



ELECTROLYTE ANALYZER

**Instructions
for use**



Local representative of EXIAS Medical GmbH

*For EXIAS distributor:
Please put your sticker
containing your contact information here.*

Manufacturer



EXIAS Medical GmbH
Kratkystraße 2
8020 Graz – Austria

Phone: +43 (316) 922953
E-Mail: office@exias-medical.com
www.exias-medical.com

Document information

Version 1.0, Nov.2019 (valid for software version: min. 1.00)

Initial content

Version 1.1, Nov.2019 (valid for software version: min. 1.00)

Change Description:

Correction of symbols in chapter 6

Version 2.0, Sep.2020 (valid for software version: min. 2.00)

Change Description:

Section "Customized settings" added in chapter 5. Measuring procedure adapted to current software version (2.0 or newer) in chapter 6. Description of new functions "Laboratory Information System" and "Result Correlations" added in chapter 9. Description of new troubleshooting routines and diagnostic functions added in chapter 10. Description of "System recovery" added in chapter 10. Further editorial changes.

Version 2.1, Jan.2021 (valid for software version: min. 2.00)

Change Description:

Extended shelf life for e|1 Cartridge from 6 to 9 months.

Version 2.2, Jun.2021 (valid for software version: min. 2.01)

Change Description:

Extended in-use time for e|1 Cartridge 150 and e|1 Cartridge 150 oQC from 28 to 42 days. Adapted and enhanced Troubleshooting routines and Diagnostic functions.

Version 2.3, Mar.2022 (valid for software version: min. 2.01)

Change Description:

Extended in-use time for e|1 Cartridge 300 and e|1 Cartridge 300 oQC from 28 to 42 days.

Version 3.0, Jul.2022 (valid for software version: min. 3.00)

Change Description:

Update of intended use. New Section *Conformity*. New sample type urine (undiluted). New performance data for sample type urine. New software features added: Levey Jennings Chart, external QC Measurement. Metrological Traceability added.

Copyright

2022, EXIAS Medical GmbH, all rights reserved.

The contents of this document may not be reproduced in any form or communicated to any third party without the prior written consent of EXIAS.

All documents are protected in terms of copyright law. The transfer and duplication of documents, even in extracts, as well as the utilization and communication of their contents are not permitted unless expressly granted in writing.

Violations are punishable and require compensation.

All rights to exercise industrial property rights are reserved for EXIAS.

Brandname

EXIAS Medical is a trademark of EXIAS Medical GmbH.

Edition

M000324, Version 3.0, Jul. 2022

Table of contents

Document information	0-3
Copyright	0-4
Brandname	0-4
Edition	0-4
1 Introduction	
Purpose and use of this document	1-3
Text convention	1-4
Symbols	1-5
Abbreviations	1-7
2 Safety Information	
General safety instructions	2-3
Biohazard exposure, precautions and disposal	2-3
Conformity	2-4
Applied standards	2-5
Disinfection	2-6
IT security advisory	2-7
Electrical safety and electromagnetic compatibility	2-8
Limitations of the e 1 Analyzer	2-8
3 Product Description	
Intended use	3-3
e 1 Analyzer	3-3
Consumables	3-5
Accessories	3-8
4 Specifications	
System Characteristics	4-3
Sample Types	4-3
Measurement Parameters	4-3
Calculated Parameters	4-4
Performance Characteristics	4-4
Interference	4-14
Linearity	4-17
Environmental Parameters	4-18
Technical Specifications	4-19
5 System Installation	
Choosing a location	5-3
Unboxing and checking contents	5-3
Installation and setup	5-4
Inserting the e 1 Cartridge	5-5
Customized settings	5-7

6 Sample Measurement	
Preanalytics	6-3
Limitations of clinical analysis	6-5
Measuring procedure	6-6
Measurement evaluation	6-9
7 Quality Control	
Quality Control Concept	7-3
Recommended QC regime by EXIAS Medical	7-3
Important information for evaluating QC results	7-4
QC measurement	7-4
QC consequences	7-7
Levey Jennings Chart	7-8
External Quality Control	7-8
8 Replacement of Consumables	
Replacement of e 1 Cartridge	8-3
Replacement of e 1 Printer paper	8-7
9 System Functions	
Main Screen	9-3
Results	9-5
Menu	9-8
Alarms / Warnings	9-27
Cartridge	9-28
Login	9-28
Laboratory Information System	9-29
Result Correlations	9-30
10 Troubleshooting	
Troubleshooting concept	10-3
Troubleshooting routines	10-6
Diagnostic functions	10-8
System recovery	10-9
Error Messages	10-10
11 Theoretical Foundations	
Reference intervals and critical limits	11-3
Calculated values	11-6
Measuring principle	11-7
Calibration principle	11-9
Metrological Traceability	11-10
12 Appendix	
Order list	12-3
Index	13-1

Chapter

1

Introduction

1 Introduction

Purpose and use of this document

These Instructions for Use provide all information and data needed for the safe operation of the **EXIAS e|1 Analyzer**. This document is intended only for qualified operators who have been trained and authorised by EXIAS Medical, or by representatives of EXIAS Medical.

Every effort has been made to ensure that the information contained in this manual is correct and up to date at the time of printing. Please contact your local representative, if you want to ensure that you are referring to the latest and current version of the Instructions for Use.

EXIAS Medical reserves the right to make any changes necessary without notice as part of ongoing product development.

This manual should be stored properly where it will not be damaged and available and accessible while using the **EXIAS e|1 Analyzer**.

A table of contents at the beginning of this manual, as well as an index at the end of this manual, assist in finding different information quickly.









EXIAS Medical GmbH is accountable for the proper functionality, safety and performance of the e|1 Analyzer only if the following conditions are met:

- 1 The **e|1 Analyzer** is installed and used in accordance to manufacturer specifications. Please refer to chapters **System Installation** and **Specifications** in this document.
- 2 All preanalytical considerations are met while performing measurements with patient samples. For further information see section *Preanalytics* in chapter **Sample Measurement**.
- 3 All consumables, accessories and spare parts used together with the device must be proprietary products either delivered by EXIAS Medical or approved by EXIAS Medical.
- 4 All operators of the device must be trained and familiar with the operation of the device. The operators must be trained either by authorized EXIAS Medical personnel, or persons trained and authorized by EXIAS Medical.
- 5 All technical interventions on the device must be carried out either by authorized EXIAS Medical personnel, or persons trained and authorized by EXIAS Medical. This includes any repair, modification or adjustments that may be required or attempted to the device.

No warranty or liability claims will be entertained, if the instrument is applied in areas other than those described or if the necessary prerequisites and safety measures are not observed.











Text convention

Symbols are used in the manual:

Symbol	Description
	Instruction
	Note
	Caution: All sections/passages that are marked with this symbol describe procedures and/or indicate conditions or dangers that could damage or lead to a malfunction of the e 1 Analyzer .
	Warning: Sections marked with this symbol contain information that must be observed to avoid potential injuries (to patients, operators or third parties).
	Biological hazard: All sections and parts of texts that are marked with this symbol describe procedures that may involve risk of infection.
	Electricity hazard: Risk of property damage and personal injury due to electrical voltage.
	Wear eye protection!
	Wear protective gloves!
	Wear protective clothing!

Symbols

Symbols used on labels and on packaging of EXIAS Medical products are in accordance with ISO 15223-1:2021⁽¹⁾, ISO 780:2015⁽²⁾, IEC 60417-1:2002⁽³⁾, Directive 98/79/EC⁽⁴⁾, Directive 2012/19/EU⁽⁵⁾ and Regulation EU 2017/746⁽⁶⁾.

Symbol	Description
	Conformité Européenne: This product complies with the requirements of the European directive 98/79/EC and the European regulation 2017/746 on in vitro diagnostic medical devices.
	Batch code
	Use-by date The product should not be used after expiry of the specified date. If a day is not indicated, apply the last day of the respective month.
	Temperature limitation The conditions necessary to preserve the product's shelf life before opening.
	In vitro diagnostic medical device
	Manufacturer
	Date of manufacture (YYYY-MM)
	Catalogue number
	Consult Instructions for Use
	Serial number (model plate)

(1) ISO 15223-1:2021: Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements.

(2) ISO 780:2015: Packaging - Distribution packaging - Graphical symbols for handling and storage of packages.

(3) IEC 60417-1:2002: Graphical symbols for use on equipment - Part 1: Overview and application.


(4) Directive 98/79/EC on in vitro diagnostic medical devices (IVDD).

(5) Directive 2012/19/EU on waste electrical and electronic equipment (WEEE).

(6) Regulation EU 2017/745 on in vitro diagnostic medical devices (IVDR).

