and then Sampler.



4.2.2 Place the serum or urine tubes with their respective barcodes attached to the sampler, the Normal Rinse (saline solution) in position 40 and then the samples from position 1 onwards. You must place the tubes so that the barcode is oriented towards the center of the sampler (see image).



Correct placement of the tube



Wear gloves in all cases.

4.2.3 After loading the tubes, press **Easy Serum** to perform a serum run or **Easy Urine** to perform a urine run.



4.2.4 The Autosampler will start to scan the tubes, detecting the number of samples entered and patient information.

4.2.5 At the end of the scan, this screen is displayed, where you can check that the tubes have been read correctly.



Sampler loaded successfully. Sampler loaded incorrectly.



-If we verify that there are tubes that were not detected, remove the tube and put it back correctly, with the barcode towards the center of the sampler and repeat step 4.2.3.

4.2.6 After checking that all the tubes are loaded press Measure.



4.2.7 The Autosampler will start with the measurement process, analyzing each sample and printing the result of the same.

5. Autosampler Options

5.1.1 To access the Autosampler Options menu from the main menu press Measure and then Sampler.



5.1.2 Then pressing **Opt**. the Autosampler Options menu is displayed.



5.2 Normal Rinse

This option enables or disables Normal Rinse during the measurement process.

The normal rinse uses saline and is used to clean the outside of the Autosampler's sampling capillary after each sample is measured.

5.2.1 Load the normal rinse into a tube. This is placed in position 40 as we see in the photo.



5.2.2 After in the Autosampler Options menu press Normal.

By default, this option is activated (an asterisk is displayed). Pressing again, the asterisk is hidden, which informs that this option has been disabled.



Norm *	Int	Prime	Dil 1:05
CC1	CC2	CC3	Esc

5.3 Clean

With this option the Sampler will perform a Clean of the Capillary for Sampling and the Autosampler tubings at the end of the Measuring operation.

5.3.1 Load the ISE Diestro Cleaning Solution into a tube in slot 39 of the sampler as indicated in the photo.



5.3.2 In the Autosampler Options menu press Int to activate or deactivate the Clean.



5.3.3 An asterisk is displayed informing that the option is active. Pressing a second time hides the asterisk, turning the option off.



5.4 Primer Solution

Primer Solution is used to improve the performance of the analyzer. It is done from the Sampler and the result is not printed.

Primer can be any serum sampler (even pool of serum).

5.4.1 Load the prime solution into a tube and place it in the position of the sampler's tube holder disk as shown in the photo.



5.4.2 In the Autosampler Options menu press Prime to activate or deactivate this option.



5.4.3 Pressing **Prime** will display the Prime Menu. On this screen you can activate **Prime**, deactivate it and choose the number of times to be measured.



5.4.4 Press the # to select the repetitions to measure the first (maximum 3)

To deactivate the first measurement, press Prime.

When the asterisk is present the option is activated, when not, it is deactivated.

5.5 Urine Dilution

5.5.1 In the Autosampler Options menu the **1:05** indicates the urine dilution to be used. **5.5.2** Press the **1:05** to select the dilution, between a range of 1:1 and 1:10. The analyzer defaults to 1:05 (1 part urine and 4 parts Diestro Urine Diluent).

5.6 Quality Controls Quality

controls can be measured from the sampler.

See the "Quality Control" section for more detailed information.

5.6.1 Load CC1 in position 38 of the sampler's tube holder disk, CC2 in position 37, and CC3 in position 36.

One, two, or all three controls can be loaded, depending on need.





QC2

QC1



QC3

5.6.2 To access the Quality Control 1 menu press QC1.



5.6.3 This is the CC1 menu. The CC2 and CC3 menus have the same options.

CC1 *	Ext.	#:	3	
				Esc

5.6.4 Press#: 3 to select how many times the control will be measured

To disable CC1 press **CC1**. When the asterisk is present the option is activated, when not, it is deactivated.

5.6.5 To carry out a quality control from the Autosampler, you can choose the **Ext**. option, which will measure 20 times the respective control.



5.6.6 When you have finished setting up QC, press **Esc** and the Autosampler Options menu will be displayed.



6. Autosampler Service Menu

6.1.1 To access the Autosampler service menu press **Serv**. from the Start Menu.



6.1.2 Press Serv. and then Sampler.



6.1.3 This is the Autosampler Service menu.



6.2 Next.

This option allows you to rotate the sampler clockwise, moving from position to position.

Autosa Serie: 0042	mpler		mV
Sig.	Prev.	▼	Esc
$\left(\begin{array}{c} - \end{array}\right)$			



6.3 Previous

This option allows you to rotate the sampler counterclockwise, moving from position to position.




6.4 Down

Pressing the down arrow will move the sampler needle down and stop when liquid is encountered.





6.5 Up

Pressing the up arrow will raise the sampler needle to its rest position.





