

HumaLyte Plus⁵ HumaLyte Plus³

| User Manual



CE

Cat.No. 17470/1

Human

Revision List of the Manual	
Rev./DATE	REVISION DESCRIPTION
01/2010-02	First edition
02/2010-08	Correction of typing errors
03/2011-09	Correction dimension
04/2012-05	Chap. 2.1, 2.2, 2.4, 2.6, 2.7, 2.8, 2.9, 2.12, 2.13, 3.2, 3.2.1, 3.3.2, 3.7.3, 3.7.5, 3.7.7, 3.8, 3.9, 5.1, 5.6, 6.2, 7.1, 8.1-8.5
05/2014-01	Software 5.5HE, iCa and pH, pre-analytics. Chap. 1.2, 2.1, 2.2, 2.15, 2.16, 3.3, 3.3.3, 3.4, 3.7.3, 3.7.6, 3.7.11, 3.9, 3.9.3, 4.1, 8.3, 8.4
06/2017-07	pH intended use change. Chap. 2.1, 2.2, 2.14, 2.16, 3.3.5, 3.3.6, 3.7.11, 8.4 and Cal descrip Chap. 3.4

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Service and Support



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1 Safety Instructions

This manual is considered part of the instrument and must be available to the operator and the maintenance personnel. For accurate installation, use and maintenance, please read the following instructions carefully. In order to avoid damage to the instrument or personal injury, carefully read the "GENERAL SAFETY WARNINGS" describing the appropriate operating procedures. Please contact the technical service department in the event of instrument failure or other difficulties with the instrument.

1.1 User Warranty

HUMAN warrants that instruments sold by one of its authorised representatives shall be free of any defect in material or workmanship, provided that this warranty shall apply only to defects which become apparent within one year from the date of delivery of the new instrument to the purchaser.

The HUMAN representative shall replace or repair any defective item at no charge, except for transportation expenses to the point of repair.

This warranty excludes the HUMAN representative from liability for any item considered as expendable in the course of normal usage, e.g.: lamps, valves, syringes, glassware, fuses, diskettes, tubing etc.

The HUMAN representative shall be relieved of any liability under this warranty if the product is not used in accordance with the manufacturer's instructions, altered in any way not specified by HUMAN, not regularly maintained, used with equipment not approved by HUMAN or used for purposes for which it was not designed.

HUMAN shall be relieved of any obligation under this warranty unless a completed installation / warranty registration form is received by HUMAN within 15 days of installation of this product.

This warranty does not apply to damages incurred during shipment. Any damage so incurred shall be reported to the freight carrier for settlement of the claim.

1.2 Intended Use of the Instrument

The instrument must be used for its intended purpose (see chapter 2). It must be operated and maintained by qualified personnel under suitable environmental / technical conditions as described in this manual under GENERAL SAFETY WARNINGS. This manual contains instructions for qualified professional operators.

1.3 General Safety Warnings

Use only chemical reagents and accessories specified and supplied by HUMAN and/or mentioned in this manual.

Place the instrument so that it has proper ventilation.

The instrument should be installed on a flat, stationary working surface that is free of vibrations.

Do not operate in an area with excessive dust.

Operate at room temperature and at a humidity level in accordance with the specifications listed in this manual.

Do not operate this instrument with covers or panels removed.

Only use the power cord specified for this product, with the grounding conductor of the power cord connected to a properly grounded outlet.

Use only the fuse type and rating specified for this instrument. The use of fuses with improper ratings may pose electrical and fire hazards.

To avoid fire or shock hazard, observe all ratings and markings on the instrument.

Do not power on the instrument in an environment where there is a risk of fire or explosion.

Prior to cleaning and/or performing maintenance on the instrument, switch it off and remove the power cord.

Only cleaning materials described in this manual may be used, as other materials may damage parts.

It is recommended to always wear protective apparel and eye protection while using this instrument.

All warning symbols that appear in this manual must be carefully observed.

1.4 Disposal Management Concept

The applicable local regulations governing disposal must be observed. It is the user's responsibility to arrange for the proper disposal of the individual components.

All parts which may contain potentially infectious materials must be disinfected following suitable, validated procedures (autoclaving, chemical treatment) prior to disposal. Applicable local regulations for disposal must be carefully observed.

The instrument and electronic accessories (without batteries, power packs etc.) must be disposed of according to the regulations for the disposal of electronic components.

Batteries, power packs and similar power sources must be removed from electric/electronic parts and disposed of in accordance with applicable local regulations.

1.5 Instrument Disinfection

Instruments or parts which may come in contact with biological samples (patient specimens, controls etc.) should be considered at least potentially infectious.

Before performing any service work on the instrument, it is very important to thoroughly disinfect all possibly contaminated parts. Before the instrument is removed from the laboratory for disposal or servicing, it must be decontaminated/disinfected. Decontamination/disinfection must be performed by trained, authorised personnel in observance of all necessary safety precautions. Instruments to be returned must be accompanied by a disinfection certificate completed by the responsible laboratory manager. If a disinfection certificate is not supplied, the returning laboratory will be responsible for charges resulting from non-acceptance of the instrument by the servicing centre or from intervention by governmental authorities.

1.6 Notice

Every effort has been made to avoid errors in text and diagrams. HUMAN, however, assumes no responsibility for any errors which may appear in this publication. It is the policy of HUMAN to improve products as new techniques and components become available. HUMAN GmbH therefore reserves the right to change specifications if necessary in the course of such improvements.



1.6-1: Biohazard

The „BIOHAZARD“ warning label must be affixed to instrument prior to first use with biological material !

2 System Description

2.1 Brief Description of the Instrument

Potassium, sodium, chloride and calcium make up the bulk of body electrolytes. It is a priority of all medical treatment to maintain the proper electrolyte balance. It is therefore very important to measure the levels of potassium, sodium, chloride and calcium in patients' body fluids.

In the past, the flame luminosity was the method most widely used to measure potassium and sodium levels. In recent years, Ion Selective Electrode (ISE) technology has become prominent with the application of sensor technology and microcomputer technology. The flame luminosity method not only requires the use of flammable gas and compressed air, it also requires that samples be centrifuged in order to obtain patient serum for dilution and testing. The Ion Selective Electrode method can measure the serum directly without any dilution. It therefore shortens the measuring time significantly. In addition, the Ion Selective Electrode method has several other advantages: it is more accurate and less sample material is needed. For these reasons, it has become the mainstream technology for electrolyte analysis.

The HumaLyte Plus line of electrolyte analyzer is specially designed for clinical analysis. The main features include:

- High precision: Guaranteed by the use of long-life, high performance electrodes and advanced automatic control software. Unique calibration programs eliminate systematic errors. Wide linear range.
- Low sample volume: Only 150µl per test.
- High throughput: Result obtained in less than 60 seconds.
- High automation: Automatic aspiration, washing and calibration. Results display and print out automatically. All models can be easily upgraded with an autosampler.
- Easy operation: User friendly software, large LCD display, touch screen. 24-hour, non-stop working mode, suitable for emergency samples.
- Large memory: Up to 200 patient results stored on board, easy to review.
- Easy maintenance: Advanced hardware design, fluid tubing system and self-diagnosis software make maintenance and troubleshooting simple.

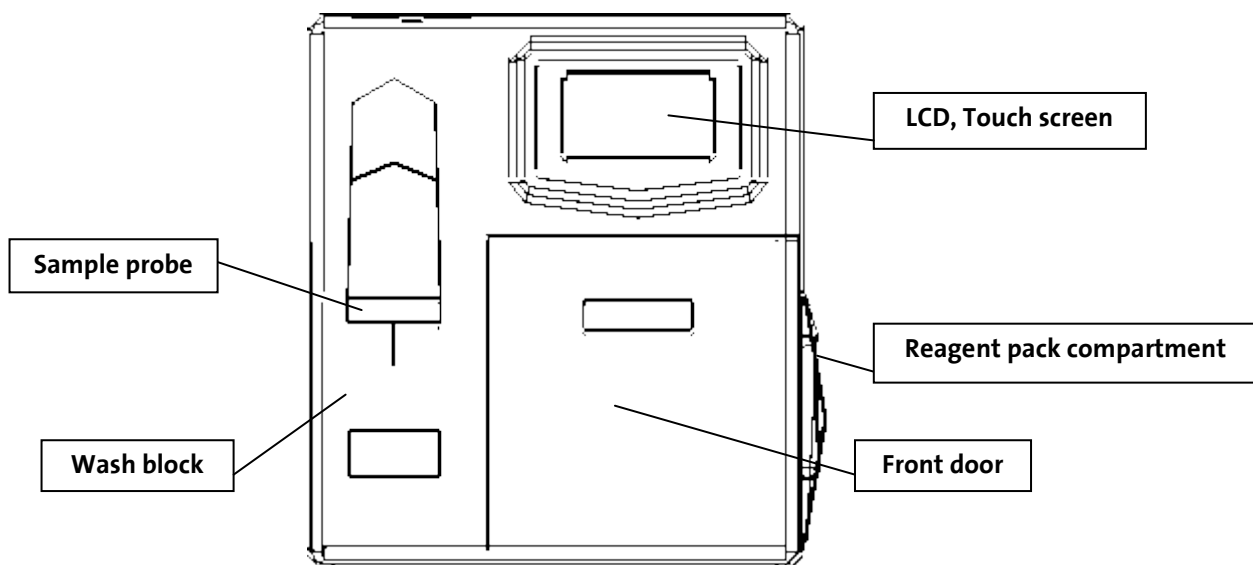
2.2 Scope of Application

The electrolyte analyzers HumaLyte Plus 5 and HumaLyte Plus 3 are automated, microprocessor-controlled analytical instruments that use ISE (Ion Selective Electrode) technology for the in vitro diagnostic measurement of ionized potassium (K), sodium (Na), chloride (Cl) and ionized calcium (iCa) in serum, plasma and whole blood (heparin between 10 and 20 U/ml, see chapter 3.3.7) pH results are used only for the correction of iCa. Potassium (K), sodium (Na), and chloride (Cl) can also be measured in diluted urine. The instrument is only accurate for the measurement of ionized calcium (iCa), total calcium (tCa) is a calculated value derived from iCa using the formula: $tCa = 1.95 \times iCa$. iCa(7.4) and pH(37) are mathematically calculated on the basis of iCa and pH (software version 5.5HE or above).

2.3

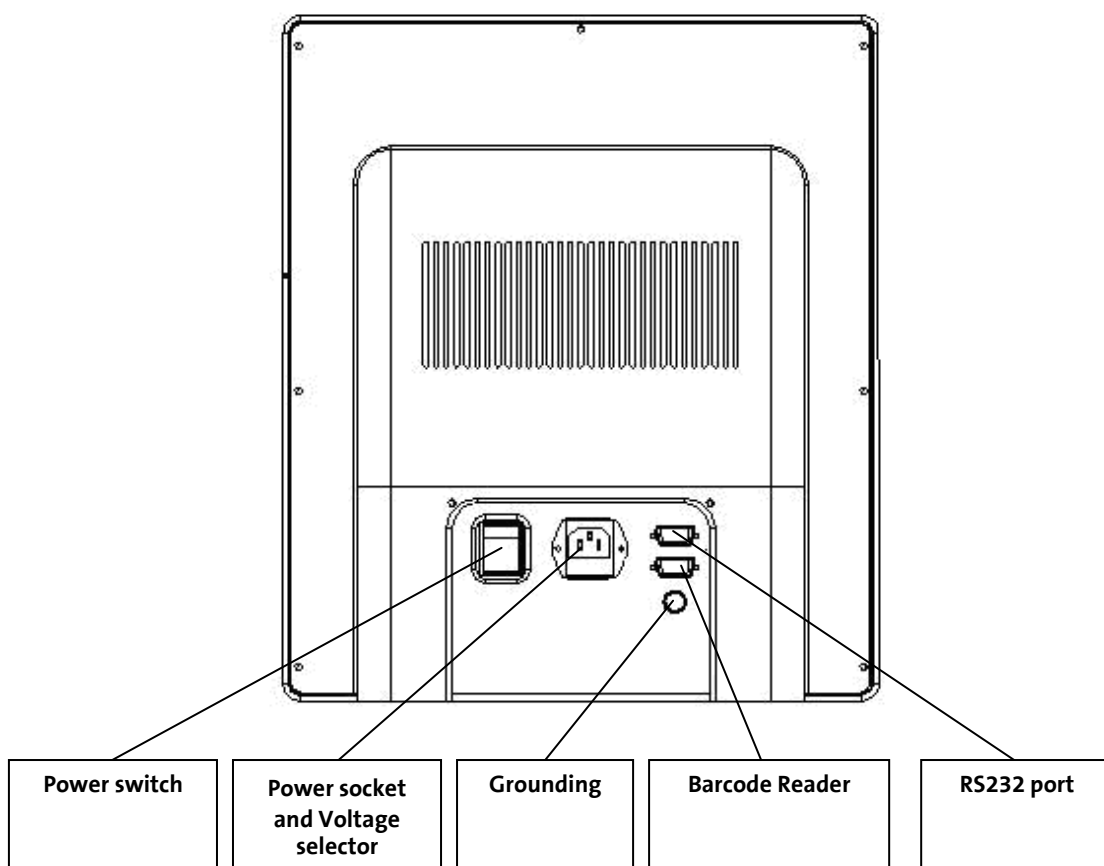
System Structure

2.3.1 Front panel



2.3.1-1

2.3.2 Rear panel



2.3.2-1

2.4 Unpacking

When unpacking the instrument, please make sure that the following items are included. In case of any damage or missing items, please contact the supplier immediately.

