



IONIX by SFRI

# A great analyzer for all



## STANDARD MODEL

- 1 POSITION SAMPLE RACK ✓
- MCI ELECTRODES: Na<sup>+</sup> & K<sup>+</sup> ✓
- HIGH ENDED C++ OBJECT SOFTWARE ✓
- LARGE COLOR TOUCH SCREEN ✓
- SUPPORTS LIS ✓
- PRIMARY TUBE TESTING ✓
- CAPACITIVE NEEDLE ✓
- INDEPENDENT WASHING SYSTEM ✓
- SECURE INTERNAL SAMPLING ✓
- COMPLETE QUALITY CONTROL ✓
- INTEGRATED THERMAL PRINTER ✓
- FULL TRACEABILITY ✓
- CLOSED REAGENT SYTEM – DONGLE AND BARCODE ✓

# Efficient electrodes & modules

## Micro Controller Integrated ELECTRODES

Na<sup>+</sup>

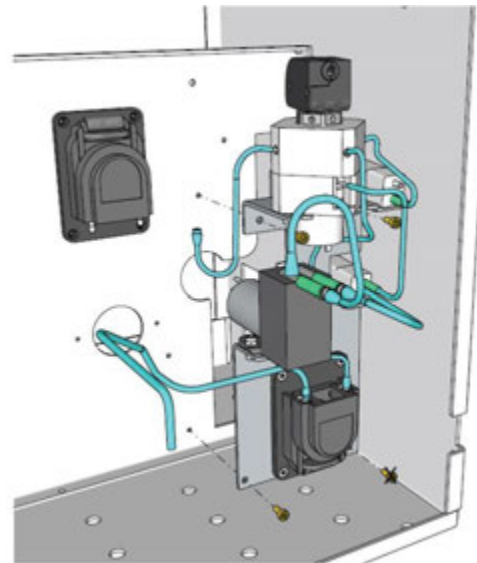
K<sup>+</sup>

Cl<sup>-</sup>

Ca<sup>2+</sup>

pH

Li<sup>+</sup>



## MODULES

MODULE TCO<sub>2</sub>

INTERNAL SAMPLE & REAGENT

BARCODE READER

12V BATTERY CONNEXION CAPABILITY

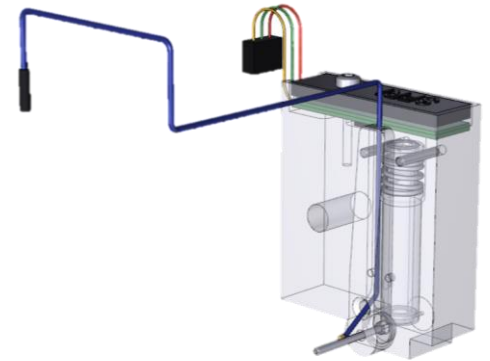
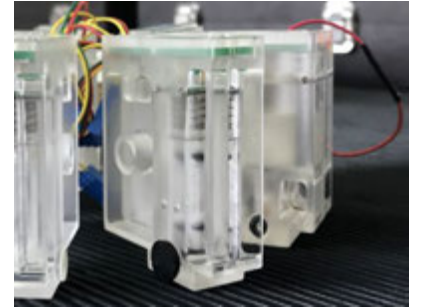
# Micro Controller Integrated electrodes

Perfect and complete traceability of the electrodes  
Serial and lot numbers, full history, installation date, maintenance, quality control ...

Highly stable

Non refillable – no more human mistake

Simple « push and plug » to change – No wire



## Practical modules

Possibility to upgrade the standard unit with 5-positions rack + barcodes reader.