6.6 Movements

6.6.1 By pressing mV the sampler needle will go down until it detects liquid and will take a sample.



6.6.2 Then the following screen will be displayed, where you can view the conductivity and the voltage measured by the electrodes.



6.6.3 By pressing **StdA** the analyzer will load Standard A and measure the conductivity and voltage measured by the electrodes.



6.6.4 Pressing **StdB** the analyzer will load Standard B and display the conductivity and voltage measured by the electrodes.



6.6.5 Moving the lever to the tube position we can load a sample to measure the conductivity and the voltage measured by the electrodes.

6.6.6 Pressing Esc returns to the Service Menu.



7. Barcode specifications

The Barcode Reader is used to enter patient data into the analyzer.

The format used to print barcodes is CODE 128 (code B) or CODE 39.

CODE 128 accepts uppercase and lowercase letters and numbers.

CODE 39 accepts only uppercase letters and numbers.

Minimum barcode element width = .18mm/7.2mil.

Recommended measures for an optimal operation of the internal barcode reader of the Autosampler:



45mm

The following photos indicate the correct way of gluing the code to the tube:







3.

Barcode affixed correctly

8. Specifications Examples of Primary Tubes and Cups





Type of primary tubes:

1-Tube 12 x 86mm, round bottom for 5ml.

2-Tube 12 x 75mm, round bottom for 5ml. (For this tube change the separators of the sampler disk. See section 10 of this chapter)

3-Tube 12 x 56mm, round bottom for 3ml.

5- Tube 12 x 100mm, round bottom for 5ml.

Type of cups for sample:

4-Cup 10 x 22mm.

Pediatric Primary Tube Type:



6-11 x 42mm Pediatric Primary Tube for 0.5ml.

For best use of the pediatric primary tube, place it inside an adult primary tube as shown in the photo below.





9. Maintenance

At the end of the work day, carry out an Intensive cleaning of Autosampler. (The Intensive cleaning from the Fill Port DOES NOT REPLACE the Intensive cleaning of the Autosampler).

To carry out the Intensive cleaning of Autosampler, carry out the following sequence:

9.1 From the Initial Menu press Measure and then Rinse.



9.2 This is the rinse menu. Place the Diestro Intensive Rinse solution in a tube in position 39 of the sampler's tube holder disc.

Remember that the Rinse must be in position 40 in the Sampler, since at the end of the Clean, a Rinse is performed.





9.3 Press "Clean Sampler" to perform a Clean.



10. Removing the Tube Holder Disc from the Sampler

10.1 In the event of a liquid spill on the sampler, it will be necessary to remove the disc in order to clean it properly.



Wear gloves in all cases. It can only be carried out by trained and authorized personnel.

- 10.2 Disconnect the power supply from the analyzer and remove all the tubes that are in the disk.
- **10.3** Locate the Allen key provided with the analyzer, on the inside front.



Allen key

Diestro 103AP V3/V4 ANALIZADOR DE ELECTROLITOS

10.4 Loosen the two screws on the top of the disk without removing them, so that you can use them later to remove the disk more easily. Newer analyzers have a piece to remove the disc, without the need to loosen them.





10.5 Remove the center screw.



10.6 Remove the disc using the previously loosened screws. On new models, use the corresponding part.



Removing the tube holder disk

10.7 Clean any debris from inside the sampler.

10.8 Replace the disk by matching the hole in the sampler to the lock on the spindle.



10.9 Adjust the center screw.



10.10 Tighten the two screws at the top.



10.11 Connect the analyzer power supply and check in the sampler configuration menu that the origin position is correct. If it is not correct, correct it in the Autosampler settings menu.



See the "Source" point in the "AutoSampler Configuration" section for more detailed information.

Changing Sampler Disk Spacers

In the case of using tubes 75mm long or shorter it is recommended to change the Sampler disk spacers to the shorter ones supplied with the analyzer. To make this change perform the following sequence.

-Remove the Sampler disk as indicated in the previous section.

- -Using the Allen key M3 remove the lower disk.
- -Remove and replace the long spacers with the shorter ones.
- -Re-screw the lower disc.
- -Replace the Sampler disk.

Diestro 30 – DIAGRAMS

1. 103APV4 SemiBasic



Front



View Side View



Front view without Front

DIESTRO 103AP V3/V4 ANALIZADOR DE ELECTROLITOS





Rear panel detail

DIESTRO 103AP V3/V4 ANALIZADOR DE ELECTROLITOS



Electrodes Assembly

Electrodes

2. 103APV4 SemiPlus



Front view



Side view



(Front open)



Rear view Rear

DIESTRO 103AP V3/V4 ANALIZADOR DE ELECTROLITOS



Connectors

Diestro



Electrodes Assembly

Electrode

3. 103APV4 AutoBasic



Side View

DIESTRO 103AP V3/V4 ANALIZADOR DE ELECTROLITOS



4. 103APV4 AutoPlus **Vista Front** Printer **Touch Screen** Pack Diestro Locking button Autosampler 9 FillPort Barcode Scanner Pack Needle Cover Autosampler Pack's Tray