[REF]	Qty	Unit	Description	Comment
17470/10	1	pcs.	HumaLyte Plus 3 Analyzer	Plus 3 only!
17470/20	1	pcs.	HumaLyte Plus 5 Analyzer	Plus 5 only!
17470/1	1	pcs.	User Manual	
17470/82	1	pcs.	Reagent Pack	Plus 3 only!
17470/83	1	pcs.	Reagent Pack	Plus 5 only!
18999	1	pcs.	Power Cord	
	1	pcs.	Grounding wire	
	1	Set	Set of electrodes	
17470/17	1	pcs.	• Reference electrode	
17470/12	1	pcs.	• Sodium (Na) electrode	
17470/11	1	pcs.	• Potassium (K) electrode	
17470/13	1	pcs.	• Chloride (Cl) electrode	
17470/15	1	pcs.	• pH electrode	Plus 5 only!
17470/14	1	pcs.	• Calcium (Ca) electrode	Plus 5 only!
	1	Set	• Accessories to hold electrodes	
17470/70	1	pcs.	QC solution	
17470/79	1	pcs.	Na conditioner	
17470/76	1	pcs.	Ca filling solution	Plus 5 only!
17470/75	1	pcs.	Na/Cl/pH filling solution	
17470/74	1	pcs.	K filling solution	
17470/78	1	pcs.	Reference filling solution	
17470/72	1	pcs.	Weekly cleaning solution	
17470/86	1	pcs.	Urine diluent	
18144/5	1	Set	Thermal paper (3 pcs.)	
	1	Set	Accessories	
	1	pcs.	• Tweezers	
	1	pcs.	• Screwdriver	
	1	pcs.	• Cleaning needle	
17470/19	1	Set	• Reference membrane (10 pcs.)	
	2	pcs.	• O-ring	
	1	pcs.	• Ref. membrane fitting tool	
17470/18	1	pcs.	• Internal electrode	
17470/42	2	pcs.	• Peristaltic pump tube	
17470/61	1	Set	• Fuse (F2AL250V) (2 pcs.)	

2.5 Environment Requirement

1. The instrument should be installed on a stable, solid platform away from any vibration source.
2. The environment should be as free as possible from dust, corrosive gas, loud noises and electrical interference.
3. Avoid placing the instrument in direct sunlight or near any source of heat or vents.
4. Ambient temperature: 15...32°C, relative humidity: <85%.
5. The power supply should be 220/110Vac \pm 10%, 50/60 Hz
6. Power supply and grounding must be connected correctly.

2.6 Installation of the Reagents

1. Remove the reagent pack.
2. Remove the red cap on the connectors.
3. Insert the reagent pack into the compartment.

The Reagent Pack is identified by the instrument using an RFID chip inside the Reagent Pack. The instrument will display an error when the chip is not present, damaged, or not in the correct position.



1. **After removing the Reagent Pack, Standard, Quality Control, Filling solutions or other reagents from the refrigerator, allow them to warm to room temperature to achieve accurate results and prevent any damage of the electrodes.**
2. **Be careful not to contaminate the reagents during installation or replacement.**

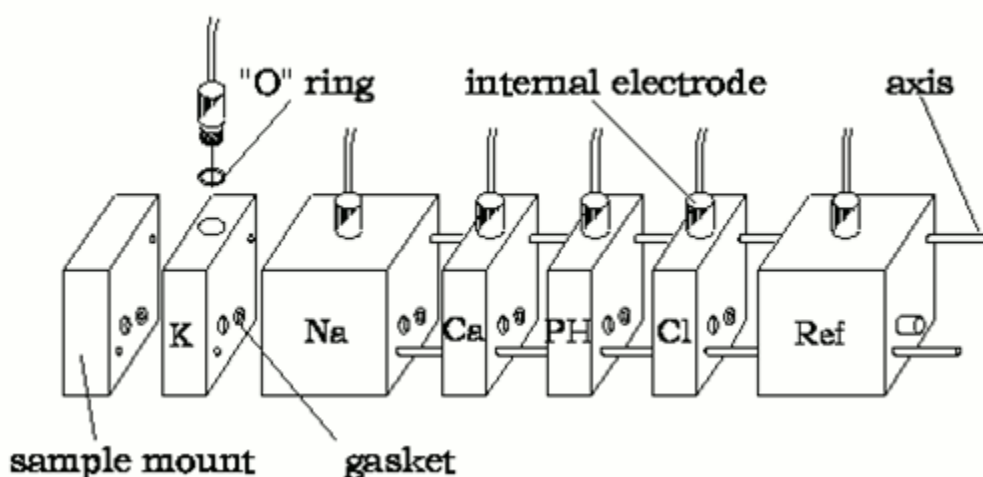
2.7 Installation of the Electrodes

1. Assemble the electrodes with the rubber gaskets according to figure 2.7-1. Slide them onto the axis rod, then tighten the nuts firmly.
2. Check the filling solution levels. If necessary, remove the internal electrodes and add the corresponding filling solution (K filling solution for the K electrode, Ca filling solution for the Ca electrode, Na/Cl/pH filling solution for the Na, Cl and pH electrodes, and reference filling solution for the reference electrode).
3. Clean and dry the electrodes with a soft tissue.
4. Install the whole electrode assembly into the electrode holder.
5. Connect the electrode lead wires and the grounding wire to the corresponding plugs according to figure 2.7-2.

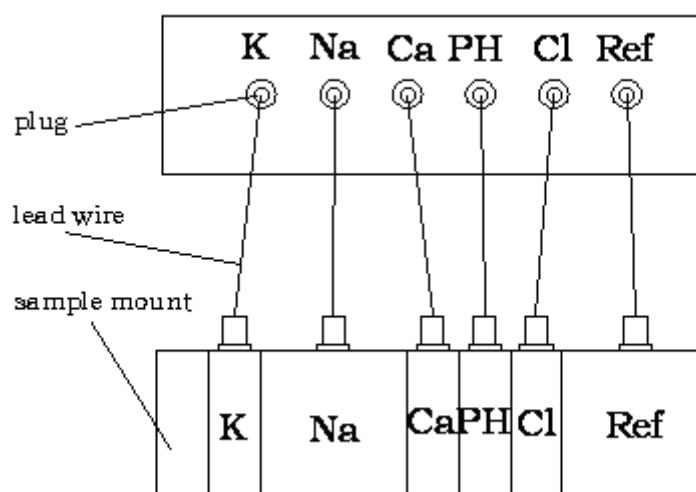
Due to the high electrolyte concentration ("salt") inside the solution, there might be salt crystals on the electrodes or other parts of the instrument (spilling). As long as there is no leakage, salt crystals will not influence the instruments function. Just turn of the instrument and use a wet cloth to clean.



Do not mix up the electrodes!



2.7-1: Humalyte Plus 5 only

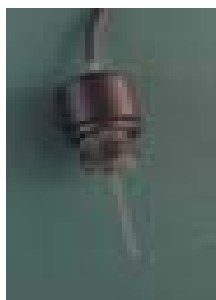


2.7-2

2.8 Filling Solutions

Filling Solutions are necessary for the function of the electrode. The “internal electrode” (metal wire, see picture) has to be at least 2/3 emerged into the Filling Solution. During weekly maintenance check if the filling level is sufficient and refill if necessary. Filling Solution also has to be replaced if the calibration of the respective parameter fails or the QC results are out of range. The approximate filling volume for each electrode is stated in the table below.

Because you rarely have to completely refill the electrodes, one 100ml bottle is more than sufficient until the end of usage time (see section 8.3 Shelf life and consumption).



2.8-1

Item	Approximate filling volume
K filling solution	300±20µl per filling
Na/Cl/pH filling solution	Na: 1170±30µl, Cl: 300±20µl, pH: 730±20µl
Ca filling solution	300±20µl
Ref. filling solution	650±30µl

2.9 Installation of the Autosampler (for autosampler models only)

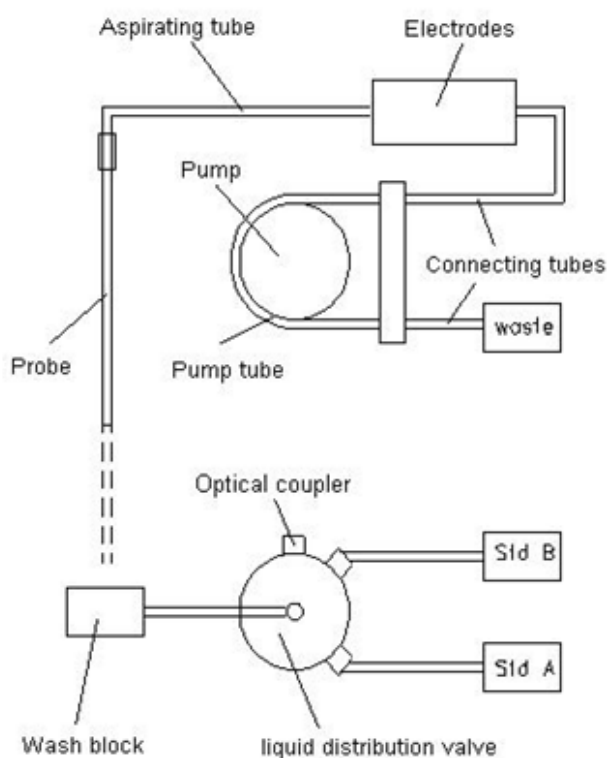
Turn off the instrument and place the main unit and the autosampler onto the junction panel. Connect the data cable correctly. When unplugging the cable, do not pull the wires, only pull the clip.

2.10 Installation of the Printing Paper

1. Insert the paper roll into the printer
2. Insert the paper into the guide slot.
3. Make sure the thermal side of the paper faces downward.
4. Pull up the lever on the right and rotate the knob until the end of the paper comes out of the printer, then push the lever down; or press "Paper" in the service menu until the paper feeds correctly.

2.11 Installation of the Tubes

Connect the tubes according to figure 2.10-1.



2.11-1

2.12 Connecting to the Power Supply

1. Make sure the input voltage selector is set to correct voltage.
2. Make sure the power switch is in the OFF position.
3. Connect the instrument to the power supply with the power cable.



The instrument must be grounded properly! Use the supplied grounding cable if necessary.

2.13 Instrument Construction

The instrument consists of electrochemical sensors (ISE), liquid and position sensors, a microprocessor control system, a peristaltic pump, a 3-way valve, a movable aspiration probe, an auto sampling system (optional), an auto calibration system and a Reagent Pack (including standard A, standard B, and a waste container).

2.14 ISE Theory

The HumaLyte Plus uses a method called ion-selective electrode (ISE) for the determination of the concentration of electrolytes (K, Na, Cl, iCa) which are used for diagnosis, treatment, and monitoring of patients. The pH results are used for the correction of iCa only.

HumaLyte Plus 3 can directly measure 3 parameters: K, Na, Cl. HumaLyte Plus 5 can directly measure 5 parameters: K, Na, Cl, iCa and pH. Based on the parameters measured directly HumaLyte Plus 5 can derive 3 more calculated parameters. These calculated parameters are iCa(7.4), tCa, pH(37). The parameters iCa(7.4) and pH(37) are only available on instruments featuring software version 5.5HE or above.

An Ion Selective Electrode is a type of electrochemical sensor. It converts ion activity into the electric potential of the electrode. This relation conforms to the Nernst equation, which shows the linear relation of the logarithm of the ion activity to the electrode potential. In addition, different electrodes are sensitive to different ions. For example, the sodium electrode is only sensitive to Na ions, and the potassium electrode is only sensitive to K ions. If the potassium electrode, sodium electrode, and chloride electrode are combined, the K ions, Na ions, and chloride ions in the sample can be measured at the same time.

The key part of the electrode is the sensitive membrane. On one side it is in contact with the sample and responds to the change in concentration of certain ions in the sample. On the other side, it is in contact with the internal filling solution and converts the ionic conduction to electronic conduction through a silver filament, i.e. internal electrode. In addition, there is a reference electrode that indicates the reference potential and forms a complete measuring circuit. Inside the reference electrode there is also an internal electrode. Its potential remains constant when the concentration of the solution changes, so it provides a reference point to measure the potential differences.