1 Introduction

Symbols

Symbol	Description
	Fragile, handle with care
	Handle with care
	Keep dry
	Biological risk
	Caution Consult Instructions for Use
	This side up
	Direct current
	Polarity
	Do not throw in trash
	Cartridge
	Contains sufficient for <n> test
	Do not re-use
	Power on / Power off
	USB Interface
	Ethernet Interface

Abbreviations

Abbreviation	Description
A	
A	Ampere
AC	Alternating current
B	
BPA	Bisphenol A
C	
Ca ²⁺	Calcium ion concentration
CAL	Calibration
1P-CAL	1 point calibration
2P-CAL	2 point calibration
2P*-CAL	Additional 2 point calibration
CE	Conformité Européenne (European Conformity)
Cl ⁻	Chloride ion concentration
CLIA	Clinical Laboratory Improvement Amendments
CLSI	Clinical and Laboratory Standard Institutes
cm	Centimeter
CV	Coefficient of variation
D	
dL	Deciliter
DC	Direct current
E	
EC	European communities
EN	European nation
EU	European union
H	
Hct	Hematocrit
Hz	Hertz
I	
IEC	International Electrotechnical Commission
ISO	International Organization for Standardization
IVD	In vitro diagnostic
IVDD	In vitro diagnostics directive (Directive 98/79/EC on in vitro diagnostic medical devices)
IVDR	In vitro diagnostics regulation (Regulation EU 2017/746 on in vitro diagnostic medical devices)
K	
K ⁺	Potassium ion concentration
kg	Kilogram

1 Introduction

Abbreviations

Abbreviation	Description
L	
LCD	Liquid cristal display
LIS	Laboratory information system
l	Liter
M	
mg	Milligram
mm	Millimeter
mmol	Millimol
mV	Millivolt
N	
Na ⁺	Sodium ion concentration
nCa ²⁺	Calcium ion concentration standardized to pH = 7.40
O	
oQC	on-board Quality Control
P	
pcs	pieces
pH	Negative decadic logarithm of the molar concentration of hydrogen ions in a solution
POC	Point of care
ppm	Parts per million
Q	
QC	Quality control
S	
SBY	Standby operating solution
SD	Standard deviation
T	
tHb(c)	Total hemoglobin (calculated)
U	
USB	Universal serial bus
V	
V AC	Volt - alternating current voltage
V DC	Volt - direct current voltage
W	
WEEE	Waste of Electrical and Electronical Equipment (Directive 2012/19/EU)

Safety Information

2 Safety Information

General safety instructions

The **EXIAS e|1 Analyzer** as well as its consumables and accessories left the factory in a flawless condition.

To ensure that this condition is maintained and for safe operation, the operator must follow the instructions and warnings described in of these Instructions for Use.

- Do not operate the device in an explosive environment or in the vicinity of explosive or combustible mixtures of anesthetics with air, oxygen or nitrous oxide.
- If objects or liquids enter the inside of the device, the device must be disconnected from its power supply and checked by qualified personnel before further use by.
- Service must be carried out by authorized personnel only. The device is suitable for long-term operation indoors.
- Mechanical damages, which could affect the normal operation of the device or could present a hazardous situation for operating persons, have to be repaired by authorized personnel.
- The device is maintenance-free, as all wear and tear parts are replaced by changing the **e|1 Cartridge**. Recurring inspections are to be carried out according to local regulations, respectively according to IEC 62353.
- The **e|1 Analyzer** may only be operated by persons whose qualifications enable them to comply with the safety measures that are necessary for operating the device.
- The device must only be operated by professionals in the field of health-care according to product training received by an EXIAS Medical trainer or a trainer authorized by EXIAS Medical.
- This device is intended to be used only for the specific purpose described in these Instructions for Use.
- To ensure the performance and accuracy of the device over long term, it is recommended to use only the consumables, accessories and spare parts specifically designed and tested for this analyzer.
- To ensure the quality of the **e|1 Analyzer**, quality control measurements must be performed daily. For further instructions see chapter 7 **Quality Control**.
- Do not use expired consumables or accessories.
- It is obliged to have the measurement results evaluated by a medical professional before further actions related to the measured values taken.

Biohazard exposure, precautions and disposal



The **e|1 Analyzer** is designed to reduce risk emerging from biohazard exposure for the operator. The **e|1 Cartridge** automatically collects used biological specimen samples. This sealed cartridge is then disposed after use, without further necessary treatment. The used **e|1 Cartridge** must **NEVER** be opened or dismantled since it contains biohazardous waste.

It is important that used e|1 Cartridges and sample containers are disposed with care, according to local regulations for biohazardous material.



Warning:

Do not dispose the **e|1 Analyzer** with regular garbage.

The **e|1 Analyzer** may has been in contact with biological samples.

It is important that e|1 Analyzer is disposed according to local regulations for biohazardous material.

2 Safety Information

Conformity



Warning:

Perform disinfection routine, before transportation of the **e|1 Analyzer**.

The **e|1 Analyzer** may have been in contact with biological samples.

As precaution, suitable safety equipment must be worn in order to prevent direct contact with biological substances:



Wear protective clothing!



Wear protective gloves!



Wear eye protection!

If necessary, a face mask should be worn. If spraying of blood appears to be possible a face shield is also required.

The external Quality-Control material of the **e|1 Analyzer** is filled in glass ampoules. The substances are not reactive still caution is advised regarding sharp edges arising from the intended use of these ampoules. The ampoules are not allowed to be disposed with regular domestic refuse.

Conformity

EXIAS Medical GmbH herewith declares, that the

EXIAS e|1 Analyzer, an in-vitro diagnostic medical device, is in conformity with the *Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017* and with *Directive 2011/65/EC of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment*, as well as the

EXIAS e|1 Cartridge, an in-vitro diagnostic medical device, is in conformity with the *Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in-vitro diagnostic medical devices* and with *Directive 2011/65/EC of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment*, as well as the

EXIAS e|1 QC Quality Control, an in-vitro diagnostic medical device, is in conformity with the *Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in-vitro diagnostic medical devices* and with *Directive 2011/65/EC of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment*.

According to rule 5b of Annex VIII of Regulation (EU) 2017/746 the **EXIAS e|1 Analyzer** is a class A in vitro diagnostic medical device.

According to Annex II of Directive 98/79/EC the EXIAS e|1 Cartridge is classified as a “general in-vitro diagnostic medical device”.

According to Annex II of Directive 98/79/EC the EXIAS e|1 QC Quality Control is classified as a “general in-vitro diagnostic medical device”.

Conformity is set out in the declarations of conformity.

Applied standards

The instrument is compliant to following standards:

Product safety

- EN 61010-1:2013 Safety requirements for electrical equipment for measurement, control and laboratory use (Part 1: General requirements).
- EN 61010-2-081:2013 Safety requirements for electrical equipment for measurement, control and laboratory use (Part 2-081: Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes).
- EN 61010-2-101:2013 Safety requirements for electrical equipment for measurement, control, and laboratory use (Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment).

Electromagnetic compatibility (EMC)

Emission: Class B according to

- EN 61326-1:2013 Electrical equipment for measurement, control and laboratory use – EMC requirements (Part 1: General requirements).
- EN 61326-2-6:2013 Electrical equipment for measurement, control and laboratory use – EMC requirements (Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment).

Immunity according to

- EN 61326-1:2013, table 1- Immunity requirements for basic electromagnetic environment
- EN 61326-2-6:2013, table 101 - Immunity requirements for IVD medical equipment

Disinfection



Use disinfection to minimize the risk of handling parts that have been in contact with biological specimens.

EXIAS recommends a disinfection procedure for the device's surfaces and its touch-display. In addition, the specific laboratory regulations must be observed to minimize the risk of infection



Note:

Disinfection of device's surfaces:

Only use liquid, alcoholic (about 70%) surface disinfectants, e.g. Isopropanol 70% and/or disinfectant with typically 0.5% to max. 1.0% of the active substance benzalkonium chloride.

Bleaching agents of any kind may not be used.

For disinfection, the device must not be sprayed directly (neither outside, nor in the interior). First apply cleaning agent to a damp cloth and then disinfect the device.

After disinfecting the device, wait 15 minutes to allow the disinfectant to evaporate.

Disinfection of the Touch-Display

To perform the disinfection of the display, choose the following functions:



[Menu] > Utilities > [Clean screen]

The touch-sensitive layer of the screen is deactivated for 30 seconds. Within this period of time the Touch-Display may be cleaned by wiping a damp cloth soaked with disinfectant across the surface.



Caution:

Only disinfect with a damp cloth (e.g. soaked in disinfectant).

Do not use water or sprays.

Disinfection of the device's surfaces

Disinfect all external surfaces of the device with the disinfectant in accordance with laboratory regulations.

IT security advisory

There is no anti-virus software installed on the **e|1 Analyzer**.

External storage media may be infected with computer malware (malware such as viruses, trojans, spyware, etc.) and may transfer such programs to the system.

Therefore, it is important to take these important precautions to prevent the transmission of malware.



Caution:

Failure to observe the following recommendations may result in data loss, loss of integrity of patient results or unavailability of the system, which may put patients at risk.

- Check all external storage devices with an anti-virus program (on another PC) to ensure that they are malware-free before using them with the **e|1 Analyzer**.
- Recheck the external storage device after usage on other devices to avoid cross-interference.
- Portable storage media, particularly USB memory drives/sticks, should never be used at home or at public computer systems and then connected to a work- or customer-system.
- Do not use the USB ports to connect other external storage devices unless stated in **e|1 Analyzer** specific documentation.
- Keep all external storage devices in a secure place so that they can be accessed only by authorized personnel.
- Do not add, move or delete any files or software unless stated in **e|1 Analyzer** specific documentation.
- Never copy and install any non-EXIAS software on the device.
- Use remote services only to connect to the service network.
- Make sure only validated computers are connected to the instrument system network.
- Ensure that other computers connected to the same network as the device are properly secured and protected from malware.

Electrical safety and electromagnetic compatibility

**Warning:**

The power cord must be plugged into a grounded power receptacle. When using an extension cord, make sure it is properly grounded.