Side view

DIESTRO 103AP V3/V4 ANALIZADOR DE ELECTROLITOS



Front view (open front)



Rear view





Electrodes

Electrodes

5. 103APV3







DIESTRO 103AP V3/V4 ANALIZADOR DE ELECTROLITOS

Diestro



Front view (open)



Rear view

31 – TECHNICAL SPECIFICATIONS

1. Size and weight

	SemiBasic	SemiPlus	AutoBasic	AutoPlus	
Height [mm]	270	270	270	270	
Width [mm]	160	160	160	470	
Depth [mm]	210	210	465	465	
Analyzer weight [kg]	4.3	4.2	5, 4	6.5	
Weight (w/ battery) [kg]		6.2	7.4	8.5	
Pack Weight [kg]	1.4			4	
Kit Weight [kg]	0.	8			
Power Supply Weight [g]	215				
Urine Diluent Weight [g]	170				
Cleaning Silution Weight [g]	120				

1.1 Size and Weight of the analyzer box

103APV4:

Height: 270 mm Width: 420 mm Depth: 470 mm SemiBasic / SemiPlus Weight: 6 kg (Box with analyzer, 1 Kit, power supply, urine diluent, and accessories) Weight with battery option: 8 kg (Box with analyzer, 1 Kit, power supply, internal battery, urine diluent, and accessories)

AutoBasic:

Weight: 6.7 kg (Box with analyzer, 1 pack, Urine Diluent fountain, Intensive Rinse and accessories) Weight with battery: 8.7 kg.

AutoPlus: Weight (without battery): 9 kg (Box with analyzer, 1 pack, Urine Diluent fountain, Intensive Rinse, barcode reader and accessories). Weight (with battery): 11 kg

<u>103APV3</u>: Height: 485mm Width: 485mm Depth: 375mm Weight: 16.5kg (Box with analyzer, 1 pack, Urine Diluent source, Intensive Rinse and accessories)

1.2 Size and Weight of the autosampler box:

Height: 320 mm Width: 350 mm Depth: 340 mm Weight without box: 1.5 kg Weight with box: 2 kg

2. Environmental Operating Conditions Ambient

temperature: Between 15° and 30° C (59°- 86°F). Humidity: Less than 80% non-condensing. Avoid direct exposure to sunlight.

3. Environmental Conditions for Storage and Transport

Ambient temperature: Between 5° and 35° C ($\overline{41}^{\circ}$ - 95° F). Humidity: Less than 80% non-condensing. Avoid direct exposure to sunlight.

4. Required mains voltage

100 - 240 V \frown 50 / 60 Hz Does not need external electrical protection.

6. Power supply specifications (Included)

Internal supply: Input voltage: 100 - 240 V ~ 50 / 60 Hz, 0.8A

External supply: Input voltage: 100 - 240 V Output voltage: 15V --- 4A / 60W

7. Samples/ Hour

Up to 60 samples/Hour (for measurements with serum).

8. Maximum sample volume for serum:

250 uL. It is the maximum volume that the analyzer will try to load of the sample.

9. Minimum sample volume for serum:

70 uL (considered for 3 ions). It is the minimum volume necessary to fill the measurement chamber.

10. Diluted urine volume

700 uL

11. Measurement specifications

	Na	K	CI	Са	Li	рН
Measurement range Serum [mmol/L]	40.0 - 220.0	1.0 - 30.0	20.0 - 250.0	0.20 – 5.00	0.30 – 5.00	6.80-7.80
Measurement range Urine [mmol/L]	20.0 - 300.0	2.0 - 150.0	20.0 - 300.0	Not applicable	Not applicable	Not applicable
Resolution [mmol/L]	0.1	0.01	0.1	0.01	0.01	0.01 [-]
Repeatability (serum)	CV<= 1%	CV<= 1 %	CV<= 1%	SD< 0.05	SD< 0.06	SD<=0.01
N = 20	140/160 mmol/L	4/8 mmol/L	90/125 mmol/L	1/1.5 mmol/L	1/1.5 mmol/L	7.00/7.60
Repeatability (<i>urine</i>) N = 20	CV<=10%	CV<=5%	CV<=5%	Not applicable	Not applicable	Not applicable

12. Electrodes

Maintenance-free selective ion electrodes.

13. Electrode Range

Gain

Electrode	Na	К	CI	Са	Li	рН
Gain	60-85	55-65	45-65	24-34	30-50	50-65

Note: This is the gain range for new electrodes, with the use this value may vary and the electrode will continue to function correctly.

Controls should be measured to verify that the values are in the valid range. Use Diestro Control or Diestro Trilevel Ampoules.

Electrode mV delta (between StdA/BufferA and StdB/BufferB)

Electrode	Na	K	CI	Са	Li	рН
delta (mV)	3.5-6.0	15.0-20.0	4.0-7.0	5.0-8.0	11-20	30-40



These values are for reference only. They depend on the operation of the electrode, installation time, correct operation of the analyzer and the Pack/Kit batch.