2.15 Measuring Principles

The instrument measures the electrode potentials, and the data is processed by the microprocessor to obtain the concentration of a given ion. The measure method is called “standard comparison”. It uses two kinds of standard solutions, one for the calibration of the base point, and the other for the calibration of the slope. The result is obtained from the potentials of the sample and two standard solutions. Both standards (standard A and standard B) are contained within the reagent pack.

The following equations are used:

$$C_X = C_A * \text{EXP} [(E_X - E_A) / S] \quad (1)$$

$$S = \frac{E_B - E_A}{\text{Log} (C_B / C_A)} \quad (2)$$

Note:

- **C_X, E_X:** the concentration and potential of the sample
- **C_A, E_A:** the concentration and potential of standard A
- **C_B, E_B:** the concentration and potential of standard B
- **S:** the slope of electrode

In order to improve the precision, the contents of the standard solutions are similar to ion concentration in a normal blood sample.

2.16 Explanation of the different parameters for calcium and pH (HumaLyte Plus 5 only)

iCa (software version 5.5HE or above)

iCa is the actual concentration of ionized calcium measured directly by the instrument using a calcium ISE under the conditions which are present in the sample at that moment.

iCa(7.4) (software version 5.5HE or above)

Only about 50% of the “total” blood Calcium (tCa) is free ionized Calcium (iCa). The remaining approximately 50% are bound to proteins or other complexes. An alteration of the pH will change the ratio of iCa to tCa, thus changing the result of the measurement of ionized Calcium. Once the sample has been collected pH will inevitably change depending on the pre-analytical conditions (see requirements in chapter 3.3.4).

iCa(7.4) is the calculated concentration of a sample normalized to pH 7.4 and is similar to the old iCa of software version 5.4HE. The iCa of version 5.4HE is also corrected to a pH of 7.4. Software version 5.4HE only uses pH instead of pH(37) for the calculation.

The version 5.5HE uses the formula

$$iCa(7.4) = iCa + [pH(37) - 7.4] / 1.89 \quad [1]$$

where iCa is the actual concentration of ionized calcium measured by the instrument, and pH(37) is the calculated pH of the sample at 37°C. The mathematical approximation is only valid in the range of pH 7.2 to 7.6. [2]

tCa

tCa is the calculated concentration of total calcium in the sample including both free ionized calcium, which can be measured as described above, and protein bound calcium using the formula

$$tCa = 1.95 * iCa(7.4)$$

pH - used for correction of iCa only

pH is measured by the instrument directly at room temperature and under the conditions which are present in the sample at that moment. Since standard A and B inside the reagent pack have been adjusted to 25°C, the pH measured by the instrument always represents the pH at 25°C.

pH(37) (software version 5.5HE or above)

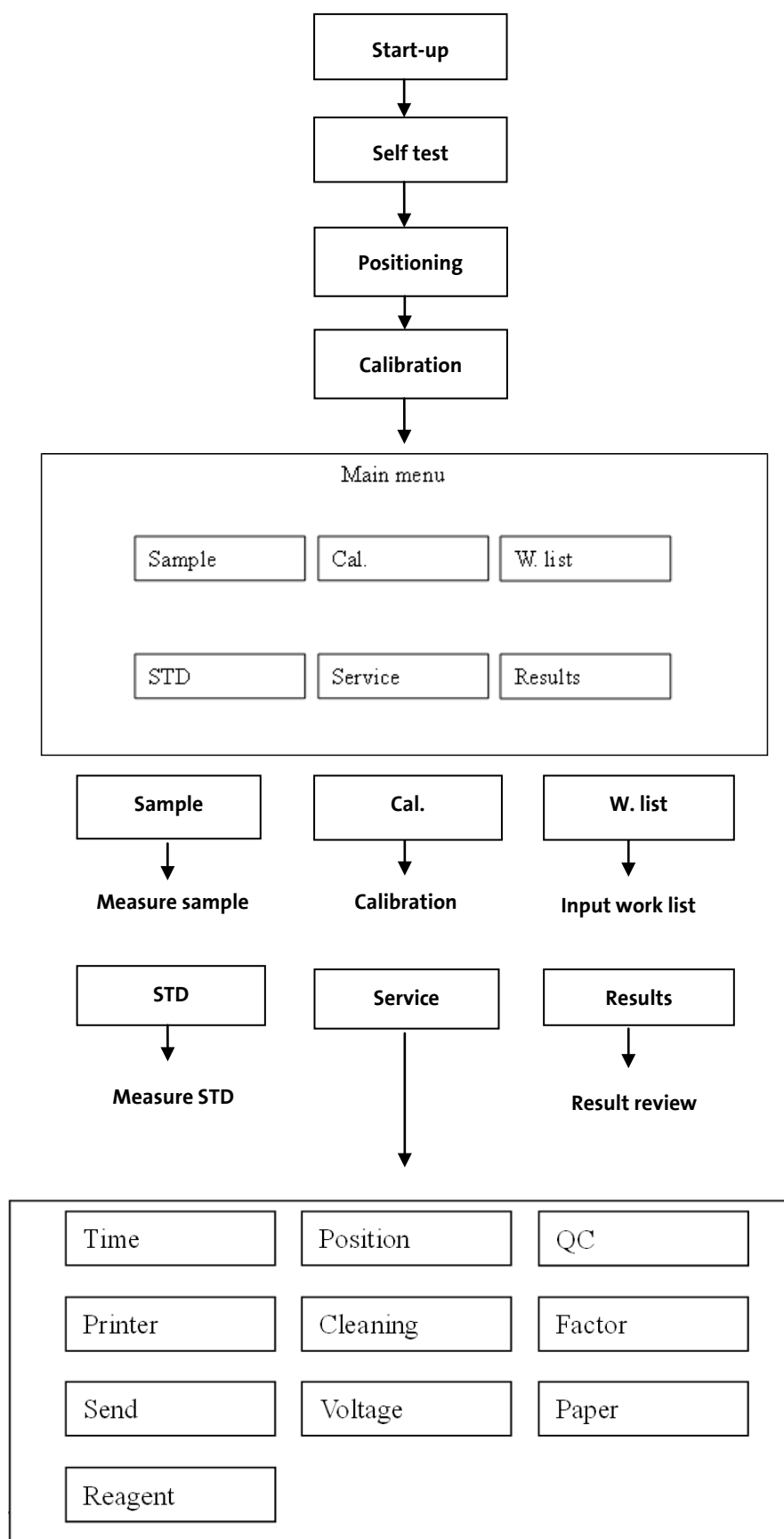
The actual pH of the sample rises linearly with the fall of temperature.

pH(37) is the calculated pH corresponding to a temperature of 37°C (thus simulating patient body temperature) using the following formula

$$pH(37) = pH - 0.0146 * (37 - 25) \quad [3]$$

3 Method of Operation

3.1 Flow Chart of the Operating Procedure



3.1-1

3.2 Startup and Self-Test

After the instrument has been correctly installed, turn on the power and boot up the instrument. The screen displays:

Initialization...

The instrument carries out a self-test for the positioner (liquid sensor on the left side of the electrodes), printer and autosampler. The sample probe will lift, and the screen displays:

Auto position OK
Printer OK
Sample tray not detected

3.2-1

Notes:

1. For autosampler models, the screen will show "Sample tray OK" if the autosampler is correctly installed.
2. The initialization will halt if any error is detected in the liquid distribution valve, elevator switch or optical couplers.

When the initialization finishes successfully, the sample probe will lower. A few seconds later, the screen displays:

Measure ISE STD.....

This indicates that the instrument is carrying out a calibration. The system checks the positioner's voltage, pump pulse numbers and electrode potentials. The screen displays:

1032 ... (the positioner's voltage (in mV) when calibrating without liquid, up to 3 readings)
127 ... (the positioner's voltage (in mV) when calibrating with liquid, up to 3 readings)
2094 2100 ... (the pump pulse number corresponding to the sample volume, up to 4 readings)
70.36 68.08 73.77 33.75 69.1 (the potential of each electrode when Standard B is aspirated)
53.98 73.56 66.59 26.15 95.1 (the potential of each electrode when Standard A is aspirated)

(The potentials with standard B and standard A are displayed in turn, up to 3 times)

When the calibration is finished, the screen displays:

Slope
K: 54.5 OK
Na: 52.3 OK
Cl: 51.6 OK
Ca: 25.5 OK
PH: 55.6 OK

3.2-2

The results will also be printed out as below:

TIME: 2009-09-30 10:08

SLOPE

K: 54.5 (27...67)

Na: 52.3 (27...67)

Cl: 51.6 (27...60)

Ca: 25.5 (15...34)

PH: 55.6 (26...70)

Note: If the slope of an electrode is unstable, “Fluc.” will be displayed on the right. If the slope of an electrode is abnormal “X” will be displayed on the right.

The normal ranges of the slopes are:

K: 27...67 mV/dec

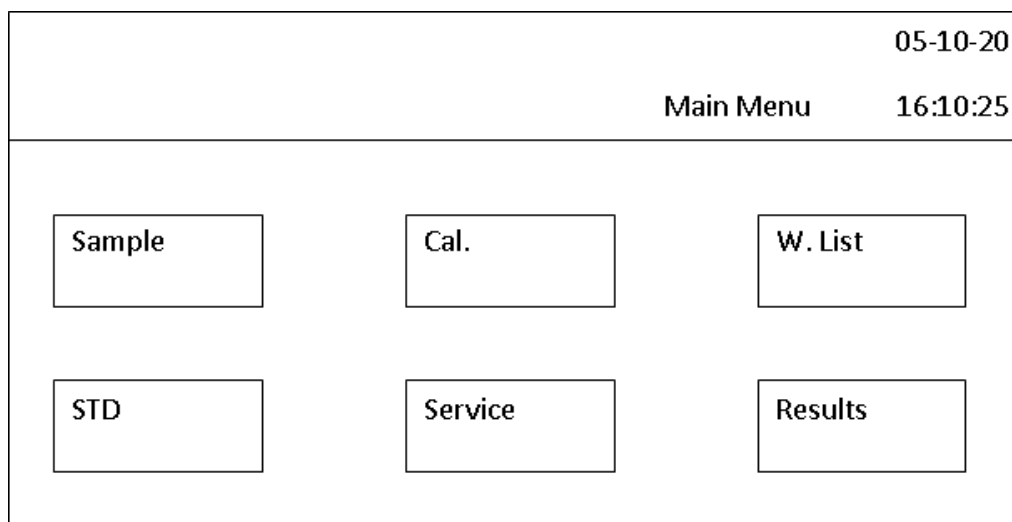
Ca: 15...34 mV/dec

Na: 27...67 mV/dec

pH: 26...70 mV/dec

Cl: 20...60 mV/dec

After the calibration, the screen will display the main menu:



3.2-3

3.2.1 First start up

When a new instrument is started for the first time or has not been used for one or more days there are some problems you may encounter but solve easily. Due to the concentration of electrolytes in the solutions there might be crystallizations inside the instrument preventing the good functioning of the instrument. This problem is common to ISE-instruments and can easily be solved.

The first thing, you always should do, is to turn off and back on the instrument two times.

Problems you may encounter and their solution:

- No liquid moving inside the tubing
 - Try to locate the position where the tubing is blocked. Disconnect the tubing and rinse the tubing using distilled water and a pipette.
- Abnormal or unstable calibration
 - Refer to the trouble shooting section of this manual. Usually this problem can be solved by replacing the filling solutions or the reference membrane.
 - If all parameters are concerned the problem is likely to be caused by the reference electrode. If only one parameter is concerned there is a problem with this specific electrode.
- “Sensor Error” 1#
 - Crystallization inside the valve blocks the movement of the valve. Check if the black disc inside the valve is turning (difficult to see, because there is only one small slot in the disc). If the valve is

not turning, open the valve (two screws) and rinse it with distilled water. Make sure not to lose any joints and put them back into the correct position.

- Crystallization on the outside of the electrodes
 - Use a wet cloth to clean from the outside.
- Brown or black color on the bottom of the electrodes
 - This will not prevent the instrument from working.

3.3 Sample Measurement

3.3.1 Operation without Autosampler

Press **Sample** to enter the sample measurement menu; the screen displays:

Sample	ID	00000000 00000000
Num: 001	Get ID	Aspirate
		Urine
		Exit

3.3.1-1

To change the sample number, press the corresponding button.

The screen then displays:

Num:		
1	2	3
4	5	6
7	8	9
./-	0	cls
	Yes	Exit

3.3.1-2

Enter the patient number and press **Yes** to save.

Once the system date changes, the sample number will restart from 001 and increase until 999 (maximum) automatically.