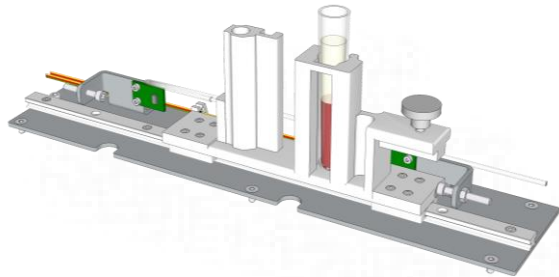
Possibility to add a TCO<sub>2</sub> module

Possibility to use a 12V DC power supply

# 100 % customizable

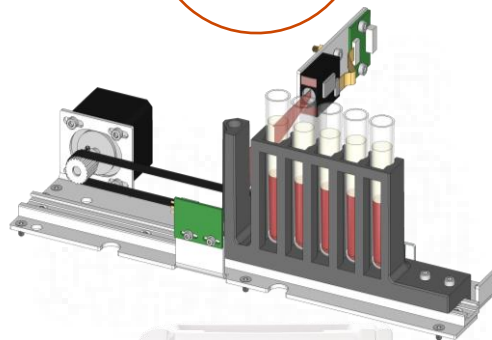
## Easy adaptation for the laboratories workflow

Standard IONIX just for small  
labs



Less than 5 tests  
per day

5-positions IONIX for most labs



From 5 tests  
per day

Fully automated IONIX for big  
labs



From 20 tests  
per day

1 position – manual – no barcode reader

5 positions – automatic –barcode reader

4\*5 positions – automatic –barcode reader

# Why are we different ?

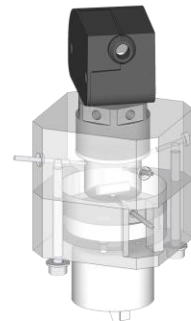
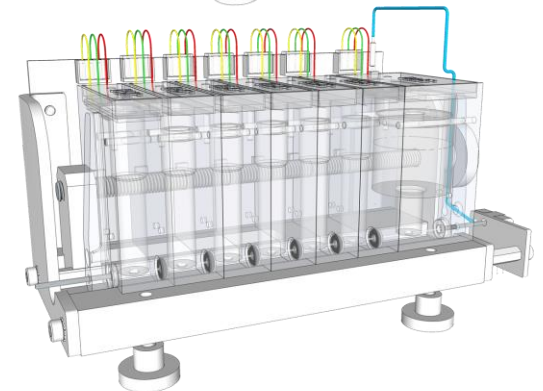
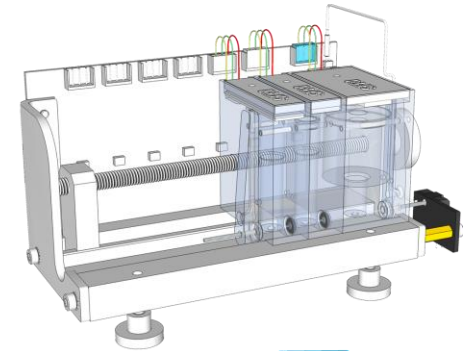
## 1 SAMPLES

Standard 5 mL tubes, serum or heparin lithium plasma  
With or without barcode  
Small “Technicon™” or “Eppendorf™” cups can be used



## 2 ADAPTATION TO LAB'S TESTS

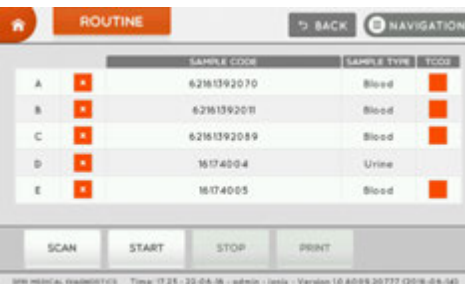
From sodium + potassium to  $\text{Na}^+$ ,  $\text{K}^+$ ,  $\text{Cl}^-$ ,  $\text{iCa}^{2+}$  + pH,  $\text{Li}^+$   
All combinations are possible  
+  $\text{TCO}_2$  for the anion gap



# Why are we different ?

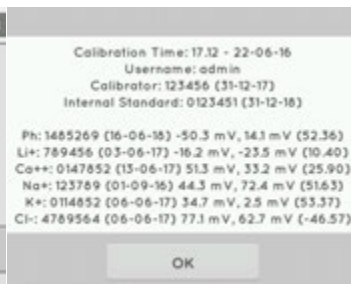
## 3 A MODERN & INTUITIVE SOFTWARE

Designed by SFRI, the IONIX's software is user-friendly, easy and complete. Integrated printer, color coded menu system, multilingual interface, supports LIS, visible & audible alarms, user level access control, full traceability (results, calibrations, controls, events, ...), virtually no limit for the database, easy updates ...