14. Internal clock

Battery 3V CR2032 Lithium

15. Backup battery

12V 5Ah 21W/Cell/1.67V/15Min

16. Specifications of external barcode reader and keyboard

In the PS2 connector, a barcode reader or an

external "qwerty".

The analyzer accepts the following barcode standards: UPC/EAN/JAN,

UPC-A & UPC-E, EAN-8 & EAN-13, JAN-8 & JAN-13, ISBN/ISSN, Code 39, Codabar,

Code 128 & EAN 128 and Code 93 among others.

ANNEX I - CLINICAL SIGNIFICANCE OF SERUM/PLASMA/BLOOD ELECTROLYTES

Potassium Concentration: cK+

1. Definition

cK₊ (P) is the potassium concentration (K₊) in plasma, whereas cK₊ (aP) is the equivalent for arterial blood. In the Ion Analyzer it is shown as K.

2. cK+ indicates

Our body has a total quantity of 3000 - 4000 mmol of potassium, from which the most part is intracellular. The plasma (and the extra cellular fluid) only contains about 4.0 mmol/L, and a total 50 mmol (the extra cellular fluid is about 12 L.). However, a given plasma concentration may be found in a body with any potassium level. Although extra cellular potassium only accounts for 1-2% of the total potassium, it is of great importance, since one of its main functions is to mediate the regulation of the entire potassium balance in the organism. A normal range of potassium is essential to regulate cardiac function. Values outside the range of 2.5-7.0, are lethal.

3. Reference Ranges

cK+ (aP) Reference Ranges (adult): 3.7- 5.3 mmol/L.

4. Clinical Interpretation

4.1 Low *c*K₊ values can be caused by:

* Potassium movement from extracellular to intracellular space: Respiratory or metabolic Alkalosis, increase of plasmatic insulin, forced Diuresis, (treatment with diuretics), Hypercalcemia, and Diabetes Mellitus.

* Less potassium intake: Low-potassium diet, Alcoholism, Anorexia Nervosa.

* Increase in gastrointestinal waste: Diarrhea, Vomits, Fistula, Gastrointestinal

Catheter Drainage, Malabsorption, Abuse of laxatives and enemas.

* Increase in urinary waste: Primary and Secondary Hyperaldosteronism, Adrenal Hyperplasia, Bartter Syndrome, Oral anticonceptives, Adrenogenital Syndrome, Kidney diseases (Renal tubular acidosis, Fanconi Syndrome, Diuretics, Thiazides, Henle's loop diuretics like Furosemide, Carbonic like Acetazolamide).

* Magnesium Depletion.

4.2 High *c*K₊ levels can be caused by:

* Pseudohyperkalemia, Hemolysis, Leukocytosis.

* Movement from intracellular to extracellular space: Acidosis, Serious

Traumatisms, Tissular Hypoxia, Insulin Deficiency, Digitalis Overdoses.

* High potassium intake: High-potassium diet, Potassium Oral supplements, Intravenous Potassium administration, large of Penicillin Potassium, old blood Transfusion.

* Diminished Potassium excretion: Renal Failure, Hyperaldosteronism (Adrenal Failure), Diuretics which block potassium tubular distal secretion, (Triamtirene, Amiloride, Spironolactone), Primary defects in Renal Tubular Potassium Secretion

* Endogenous Metabolic Acidosis, (Lactate, Ketones in sepsis).

5. General Comments

High cK_+ levels can be caused by Hemolysis. This is because red blood cells present a higher concentration of this ion regarding serum or plasma, from this, there may be an artificially augmented cK_+ .

It is very common when a traumatic extraction is performed, but it may also occur when taking a scant sample, (capillary sample). To minimize Hemolysis risks, it is advisable to separate serum or plasma as soon as possible from the globular Packet, as well as softly mix the sample with anticoagulants. When Hemolysis is evident, the values obtained are very high. For this reason, if the coloration seems to be more reddish than normal in plasma and serum samples, it is recommended to either repeat the sample or to add a comment about color next to the ck+ results.

Sodium Concentration: cNa+

1. Definition

 $cNa_{+}(P)$ is the concentration of sodium in plasma. The systematic symbol for arterial blood is $cNa_{+}(aP)$. The Analyzer symbol is Na.

2. cNa+ indicates:

The body has a total sodium level of about 60 mmoL/Kg, the majority of which is divided between the bone and the extra cellular fluid. The plasma level (about 140 mmol/l), is regulated by the plasma content of sodium, water and intracellular potassium. Therefore, high-plasma sodium may be due to low-body water – or vice versa. It represents about the 90% of the inorganic cations in plasma, making it responsible for almost half the osmolality of the plasma.

3. Reference Ranges

cNa+ (aP) Reference Range (adult): 135 -148 mmol/L.