To change the patient ID number using a barcode reader, scan the barcode on the sample tube. The ID will be displayed after “ID”:

Sample	ID	1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8
Num: 001	Get ID	Aspirate Urine Exit

3.3.1-3

To change the patient ID number manually, press the button **Get ID**; the screen displays:

ID: _____		
1	2	3
4	5	6
7	8	9
./-	0	Cls
Yes		Exit

3.3.1-4

Enter the ID number and press **Yes** to save.

Place the sample under the sample probe and press **Aspirate**. The sample will be aspirated into the system. Remove the sample from the sample probe when the system emits a beep and the screen shows “Remove sample”. The results will be displayed within 60 seconds:

K:	5.09	PH:	7.56
Na:	145.5	Cl:	105.3
Ca:	1.31		

3.3.1-5



When the instrument beeps, the sample should be removed from the sample probe immediately!

Printout

The results will also be printed out as below:

TIME: 2009-09-30 10:12

SAMPL-No: 001

PAT ID: 123456789012345678

K	5.09	mmol/l	3.5...5.2
Na	145.5	mmol/l	135...145 H
Ca	1.31	mmol/l	1.1...1.4
Cl	105.3	mmol/l	98...108
TCa	2.55	mmol/l	2.2...2.9

Notes:

- “H” indicates the result is higher than the normal range.
- “L” indicates the result is lower than the normal range.
- “?” indicates the slope is abnormal or the electrode has not been calibrated properly.

Normal ranges

Many studies and clinical experience have proven that results of different instruments and different patient populations are not necessarily comparable. Laboratories have to determine local reference ranges for all parameters using the local instrument, specimen type, collection protocol, and reference subjects representative of their patient population.

3.3.2 Urine Testing Method

“U/C” without backlight signifies that the sample is serum.

The screen displays:

Sample		ID	
Num:	001	Get ID	Aspirate
			U/C
			Exit

3.3.2-1

For urine testing, press “U/C” and it will switch to “Urine”, indicating that the sample is urine. The screen displays:

Sample		ID	
Num:	001	Get ID	Aspirate
			Urine
			Exit

3.3.2-2

Press "Urine" again to switch to "CHYLE B", which indicates that the sample is whole blood or lipemic serum.

	Sample	ID	
Num:	001	Get ID	Aspirate
			CHYLE B
			Exit

3.3.2-3

Pressing "CHYLE B" again will switch back to "U/C".

The default type is "U/C" (serum). In "Urine" mode you have to pre-dilute the urine sample 1+1 and the instrument will calculate and print out the correct concentration itself.

In "Chyle B" mode the instrument will turn off the liquid positioner (sensor on left side of the electrodes). In this case you will have to position the liquid inside the tubing manually. Position the liquid in a way that there is no air inside electrode pathway, only liquid.

Notes:

1. Urine testing is possible for Na, K and Cl only.
2. For urine testing, only HUMAN urine diluent can be used, mixed with the urine sample in a 1+1 ratio.
3. For fully automated operation, the specimen types (serum, urine, chylous blood) can be pre-defined in the "W.list" menu.
4. For urine testing, the instrument aspirates 240 µl (after dilution) of sample. The testing time will be 6 seconds longer than for serum.

If the instrument is not operated for more than X minutes (depending on the setup), the screen will display Wake up, and the sample probe will lower. A few seconds later, the instrument will enter standby mode. To begin measuring samples again, press Wake up to activate the instrument. If the standby time is over 30 minutes, the instrument will perform a calibration automatically when it is called out of standby mode. The electrodes will be maintained during the standby time by automatic priming.

05-10-20
16:15:57
Wake up

3.3.2-4

3.3.3 Operation with Autosampler

Press **Sample** to enter the sample measurement menu; the screen displays:

Sample		
Tray Num	<input type="text" value="01"/>	<input type="button" value="QC 1"/>
First Num	<input type="text" value="01"/>	<input type="button" value="QC 2"/>
Last Num	<input type="text" value="20"/>	<input type="button" value="Eme. 1"/>
		<input type="button" value="Eme. 2"/>
	<input type="button" value="Start"/>	<input type="button" value="Exit"/>

3.3.3-1

Press the button after Tray Num and input the tray number.

Input the first sample number and last sample number in the same way. The first number can be any number between 1 and 20, while the last number should be between the first number and 20.

To measure controls, press **QC 1** and/or **QC 2**. The screen will show **QC 1√** and/or **QC 2√**. Before or after testing the samples, the instrument will measure the controls placed in positions "QC 1" or "QC 2" automatically. For example, if only **QC 1** is pressed, the instrument will measure the control in position "QC 1" before testing the samples. If only **QC 2** is pressed, the instrument will measure the control in position "QC 2" after testing the samples.

If emergency samples must be tested during the regular measurement procedure, they should be placed in position "E 1" or "E 2" on the sample tray. If there is only one emergency sample, it must be placed in position "E 1". Pressing **E 1** or **E 2** will display **E 1√** or **E 2√**. After measuring the current sample, the instrument will measure the emergency samples. When the measurement of the emergency samples finishes, "√" will disappear from the screen and the instrument will return to the measurement of the regular samples.

During the sample measuring procedure, **Exit** can be pressed at any time to quit. After finishing the measurement for the current sample, the instrument will return to the main menu.

Should the autosampler fail power off the instrument and disconnect the autosampler from the main unit. When the instrument is powered on again, it will automatically switch to stand-alone working mode. The instrument can then continue to operate without the autosampler.

3.3.4 Pre-analytics: Sample Collection and Handling

Sample collection and handling must be carried out by the professionals. Always avoid haemolysis. In addition, the following points should be noted:

1. The serum or plasma can be stored in the refrigerator, but they must be warmed to the room temperature before testing.
2. When preparing blood serum samples, do not add any materials such as surfactants that may interfere with the measurement or even damage the sensor.

3.3.5 Measurement of ionized Calcium and pH (Humalyte Plus 5 only)

General comments on the measurement of iCa and pH

In contrast to Sodium, Potassium, and Chloride, ionized Calcium and pH do not remain stable within patient- and artificial samples. Thus for measuring iCa and pH it is absolutely essential to respect pre-analytical steps and measuring conditions. Without these pre-conditions the concentration of iCa and pH in the sample will inevitably change and it is impossible to achieve meaningful results.

Blood collection procedure, pre-analytical handling, sample matrix, anti-coagulant, medication and other analytes have a significant influence on the concentration of iCa and pH in the sample and the ISE response. Centrifugation and measurement should be performed immediately after blood collection, contact of the sample with air should be avoided, and tubes are to remain tightly closed. [2] [4] [5] [6] [7]

Comparability of the results

Humalyte Plus 5 is measuring the pH and iCa in the sample under the actual conditions during the measurement (e.g. temperature). Many Blood Gas Analyzers pre-heat the sample to 37°C before the measurement. This is not the case for Humalyte Plus 5, which is an ISE analyzer for the clinical laboratory which operates at room temperature.

Humalyte Plus 5 with software version 5.5HE or above features additional mathematical functions that make results between the two different types of analyzers more comparable.

Laboratories anyway have to determine local reference ranges for all parameters using the local instrument, specimen type, collection protocol, and reference subjects representative of their patient population.

Quality control

Human recommends using Human QC Solution (REF 17470/70 and 17470/110) for the quality control of the instrument. Artificial control sera, including Humatrol N, Humatrol P, Serodos, and Serodos Plus, which do not have defined and stable concentrations of iCa are not suitable for the control of iCa. Though they may well be used for Na, K and Cl.

Results for ionized calcium using the new software 5.5HE (or above) will change slightly compared to 5.4HE. Target values for Human QC Solution (REF 17470/70 and 17470/110) will thus also change slightly.

New target values for ionized calcium for software version 5.5HE (or above):

The target value on the label of REF 17470/70 and 17470/110 corresponds to software version 5.4HE. The following table shows the unchanged target value for version 5.4HE and the new target values for version 5.5HE (or above). In both cases the range +/-0.1 mmol/l remains unchanged.

Target in mmol/l	5.4HE	5.5HE or above
iCa	1.3	1.33
iCa(7.4)	-	1.24

Please use these modified target values and the range indicated above in order to release the instrument for measurements of patient samples.

3.3.6 Stability of iCa and pH in specimen

Stability of pH (used for the correction of iCa results only)

Influencing factors that change the pH of the sample in-vitro are for example:

- pH rises linearly with the fall of temperature [3]
- Exposure of the sample to air (loss of CO₂) [2] [5]
- Glycolysis [5]
- Sample collection, handling, transport and storage (e.g. refrigeration, time)

Stability of ionized Calcium

Only 50% of the “total” blood Calcium (tCa) is free ionized Calcium (iCa). 5% are complex-bound (citrate, lactate, phosphate, bicarbonate), and 45% are protein-bound (albumin, globulin). [5]

A change of the concentration of the mentioned substances, but also the pH and added anticoagulants will change the ratio of iCa to tCa, thus changing the result of the measurement of ionized Calcium.

Influencing factors that change the concentration of iCa in the sample in-vitro are for example [2] [5]:

- pH alterations (and indirectly temperature, contact with air) [7]
- Binding of calcium by anticoagulant
- Sample dilution by anticoagulant
- Metabolism of blood cells or damage to the cells (hemolysis: K ↑ and iCa ↓)
- Sample collection, handling, transport and storage (e.g. refrigeration, time)

3.3.7 Acceptable patient samples and anticoagulant

The instrument is designed for clinical diagnosis of patient specimen in heparinized whole blood, plasma and serum samples.

Sodium and lithium heparin can be used [6]. Sodium heparin cannot be used for the evaluation of patient sodium level. The heparin concentration in a blood sample should be between 10 and not more than 20 IU per mL.

Specimen containers

Blood can be collected in glass or plastic tubes. Glass is an inert material impermeable to gases, thus glass tubes are suitable for sampling, storage, and transport of specimens for electrolyte determinations. Plastic materials are permeable to gases, thus plastic syringes cannot be considered as perfectly gas-tight. The permeability may cause a shift of the original values of pCO₂ and further affect the pH and iCa values. The degree of this shift is dependent on the material and the syringe design such as thickness of the wall, surface to volume relationship, and fitting of plunger and stopper, etc. Plastic syringes with tightly fitting plungers and stoppers are suitable for the determination of acid-base status (pH) and electrolytes if the storage interval is less than 30 min. To avoid remixing of the blood cells, it is recommended to use a gel separator tube (e.g. HumaTube Serum Gel-C/A (Z) Cat. No. 73030/12).

General requirements for sampling

Blood may be collected for electrolyte determinations under the following requirements:

- The sample has to be drawn and handled without contact with air in order to keep the gas tensions, pH, and the concentration of ionized calcium unchanged. Sample must be collected without air spaces or gaps in capillary. Pouring the liquid from one tube to another is not suitable [2].
- The sample must be anti-coagulated immediately and sufficiently in order to avoid the formation of clots which may obstruct the analytical instrument.
- Damage to the cells (hemolysis) must be avoided since hemolysis may cause an increase in potassium, and a decrease in ionized calcium.
- Immediate centrifugation (shift of Na-K-relation may occur) [7]

Storage of samples

The following limitations to storage time and conditions apply for the mentioned parameters.

It is always recommended that the sample should be refrigerated at 4°C or ice-water is used if the measurement of ionized calcium and pH is included. [6] [2] [8]

Whole blood

Temperature	Glass tube	Plastic tube
Room temperature (21°C)	Na, K: 2 hours Calcium, pH: 15 minutes	
4°C	K: 1 hour Calcium, pH: 2 hours	K: 1 hour Calcium, pH: 30 minutes
Ice-water bath	K: 1 hour Calcium, pH: 2 hours	K: 1 hour Calcium, pH: 30 minutes

Serum and plasma

Temperature	Glass or plastic tube
Room temperature (21°C)	Na, K, Calcium, pH: 12 hours
4°C	Na, K, Calcium, pH: 24 hours

Aspirate sample

Samples need to reach room temperature before starting the measurement. It is always recommended to aspirate sample from the middle of the solution in the tube for measurements.

3.4 Calibration

When systematic bias errors (results are always too low or too high) exist, the factors can be adjusted using the Cal. function. NOTE: All system malfunctions should be excluded before using the function. A calibration will be performed using an external calibrator and the calculated factors will be stored automatically. It is not necessary to use this function on a daily base, as the system automatically calibrates in fixed intervals using the internal calibrators.