	SAMPLE CODE	SAMPLE TYPE	TCOD
A	62161392070	Blood	OK
B	62161392071	Blood	OK
C	62161392089	Blood	OK
D	16174004	Urine	OK
E	16174005	Blood	OK

Buttons: SCAN, START, STOP, PRINT



Calibration Time: 17:12 - 22-06-16  
Username: admin  
Calibrator: 123456 (31-12-17)  
Internal Standard: 0123451 (31-12-18)

Ph: 1485269 (16-06-16) -50.3 mV, 14.1 mV (52.36)  
Li+: 789456 (03-06-17) -16.2 mV, -23.5 mV (10.40)  
Co++: 0147852 (15-06-17) 51.3 mV, 33.2 mV (25.90)  
Na+: 123769 (01-09-16) 44.5 mV, 72.4 mV (51.63)  
K+: 0114852 (06-06-17) 34.7 mV, 2.5 mV (53.37)  
Cl-: 4789564 (06-06-17) 77.1 mV, 62.7 mV (-46.57)

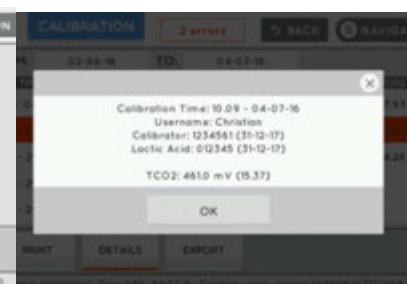
	IN	CA	NA	K	CL
Slope 1	25.33	9.72	4.62	37.47	-2.91
Slope 2	53.22	26.42	42.60	52.22	-49.40
Average	39.27	19.07	23.71	44.85	-26.36
CV	35.5%	49.0%	80.5%	16.4%	66.9%

Buttons: START, STOP, VALIDATE, PRINT, OK



Calibration Time: 10:09 - 04-07-16  
Username: Christian  
Calibrator: 123456 (31-12-17)  
Lactic Acid: 012345 (31-12-17)  
TCOD: 461.0 mV (15.37)

Buttons: OK



FROM	TO	TIME	CODE	IN	LI	CA	NA	K	CL
09:58	10-06-16	161671	7.29	0.74	112	131.01	3.76	99.02	
09:58	10-06-16	161671	7.31	0.74	112	132.37	3.77	99.09	
09:58	10-06-16	161671	7.36	0.78	113	136.55	3.76	99.20	
09:58	10-06-16	161671	7.33	0.82	113	135.49	3.78	99.34	
09:58	10-06-16	161671	7.32	0.78	113	132.35	3.79	98.93	

Buttons: PRINT, DETAILS, STATISTICS, EXPORT



NAME	VALUE
Electrode Read Time (s)	30
CO2 Read Time (s)	30
CO2 Clean Time (s)	5.00
CO2 Empty Time (s)	10.00
Autoloader Barcode First Position (steps)	5100
Autoloader Needle First Position X (steps)	3200
Autoloader Needle First Position Y (steps)	2700

Buttons: PRINT, DETAILS, STATISTICS, EXPORT



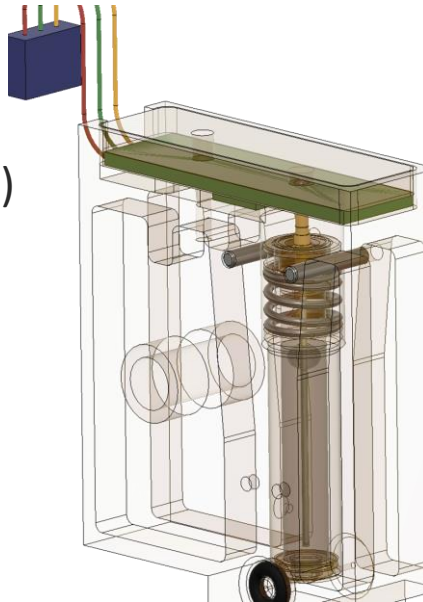
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Buttons: PRINT, DETAILS, STATISTICS, EXPORT

# Why are we different ?

## 4 SECURITY OF RESULTS

- Electrodes with their own memory
- Working solutions (internal reference, calibrators, controls, maintenance solutions) protected with dongles and bar codes
- Data log of calibrator, control and reagent lot numbers
- Maintenance and alarm logs
- Electrodes voltages and slopes recorded
- Access to all quality controls conducted
- User ID log
- Possibility to use external controls (no limit)
- Database “engraved” in granite.