- The power cable must conform to country-specific requirements.
- Any rupture of the power cable may result in hazardous operating conditions for the operating personnel.
- Intentional disconnection of the grounding is not permitted.
- The device is not suitable for operation with a direct current power supply.
- Use the original power supply for the **e|1 Analyzer** only. The power supply must not be repaired or opened.

**Warning:**

Place the power supply in a way, that it can be easily unplugged at any time.

- In case of malfunction of the instrument, it must be possible to disconnect the power supply immediately.

**Warning:**

The USB ports must not be used in connection with devices, that use their own power supply.

- A failure of the power supply could cause severe damage to the **e|1 Analyzer**.

**Warning:**

Make sure that the power supplies of all connected devices use protective ground.

- All connected devices (e.g. switches) must conform to national and international standards.
- If protective ground is not available, use a network isolator for galvanic isolation.

**Warning:**

Do not use this device near sources of strong electromagnetic radiation (e.g. unshielded intentional RF sources), as these can impede proper operation.

- Make sure, the electromagnetic environment was evaluated, before operating the instrument.

Limitations of the e|1 Analyzer

**Warning:**

Do not use the instrument outside the operation conditions, see chapter 4 **Specifications**.

- Implemented protection measures may become ineffective.

**Warning:**

Whole blood samples from patients may contain drugs and / or compounds which interfere with the determination of desired parameters, see chapter 6 **Sample Measurement**.

**Warning:**

The analyzer is not meant to be used by lay persons. It is a device for near-patient testing, but not for self-testing. The handling by a professional is always obliged.

Product Description

3 Product Description

Intended use

The **EXIAS e|1 Analyzer** is a fully automated in-vitro diagnostic medical device used in combination with the multi-use consumable EXIAS e|1 Cartridge intended to quantitatively measure the electrolytes Sodium (Na^+), Potassium (K^+), ionized Calcium (Ca^{2+}) and Chloride (Cl^-) as well as pH and Hematocrit (Hct) in human whole blood, serum, plasma, undiluted urine and aqueous solutions.

The device is dedicated for the use in laboratories and Point-of-Care (POC) environments and is intended for professional use only.

e|1 Analyzer

The **e|1 Analyzer** is a system consisting of the instrument, including touch screen, printer, removable cover, and the **e|1 Cartridge**.



- A Touch Display
- B Sample Input Unit (e|1 Cartridge)
- C Removable cover

Figure 3-1

Touch display

The 7" LCD color touch screen enables intuitive and simple operation of the device and can be cleaned easily.



Figure 3-2

3 Product Description

e|1 Analyzer

Rear panel

On the rear panel of the instrument there are the built-in printer, the ON/OFF button, the power supply plug as well as USB and Ethernet ports.

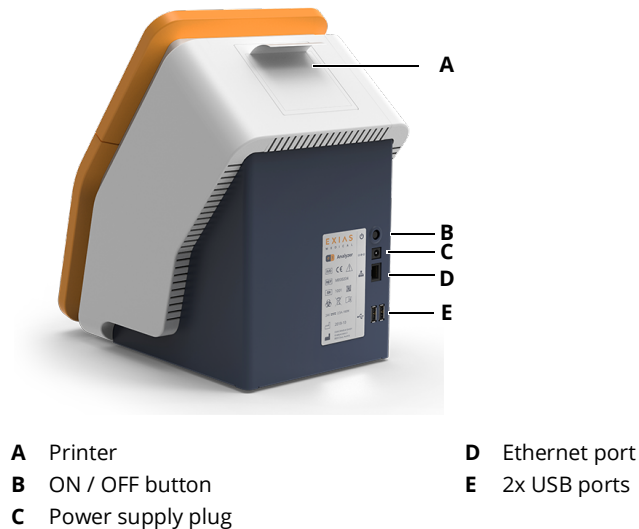


Figure 3-3



Note:

Pressing the (On/Off) button does not disconnect the instrument from power supply. For a total disconnection from power supply, the power cable of the device must be unplugged.

Printer

The integrated low noise thermal printer, for printing measurement and QC results, includes an "easy load" mechanism, which allows a quick and easy change of the 2" paper roll.



Figure 3-4 Printer

Consumables



Note:

For material numbers and order information see chapter 12 **Appendix**.

e|1 Cartridge

The **EXIAS e|1 Cartridge** is a multi-use in-vitro diagnostic medical device consumable used in combination with the **EXIAS e|1 Analyzer** intended to quantitatively measure the electrolytes Sodium (Na^+), Potassium (K^+), ionized Calcium (Ca^{2+}) and Chloride (Cl^-) as well as pH and Hematocrit (Hct) in human whole blood, serum, plasma, undiluted urine and aqueous solutions.

The device is dedicated for the use in laboratories and Point-of-Care (POC) environments and is intended for professional use only.

The **e|1 Cartridge** contains the sample input mechanism, all fluidic components, the measuring cell, the calibration fluids and, dependent on the model of the cartridge, the quality control solutions.

The waste of measured samples and the used calibration and control fluids are also collected inside the cartridge.

The advantage of this all-in-one cartridge concept is that all parts which encounter biological samples and all wear and tear components are collected in one cartridge. Hence, no additional maintenance steps are necessary, besides replacement of the cartridge by the operator.

On an integrated memory chip lot-specific data is stored to provide specific concentration information of the solutions. Additionally, data such as the cartridge type and expiration date, are stored. This data is checked automatically for validity by the **e|1 Analyzer** when a cartridge is inserted into the system.



Figure 3-5

Depending of the number of required sample measurements and of the need of an on-board quality control, six different types of measuring cartridges are available:

e 1 Cartridge 150	up to 150 samples within 42 days
e 1 Cartridge 300	up to 300 samples within 42 days
e 1 Cartridge 600	up to 600 samples within 28 days
e 1 Cartridge 150 oQC	up to 150 samples within 42 days including on board QC
e 1 Cartridge 300 oQC	up to 300 samples within 42 days including on board QC
e 1 Cartridge 600 oQC	up to 600 samples within 28 days including on board QC

3 Product Description

Consumables



Note:

A maximum of 150 urine samples can be measured with all six Cartridge types.



Note:

The counted samples include patient samples, as well as all QC samples run on the device within its maximum in-use time (28 days / 42 days).

Sample modes

The sample input module enables the application of different sample containers like sample tubes, syringes or capillary tubes. A sample probe is used for aspirating the sample out of tubes, syringes or ampoules. Capillary tubes are attached to a rubber fill port.

Syringe / sample tube mode



Capillary tube mode



Figure 3-6

Fluids

For calibrating the **e|1 Analyzer** the “standby” and “calibration” solutions are used. For cartridge types with on-board QC, additionally three quality control solutions (Level 1, 2 and 3) are integrated.

The individual solutions are filled in impermeable and gas-tight bags. They are closed with a valve that is opened by inserting the cartridge into the device for the first time.

The five solutions consist of inorganic salts: Sodium chloride, Potassium chloride, Sodium Acetate and Calcium chloride. The buffer system is based on 2- (4- (2-hydroxyethyl) -1-piperazinyl) -ethane sulfonic acid (HEPES) and its alkali metal salts.

Part of the solutions are also a preserving agent mixture based on Isothiazolinones and 5-bromo-5-nitro-1,3-dioxane with total active substance concentrations <50 ppm and a wetting agent, based on polyethylene glycol and polypropylene glycol with total concentrations <50 ppm.

Tubing

The multi-channel distribution valve operates automatically and releases the fluids required for device operation and measurement. All fluid paths are integrated, including the pump tubing for the peristaltic pump to transport the fluids. The peristaltic pump itself is part of the instrument.

Waste

An integrated waste pouch absorbs all used fluids as well as the measured sample material. At the end of the operating time of the **e|1 Cartridge**, the used **e|1 Cartridge** must be disposed as biohazardous waste.

Electronic contacts

At the top of the **e|1 Cartridge**, the contact plate is located. It performs as the electrical interface to the instrument when the cartridge is correctly inserted. The electronics inside the cartridge are used for reading signals of potentiometric sensors, for measuring temperatures and temperature control, for positioning of samples and for reading stored data.



Figure 3-7



Note:

The contact surface must not be touched when dealing with and/or handling the cartridge.

Memory chip

The integrated memory chip stores the following information:

- Cartridge type
- Lot specific concentration of ingredients of the solutions
- Lot number / Serial number
- Expiration date
- Installation date
- Maximum and remaining number of samples (including QC samples)
- Maximum and remaining in-use time

Printer paper

The printer paper used for the **e|1 Analyzer** is a 57 mm wide BPA-free thermal paper. One roll has a length of 25 meters and can be used for approx. 180 print-outs (using default settings).



Figure 3-8



Note:

The printout will bleach, if it is exposed to light for a long time.

Accessories

**Note:**

For material numbers and order information see chapter 12 **Appendix**.

e|1 QC Quality Control

The **EXIAS e|1 QC Quality Control** is an assayed multi analyte quality control material used for manual quality control measurements to monitor the performance of the **EXIAS e|1 Cartridge** in combination with the **EXIAS e|1 Analyzer** for the analytes Sodium (Na^+), Potassium (K^+), ionized Calcium (Ca^{2+}), Chloride (Cl^-), pH and Hematocrit (Hct).

The device is dedicated for the use in laboratories and Point-of-Care (POC) environments and is intended for professional use only. It is not intended to be used with analyzers from other manufacturers.