Press **Cal** in the main menu; the screen displays:

Target

K: 0.00

Na: 0.0

Cl: 0.0

Cal. Exit

3.4-1

Press the button after K; the screen displays:

K:

1 2 3

4 5 6

7 8 9

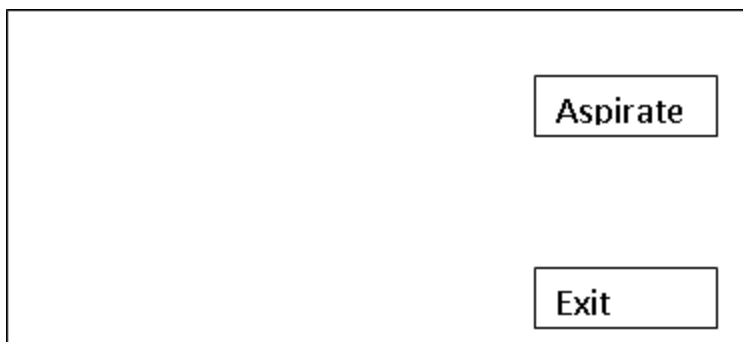
./- 0 cls

Yes Exit

3.4-2

Enter the target value for K and press **Yes** to save.

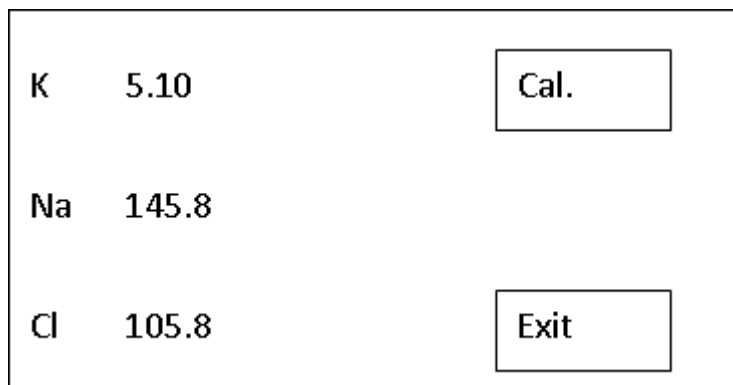
Enter the Na and Cl target values in the same way. When all target values have been entered, press **Cal**; the screen displays:



The screenshot shows a rectangular screen with two buttons on the right side. The top button is labeled 'Aspirate' and the bottom button is labeled 'Exit'.

3.4-3

Place the control under sample probe and press **Aspirate**, the instrument aspirates the control and tests it. After a few moments, the screen displays:

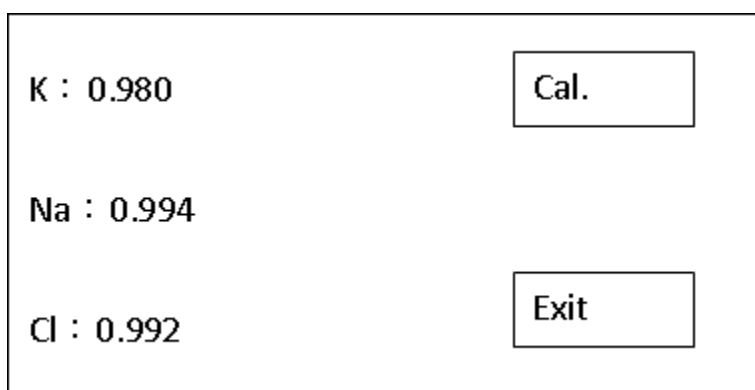


The screenshot shows a rectangular screen with three rows of text on the left and two buttons on the right. The first row shows 'K' followed by '5.10'. The second row shows 'Na' followed by '145.8'. The third row shows 'Cl' followed by '105.8'. The top button is labeled 'Cal.' and the bottom button is labeled 'Exit'.

3.4-4

The values displayed on the screen are calibrated values (calibrated value = actual measuring value * current factor). If necessary, press **Cal** to calibrate and obtain other factors; otherwise press **Exit** to quit.

After calibration, the screen displays the new factors:



The screenshot shows a rectangular screen with three rows of text on the left and two buttons on the right. The first row shows 'K : 0.980'. The second row shows 'Na : 0.994'. The third row shows 'Cl : 0.992'. The top button is labeled 'Cal.' and the bottom button is labeled 'Exit'.

3.4-5

The new factors will also be printed out if printing is activated.

3.5 W. List

To input the work list, press **W. List** in the Main Menu; the screen displays:

Sample Number

Num 001

ID00000000000000000000

Num▲

Num▼

Exit

3.5-1

Press **Num▲** or **Num▼** to increase or decrease the sample number. The number can also be changed by pressing the button after Num. The screen displays:

Num:

1 2 3

4 5 6

7 8 9

./- 0 cls

Yes Exit

3.5-2

Enter the sample number and press **Yes** to save.

To change the patient ID number using a barcode reader, scan the barcode on each sample tube, one by one. After each tube is scanned, the ID will be displayed after "ID", and the number will be increased automatically.

Note: In the definition of the type and number of samples in the "W.list" menu, you should first select the type of sample (if necessary - the default sample setting is serum), and then enter or scan the sample number. When the number changes, the instrument will automatically switch to the next sample.

To change the patient ID number manually, then press the button **Get ID**; the screen displays:

The screenshot shows a screen titled "ID:". Below the title is a 4x3 grid of buttons. The first three rows contain digits 1 through 9. The fourth row contains a decimal point followed by a hyphen (./-), the digit 0, and the text "Cls". Below this grid are two buttons: "Yes" and "Exit".

1	2	3
4	5	6
7	8	9
./-	0	Cls
Yes		Exit

3.5-3

Enter the ID number and press **Yes** to save.

3.6 Measure STD

This program calibrates the slope of the electrode. The procedure is same as for "section 3.2 Startup and Self-Test".

Press **STD**; the screen displays:

The screenshot shows a screen with three buttons arranged vertically. The top button is labeled "Sel. ISE", the middle button is labeled "Sel. AB", and the bottom button is labeled "Exit".

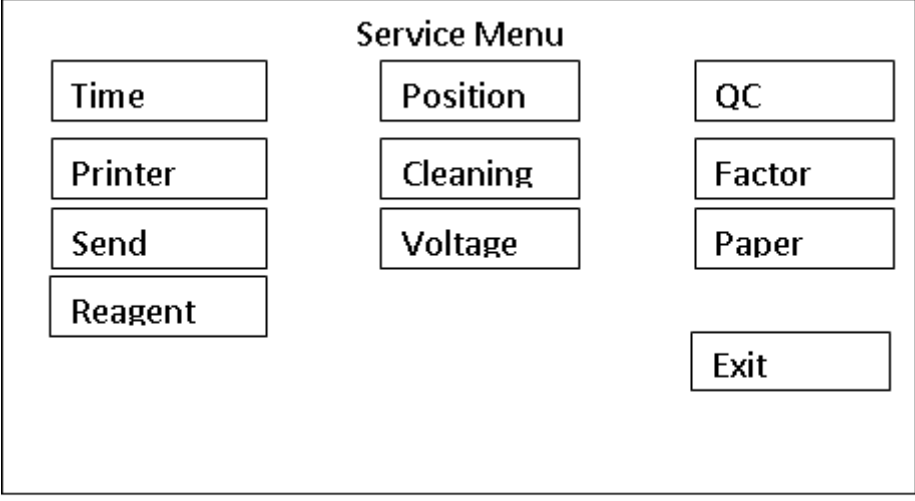
Sel. ISE
Sel. AB
Exit

3.6-1

Press **Sel. ISE** to calibrate the slope of the K/Na/Cl/Ca electrode. The calibration procedure is same as for "section 3.2 Startup and Self-Test".

3.7 Service

The instrument has a comprehensive set of service programs. Press **Service** in the main menu; the screen displays:



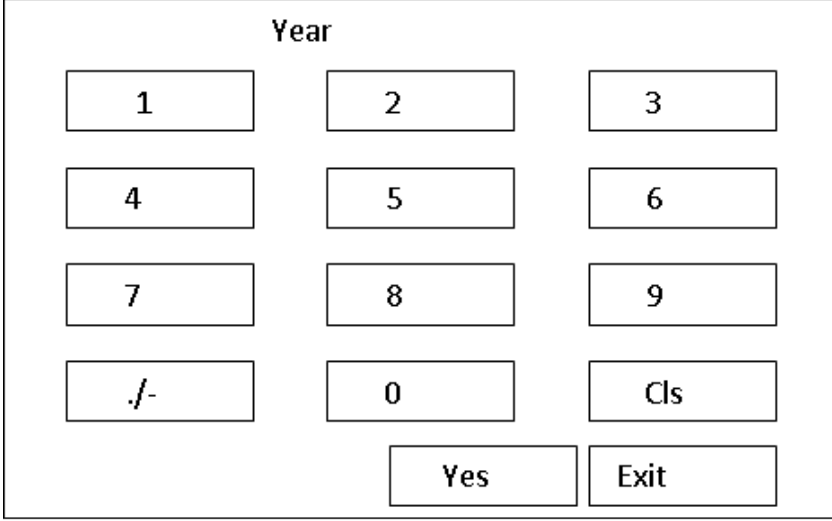
The Service Menu screen displays a grid of buttons for various service programs. The buttons are arranged in three columns. The first column contains Time, Printer, Send, and Reagent. The second column contains Position, Cleaning, and Voltage. The third column contains QC, Factor, Paper, and Exit.

Service Menu		
Time	Position	QC
Printer	Cleaning	Factor
Send	Voltage	Paper
Reagent		Exit

3.7-1

3.7.1 Change Date and Time

Press **Time**; the screen displays:



The Year selection screen displays a grid of buttons for selecting the year. The buttons are arranged in four rows and three columns. The first three rows contain digits 1 through 9. The fourth row contains a decimal point followed by a hyphen, 0, and Cls. Below the grid are two buttons: Yes and Exit.

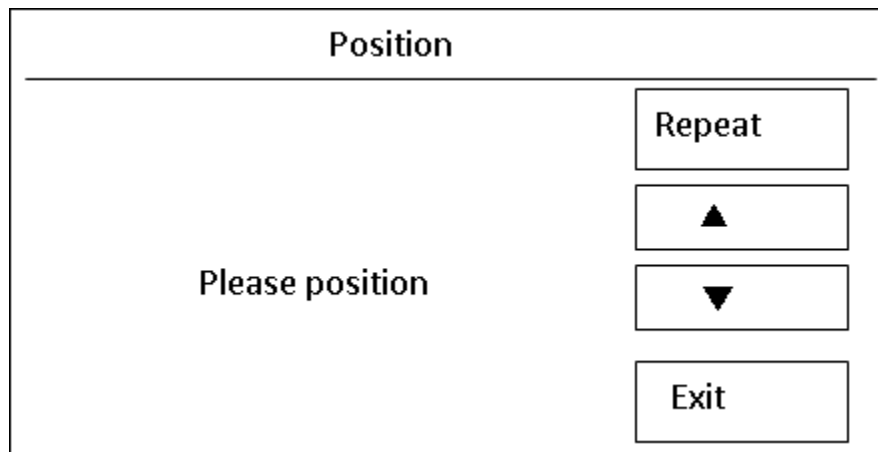
Year		
1	2	3
4	5	6
7	8	9
./-	0	Cls
Yes		Exit

3.7.1-1

Enter the value for "Year". Press **Yes** to save. Set the month, date and time in the same way.

3.7.2 Position

This program is to set up the correct aspiration volume. Press **Position** and the instrument will aspirate the liquid. The screen displays:



The screenshot shows a rectangular screen with a black border. At the top, the word "Position" is centered in a bold font. Below this, the text "Please position" is centered. On the right side of the screen, there are four rectangular buttons stacked vertically. The top button is labeled "Repeat". The second button contains an upward-pointing triangle. The third button contains a downward-pointing triangle. The bottom button is labeled "Exit".

3.7.2-1

Check for the correct liquid level: the liquid surface should be about 2cm away from the inlet of the electrode assembly. Press **▲** to increase the aspirating volume if the liquid level is too low, press **▼** to decrease the aspirating volume if the liquid level is too high.

This program should be run after any service performed.

The above operation can be skipped if the instrument has a positioner (fluid position sensor) installed.

However, if the positioner is defective, the instrument will use the parameter obtained with the above operations. For this reason, running this program is recommended whenever a new instrument is installed.

3.7.3 Quality Control

Quality Control Solution (see section 8.1 Consumables and accessories) is used to verify the good function of the instrument. It is very sensitive to contamination or evaporation. If you are using the 100ml bottle of QC Solution, work with a clean pipette, close the lid immediately after use, do not aspirate directly from the bottle, store the open bottle in a refrigerator, and respect the usage time. To avoid these problems we suggest using QC Solution supplied in 2ml ampoules. Target values are marked on the packaging of the QC Solution. See also chapters 3.3.5 and 4 for information concerning quality control of iCa and pH.