## 5 ALL REAGENTS HOUSED INSIDE

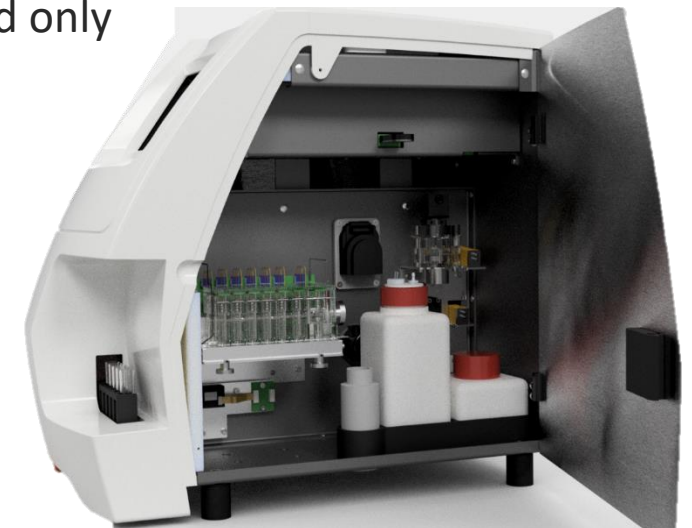
High quality and stability reagents housed inside our IONIX

Space saving

Closed and secured reagent system

Dongle and barcode

1 internal standard only



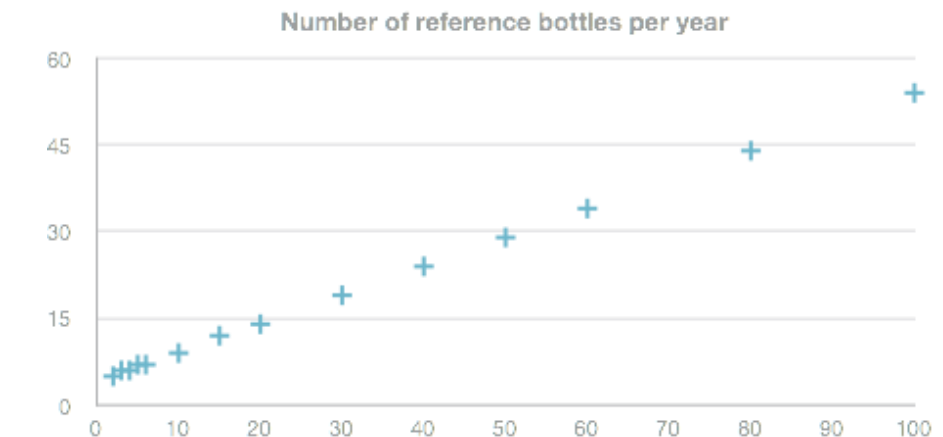
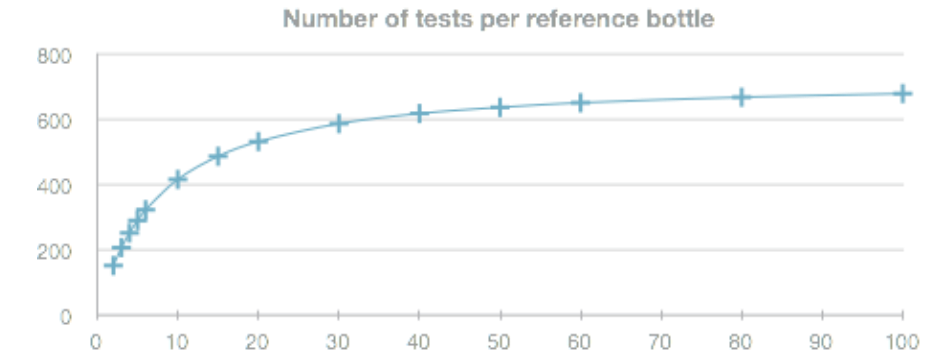
# Why are we different ?