4. Clinical Interpretation

4.1 Low values of *c*Na₊ can be caused by:

* Excessive increase of water load than that of sodium: Heart failure, renal failure,

Liver disease, Nephrotic syndrome, Increased ADH secretion, excessive water intake, (Polydipsia).

* Excessive sodium deficit than that of water: vomits, diarrhea, fistula, intestinal obstruction, Diuretic treatment, burns, Adrenal failure (Hyperaldosteronism).

* Sodium movement from extracellular to intracellular space: Adrenal failure

(Hyperaldosteronism), Anemic Hemolytic syndrome- shock.

* Pseudo Hypernatremia: Hyperglycemia, Hyperlipidemia, Hyperglobulinemia.

4.2 High values of cNa+ can be caused by:

* Excessive increase of sodium load thanthat of water: Excessive sodium intake,

NaCl or NaHCO₃ administration, Hypertonics, Primary Hyperaldosteronism. * Excessive water load deficit than that of sodium: Excessive sweating (exercise, fever, warm

ambient), burns and certain diarrheas and vomits where there is an increased loss of water greater than that of sodium, as well as in Osmotic Diuresis, (Diabetes

Mannitol infusion), Hyperventilation, Diabetes insipidus, (ADH or nephorgenic deficiency), Decrease in water intake.

* Steroids.

5. General comments

Regional edema in the sampling area can cause false decreased values of cNa+. Chloride Concentration: cCl-

1. Definition

cCl-(P) is the concentration of chloride (Cl-) in plasma. The systematic symbol for arterial blood is cCl-(aP). The Analyzer symbol is shown as Cl.

2. cCl indicates:

The chloride ion is the body's major anion in the extra cellular fluid. The plasma level is about 100 mmol/L, representing the largest fraction of inorganic ions. Sodium and chloride together represent the majority of the osmotically active plasma components.

The kidney plays a major role in the body's handling of chloride. Chloride accompanies a large part of the sodium filtered by the glomerulus and is also active in the chloridebicarbonate exchange.

3. Reference Range

cCI-(aP) reference range (adult): 98-109 mmol/L.

4. Clinical Interpretation

cCl-itself as a single parameter is of minor importance in most settings. However, low values can cause muscles seizures, apathy and anorexia. High values may cause

Hyperchloremic metabolic acidosis.

5. General Comments

The importance of *c*Cl- is related to the calculation of the anion gap.

Calcium Concentration: cCa++

1. Definition

 $cCa_{++}(P)$ is the concentration of Calcium in plasma. The systematic symbol for arterial blood is $cCa_{2+}(aP)$. The Analyzer symbol is Ca.

2. *c*Ca++ indicates

Ionized Calcium in plasma is the metabolically active part of total calcium, making up around 50% of the total calcium. Total calcium in plasma is in part bound to proteins (mainly albumin) 40%, and the remaining 10% bicarbonate, citrate, phosphate, and lactate anions. The binding to proteins depends on pH. The ionized calcium is necessary for a number of enzymatic processes and membrane transport mechanisms.

It thereby plays a key role in blood coagulation, cellular growth, neuro-muscular transmission, and a series of other vital functions.

3. Reference Range

*c*Ca++(aP) reference range (adult): 1.00 -1.40 mmol/L (4.0 – 5.6 mgrs%).

4. Clinical Interpretation

- 4.1 Low values of *c*Ca++ can be caused by:
- * Alkalosis.
- * Renal Failure.
- * Acute circulatory Insufficiency.
- * Lack of Vitamin D.
- * Hypoparathyroidism.

4.2 High values of *c*Ca++ can be caused by:

- * Cancer.
- * Thyreotoxicosis.
- * Pancreatitis.
- * Immobilization
- * Hyperparathyroidism.
5. General Comments

There are a number of factors that can affect the cCa_{++} measured values. To minimize the risks of mistakes, it is recommended: no more than 30- second estasis applied to the extremity where the sample is being taken; the patient should remain

sitting for more than 5 minutes before the venipunction; the use of small tubes without anticoagulant; use tubes with balanced heparin for whole blood or plasma; complete the tube with sample so as to minimize air drawn into it, and process the sample within the hour after the sample has been taken.

Whole blood samples taken in tubes with Li or Na heparin, show low *c*Ca++ values compared to those obtained in the same sample without heparin. This is because heparin completes and diminishes *c*Ca++. There is commercially balanced heparin which would diminish this effect. If the amount of heparin added to the tube or syringe may be diminished, then this mistake would diminish as well, but low levels of anticoagulant increase the risk of sample coagulation.

Anticoagulated blood with Oxalate or EDTA is not accepted since these compounds are strong calcium chelators. Venous estasis and an upright position may contribute to elevate calcium. Estasis produced by keeping tourniquets longer than 1 minute may lead to anaerobic glycolysis with lactic acid production, which diminishes pH and varies the free Ca++ since the Ca-protein bind is dissociated, showing augmented cCa++ values.