To run the QC program, press **QC**; the screen displays:

Q C	
	Aspirate
	Stat.
	Lot No.
	Exit

3.7.3-1

To enter a new Lot number, press **Lot No.**; the screen displays:

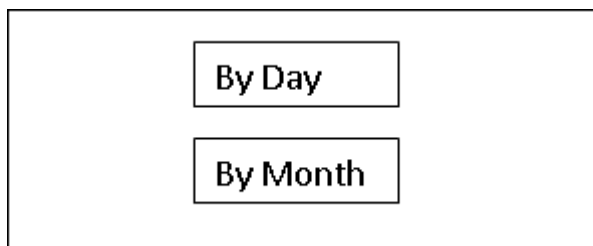
Lot No.		
1	2	3
4	5	6
7	8	9
./-	0	cls
Yes		Exit

3.7.3-2

Enter the new lot number (8 digits, e.g. 0000H023), press **Yes** to save.

Note: All QC data stored in the instrument will be deleted automatically when a new lot number is entered!

Place the control under sample probe and press **Aspirate**. The control will be aspirated into the system for measuring. (For autosampler models, the control should be placed in position “QC1” on the sample tray.) The result will be displayed and printed out within 60 seconds. When there are 5 or more QC results (up to 220), a statistical report can be obtained. Press **Stat**; the screen displays:



3.7.3-3

Press **By Day** to display a statistical report including mean value (Mean), standard deviation (SD) and coefficient of variation (CV %).

	Mean	SD	CV	
K	5.01	0.03	0.60	
Na	145.2	0.51	0.41	
Cl	105.5	0.35	0.30	
Ca	1.31	0.03	0.29	
				Exit

3.7.3-4

The report will also be printed out as below:

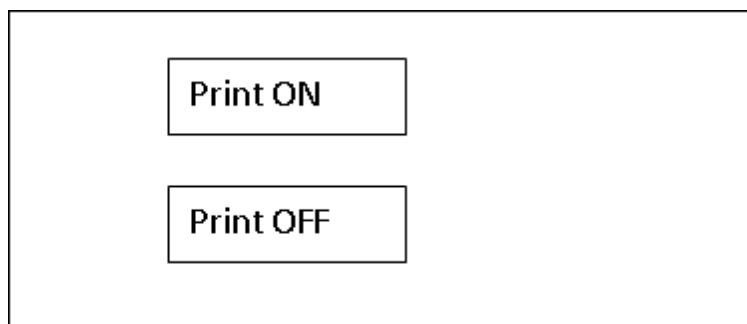
STATISTIC REPORT
 TIME: 2009-09-30 11:23
 Lot No: 00000000000020050330 (only the last 8 digitals are valid)

ITEM	Mean	SD	CV(%)
K	5.01	0.03	0.60
Na	145.2	0.51	0.41
Cl	105.5	0.35	0.30
Ca	1.31	0.03	0.29
N=10			

Press **By Month** to print out a statistical report for all of the last QC results of each day.

3.7.4 Printer

Press **Printer**; the screen displays:



3.7.4-1

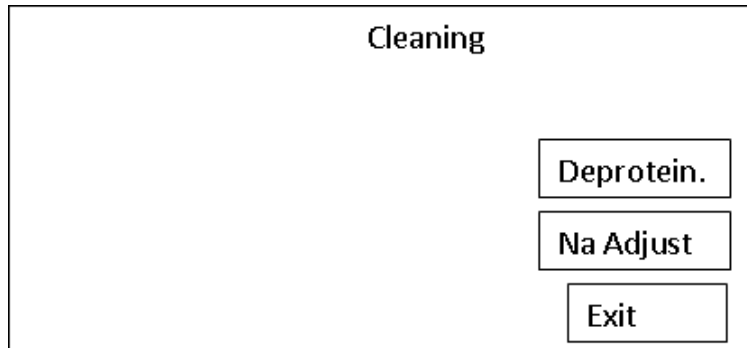
Press **Print ON** to enable the printer, press **Print OFF** to disable the printer.

3.7.5 Cleaning the instrument and Na-Conditioner

This chapter explains the use of the Daily Cleaning Solution, the Weekly Cleaning Solution and the Na-Conditioner.

Under normal condition it is sufficient to clean the instrument using the Weekly Cleaning Solution once a week. The Daily Cleaning Solution should only be used if you are measuring whole blood or lipemic samples. For Daily and Weekly Cleaning Solution you use the option “Deprotein” in the “Service”-“Cleaning”-menu. The Na-Conditioner has to be used if the slope of Sodium is below 50. Please use the option “Na Adjust” for this purpose. The procedure takes only a few minutes and is very similar for all three solutions. You press the respective cleaning option in the menu and the needle will aspirate the respective solution and clean the instrument automatically. The consumption of the respective solution is stated in the table below.

Press **Cleaning**; the screen displays:

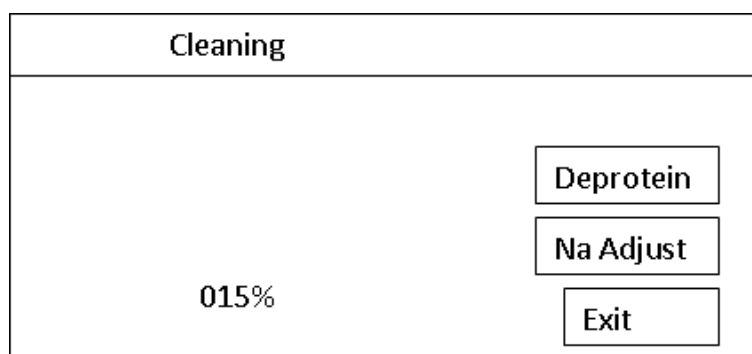


3.7.5-1

For autosampler models, the cleaning solution should be placed in the position “Calib” on the sample tray.

For Daily and Weekly Cleaning Solution use **Deprotein**.

Press **Deprotein** to display **Aspirate** on the screen. Place the cleaning solution under sample probe. Press **Aspirate** to aspirate the cleaning solution into the instrument. After aspiration, **Aspirate** disappears from the screen and the percentage progress is displayed:



3.7.5-2

The whole process will take about 5 minutes.

To “re-condition” the Na filling solution inside the electrode use Na-Conditioner and the option **Na Adjust**.

Press **Na Adjust**, the screen displays **Aspirate**. Place the Na conditioner under sample probe. Press **Aspirate** to aspirate the Na conditioner into the instrument. After aspiration, **Aspirate** disappears from the screen and the percentage progress is displayed.

It takes about 1 minute to finish the “Na Adjust” program. The Na slope should be above 50 for the electrode to be in the best working condition which can prolong the using time of the electrode.

Note: Run the “Na adjust” program when the Na slope is less than 50.

Item	Approximate consumption
Na conditioner	430μl per conditioning cycle
Daily Cleaning Solution	1300μl per cleaning cycle
Weekly Cleaning Solution	1300μl per cleaning cycle

If you are planning not to use the instrument for more than one week, you should drain the fluidic system. Please pull out the Reagent Pack approximately 2cm and perform a “STD” calibration (option “STD” in the main menu). The instrument will aspirate air instead of standard solution from the Reagent Pack, thus draining the fluidic system.



Falsely using the Weekly Cleaning Solution for everyday cleaning will lead to a deterioration of the life time of the electrodes!

3.7.6 Factor

You can manually define a slope (a) and an intercept (b) to achieve correlation to a reference instrument. The slope can also be changed by using the “Cal.”-function in the main menu.

To change the calibration factors manually, press **Factor**; the screen displays:

	a	b
Exit	K:	x1.000 +0.000
	Na:	x1.000 +0.000
	Cl:	x1.000 +0.000
	Ca:	x1.000 +0.000

3.7.6-1

Note: a – slope, b – intercept

Select the item to be changed, for example K; the screen displays:

K: a		
1	2	3
4	5	6
7	8	9
/-	0	cls
Yes		Exit

3.7.6-2

Enter the new slope value (a) and press **Yes** to save; the screen displays:

K: b		
1	2	3
4	5	6
7	8	9
./-	0	cls
Yes		Exit

3.7.6-3

Enter the new intercept value (b). Press **Yes** to save.

3.7.7 Data Transfer

Press **Send**; the patient results will be transferred using the serial port on the back of the instrument. Be aware that this is not a standardised protocol and no program is provided by Human to be installed on a host computer. If you wish to use this data, please ask a computer specialist to provide help with the RS-232 data received from the instrument.

3.7.8 Voltage

Press **Voltage** to check the potential of each electrode:

Voltage	
	Aspirate
	Exit

3.7.8-1

Press **Aspirate** to aspirate a sample and check the voltages. For autosampler models, place the sample in the position "Calib" on the sample tray.

The screen displays the voltages (in mV) every two seconds:

Voltage	
K :	57.03
Na :	73.25
Cl :	61.30
Ca :	25.12
PH :	140.9
Phot. :	1510
<div>Exit</div>	

3.7.8-2

Press **Exit** to quit.

Check the performance of the electrodes using this program. For standard A or control, the normal values of K, Na and Cl should be approx. 50.

If the values of K, Na and Cl are all smaller than 20, the most likely causes are a too-low level of reference filling solution or an aging reference membrane. Add filling solution or replace the reference membrane.

3.7.9 Feed Paper

Press **Paper** to feed the printing paper.

3.7.10 Reagent

To check the residual volume of the reagents, press **Reagent**. The screen displays:

Std A : 650 ml
Std B : 280 ml
<div>Refill</div> <div>Exit</div>

3.7.10-1

The residual volume of the reagents will be displayed on the screen. When loading a new reagent pack, press **Refill**. The screen displays:

PSW:

1	2	3
4	5	6
7	8	9
./-	0	cls
Yes		Exit

3.7.10-2

Enter the password: 123 and press **Yes** to confirm or **Exit** to quit; then the screen displays:

Std A : 650 ml

Std B : 350 ml


Refill


Exit


3.7.10-3

The residual volume of the reagents has been reset successfully.

Note:

- 

1. When the icon appears on the main menu screen, this indicates that the remaining reagents are sufficient to run approx. 150 samples.
- 

2. When the icon appears on the main menu screen, the remaining reagents are sufficient to run only approx. 20 samples.
- 

3. When the icon appears on the main menu screen, the reagents have run out.

3.7.11 Choosing the parameters you want to display (Humalyte Plus 5 only)

With software version 5.5HE and the standard settings of the instrument iCa(7.4) and pH (used for correction of iCa results only) will be displayed and printed. The iCa(7.4) actually is comparable to the old iCa of software version 5.4HE. If you wish to also display and print iCa, pH(37) and tCa, contact your local distributor to set up the instrument accordingly.

3.8 Result Review

The instrument stores patient results for review.

Press **Results**; the screen displays:

Results ID		000000000 000000000
K : 5.03	PH : 7.56	Num 001
Na : 145.5		▲
Cl : 105.2		▼
Ca : 1.30		Print
	All	Exit

3.8-1

To review the results by sample number, press **Num 001**, the screen displays:

Num		
1	2	3
4	5	6
7	8	9
./-	0	cls
	Yes	Exit

3.8-2

Input the sample number and press **Yes**; the corresponding result will be displayed on the screen. You can also press **▲** or **▼** to change the sample number.

Press **Print** to print out the sample results.

Press **All** to print out all sample results. If there is no data stored, the screen will display “No data”.

Note: To print out results, the printer should be enabled first. Refer to section 3.7.4.

The printing format is the following:

```
001 PAT ID: 000000000000000000
5.09    145.3    105.3    1.31    7.56    0.1
002 PAT ID: 000000000000000001
5.09    145.3    105.3    1.31    7.56    0.1
003 PAT ID: 000000000000000002
5.09    145.3    105.3    1.31    7.56    0.1
```

3.9 Reagent consumption

Reagent consumption of the HumaLyte Plus greatly depends on the use of the instrument.

The “Reagent” Pack contains two solutions that are used to calibrate the instrument: Standard A (Std. A, 650ml) and Standard B (Std. B, 350ml)

In order to assure valid results, the instrument has to calibrate regularly. The number of calibrations the instrument has to perform will determine the number of samples you can measure with one Reagent Pack, because the calibration will also consume reagent.

- a) When turning on the instrument, it will perform a triplet of two point (Std. A and Std. B) calibrations. This Start-Up-Calibration will consume 7.26ml of Std. A and 3ml of Std. B.
- b) When the instrument is not used it will fall into a sleeping mode (*). If you wake up the instrument within the next 30 minutes, the Small-Wake-Up-Calibration will consume 0.19ml of Std. A.
- c) If you wake up the instrument later than 30 minutes after going into sleeping mode, the Big-Wake-Up-Calibration will consume 2.13ml of Std. A and 1.39ml of Std. B.
- d) During sleeping mode (stand-by) the instrument will automatically rinse the electrodes every 4 hours. This maintenance of the electrodes will consume 2.3ml of Std. A and 1.4ml of Std. B.
- e) When you perform a manual calibration by pressing the “STD” option in the main menu, the Manual-Calibration will also consume 2.13ml of Std. A and 1.39ml of Std. B.
- f) The measurement of a sample will consume 0.45ml of Std. A and 0ml of Std. B (one point calibration with every measurement).