## 6 WELL-THOUGH REAGENTS

Ionoref: the internal reference solution, 250 mL vials

Ionokit: kit including Ionocal, Ionotrol normal, cleaning solutions. 8 to 9 kits per year (6 or 7 working days per week)

Pathologic controls on request





## Our specialties

# FINALLY PRECISE IONIZED CALCIUM RESULTS IN A MODERN & COMPACT INSTRUMENT

## IDEAL INSTRUMENT FOR CALCIUM & LITHIUM TESTS

### CALCIUM OR LITHIUM IS YOUR ROUTINE?

The IONIX is the **ONLY** solution as of today

- 1 Test on primary tube : better stability of the sample.
- 2 Temperature controlled -> pH correction for a sample at 37°C
- 3 Ca<sup>2+</sup> electrode stable, robust, fully traceable and highly precise



### LARGE LABORATORY WISHING FOR PRODUCTIVITY ? BUILD YOUR EFFORTLESS NEW ROUTINE WITH THE IONIX

Autoloader 4x5 positions

#### REAL CONTINUOUS LOADING

Place rack whenever you want in the autoloader, the IONIX will know automatically it has to process it !!

No more batch testing, now **make it faster** by using the IONIX continuous loading.  
20 ou 400 tubes that's the same, the IONIX just keep testing.

\*\*\* NEVER STOP \*\*\*  
PROMISE A FULL TRACEABILITY

If your country praises **ionized calcium & lithium tests**, if your routine is made of hundreds of ionized calcium tests,

#### STOP AND TRY THE IONIX

- Excellent results
- Full traceability
- Precise & reliable electrodes
- Made in France instrument
- **YOUR ONLY ALLY**



*Reminder : ionized calcium is – compared to the total calcium - the only parameter with therapeutical interest AND precise and exact results*

#### CHOOSING THE IONIX IT IS ALSO

- ANSWERING TO ISO 15189 LABORATORY STANDARDS
- THE NEWEST INSTRUMENT ON ITS MARKET THAT GIVES EXCELLENT AND PROVED RESULTS
- KNOWING THAT CONTINUOUS LOADING OFFERS A HUGH TIME GAIN TO ANY LAB



# LARGE STUDIES CONDUCTED BY EXTERNAL LABORATORIES

3 studies, conducted by external laboratories, to prove the repetability, reproducibility and accuracy of the IONIX and its electrodes.

A comparison to NOVA 8 by NOVA BIOMEDICAL, to 103AP by DIESTRO and to ABL from RADIOMETER.

Calcium standardization at a pH of 7.4 is highly recommended, impossible without a pH electrode.