The **e|1 QC Quality Control** is designed to detect instrument malfunctions that would affect analytical results. As this is not a blood-based material, it may not detect circumstances that would affect the testing of biological samples.

The product is intended to be used as a quality control material and not as a calibration standard. Its use should not replace other aspects of a complete quality control procedure.

The **e|1 QC Quality Control** is providing analyte concentrations within the clinical range and is available in three different levels filled in sealed glass ampoules, each containing 2.5 ml of solution.

e 1 QC-1 Quality Control	30 Pcs. of Level 1 Quality Control Ampoules
e 1 QC-2 Quality Control	30 Pcs. of Level 2 Quality Control Ampoules
e 1 QC-3 Quality Control	30 Pcs. of Level 3 Quality Control Ampoules



Figure 3-9 QC material

The material consists of buffered aqueous solutions containing electrolytes (Na^+ , K^+ , Cl^- and Ca^{2+}). The electrical conductivities provide control means for hematocrit measurement of the **e|1 Analyzer**.

- **Level 1** contains low reference values for Na^+ , K^+ , Cl^- , pH and Hct, high value for Ca^{2+}
- **Level 2** contains normal values for all parameters
- **Level 3** contains high reference values for Na^+ , K^+ , Cl^- , pH and Hct, low value for Ca^{2+}

**Note:**

The **e|1 Analyzer** is not designed to accept commercial liquid QC materials from third party providers to monitor the performance of the **EXIAS e|1 Cartridge**.

**Note:**

The quality control solutions contain no preservative and no human or biological material.

**Note:**

Further information can be found in the enclosed insert sheet of the QC material.

Barcode scanners

EXIAS offers two barcode scanners for convenient usage of the **e|1 Analyzer**. Either a 1D or 2D scanner can be connected to the instrument via the USB interface as an optional accessory. Patient, operator or external QC material data like material, LOT and level specific values can be entered easily.

Barcode scanner 1D**Barcode scanner 2D**

Figure 3-10

**Note:**

Press the button to enable the scanner. The scanner beeps and the LED on the top flashes once to indicate a successful scan of the barcode.

Recommendations for ensuring good barcode scanning quality:

- The label or piece of paper with the printed barcode should be smooth and without folds.
- The printed barcode must not be distorted during the printing process (ensure good quality ink, printer ribbon or toner).
- Do not use printing materials with shiny or reflective surfaces.
- Try different scanning angles and distances between scanner and paper

**Note:**

For further information about configuring the scanner for different types of barcodes, refer to the manual that came with your barcode scanner.

3 Product Description

Accessories

Capillary tubes

EXIAS Medical offers heparinized single-use Capillary tubes as sample receptacles from the third party manufacturer "SC Sanguis Counting". The capillaries are intended for fast collection, transport and automated processing of blood for pH/blood gas, electrolyte, oximetry and metabolite analysis. The tubes are made of plastic and heparinized with 100 I.U. balanced heparin to avoid blood clotting. The volume of the tubes is 50 microlitres and meant to be used in combination with systems of EXIAS. One box contains 10 dispensers for 100 capillaries each.



Figure 3-11



Note:

Further information can be found in the enclosed insert sheet of the Capillary tubes.

Chapter **4**

Specifications

4 Specifications

System Characteristics

Sample volume	20 µl
Time to display	25 seconds
Troughput	typical 104 samples / hour
Calibration times	30 seconds for 2 point calibration

Table 4-1 General performance features

Sample Types

- Whole blood
- Serum
- Plasma
- Urine (undiluted)
- Aqueous solutions
- Recommended QC-materials

Measurement Parameters

Parameter	specified for	measuring range	Unit	Conversion
Na ⁺	B/S/P/Q	85.0 - 200.0	mmol/l	
	U	5.0 - 300.0	mmol/l	
K ⁺	B/S/P/Q	1.00 - 15.00	mmol/l	
	U	5.00 - 120.00	mmol/l	
Cl ⁻	B/S/P/Q	60.0 - 150.0	mmol/l	
	U	5.0 - 300.0	mmol/l	
Ca ²⁺	B/S/P/Q	0.100 - 3.200	mmol/l	0.4 - 12.83 mg/dl ^(a)
Hct	B	10.0 - 75.0	Hct%	
pH	B/S/P/Q	6.700 - 8.000	pH	

Table 4-2 Measurement parameters

(a) 1 mmol/l = 4.008 mg/dl

B	Whole blood
S	Serum
P	Plasma
U	Urine (undiluted)
Q	Aqueous solutions

4 Specifications

Calculated Parameters

Calculated Parameters

Parameter	specified for	specified range
tHb(c) ^(a)	B	Reported value for Hct required
nCa ²⁺	B/S/P	Reported value for pH and Ca ²⁺ required. The pH reported value must be between 7.2 and 7.6 units.
Na ⁺ 24h	U	24 hour Urine in [mmol/l]
K ⁺ 24h	U	24 hour Urine in [mmol/l]
Cl ⁻ 24h	U	24 hour Urine in [mmol/l]

Table 4-3 Calculated parameters

(a) Note: Calculation of tHb(c) requires Mean Corpuscular Hemoglobin Concentration (MCHC) as mandatory input value. A default value of 34 g/dL is considered, and can be changed during measurement if required.

For detailed information of the calculated parameters see chapter 11 **Theoretical Foundations** section *Calculated values*.

Performance Characteristics

Accuracy of measurement

The accuracy of a measurement result is a combination of trueness and precision, where trueness is affected by systematic error (bias) and measurement precision by random error (standard deviation). Both characteristics contribute as individual components to the total error measurement and affect the measurement accuracy, which is evaluated in Trueness of measurement as Total Analytical Error.

Precision

The precision of the **e|1 Cartridge** in combination with the **e|1 Analyzer** displays the variability in results of repeated measurements of homogeneous samples and represent the random measurement error. Thus precision is a qualitative concept and defined by the measurement of two characteristics, which are repeatability and reproducibility. Repeatability is evaluated by keeping main controllable factors constant, whereas reproducibility is defined when main controllable factors vary. These controllable factors are: analyzer, solution lots, calibration material, location, environmental conditions and time.

The estimates for repeatability and reproducibility are based on 8 samples x 20d x 2runs x 2replicates x 7devices in single (per device; run nested within day) and pooled (all devices; days nested in cartridge, run nested in day, replicates nested in run) evaluation, as well as 11 samples x 3devices x 5day x 5replicates (day nested in device; each site represents a single lot)) evaluation, whereat 3 different lots and aqueous (QC) as well as plasma-based samples are incorporated in the experiment.

The following tables show the standard deviation (SD) and coefficient of variation (CV [%]) of the repeatability and reproducibility of each measured parameter of the **e|1 Cartridge** in combination with the **e|1 Analyzer**.

(a) The precision is defined for different sample types (ST) aqueous solutions (Q – QC material level 1-3) and plasma (P – at low, native and high concentration).

- (b) For the aqueous solutions the pooled precision estimates and the weighted average of the variances (weighting-factor N) are the results of the [3x5x5] experiment day nested in site (each site represents a single device and single lot/cartridge) and single-site experiment [20x2x2] run nested in site, replicates nested in run. Respectively [7x20x2x2] days nested in cartridge, run nested in day, replicates nested in run.
- (c) For plasma and urine the multisite-experiment [3x5x5], day nested in site (each site represents a single device and single lot/cartridge) was used to define its precision depending on low, native and high concentration.
The reproducibility of plasma alters due to limited stability of biological samples (day-to-day-variability)
- (d) The overall precision of the parameter is the pooled precision estimates and the average of the variances.



The precision study is conducted and analyzed in accordance with *CLSI EP05-A3*.

Sodium (Na⁺)

ST ^(a)	Pool	N	Level	Repeatability		Reproducibility		Unit
				SD	CV _%	SD	CV _%	
Q ^(b)	oQC1	635	119.4	0.36	0.30%	0.45	0.38%	mmol/l, %
	oQC2	635	136.1	0.27	0.19%	0.36	0.27%	mmol/l, %
	oQC3	631	161.1	0.30	0.18%	0.39	0.24%	mmol/l, %
p ^(c)	low	75	118.6	0.16	0.13%	1.06	0.89%	mmol/l, %
	native	60	141.3	0.35	0.25%	1.03	0.73%	mmol/l, %
	high	75	154.0	0.30	0.19%	1.31	0.85%	mmol/l, %
overall^(d)		-	-	0.25	0.18%	0.66	0.48%	mmol/l, %

Table 4-4 Precision Sodium (Na⁺), Sample types B/P/S/Q

ST ^(a)	Pool	N	Level	Repeatability		Reproducibility		Unit
				SD	CV _%	SD	CV _%	
U ^(c)	low	175	34.9	0.6	1.73%	1.62	4.64%	mmol/l, %
	native	175	107.2	0.47	0.44%	4.29	4.01%	mmol/l, %
	high	175	233.5	0.77	0.33%	1.02	0.44%	mmol/l, %
overall^(d)		-	-	0.63	0.50%	2.71	0.48%	mmol/l, %

Table 4-5 Precision Sodium (Na⁺), Sample types U

4 Specifications

Performance Characteristics

Potassium (K⁺)