(*) You may change the time before the instrument falls into sleeping mode (please refer to your local service engineer in order to do this).

Based on the numbers given above, the following table gives an approximation of how many samples you can measure with one Reagent Pack.

Number of samples per day	Number of samples per Reagent Pack
5	100-190
10	200-350
20	350-550
50	600-850
100	850-1050

What will most influence the consumption of reagent is:

- The number of samples you measure per day
- The number of samples you measure in one batch (e.g. 30 samples in the morning and 30 samples in the afternoon will consume a lot less reagent than measuring 20 times a day but only 3 samples per batch)

4 Precautions

4.1 Operation Precautions

1. The analyzer is designed to work continuously for 24 hours a day. There is no need to shut down the machine every day. It is important that the membranes of the electrodes are humidified regularly by the automatic rinse function of the analyzer. Shutting off the analyzer during the night or during a weekend will result in a decrease of the electrodes life time and usage time.
2. Do not use standard solutions intended for use with flame luminosity. They contain strong acid and other supplements that may damage the electrodes.
3. Not all commercial controls are suitable for ISE measurement. Some contain too many chemical additives that may interfere with the measurement. Especially HumaTrol N, HumaTrol P, Serodos, and Serodos Plus, which do not have defined and stable concentrations of pH and iCa are not suitable for the control of iCa and pH. Though they may well be used for Na, K and Cl. Please refer to the leaflet of the respective control.
4. Bubbles should be prevented during sample aspiration; otherwise the results will be unreliable.
5. When the sample reaches the testing point, make sure there are no bubbles in it; otherwise the sample should be run again.
6. If the ambient temperature fluctuates by more than 5°C, the instrument should be calibrated again.
7. The pH value of the standard solutions and the samples should be within a range of 6 to 9, otherwise the measurement of sodium ions may be inaccurate.
8. Discard the reagent if it becomes mouldy or a deposit forms.
9. Perform the routine maintenance according to the instructions.

4.2 Safety Precautions

1. The electric voltage inside the instrument is hazardous. Do not open the instrument before disconnecting it from the power supply.
2. Because the samples may contain pathogenic bacteria or viruses, all replaced tubes, electrodes and waste containers should be discarded according to the safe laboratory procedures and government regulations.
3. The reagents are irritating to eyes, skin and the lungs. Wear proper personal protective equipment (e.g. gloves, lab coat, etc.) and follow safe laboratory procedures when handling them in the laboratory.
4. The reagents are irritating to the skin. In the case of skin contact, wash the skin with plenty of water and, if irritation persists, see a doctor.
5. *If the reagents come into contact with the eyes, flush them with plenty of water and see a doctor immediately.*

5 Maintenance

5.1 Daily Maintenance

Monitor the residual reagent volume and replace the reagent pack when necessary.

Run the cleaning program in the service menu every day, using “Daily Cleaning Solution”, if you measure whole blood or lipemic samples. Please refer to section 3.7.5.

5.2 Weekly Maintenance

1. Check to ensure that the internal filling solution level of each electrode is sufficient. Add filling solution if the level is less than 2/3 of the total volume.
2. Check if there is a salty crust on the electrode, if so, remove it with a moist cloth.
3. Check if the sample aspiration volume is correct. If necessary, adjust the pump according to section 3.7.2.
4. Run the cleaning program in the service menu once a week if more than 25 samples are measured every day. If fewer than 20 samples are measured per day, the cleaning program needs to be run only every 2-3 weeks. Please refer to section 3.7.5.
5. Run the “Na adjust” program if the slope of Na electrode is less than 50. Please refer to section 3.7.5.
6. Check the voltage of each electrode. If necessary, replace the reference filling solution or reference membrane. Please refer to section 3.7.8.

5.3 Spare Parts Replacement

Check the following parts periodically:

1. Pump tube
2. Aspirating tube
3. Connecting tubes
4. Valve
5. Internal electrodes

Replace worn parts.

5.4 Check the Tubing System

If the aspirating speed and volume is abnormal, check the tubing system to see if there is any leakage.

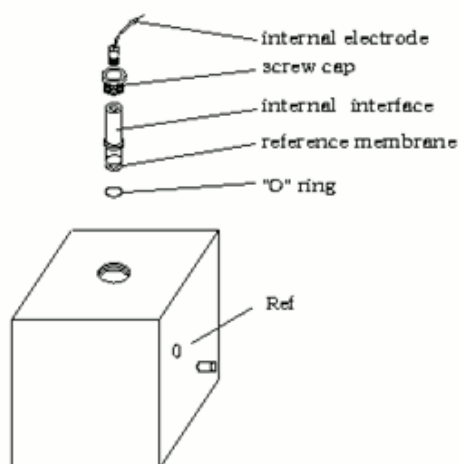
1. Run the calibration program.
2. Check the flow inside the electrode assembly.
3. Check the flow inside the tubing system.
4. The normal condition is a long section of air followed by a long section of liquid. If the tubing connection is loose, bubbles can be found near the connector. Reconnect the tubing.
5. If there is a leak anywhere between the electrodes, disassemble the electrodes and check the gaskets (O-rings).
6. If the tubes are tightly connected, check if there is any blockage.
7. Replace the pump tube if it is seriously distorted, otherwise the aspiration volume will not be sufficient.

5.5 Replace the Electrode

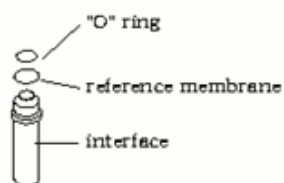
1. Pull out all of the electrode wires from the plugs. Remove the tubes from the inlet and outlet of the electrode assembly.
2. Loosen the fixing nuts of the electrode assembly.
3. Disassemble the whole electrode assembly.
4. Discard the electrode to be replaced.
5. Take a new electrode and add the filling solution.
6. Assemble the electrodes in the correct order. Make sure that the rubber gaskets are in right position.
7. Tighten the fixing nuts of the electrode assembly.
8. Connect the tubing. Insert the electrode wires back to the plugs.
9. Calibrate the instrument.

5.6 Replace the Reference Membrane

If you experience a problem (e.g. unstable or abnormal slopes) for **all** parameters, it is probably due to the reference electrode. It is usually not necessary to replace the complete electrode, because you can maintenance the electrode yourself. First check the cable connection and replace the filling solution of the electrode. If unsuccessful replace the reference membrane as described in the user manual. In most cases this will solve the problem and you don't have to replace the whole electrode.

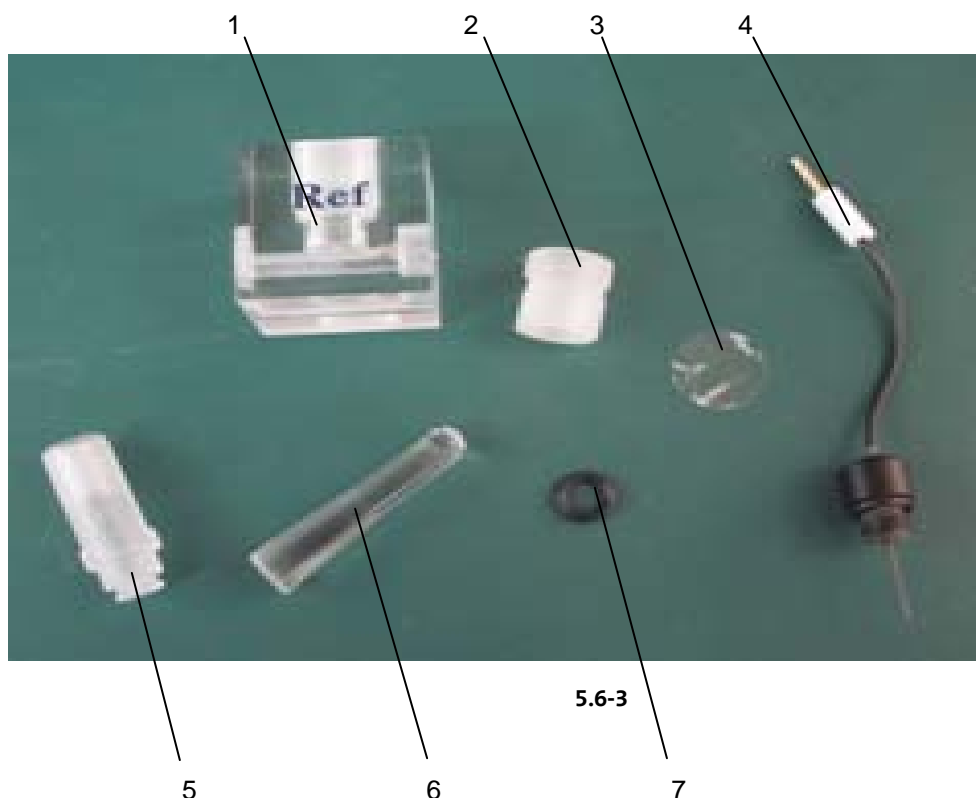


5.6-1



5.6-2

Reference electrode components are shown in the following figure:



5.6-3

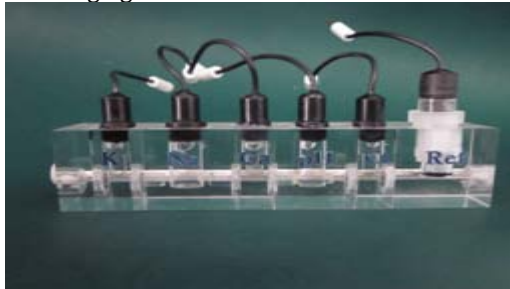
1. Ref 2. Screw cap 3. Reference membrane 4. Internal electrode
5. Internal interface 6. Interface (Ref. membrane fitting tool) 7. O-ring

1. Open the instrument front door and pull out all the electrode wires from the plugs. Remove the tubes from the inlet and outlet of the electrode assembly. See the following figure:

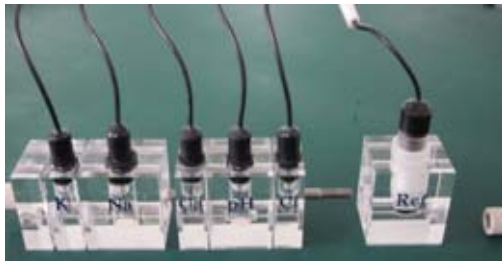


5.6-4

2. Loosen the fixing nuts of the electrode assembly and take out the reference electrode. See the following figures:



5.6-5



5.6-6

3. Disassemble the reference electrode: Loosen the screw cap, take out the internal electrode, and remove the filling solution, the O-ring and the old reference membrane. Clean the internal interface and Ref with distilled water, and wipe it with clean cotton or tissue.
4. Soak a new reference membrane in the distilled water.
5. Place the O-ring on the interface as shown in the following figure.



5.6-7

6. Place the new reference membrane evenly on the internal interface See the following figure:



5.6-8

7. Connect the interface with the internal interface and pull the 'O' ring onto the internal interface. See the following figure:



5.6-9

8. Remove the interface. Make sure that the reference membrane is smooth and not damaged. See the following figure:



5.6-10

9. Insert the internal interface into Ref-block without damaging the new reference membrane. Tighten the screw cap. See the following figure:



5.6-11

10. Fill the internal interface with reference filling solution using a pipette or syringe (up to 2/3 of the total volume avoiding to damage the membrane and without any bubbles on the bottom)
11. Screw in the internal electrode. If there is any filling solution overflowing, wipe it with clean tissue. Otherwise, it will produce white salt crystals after evaporation of water.
12. Re-assemble the electrodes in correct order, tighten the fixing nuts, and then connect the tubing to inlet and outlet. Insert all the wires into the plugs. Run calibration again.

Notes: The instrument may give "Error" signals in the first calibration after replacement of the membrane. In this case, perform calibrations for several more times and the results will be good. If the results are still not good after several calibrations, check as following:

- 1- Check whether the reference membrane is properly replaced. Replace it again if necessary.

- 2- Check whether the reference filling solution is invalid or contaminated. Replace with new reference filling solution if necessary.
- 3- Check whether there are bubbles at the bottom of the reference electrode. Get rid of the bubble if there is any on the bottom.
- 4- Check the internal electrode and make sure its coating doesn't flake off. Change it if necessary.