Lithium Concentration: cLi+

1. Definition

 $cLi_{+}(P)$ is the concentration of lithium (Li_{+}) in plasma, while $cLi_{+}(PDB)$ is the equivalent to the arterial blood. In Ion Analyzer displays as Li_+.

2. *cLi*+ indicates

Lithium is a metallic monovalent cation that is usually absent in the body. It is used to treat manic - depressive psychosis. The drug produces significant effects, but there may be significant clinical complications associated with their use. The binding of lithium to plasma proteins is less than 10% and their average life is 7 to 35 hours. Its elimination is mainly urinary (95 to 99% of the daily intake, after fixed state).

3. Reference Range

Lithium has a very narrow therapeutic range. The initial doses are between 0.80 and

1.20 mmol / L.

Reference range CLI + (AP) (adult): 0.50 -1.00 mmol / L

5. General Comments

During treatment with lithium and during its preservation (prophylaxis) it is important to adjust the dosage to achieve plasma levels required because the lithium can cause acute toxicity if their concentration is just above the therapeutic dosage (about 2.00 mmol

/ L, although some patients seem to be more sensitive and show side effects such as tremors or confusion with even lower doses).

ANNEX II - CLINICAL SIGNIFICANCE OF URINARY ELECTROLYTES

The *urinary ionogram* is extremely variable from one individual to another, and from one day to the other in the same individual. Therefore, it must be compared to *plasma ionogram* as well as with the patient's vital signs.

For example, potassium concentration in a urine sample cannot be given any value if the patient's potassium input and the degree of hydratation of the patient are unkown.

The Electrolytes present in the body as well as those inggested with the daily diet, are excreted via the renal system in urine.

Urine Electrolytes determination provides relevant information about the kidneys efficiency and other pathological situations.

Determination can be performed in a urine sample collected during 24 hours. The amount of electrolytes excreted per day is obtained multiplying the measured concentration (mmol/ L) by the total quantity of urine excreted in a day.

Sodium and Chloride Concentration

Chloride concentrations usually present great variations related to salt intake, being able to reach values oscillating between 5 and 20g / 24 hours.

Decreases chloride concentrations: In all the hypodrotyc syndromes (asistolia, nephrotic syndrome), where salt is retained in edema fluids, bleeding; in the great infiltrators, in pneumonia, in exudative processes; in saline dehydration syndrome because of abundant extrarenal wastes: repeated vomits, diarrhea, intestinal fistula, excessive sweating, extended burns, in the intestinal obstruction; in the free-salt diet, in insipid diabetes, advanced renal failure, immediate postoperatory period, by chloride tissue retention.

Increases chloride elimination: in rich-salt diet, during the diuretic effect of saluretics and other similar preparations; in certain acute nephropathies (tubular necrosis), in the poliuric phase that follows anuria; in chronic nephropathies (pielonephritis, chronic glomerulonephritis or polycystic kidney), with the saline incontinence syndrome, in suprarenal insufficiency of Addison's disease; hypernatruria; it appears in Schwartz-

Bartter syndrome (excessive ADH secretion).

Determination of urinary sodium is useful for diagnoses in the following clinical situations:

1) A diminished sodium urinary concentration indicates there is an extrarenal sodium loss, whereas a high sodium concentration indicates a renal salt loss or an adrenal insufficiency.

2) In the differential diagnoses of an acute renal insufficiency, along with additional diagnoses elements.

3) In hyponatremia, a reduced sodium urinary concentration indicates sodium retention, which can be adscribable to a severe volume reduction or to a state of saline retention observed in cyrrosis, nephrotic syndrome and cardiac congestive insufficiency

Urine Potassium (Potasuria)

Diestro

Elimination of Urine Potassium varies within great limits according to the diet. On a normal mixed diet, normal potasuria oscilates between 1.5 and 3.5 g/ 24 hours, i.e. it does not exceed 90 mEq./day.

Hyperpotasuria appears in the following cases: Renal diseases, repeated administering of Mercurial diuretics, Thiazides or carbonic anhydrase inhibitors, carbenoxolona or regaliz; in processes in course with proteic hypercatabolism like inhanition or hypotonic dehydration, diabetic acidosis, Cushing syndrome, and treatments with ACTH, corticoids, etc; in Primary Hyperaldosteronism (Conn syndrome), or after excessive administering of DOCA; in *Bartter syndrome* (secondary Hyperaldosteronism by hyperreninemia), and in *alcalosis* of any origin.

Hypopotasuria may be observed in: intense and prolonged diarrheas, important disorders in intestinal absorption, acute renal insufficiency, and prolonged diets deficients in potassium.

ANNEX III - WORKING PRINCIPLE

Measurement Technology

Ion selective electrodes (ISE) measure electrolytes by two different technologies, direct and indirect, commonly known as Direct ISE and Indirect ISE (ISE = Ion Selective Electrode).

Direct ISE

The measurement is performed directly on the whole blood, plasma or serum sample. The use of whole blood does not involve prior sample preparation.