ST ^(a)	Pool	N	Level	Repeatability		Reproducibility		Unit
				SD	CV _%	SD	CV _%	
Q ^(b)	oQC1	635	1.98	0.023	1.15%	0.025	1.28%	mmol/l, %
	oQC2	635	4.39	0.012	0.27%	0.017	0.38%	mmol/l, %
	oQC3	631	6.54	0.020	0.31%	0.027	0.41%	mmol/l, %
P ^(c)	low	75	2.52	0.006	0.24%	0.021	0.83%	mmol/l, %
	native	60	3.87	0.009	0.23%	0.029	0.75%	mmol/l, %
	high	75	6.19	0.031	0.50%	0.065	1.05%	mmol/l, %
overall^(d)		-	-	0.016	0.46%	0.031	0.70%	mmol/l, %

Table 4-6 Precision Potassium (K⁺), Sample types B/P/S/Q

ST ^(a)	Pool	N	Level	Repeatability		Reproducibility		Unit
				SD	CV _%	SD	CV _%	
U ^(c)	low	175	36.060	0.160	0.44%	0.516	1.43%	mmol/l, %
	native	175	58.830	0.523	0.89%	1.493	2.54%	mmol/l, %
	high	175	97.400	0.594	0.61%	1.981	2.03%	mmol/l, %
overall^(d)		-	-	0.46	0.73%	1.463	2.28%	mmol/l, %

Table 4-7 Precision Potassium (K⁺), Sample types U

Calcium (Ca²⁺)

ST ^(a)	Pool	N	Level	Repeatability		Reproducibility		Unit
				SD	CV _%	SD	CV _%	
Q ^(b)	oQC1	635	1.494	0.009	0.59%	0.015	0.98%	mmol/l, %
	oQC2	635	1.129	0.005	0.43%	0.008	0.71%	mmol/l, %
	oQC3	631	0.596	0.006	0.93%	0.009	1.45%	mmol/l, %
P ^(c)	low	75	0.813	0.004	0.50%	0.006	0.76%	mmol/l, %
	native	55	1.076	0.006	0.53%	0.013	1.22%	mmol/l, %
	high	75	1.447	0.007	0.47%	0.019	1.31%	mmol/l, %
overall^(d)		-	-	0.006	0.81%	0.013	1.57%	mmol/l, %

Table 4-8 Precision Calcium (Ca²⁺), Sample types B/P/S/Q

Chloride (Cl⁻)

ST ^(a)	Pool	N	Level	Repeatability		Reproducibility		Unit
				SD	CV _%	SD	CV _%	
Q ^(b)	oQC1	635	83.0	0.38	0.45%	0.50	0.60%	mmol/l, %
	oQC2	635	100.9	0.50	0.49%	0.59	0.58%	mmol/l, %
	oQC3	631	131.4	0.49	0.38%	0.62	0.48%	mmol/l, %
P ^(c)	low	75	75.1	0.25	0.33%	0.81	1.08%	mmol/l, %
	native	60	104.2	0.71	0.68%	1.42	1.36%	mmol/l, %
	high	75	113.7	0.62	0.55%	0.88	0.77%	mmol/l, %
overall^(d)		-	-	0.46	0.43%	0.74	0.74%	mmol/l, %

Table 4-9 Precision Chloride (Cl⁻), Sample types B/P/S/Q

ST ^(a)	Pool	N	Level	Repeatability		Reproducibility		Unit
				SD	CV _%	SD	CV _%	
U ^(c)	low	175	59.70	0.43	0.72%	0.95	1.60%	mmol/l, %
	native	175	139.10	0.58	0.42%	3.71	2.66%	mmol/l, %
	high	175	268.10	1.51	0.56%	3.98	1.49%	mmol/l, %
overall^(d)		-	-	0.97	0.62%	3.19	2.05%	mmol/l, %

Table 4-10 Precision Chloride (Cl⁻), Sample types U

pH (pH)

ST ^(a)	Pool	N	Level	Repeatability		Reproducibility		Unit
				SD	CV _%	SD	CV _%	
Q ^(b)	oQC1	635	7.142	0.002	0.03%	0.003	0.05%	pH, %
	oQC2	635	7.397	0.001	0.02%	0.002	0.02%	pH, %
	oQC3	631	7.642	0.002	0.03%	0.004	0.05%	pH, %
P ^(c)	low	75	7.184	0.002	0.03%	0.013	0.18%	pH, %
	native	60	7.477	0.006	0.07%	0.019	0.25%	pH, %
	high	75	7.642	0.006	0.07%	0.014	0.18%	pH, %
overall^(d)		-	-	0.003	0.04%	0.009	0.15%	pH, %

Table 4-11 Precision pH (pH), Sample types B/P/S/Q

4 Specifications

Performance Characteristics

Hematocrit (Hct)

ST ^(a)	Pool	N	Level	Repeatability		Reproducibility		Unit
				SD	CV _%	SD	CV _%	
Q ^(b)	oQC1	635	58.3	0.35	0.59%	0.37	0.63%	Hct%, %
	oQC2	635	45.5	0.51	1.13%	0.57	1.26%	Hct%, %
	oQC3	619	25.2	0.46	1.83%	0.52	2.07%	Hct%, %
B ^(c)	low							Hct%, %
	native	153	-	0.50	1.19%	0.92	2.19%	Hct%, %
	high							Hct%, %
overall^(d)		-	-	0.45	1.64%	0.53	2.00%	Hct%, %

Table 4-12 Precision Hematocrit (Hct), Sample types B/P/S/Q

Trueness of measurement

Measurement trueness is the performance characteristic representing lack of systematic measurement error in a series of measurement result from a homogeneous sample. Thus the bias is evaluated which requires a suitable reference material and measurement procedure that is used to determine a reference quality value of the **e|1 Cartridge** in combination with the **e|1 Analyzer**. This is achieved by performing method-comparison-experiments.

The clinical method-comparison-experiments were performed within the performance evaluation study on three independent clinical sites with three **e|1 Analyzers**. An extended nonclinical method-comparison-experiment was performed within an inhouse study in laboratories of EXIAS Medical with up to eight **e|1 Analyzers**. For both studies Roche cobas b 221 analyzers were used as reference devices. Heparinized whole blood left-over samples and contrived blood samples were analyzed in the course of both studies (two replicates per sample). For nonclinical urine study Roche 9180 Electrolyte analyzers were used as predicate device.

The following tables show the results of measurement trueness of each parameter of the **e|1 Cartridge** in combination with the **e|1 Analyzer**.

- As regression a Deming-Regression is defined with $y=b_1 x + b_0$ and R^2 representing the Pearson's correlation coefficient.
- The bias is based on a regression analysis with a confidence interval of 95% using a jackknife approach. For the comparison of the **e|1 Analyzer** and Roche cobas b221 the cobas b221 was adjusted by result correlation.
- The Total Analytical Error (TAE) is defined as percentiles corresponding to lower and upper values.
- The Allowable Total Error (ATE) defines the maximum error for patient result that a single result can show with a probability of 95%.
- The bias is based on a regression analysis with a confidence interval of 95% using a jackknife approach for the comparison of the **e|1 Analyzer** and Roche 9180 Electrolyte Analyzer.



The method comparison study is conducted and analyzed in accordance with *CLSI EP09-A3, EP14-A2 and EP21 2nd Edition*.

Sodium (Na⁺)

Information		Value	Unit	
Samples (N)	Clinical Study	1294		
	Non Clinical Study	586		
Covered Range	min	85.4	mmol/l	
	max	191.1	mmol/l	
Regression ^(a)	b₀	0.5622	mmol/l	
	b₁	0.9946	1	
	R²	0.9943	1	
Bias ^(b)	concentration	bias		
	85	0.1	mmol/l	
	120	-0.1	mmol/l	
	135	-0.2	mmol/l	
	145	-0.2	mmol/l	
	155	-0.3	mmol/l	
Accuracy	Limit	low	high	
	TAE ^(c)	-2.3	2.0	mmol/l
	ATE ^(d)	-6.7	6.7	mmol/l
	ATE:TAE ratio	2.9	3.4	1
	P_{within},%		100	%

Table 4-13 Method comparison Sodium (Na⁺), Sample types B/P/S/Q

Information		Value	Unit	
Samples (N)	Clinical Study	0		
	Non Clinical Study	2324		
Covered Range	min	5.1	mmol/l	
	max	277.7	mmol/l	
Regression ^(a)	b₀	-1.1873	mmol/l	
	b₁	0.9960	1	
	R²	0.9848	1	
Bias ^(b)	concentration	bias		
	5	-1.2	mmol/l	
	40	-1.3	mmol/l	
Accuracy	Limit	low	high	
	TAE ^(c)	-10.4	8.2	mmol/l
	ATE ^(d)	-25.9	25.9	mmol/l
	ATE:TAE ratio	2.5	3.2	1
	P_{within},%		98.9%	%

Table 4-14 Method comparison Sodium (Na⁺), Sample types U

4 Specifications

Performance Characteristics

Potassium (K⁺)

Information		Value	Unit	
Samples (N)	Clinical Study	1326		
	Non Clinical Study	554		
Covered Range	min	1.05	mmol/l	
	max	14.88	mmol/l	
Regression ^(a)	b₀	0.0162	mmol/l	
	b₁	0.9914	1	
	R²	0.9991	1	
Bias ^(b)	concentration	bias		
	1	0.01	mmol/l	
	2.5	-0.01	mmol/l	
	3.5	-0.01	mmol/l	
	5.1	-0.03	mmol/l	
	6.2	-0.04	mmol/l	
Accuracy	Limit	low	high	
	TAE ^(c)	-0.15	0.1	mmol/l
	ATE ^(d)	-0.64	0.64	mmol/l
	ATE:TAE ratio	4.3	6.4	1
	P_{within},%		100	%