6 Error Code

6.1 Printed Error Code

Code	Description
Error 0#	Liquid positioning failed
Error 1#	Liquid detection failed
Warn 2#	Bubbles detected
Error 3#	Too much or too little sample aspirated
Error 4#	Slope abnormal
Error 5#	Slope unstable

6.2 Displayed Error Code

Code	Description
1# ("Sensor Error")	Liquid distribution valve failed. Please check if the black disk inside the distribution valve is turning. In case it is not turning please ask an engineer to clean the valve from the inside using distilled water.
2#	Elevator switch failed
3#	Optical coupler for the sample tray home failed
4#	Optical coupler for the sample tray cup failed

7 Troubleshooting

7.1 Slope unstable

Cause	Recommended solution
Unreliable grounding	Check the connection of the grounding wire
No standard A or standard B aspirated	Check and replace Standard A or B; Check the tubing connection
Incorrect positioning of the standard solution	Adjust position again
The reference filling solution or reference membrane is not working	If the problem (unstable or abnormal) occurs for all parameters there is a problem with the reference electrode. Check cable connection and replace filling solution. If unsuccessful replace the reference membrane as described above.
The internal electrode turns gray	Replace when necessary
Poor connection of the electrode wire	Check and connect again
Electrode membrane leaks	Replace when necessary
Power supply voltage fluctuates	Use UPS or power stabilizer
Humidity too high	Lower the humidity or move the instrument to a dryer place
Bubbles inside the tubing	Check the tubing system
Liquid leakage inside the valve	Replace gasket or valve when necessary
The electrode is not activated or the activating time is insufficient	Activate the electrode first
Reference membrane defective	Replace the reference membrane

7.2 Slope abnormal

Cause	Recommended solution
Too many organic deposits on the electrode membrane	Clean the instrument with Weekly and/or Daily Cleaning Solution
Reagent contaminated	Replace the reagent
Insufficient filling solution	Add filling solution
Electrode does not work	Replace the failed electrode
Bubble at the bottom of the electrode	If an air bubble is stuck at the bottom of an electrode, remove the complete electrode set and tap it carefully on the table.
Dust or moisture around the electrode or plug	Clean and dry the electrode and plug
Tubing blocked	Crystallization may block the tubing. Please watch and check if the liquid is flowing in all tubes. If a tube is blocked, disconnect and clean it using a pipette and distilled water.

7.3 Aspiration abnormal

Cause	Recommended solution
Aspirating tube loose or broken	Connect again or replace

Pump tube sticks	Replace the tubing
Pump tube broken	Replace the tube
Pump tube blocked	Clear the blockage
The gasket between the electrodes is not aligned properly or is missing	Align the gasket properly or replace if necessary
The electrode assembly leaks	Tighten the assembly again
Dust on the liquid sensor or sensor is damaged	Clean or replace

8 Appendix

8.1 Consumables and accessories

REF	Description
17470/11	K - electrode
17470/12	Na - electrode
17470/13	Cl - electrode
17470/14	Ca - electrode
17470/15	pH - electrode
17470/17	Reference electrode
17470/18	Internal electrode
17470/19	Reference membrane (10 pcs)
17470/82	Reagent Pack HumaLyte Plus 3 (1000ml/pcs)
17470/83	Reagent Pack HumaLyte Plus 5 (1000ml/pcs)
17470/70	QC solution (100ml/bottle)
17470/110	QC solution (10 x 2ml ampoules)
17470/71	Daily Cleaning Solution (100ml/bottle)
17470/72	Weekly Cleaning Solution (100ml/bottle)
17470/74	K filling solution (100ml/bottle)
17470/75	Na/Cl/pH filling solution (100ml/bottle)
17470/76	Ca filling solution (100ml/bottle)
17470/78	Ref. filling solution (100ml/bottle)
17470/79	Na conditioner (100ml/bottle)
17470/86	Urine diluents (100ml/bottle)
17470/41	Aspirating tube
17470/42	Peristaltic pump tube
17470/91	Connection tube
18144/5	Thermal paper (5 pcs.)
17470/30	Autosampler for 20 sample cups
17470/59	Sample cup 2.0 ml for Autosampler (500 pcs)

8.2 Autosampler (REF 17470/30)

The autosampler is an optional accessory that has to be ordered separately. The following items are included in the delivery of the optional autosampler.

REF	Qty	Unit	Description	Comment
-	1	pcs.	Main unit	
17470/31	2	pcs.	Autosampler tray	
-	1	pcs.	Connection cable	
17470/32	1	pcs.	Bottom plate	
17470/59	1	Set	Sample cups (60 pcs. only)	
17470/71	1	pcs.	Daily cleaning solution	

8.3 Shelf life and consumption

Item	Unit	Shelf Life (*)	Storage Conditions	Usage Time (*)
Sodium Electrode	1 pc	24 months	5 ... 30°C	12 months
Potassium Electrode	1 pc	12 months	5 ... 30°C	6 months
Chloride Electrode	1 pc	12 months	5 ... 30°C	6 months
Calcium Electrode	1 pc	12 months	5 ... 30°C	6 months
pH Electrode	1 pc	24 months	5 ... 30°C	12 months
Reference Electrode	1 pc	24 months	5 ... 30°C	12 months
Reference membrane	10 pcs	24 months	5 ... 35°C	6 months
QC Solution	100ml	24 months	5 ... 8°C open 5 ... 35°C closed	2 months
QC Solution	2ml	24 months	5 ... 8°C open 5 ... 35°C closed	1 day
K Filling Solution	100ml	24 months	5 ... 35°C	12 months
Na/Cl/pH Filling Solution	100ml	24 months	5 ... 35°C	12 months
Ca Filling Solution	100ml	24 months	5 ... 35°C	12 months
Ref. Filling Solution	100ml	24 months	5 ... 35°C	12 months
Na Conditioner	100ml	24 months	5 ... 35°C	12 months
Urine Diluent	100 ml	24 months	5 ... 35°C	2 months
Daily Cleaning Solution	100ml	24 months	5 ... 35°C	12 months
Weekly Cleaning Solution	100ml	24 months	5 ... 35°C	12 months
Reagent Pack	1 pc	18 months	5 ... 35°C	4 months

(*) Usage Time is the estimated minimum time you are able to use the item, starting from the point of time when you install/open the item. (For Filling Solutions the Usage Time specifies the time you can use an open bottle to refill the electrodes.) Shelf Life is the life time of the item, starting at the production date and ending at the expiry date, even if the item remains unused.



Electrodes are consumables! They have to be replaced on a regular basis! Plan to replace the electrodes according to the Usage Time stated in the table above.

8.4 Specifications

System overview	Analyzer type:	Stand-alone ISE Electrolyte Analyzer
	Principle:	Direct measurement by Ion Selective Electrode (ISE)
	Measured parameters:	Humalyte Plus 3: Na ⁺ (sodium) K ⁺ (potassium) Cl ⁻ (chloride) Humalyte Plus 5: Na ⁺ (sodium) K ⁺ (potassium) Cl ⁻ (chloride) iCa ⁺⁺ (ionized calcium) pH (used for correction of iCa results only) tCa (calculated value) iCa(7.4) (calculated value) ph(37) (calculated value, used for correction of iCa results only)
	Sample type:	Serum, plasma (heparin 10 – 20 U/ml), whole blood (heparin 10 – 20 U/ml), diluted urine
	Throughput:	Up to 60 samples/hour
	Sampling:	Manually through aspiration needle or optional Autosampler (with STAT)
	Operation Modes:	Standard mode: Daily use operation; QC mode: QC measurement for statistical interpretation (two levels)
Measurement	Sample volume:	150 µL
	Measuring range (serum, plasma, whole blood):	
	K ⁺	0.50 – 15.00 mmol/L
	Na ⁺	30.0 – 200.0 mmol/L
	Cl ⁻	30.0 – 200.0 mmol/L
	iCa ⁺⁺	0.10 – 5.00 mmol/L
	pH	4.00 – 9.00 units
	Measuring range (urine):	
	K ⁺	10 - 100 mmol/l
	Na ⁺	50 - 250 mmol/l
	Cl ⁻	50 - 250 mmol/l
	iCa ⁺⁺	n.a.
	pH	n.a.
	Precision within run (CV%, for serum):	
	K ⁺	≤1.5%
	Na ⁺	≤1.0%
	Cl ⁻	≤1.5%
	iCa ⁺⁺	≤3.0%
	pH	≤2.0%
	Carryover:	<1.5% sample to sample

	Calibration:	Automatic 2-point calibration every 4 hours or on demand. 1-point calibration with each sample for temperature and drift compensation.
	Sample positions:	1 aspiration position, (20 sample positions with Autosampler)
	Sample tubes:	All regular tubes/cups up to 50 mm length. Sample cups (17470/59) for Autosampler.
Operation	Data storage:	Sample results (for 200 patients with patient ID), QC results
	Reports:	QC (Mean, SD, CV%), patient results
	Warnings:	Analytical limits (high/low), calibration criteria
	User interface:	LCD touch screen (110 x 62 mm, with LED back light)
	Printer:	Build-in thermal printer, 32 characters per line; Printing Width: 58 mm; Printing Speed: 46 characters per second
	Connectivity:	RS-232 serial port (uni-directional)
	Periphery:	Barcode reader can be connected via RS-232
	Language:	English
General	Operating temperature:	15 – 32°C
	Relative humidity:	≤85%, non-condensing (at 30°C)
	Input voltage:	110/220 V AC ± 10%, 50/60 Hz
	Power consumption:	60 VA
	Dimensions (WxDxH):	Instrument without any components: 38 x 35 x 44 cm Space required for routine use: 63 x 61 x 52 cm Packaging: 49 x 45 x 56 cm Space required for use with autosampler: 69 x 61 x 52 cm
	Weight:	HumaLyte Plus 3: Gross: 13.3 kg, Net 7.8 kg HumaLyte Plus 5: Gross: 13.9 kg, Net 7.8 kg Autosampler (option): Net 1.3 kg
	Fuse:	F2AL250V
Usage	Pump:	Peristaltic pump
	Valve:	Rotary valve
	Sensor:	Optical liquid sensor for positioning
	Reagent:	Only one Reagent Pack necessary for all parameters. Closed system, only usable with Human Reagent Pack.
	Disposal of waste:	Contaminated waste, container integrated in Reagent Pack

8.5 Reagent

HumaLyte Plus 3 Reagent Pack	Standard A 650ml KCl 4.00 mmol/l NaCl 96.0 mmol/l Na acetate 44.0 mmol/l
	Standard B 350ml KCl 8.00 mmol/l NaCl 59,9 mmol/l Na acetate 20.1 mmol/l
HumaLyte Plus 5 Reagent Pack	Standard A 650ml KCl 4.00 mmol/l NaCl 94.0 mmol/l Na acetate 46.0 mmol/l CaCl ₂ 1.0 mmol/l
	Standard B 350ml KCl 8.00 mmol/l NaCl 58,0 mmol/l Na acetate 52.0 mmol/l CaCl ₂ 2.0 mmol/l

Na/Cl/pH filling solution 100ml	< 1% NaCl < 1% N-(2-hydroxyethyl) piperazine-(2-ethanesulfonic acid) < 1% Tris(hydroxymethyl)aminomethane
K filling solution 100ml	< 1% Potassium chloride
Ca filling solution 100ml	< 1% Calcium chloride
Reference filling solution 100ml	< 1.5% Potassium chloride
Na conditioner 100ml	< 1% Ammonium hydrogenfluoride
QC solution Target values (software 5.4HE) K: 5.0 ± 0.1 mmol/L Na: 145.0 ± 2.0 mmol/L Cl: 105.0 ± 2.0 mmol/L iCa: 1.3 ± 0.1 mmol/L	KCl 5.0 mmol/l NaCl 97.6 mmol/l Na acetate 47.4 mmol/l CaCl ₂ 1.2 mmol/l
Weekly cleaning solution 100ml	< 1% Sodium hypochlorite
Daily cleaning solution 100ml	< 1% Pepsin < 1% Trypsinase < 1% Papain
Urine diluent	< 0.3% Magnesium acetate < 0.2% Trishydroxymethyl-aminomethane (TRIS) < 0.2% N-(2-Hydroxyethyl)-piperazine-N-2-ethanesulfonic acid (HEPES) < 0.2% Triton X-100

8.6 List of references

For further information kindly refer to the following list of references. Many of the cited references are available online (e.g. [2] [6] [3] [1]).

- [1] Sachs, „Anomalies in pH 7.40 correction in ionized calcium analyzers,“ Ann. Clin. Biochem., Nr. 26, 1989.
- [2] Boink, Buckley und Christiansen, „IFCC Recommendation on Sampling, Transport and Storage for the Determination of the Concentration of Ionized Calcium in Whole Blood, Plasma and Serum,“ Eur. J. Clin. Chem. Clin. Biochem., Nr. 29, pp. 767-772, 1991.
- [3] Rosenthal, „The effect of temperature on the pH of blood and plasma in vitro,“ J. Biol. Chem., Nr. 173, pp. 25-30, 1948.
- [4] G. Dimeski and T. Badrick, "Ion Selective Electrodes (ISEs) and interferences - A review," Clinica Chimica Acta, no. 411, pp. 309-317, 2010.
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- [8] A. Kallner, „Preanalytical Procedures in the Measurement of Ionized Calcium in Serum and Plasma,“ Eur J Clin Chem Clin Biochem, Nr. 34, pp. 53-58, 1996.

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