**Finally factual results to establish the IONIX in the best ion analyzers on the market.**

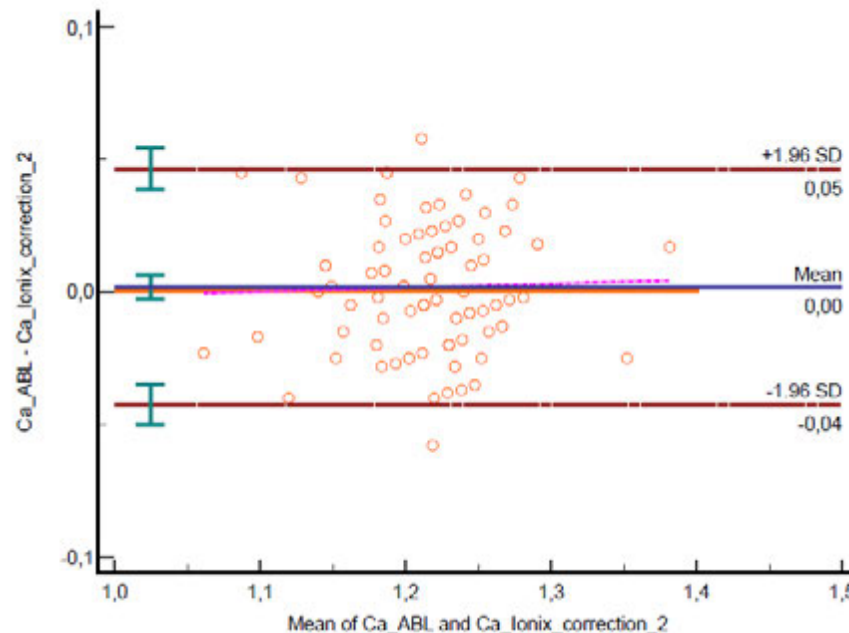
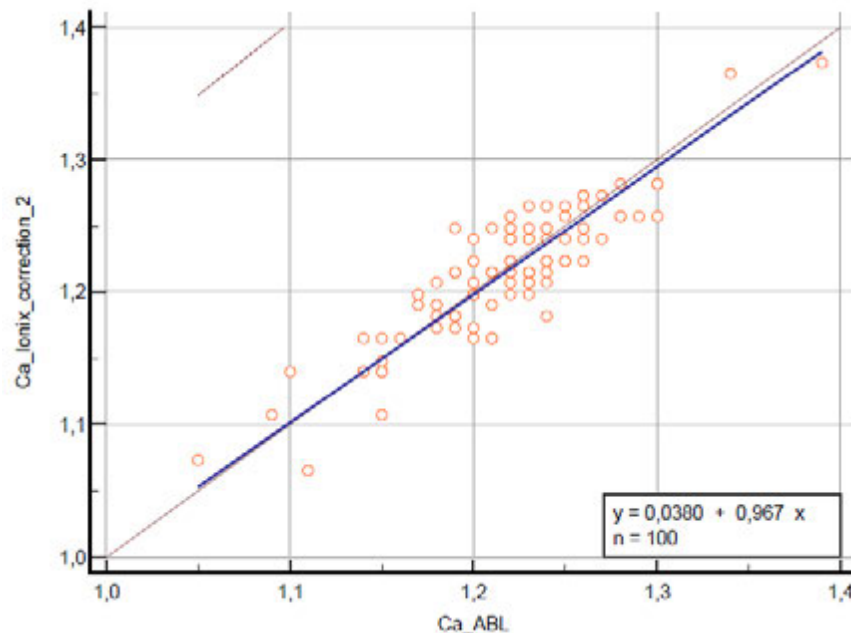
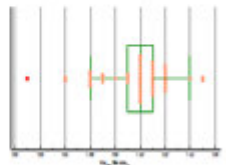


Table 9:

Ion	Na Ionix	Na Diestro	K Ionix	K Diestro	Cl Ionix	Cl Diestro	Ca Ionix	Ca Diestro
39	135,8	140	4,41	4,7	104,6	108,7	1,08	1,33
40	137,7	140	4,38	4,6	102,6	106,1	1,19	1,38
41	140,3	139	4,19	4,2	107,2	104,7	1,28	1,38
42	139,1	137	4,53	4,5	109,1	109,9	1,25	1,38
43	143,4	141	4,17	4,2	107,9	104,8	1,31	1,33
44	143,6	140	4,47	4,5	108,4	106,6	1,3	1,3
45	145,1	141	4,06	4,1	111,4	107,7	1,31	1,3
46	146,7	141	4,31	4,3	108,1	106,8	1,25	1,25
47	143,6	140	4,98	5	108,9	105,1	1,33	1,35
48	140,4	140	3,77	3,8	106	103,7	1,25	1,3
49	143,1	140	4,73	4,7	109,8	108,1	1,3	1,29
50	141	140	4,68	4,6	117,3	106,4	1,29	1,3
Mean	141,29	139,70	4,46	4,54	104,38	105,86	1,24	1,27
SD	2,36	2,75	0,36	0,38	2,87	1,6	0,06	0,04
Mini	135,7	137	3,71	3,8	99,7	99,3	1,08	1,17
Maxi	145,7	145	5,01	5,7	112,1	109,1	1,38	1,35
$\Delta$	0,99		-0,05		-1,28		-0,02	
$\Delta(\%)$	0,47%		-1,08%		-1,27%		-0,84%	

a) Considered as an outlier by Grubbs or Tukey tests. But this sodium is low with Ionix, so the sample has not been rejected.