Table 4-15 Method comparison Potassium (K⁺), Sample types B/P/S/Q

Information		Value	Unit	
Samples (N)	Clinical Study	0		
	Non Clinical Study	2394		
Covered Range	min	10.07	mmol/l	
	max	114.75	mmol/l	
Regression ^(a)	b₀	0.3083	mmol/l	
	b₁	1.0120	1	
	R²	0.9842	1	
Bias ^(b)	concentration	bias		
	5	0.37	mmol/l	
	20	0.55	mmol/l	
Accuracy	Limit	low	high	
	TAE ^(c)	-6.53	8.96	mmol/l
	ATE ^(d)	-11.87	11.87	mmol/l
	ATE:TAE ratio	1.8	1.3	1
	P_{within},%		100	%

Table 4-16 Method comparison Potassium (K⁺), Sample types U

Calcium (Ca²⁺)

Information	Value		Unit	
Samples (N)	Clinical Study	1300		
	Non Clinical Study	456		
Covered Range	min	0.1	mmol/l	
	max	3.173	mmol/l	
Regression ^(a)	b₀	0.019	mmol/l	
	b₁	0.9994	1	
	R²	0.9911	1	
Bias ^(b)	concentration	bias		
	85	0.019	mmol/l	
	120	0.018	mmol/l	
	135	0.018	mmol/l	
	145	0.018	mmol/l	
	155	0.018	mmol/l	
	200	0.017	mmol/l	
Accuracy	Limit	low	high	
	TAE ^(c)	-0.049	0.074	mmol/l
	ATE ^(d)	-0.24	0.24	mmol/l
	ATE:TAE ratio	4.9	3.2	1
	P_{within},%		100	%

Table 4-17 Method comparison Calcium (Ca²⁺), Sample types B/P/S/QChloride (Cl⁻)

Information	Value		Unit	
Samples (N)	Clinical Study	1322		
	Non Clinical Study	508		
Covered Range	min	71.4	mmol/l	
	max	149.5	mmol/l	
Regression ^(a)	b₀	0.1928	mmol/l	
	b₁	0.9968	1	
	R²	0.9747	1	
Bias ^(b)	concentration	bias		
	60	0.0	mmol/l	
	80	-0.1	mmol/l	
	98	-0.1	mmol/l	
	107	-0.1	mmol/l	
	120	-0.2	mmol/l	
	150	-0.3	mmol/l	
Accuracy	Limit	low	high	
	TAE ^(c)	-3.1	3.5	mmol/l
	ATE ^(d)	-9.6	9.6	mmol/l
	ATE:TAE ratio	3.1	2.7	1
	P_{within},%		99.78	%

Table 4-18 Method comparison Chloride (Cl⁻), Sample types B/P/S/Q

4 Specifications

Performance Characteristics

Information		Value	Unit	
Samples (N)	Clinical Study	0		
	Non Clinical Study	2376		
Covered Range	min	6.4	mmol/l	
	max	299.4	mmol/l	
Regression ^(a)	b₀	1.8386	mmol/l	
	b₁	1.0168	1	
	R²	0.9842	1	
Bias ^(b)	concentration	bias		
	5	1.9	mmol/l	
	40	2.5	mmol/l	
	300	6.9	mmol/l	
Accuracy	Limit	low	high	
	TAE ^(c)	-8.3	32.4	mmol/l
	ATE ^(d)	32.4	-32.4	mmol/l
	ATE:TAE ratio	3.9	1.9	1
	P_{within},%	98.99		%

Table 4-19 Method comparison Chloride (Cl⁻), Sample types U

pH (pH)

Information		Value	Unit	
Samples (N)	Clinical Study	1154		
	Non Clinical Study	204		
Covered Range	min	6.850	pH	
	max	7.903	pH	
Regression ^(a)	b₀	-0.0379	pH	
	b₁	1.0045	1	
	R²	0.9829	1	
Bias ^(b)	concentration	bias		
	6.7	-0.007	pH	
	7.2	-0.005	pH	
	7.32	-0.005	pH	
	7.43	-0.004	pH	
	7.6	-0.003	pH	
Accuracy	Limit	low	high	
	TAE ^(c)	-0.039	0.028	pH
	ATE ^(d)	-0.088	0.088	pH
	ATE:TAE ratio	2.3	3.1	1
	P_{within},%	99.41		%

Table 4-20 Method comparison pH (pH), Sample types B/P/S/Q

Hematocrit (Hct)

Information	Value	Unit
Samples (N)	Clinical Study	1228
	Non Clinical Study	276
Covered Range	min	12.6 Hct%
	max	74.9 Hct%
Regression ^(a)	b₀	-1.2967 Hct%
	b₁	1.0231 1
	R²	0.991 1
Bias ^(b)	concentration	bias
	10	-1.1 Hct%
	20	-0.8 Hct%
	36	-0.5 Hct%
	53	-0.1 Hct%
	60	0.1 Hct%
Accuracy	Limit	low high
	TAE ^(c)	-1.7 1.5 Hct%
	ATE ^(d)	-6.6 6.6 Hct%
	ATE:TAE ratio	3.9 4.4 1
	P_{within},%	99.8 %

Table 4-21 Method comparison Hematocrit (Hct), Sample types B/Q

Analytical Sensitivity

The analytical sensitivity of the **e|1 Cartridge** in combination with the **e|1 Analyzer** is described by its Limits of Detection (LoB, LoD) and Limits of Quantitation (LoQ). These limits are determined for K⁺ in plasma, Ca²⁺ in plasma and Hct in whole blood. The detection limits for Na⁺, Cl⁻, and pH are not determined since the measuring range exceeds pathological variations. However, the LoQ for Na⁺, Cl⁻, and pH can be determined. All limits are listed in the following tables:

Limit	Definition
Limit of Blank (LoB)	concentration at which there is a 95 % probability that a sample is analyte-free.
Limit of Detection (LoD)	concentration at which there is a 95 % probability that a sample contains analyte.
Limit of Quantitation (LoQ)	lowest amount of analyte in a sample that can be quantitatively determined with acceptable precision and trueness.

Table 4-22 Definition of limits of analytical sensitivity

4 Specifications

Interference

Analyte	Sample Type	Limits								Unit
		N	LoB	N	k	LoD	N	k	LoQ	
Sodium (Na ⁺)	P	-	-	-	-	-	55	4	75.2	mmol/l
	U	87	0.0	120	4	1.99	120	4	1.991	mmol/l
Potassium (K ⁺)	S	212	0.25	305	4	0.26	305	4	0.26	mmol/l
	U	87	0.55	120	4	1.09	120	4	1.09	mmol/l
Calcium (Ca ²⁺)	S	100	0.00	290	4	0.016	290	4	0.016	mmol/l
Chloride (Cl ⁻)	P	-	-	-	-	-	55	4	44.1	mmol/l
	U	87	0.1	120	4	1.7	120	4	1.7	mmol/l
pH (pH)	P	-	-	-	-	-	67	3	6.65	pH
Hematocrit (Hct)	B	103	1.67	240	4	2.97	240	4	2.97	Hct%

Table 4-23 Limits of analytical sensitivity

Analytical Specificity

The analytical specificity describes how different endogenous substances and drugs potentially interfere with parameters measured with the **e|1 Cartridge** in combination with the **e|1 Analyzer** and how precise the measurement detects only those analytes to be detected. Here the following substances must be taken into consideration:

- substances used for patient treatment (e.g. therapeutic drugs, anticoagulants, etc.);
- substances ingested by the patient (e.g. over the counter medications, alcohol, vitamins, foods, etc.);
- substances added during sample preparation (e.g. preservatives, stabilizers);
- substances encountered in specific specimens' types (e.g. hemoglobin, lipids, bilirubin, proteins);
- analytes of similar structure (e.g. precursors, metabolites) or medical conditions unrelated to the test condition including specimens negative for the assay but positive for a condition that may mimic the test condition.

Interference

Interferences can be significant sources of error in clinical analysis. While the precision can be determined by internal QC and the correctness can be determined by verifying reference samples, possible sources of interference cannot be identified during ongoing operation. For this reason, the effect of potentially interfering substances is determined.



For additional information, refer to Interference Testing in Clinical Chemistry; Approved Guideline EP-7 Vol, 25; No. 27 of the Clinical and Laboratory Standard Institutes (CLSI).

Substances without effect

The following substances were tested and do not show any effect on the measurement parameters and do not violate the specifications.