The Direct ISE measures the activity of the electrolyte in plasma (mmol/Kg H2O), or "plasma concentration (mmol/L)". The electrochemical activity of ions in water is converted to the corresponding concentration by means of an Ion-specific factor. This is only applicable for a given concentration range. The use of this factor ensures that the Direct ISE reflects the current situation, clinically relevant activity, regardless of protein and/or lipid values. However, the result is traditionally called "concentration." This conversion is based on the recommendations of the IFCC Expert Panel on pH and Blood Gases, to avoid the confusion of having two types of electrolyte results.

This technology is used in Blood Gas Analyzers and Point of Care Analyzers.

The reported result is independent of the solids content of the sample.

The results obtained by Direct ISE correlate well when working with samples with normal lipid and protein content. This obviously requires the elimination of preanalytical errors.

The Analyzer uses the Direct Selective Ion method for the determination of electrolytes. It is based on the properties of its transducers or sensors (electrodes) to be selective to a specific Ion in solution.

This is achieved thanks to the fact that the membranes of the lon-selective Electrodes develop a potential (with respect to a Reference electrode) proportional to the activity of the lon in solution for which they are selective.

This potential obeys the Nernst formula.



$$E = E^0 \pm \left(\frac{RT}{nF}\right) \ln a_i$$
. ("+" for cations and "-" for anions)

But
$$a_i = f_i \cdot c_i$$
, then $E = E^0 \pm \left(\frac{RT}{nF}\right) \ln(f_i \cdot c_i)$

E = Electrical potential measured $E^{o} = Electrical potencial (constant) that depends on the measure system.$ $a_{i} = Electrolyte activity.$ R = General constant of gases. T = Temperature n = Electrolyte Valence. F = Faraday constant. $c_{i} = Electrolyte concentration.$ $f_{i} = Electrolyte activity.$ Enunciating the equation in terminus of Analyzer functions

 $E = E^0 \pm P \cdot \ln(f_i \cdot c_i)$

P = Slope of the Electrode equation for the working temperature.

This is calculated by the Analyzer measuring the Standard Calibrators A and B and knowing the concentration of each electrolyte.

$$E_{sample} = E^{0} + P \cdot \log((f_{i} \cdot c_{i})_{sample})$$
$$E_{standard} = E^{0} + P \cdot \log((f_{i} \cdot c_{i})_{standard})$$

 $\Delta E = E_{sample} - E_{standard} = P \cdot \log((c_i)_{sample} - (c_i)_{standard})$

Finally the equation to find the Electrolyte concentration is

$$c_{i_{sample}} = c_{i_{standard}} 10^{\left(\frac{\Delta E}{P}\right)}$$

This is the algorithm for the Analyzer Diestro® 103 AP

ANNEX IV – REFERENCES VALUES

1. Electrolyte range

It is recommended that each laboratory establishes its own criteria to determine the normal ranges and critical values of its electrolytes.

The following table is a guide and serves as a reference:

ELECTROLYTE	UNIT	Low critical Value (Serum)	Normal Range (Serum)	High critical Value (serum)	Normal range (24hs Urine)
Sodium	mmol / L	120	135 - 148	158	75 – 200
Potassium	mmol / L	2.8	3.7 - 5.3	6.2	40 - 80
Chloride	mmol / L	75	98 - 109	156	140 – 250
Calcium	mgr./ %	3	4 - 5.6	6.4	No aplica
Lithium	mmol / L	-	0.5 – 1.0	>2.0 Tóxico	No aplica
pН	-	7.35	7.40	7.45	No Aplica

The normal values of urine samples depend largely on the diet and treatment to which the patient is subjected.

In the table, the reference values for 24 Hour Urine samples are indicated in mmol/l.

To obtain the value in mmoles/24 hours, it must be multiplied by the patient's 24-hour sample volume, expressed in liters

ANNEX V - PARTS, REFERENCE CODE AND GUARANTEES

REF	NAME	Installation Date	WARRANTY	PICTURES
EL 0001D	Digital Reference Electrode	6 months	6 months	
EL 0002D	Digital Sodium Electrode	6 months	6 months	
EL 0003D	Digital Potassium Electrode	6 months	6 months	4
EL 0004D	Digital Chloride Electrode	6 months	6 months	-F
EL 0005D	Digital Calcium Electrode	6 months	6 months	
EL 0006D	Digital Lithium Electrode	6 months	6 months	
EL 0008D	Digital pH Electrode	6 months	6 months	
EL 0007D	Digital Sample Detector Electrode	N/A	12 months	
IN 0100	ISE Calibrating Pack	Use before expiration date		
IN 0102	ISE Calibrating Pack and pH	Use before expiration date		
IN 0200	ISE Calibrating Kit	Use before expiration date		
IN 0300	ISE Urine diluent	Use before expiration date		e contra
IN 0400	ISE Cleaning solution	Use before expiration date		
IN 0600	Sodium conditioner	Use before expiration date		
IN 0050	Fill Port Cleaner	N/A	3 months or 800 samples	4 4
RE 0100	Peristaltic Pump Tubing	N/A	3 months	
RE 0200	Capillary for Sampling (AP)	N/A	3 months	
RE 0300	Spare Tubing kit (v2)	N/A	3 months	
RE 0305	Pack Connection Tubing Kit AP/APV3	N/A	3 months	
RE 0306	Pack Connection Tubing Kit V4	N/A	3 months	
RE 0319	Spare Tubing Kit V4 SB/SP	N/A	3 months	
RE 0320	Spare Tubing Kit V4 AB VS (NS<2353)	N/A	3 months	
RE 0321	Spare Tubing Kit V4 AB VT (NS≥2353)	N/A	3 months	