b) Deleted  
c) High potassium on both instruments

# IONIX vs. DIESTRO V4

## DIESTRO V4

- **Traceability** : limited to 1 000 memory storage vs. IONIX **illimited** data stored.
- **Autoloader**: limited to 40 positions AND not adequate to the calcium ionized measurement since the V4 cannot respect the IFCC recommendation vs. IONIX's loader is **walk-away continous loading**. You can place your calcium test when you need to.
- No **pH electrode** – no normalisation to 7,4 pH. Calcium results are raw and not adjusted – not reliable vs. IONIX with a precise pH electrode
- User-friendly: **Screen** is monocolor, small and not practical vs. IONIX with a large colorfull touchscreen



# IONIX HARDWARE SPECIFICATIONS

## Instrument specifications

Dimensions:	Height: 380 mm (15 in.)
	Width: 270 mm) (10.6 in.)
	Depth: 420 mm) (16.50 in.)
Weight:	~13 kg. With packaging, ~16.5 kg
Power supply Input (AC):	100-240VAC 2.0A 50/60 Hz
Electric consumption:	~50 Watts
Noise	58.8 dB(A)
Display:	Color LCD 800 x 480
	Landscape Mode
	Touch screen with backlight
Barcode (option):	
Memory capacity:	> 1000000 records (Demographics, results and controls)
Connections:	USB
	Ethernet (TCP/IP) or (UDP/IP)

# IONIX SPECIFICATIONS

DETECTION LIMIT (WHOLE BLOOD, SERUM, PLASMA & URINE)		
Na	3.80	
K	0.19	
Cl	4.52	
pH	NA	
Ca	0.11	
Li	0.05	
LINEARITY (SERUM)		
	Range (mmol/l)	Range (mEq)
Na	110 - 185	110 - 185
K	1 - 9	1 - 9
Cl	65 - 140	65 - 140
pH	6.96 - 7.73	NA
Ca	0.4 - 3	0.8 - 6
TCO <sub>2</sub>	NA	NA
LINEARITY (URINE)		
	Range (mmol/l)	Range (mEq)
Na	5 - 200	5 - 200
K	5 - 200	5 - 200
Cl	5 - 400	5 - 400
ACCURACY		
	CV%	On normal range (mmol/L)
Na	< 1	135 - 145
K	< 1	3 - 6
Cl	< 1	90 - 110
pH	< 1	7.25 - 7.40
Ca	< 2	1.1 - 1.3
TCO <sub>2</sub>	< 3	23 - 27
Li	< 2	0.1 - 2
REPRODUCIBILITY		
	CV%	On normal range (mmol/L)
Na	< 2	135 - 145
K	< 2	3 - 6
Cl	< 1.5	90 - 110
pH	< 3.9	7.25 - 7.40
Ca	< 2.5	1.1 - 1.3
TCO <sub>2</sub>	< 4.86	23 - 27

Within-subject and between-subject CV values of analytes and Desirable Analytical Quality Specifications for imprecision, bias and total error

Sample	Analyte	Biological variation		Desirable specification		
		CV <sub>i</sub> <sup>a</sup>	CV <sub>g</sub> <sup>b</sup>	I(%) <sup>c</sup>	B(%) <sup>d</sup>	TE(%) <sup>e</sup>
Blood	Sodium	0.6	0.7	0.3	0.23	0.73
Urine	Sodium	28.7	16.7	14.4	8.3	32
Blood	Potassium	4.6	5.6	2.3	1.81	5.61
Urine	Potassium	24.4	22.2	12.2	8.2	28.4
Blood	Chloride	1.2	1.5	0.6	0.5	1.5
Blood	iCalcium	1.7	1.9	0.9	0.6	2.0
Blood	pH(pH units)	0.2	...	0.1	...	...
Blood	Bicarbonates	4.8	4.7	2.4	1.7	5.6

a. CV<sub>i</sub> = within-subject biologic variation

b. CV<sub>g</sub> = between-subject biologic variation

c. I = desirable specification for imprecision

d. B = desirable specification for inaccuracy

e. TE = desirable specification for allowable total error





# SFR

Medical Diagnostics