Generic name (substance)	Concentration	Tested analyte
Ammonium chloride *	0.151 mmol/l	Na ⁺ , K ⁺ , Cl ⁻ , Ca ²⁺ , pH
Ammonium chloride (for urine)	107 mmol/l	Na ⁺ , K ⁺
Bicarbonate (for urine)	50 mmol/l at pH 7.6	K ⁺ , Cl ⁻
L- Ascorbic acid *	0.298 mmol/l	Na ⁺ , K ⁺ , Cl ⁻ , Ca ²⁺ , pH
Bilirubin, conj. (Bilirubin ditaurate, disodium salt) *	0.684 mmol/l	Na ⁺ , K ⁺ , Cl ⁻ , Ca ²⁺
Calcium (total, calcium chloride dihydrate) *	5 mmol/l	Na ⁺ , K ⁺ , pH
Chloride (sodium salt) *	120 mmol/l	K ⁺ , Ca ²⁺ , pH
Dobesilate *	0.144 mmol/l	Na ⁺ , K ⁺ , Cl ⁻ , pH
Dopamine (HCl) *	0.004 mmol/l	Na ⁺ , K ⁺ , Cl ⁻ , Ca ²⁺ , pH
Ethanol *	130 mmol/l	Na ⁺ , K ⁺ , Cl ⁻ , Ca ²⁺ , pH
Fluorescein *	0.904 mmol/l	Na ⁺ , K ⁺ , Cl ⁻ , Ca ²⁺ , pH
Fluoride *	0.063 mmol/l	Na ⁺ , K ⁺ , Cl ⁻ , Ca ²⁺ , pH
Ibuprofen *	1.06 mmol/l	Na ⁺ , K ⁺ , Cl ⁻ , Ca ²⁺
Intralipid	2%	Na ⁺ , K ⁺ , Cl ⁻ , Ca ²⁺ , pH
Iodide (sodium iodide)	1 mmol/l	Na ⁺ , K ⁺ , Cl ⁻ , Ca ²⁺ , pH
L-Lactate (sodium salt) *	10 mmol/l	K ⁺ , Cl ⁻ , Ca ²⁺
L-Lactate (sodium salt) (for urine)	22 mmol/l	K ⁺ , Cl ⁻
Lithium (lithium chloride)	3.2 mmol/l	Na ⁺ , K ⁺ , Cl ⁻ , Ca ²⁺ , pH
Nitroprusside (Nitroprusside sodium dihydrate)	2.35 mmol/l	Na ⁺ , K ⁺ , Cl ⁻ , Ca ²⁺ , pH
Oxalate (dipotassium salt monohydrate) *	0.09 mmol/l	Na ⁺ , K ⁺ , Cl ⁻ , Ca ²⁺ , pH
Perchlorate (sodium salt monohydrate)	1.5 mmol/l	Na ⁺ , K ⁺ , Cl ⁻ , Ca ²⁺ , pH
Phosphate (phosphate buffer) *	3.9 mmol/l	Cl ⁻ , Ca ²⁺
Phosphate (phosphate buffer) (for urine)	42 mmol/l	Cl ⁻
pH value high (sodium carbonate) *	pH 8	K ⁺ , Cl ⁻
pH value low (acetic acid)	pH 6.8	Na ⁺ , K ⁺ , Cl ⁻
Potassium (potassium chloride) *	8 mmol/l	Na ⁺ , Cl ⁻ , Ca ²⁺ , pH
Protein total (albumine) *	120 g/l	Na ⁺ , K ⁺ , Cl ⁻
Salicylic acid (sodium salicylate) *	0.207 mmol/l	Na ⁺ , K ⁺ , Cl ⁻ , Ca ²⁺ , pH
Sodium (sodium acetate) *	170 mmol/l	K ⁺ , Cl ⁻ , pH
Sulfate (for urine)	41 mmol/l	K ⁺ , Cl ⁻
Thiocyanate (potassium salt)	0.898 mmol/l	Na ⁺ , Cl ⁻ , Ca ²⁺ , pH
Zinc (zinc chloride)	0.17 mmol/l	Na ⁺ , K ⁺ , Cl ⁻ , Ca ²⁺ , pH

Table 4-24 Substances not interfering the measurement result

* The substance and concentration are listed in the recommendation for Interference Testing in Clinical Chemistry; Guideline EP07, 3rd ed. of the Clinical and Laboratory Standards Institute.

4 Specifications

Interference

Substances with effect

The following substances were tested and do show an effect on the measurement parameters violate the specifications.

Generic name (substance)	Concentration	Unit	Analyte	Analyte level	Effect of substance	ATE	Unit
Benzalkonium chloride	0.0285	[mmol/l]	Na ⁺	140.4	6.6 ± 0.4	4.2	[mmol/l]
	0.0285	[mmol/l]	Ca ²⁺	1.101	0.274 ± 0.009	0.160	[mmol/l]
	0.0214	[mmol/l]	Na ⁺	140.4	5.0 ± 0.3	4.2	[mmol/l]
	0.0214	[mmol/l]	Ca ²⁺	1.101	0.200 ± 0.006	0.160	[mmol/l]
	0.0143	[mmol/l]	Na ⁺	140.4	3.6 ± 0.2	4.2	[mmol/l]
	0.0143	[mmol/l]	Ca ²⁺	1.101	0.152 ± 0.005	0.160	[mmol/l]
Bromide (sodium salt)	4.0	[mmol/l]	Cl ⁻	103.3	13.6 ± 0.9	6.0	[mmol/l]
	3.0	[mmol/l]	Cl ⁻	103.3	10.4 ± 0.6	6.0	[mmol/l]
	2.0	[mmol/l]	Cl ⁻	103.3	6.9 ± 0.4	6.0	[mmol/l]
	1.0	[mmol/l]	Cl ⁻	103.3	3.4 ± 0.2	6.0	[mmol/l]
Cefoxitin *	15.50	[mmol/l]	Cl ⁻	103.6	6.3 ± 0.3	6.0	[mmol/l]
	11.63	[mmol/l]	Cl ⁻	103.6	4.8 ± 0.4	6.0	[mmol/l]
Citrate (trisodium salt dihydrate) *	40	[mmol/l]	K ⁺	3.74	-0.93 ± 0.00	0.40	[mmol/l]
	40	[mmol/l]	Cl ⁻	102.6	16.2 ± 0.4	6.0	[mmol/l]
	30	[mmol/l]	K ⁺	3.74	-0.76 ± 0.00	0.40	[mmol/l]
	30	[mmol/l]	Cl ⁻	102.6	12.1 ± 0.4	6.0	[mmol/l]
	20	[mmol/l]	K ⁺	3.74	-0.55 ± 0.00	0.40	[mmol/l]
	20	[mmol/l]	Cl ⁻	102.6	8.6 ± 0.2	6.0	[mmol/l]
	10	[mmol/l]	K ⁺	3.74	-0.30 ± 0.00	0.40	[mmol/l]
	10	[mmol/l]	Cl ⁻	102.6	4.1 ± 0.3	6.0	[mmol/l]
CO ₂ (total, sodium hydrogencarbonate) *	35.00	[mmol/l]	Cl ⁻	101.4	6.9 ± 0.5	6.0	[mmol/l]
	26.25	[mmol/l]	Cl ⁻	101.4	4.9 ± 0.3	6.0	[mmol/l]
EDTA (disodium salt dihydrate) *	15.00	[mmol/l]	K ⁺	4.41	-0.40 ± 0.00	0.40	[mmol/l]
Heparin (lithium salt) *	300	[kU/L]	Ca ²⁺	1.177	-0.322 ± 0.002	0.160	[mmol/l]
	300	[kU/L]	pH	7.419	0.167 ± 0.003	0.059	pH
	229.3	[kU/L]	Ca ²⁺	1.177	-0.243 ± 0.002	0.160	[mmol/l]
	229.3	[kU/L]	pH	7.419	0.096 ± 0.002	0.059	pH
	158.5	[kU/L]	Ca ²⁺	1.177	-0.169 ± 0.002	0.160	[mmol/l]
	158.5	[kU/L]	pH	7.419	0.061 ± 0.002	0.059	[mmol/l]
	87.8	[kU/L]	Ca ²⁺	1.177	-0.085 ± 0.003	0.160	[mmol/l]
	87.8	[kU/L]	pH	7.419	0.027 ± 0.003	0.059	pH
Magnesium (chloride, hexahydrate) *	4.100	[mmol/l]	Ca ²⁺	1.051	0.259 ± 0.003	0.160	[mmol/l]
	3.075	[mmol/l]	Ca ²⁺	1.051	0.206 ± 0.003	0.160	[mmol/l]
	2.05	[mmol/l]	Ca ²⁺	1.051	0.139 ± 0.004	0.160	[mmol/l]

Table 4-25 Substances interfering the measurement result

* The substance and concentration are listed in the recommendation for Interference Testing in Clinical Chemistry; Guideline EP07, 3rd ed. of the Clinical and Laboratory Standards Institute.

Linearity

The linearity study is conducted to demonstrate that measurements across the claimed measuring range for each parameter are linear (are directly proportional to the concentration of the analyte in the test-result). Five **e|1 Analyzers** were used in the course of the nonclinical studies to evaluate the linearity of the **e|1 Cartridge** in combination with the **e|1 Analyzer**. Three cartridge-lots were analyzed in the course of the experiments. Fundamental linearity can be demonstrated for all analytes in all investigated sample types based on $k = 7 - 9$ equally spaced intermediate concentrations prepared by proportionately mixing the high and low pools, measuring $N = 5$ replicates per pool and device.



The linearity evaluation is conducted and analyzed in accordance with *CLSI EP06-A*.

The following table shows the linearity of the measurement parameters.

(a) The covered range represents the range within which linearity can be demonstrated. This measuring range was covered in nonclinical studies.

(b) Linearity goals are specified for lower (min) and upper (max) measurement range.