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RE 0322	Spare Tubing Kit V4 A+ VS (NS<2353)	N/A	3 months	
RE 0323	Spare Tubing Kit V4 A+ VT (NS≥2353)	N/A	3 months	
RE 0324	Waste tubing Kit V4 Semi	N/A	3 months	
RE 0325	Spare Tubing Kit V3 AB VS (NS<2353)	N/A	3 months	
RE 0326	Spare Tubing Kit V3 AB VT (NS≥2353)	N/A	3 months	
RE 0327	Spare Tubing Kit A+ VS (NS<2353)	N/A	3 months	
RE 0328	Spare Tubing Kit A+ VT (NS≥2353)	N/A	3 months	
RE 0350	Fill Port V4	N/A	3 months	
RE 0350	Fill Port Sampler	N/A	3 months	
RE 0400	Capillary adapters	N/A	3 months	142
RE 0501	Pinch Valv (Black)	N/A	12 months	a
RE 0505	Pinch Valv (white)	N/A	12 months	
RE 0806	Operator's and Service Manual Diestro 103AP V3/V4 Spanish			Demogram
RE 0807	Operator's and Service Manual Diestro 103AP V3/V4 English			
RE 0905	External Power Source 15V 4A	N/A	6 months	
RE 1000	Ground Wire	N/A		\bigcirc
RE 1003	Gel Battery 12V 5Ah	6 months	12 months	100

Installation Date: Use of the component must begin on the "install before" date (maximum) to guarantee the component warranty period.

JS MEDICINA ELECTRONICA SRL LIMITED WARRANTY

<u>Coverage.</u> JS Medicina Electrónica SRL guarantees its product (the analyzer Diestro 103AP) to the original purchaser, free of failures for manufacturing defects for one year, from the date of its purchase from the company or a distributor or seller duly authorized by JS. The electrodes of analyzer Diestro 103AP have a 6 months guarantee, in the same conditions.

This guarantee, in the period of time indicated and free of charge, will cover any manufacturing failure, provided that the failure arose as a result of the correct use of the analyzer, or its operation according to the manual. In case there is a failure, JS Medicina Electrónica SRL, at its option, may repair or replace the defective parts, or replace the Analyzer itself by a new one with identical quality, following the return of the Analyzer. In the event that at the time of replacement JS Medicina Electrónica SRL does not have a product of the same type or quality (either by discontinuity of its production, lack of stock or any other reason) it may be replaced by another of similar characteristics or even higher quality. If, after a reasonable period of time, the unit cannot possible be repaired or replaced, the user will have the right to receive a refund for the purchase price as the sole compensation.

<u>Exclusions</u>. Warranty deadlines do not include those parts or consumables that wear off or are consumed or expended because of the operational and normal use of the product. In these cases, the warranty period will be the indicated in the manual of the operator as "install by" or "expiration date".

<u>Reasons for the cancellation of this guarantee</u>, if the product has been subjected to bangs, drops or accidents of any nature, misuse, excess or drops of electrical voltage involving use in abnormal situations, improper alterations, reparations or installation performed by personnel not authorized by JS Medicina Electrónica SRL.

<u>The guarantee lacks validity</u> if any amendments or deletions in the guarantee certificate or purchase invoice are made, or if this last one is missing, or the purchase date has not been clearly written on it.

Limitation. The guarantee that has been described is exclusive of JS Medicina

Electrónica SRL and makes null and void any other implicit or explicit guarantee, and consequently any other person, society or association is not authorized to assume on our behalf any responsibility with respect to our products.

<u>Exemption of liability</u>. In no event shall JS Medicina Electrónica SRL be liable to the buyer and any person for personal injury or property damage that could cause the use or malfunction of the analyzer, including its lack of maintenance.

The terms and conditions of this guarantee are exclusively subject to the legislation of the Argentine Republic, and to the jurisdiction of the National Justice from the City of Buenos Aires-RA. These terms and conditions are not subject to any other legislation in any other jurisdiction.

In the Argentine Republic, call 11-4709-7707, or email info@ diestroweb.com.ar

Outside of the territory of Argentina contact your local distributor.