Analyte	Covered Range ^(a)		Linearity Goals ^(b)			Unit
	min	max	k	min	max	
Sodium (Na ⁺)	72.2	222.1	9	1.20	1.80	mmol/l
Potassium (K ⁺)	0.83	16.42	9	0.10	0.24	mmol/l
Calcium (Ca ²⁺)	0.000	3.426	9	0.04	0.08	mmol/l
Chloride (Cl ⁻)	46.6	182.9	9	1.80	2.25	mmol/l
pH (pH)	6.656	8.095	9	0.0134	0.016	pH
Hematocrit (Hct)	6.4	74.6	11	1.6	2.0	Hct%

Table 4-26 Linearity of all measurement parameter, , Sample types B/P/S/Q

Analyte	Covered Range ^(a)		Linearity Goals ^(b)			Unit
	min	max	k	min	max	
Sodium (Na ⁺)	0.0	318.5	9	2.0	15.0	mmol/l
Potassium (K ⁺)	0.0	140.1	9	1.0	6.0	mmol/l
Chloride (Cl ⁻)	0.0	331.1	9	2.0	15.0	mmol/l

Table 4-27 Linearity of all measurement parameter, , Sample types U

4 Specifications

Environmental Parameters

Environmental Parameters

Operating, Storage and Transport Conditions

e|1 Analyzer

Operating conditions

Ambient temperature:	between +15°C and +32°C
Sea level:	between -100 and +4000 m sea level
Humidity:	between 15% and 90% rel. humidity (not condensed)

Storage and transport conditions in original packaging

Temperature:	between -20°C and +50°C
Humidity	between 15% and 90% rel. humidity (not condensed)

e|1 Cartridge

Storage conditions in original packaging / shelf life

Temperature:	between +2°C and +25°C up to 9 months
Humidity:	between 15% and 90% rel. humidity (not condensed)

Transport conditions in original packaging

Temperature:	between +2°C and +30°C up to 7 days including 24 hours at + 40°C (to cover temperature peaks during transport)
--------------	---

e|1 QC-Material

Storage conditions in original packaging / shelf life

Temperature:	between +2°C and +25°C up to 48 months
--------------	--

Transport conditions in original packaging

Temperature:	between +2°C and +45°C up to 5 days
--------------	-------------------------------------


Technical Specifications

Device

Electrical data	Mains voltage range:	24V DC
	Current:	2.5A
	Required power:	min. 15 W, max. 60 W
Classification	Protection class:	I (1)
	Overvoltage category:	I (1)
	Contamination level:	II (2)
Dimensions	Width:	20 cm
	Height:	31 cm
	Depth:	28 cm
	Weight	4 kg

Power supply

Type	Manufacturer:	MEAN WELL ENTERPRISES CO., LTD.
	Manufacturer part number:	GSM60A24-P1J
Electrical data	Mains voltage range:	100 - 240VAC
	Frequency:	50/60 Hz
	Current:	1.4 – 0.7A
	Protection:	Short circuit / overload / over voltage / over temperature
Connection	Inlet:	3 pole AC, class 1, IEC320-C14
	Outlet:	Barrel connector, 2.1mm ID x 5.5mm OD x 11mm

Outside  Inside

Printer

Type:	"Easy load" thermal printer
Paper width:	2"

Touch Display

Format:	7"
Resolution:	800 x 480 pix

4 Specifications

Technical Specifications

Chapter **5**

System Installation

5 System Installation

Choosing a location

A well-chosen location is important for trouble-free operation of the **e|1 Analyzer**. Before you begin setup, choose a site that is convenient for your sampling needs and meets the following physical requirements:

- The analyzer must be placed on a flat surface.
- The electrical outlet must be well grounded.
- The analyzer must not be placed in direct sunlight, or direct draft of air-conditions.
- To allow enough air to circulate there must be substantial space around the unit (15 cm upwards and backwards as well as 15 cm to the left and right must remain free).
- The analyzer must not operate close to strong electromagnetic fields, such as those created by electric motors and X-ray equipment.
- The analyzer must not be placed next to explosive gases or vapours.
- If the analyzer is connected to a network via Ethernet cable, a cable with a maximum length of ten meters must be used.

For further necessary environmental conditions refer to chapter 4 **Specifications**, section *Environmental Parameters*.

Unboxing and checking contents

Before installation, the instrument, consumables and accessories should be checked for completeness and potential damage.

The following items are included in the standard delivery of the **e|1 Analyzer**:

- **e|1 Analyzer**
- Power Supply Unit
- Printer Paper (box of 5)

The **e|1 Cartridge** is a consumable and is ordered separately

The **Barcode scanner 1D** or **2D**, **e|1 QC Quality Control** and **Capillary tubes** are optional accessories and are ordered separately.



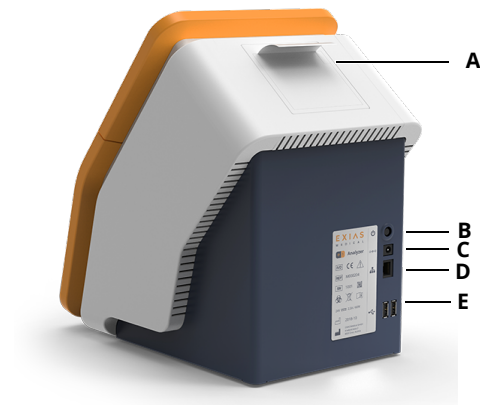
Caution:

Before installing the **e|1 Analyzer** or using the **e|1 Cartridge** it must be assured that the products have room temperature. Cold temperature while storage or transportation can lead to condensation, which may cause malfunction of the system. Hence the products must be acclimatized to room temperature for at least two (2) hours before use.

Installation and setup

Place the **e|1 Analyzer** as described above and connect the power supply unit and, if needed, the barcode scanner and the Ethernet cable to the rear panel.

Switch on the instrument by pressing the ON/OFF button B.



- A Printer
- B ON/OFF button
- C Power supply plug
- D Ethernet port
- E 2x USB ports

Figure 5-1 Rear panel

The analyzer goes through the initial boot-up routine that may take 3 to 5 minutes. This initial routine ends with the analyzer displaying a message that no **e|1 Cartridge** is currently inserted.

Setting Date, Time and Language

Make sure the date and time are set correctly and set the desired language.



[Menu] > [Settings] > [Date/time]

Here Date/time can be set. For further instructions see chapter 9 **System Functions**, section *Settings*.



[Menu] > [Settings] > [Language]

Here the language can be edited. For further instructions see chapter 9 **System Functions**, section *Settings*. The default language for shipped devices is English.

Inserting the e|1 Cartridge



Caution:

Before inserting the **e|1 Cartridge** it is important to set the local date, time and region where the analyzer is being installed. This ensures that the installation date of installed cartridge will be correct.



Caution:

It is important and mandatory that quality control tests are performed immediately after inserting the **e|1 Cartridge**. This must be done before patient testing.

To insert the **e|1 Cartridge**, press **Insert** on the Alarms / Warnings-Screen to start the installation workflow. The analyzer provides step-by-step instructions, with animated pictures to guide the operator, for further instructions see chapter 8 **Replacement of Consumables**, section *Replacement of e|1 Cartridge*.

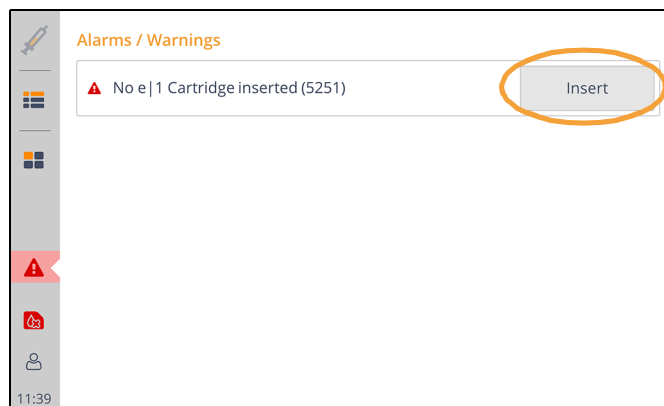


Figure 5-2

It is recommended to hold the analyzer with one hand, when inserting the **e|1 Cartridge**. This helps inserting the cartridge correctly. Inserted properly, the cartridge locks into the system and makes an audible clicking sound.

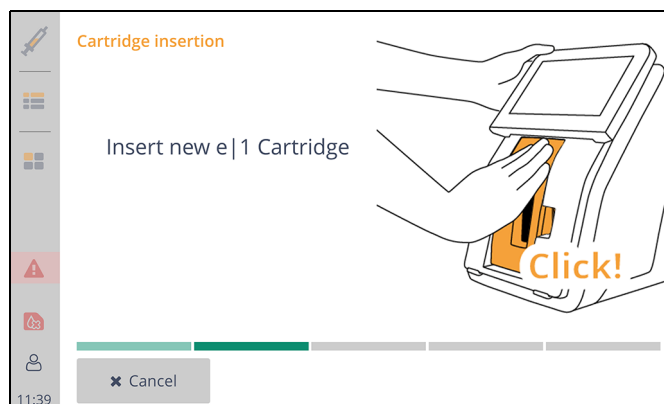


Figure 5-3

If the cartridge is confirmed, initialization of unused cartridges takes about 30 minutes.

5 System Installation

Inserting the e|1 Cartridge

The **e|1 Analyzer** can be programmed to run automatic on-board quality control measurements (oQCs), or request for manual QC after a cartridge replacement. For further instructions see chapter 9 **System Functions**, section *Settings*.

Current state of inserted cartridge

The operator can access cartridge information anytime. Next to the cartridge icon on the main screen remaining days as well as measurements left are listed.

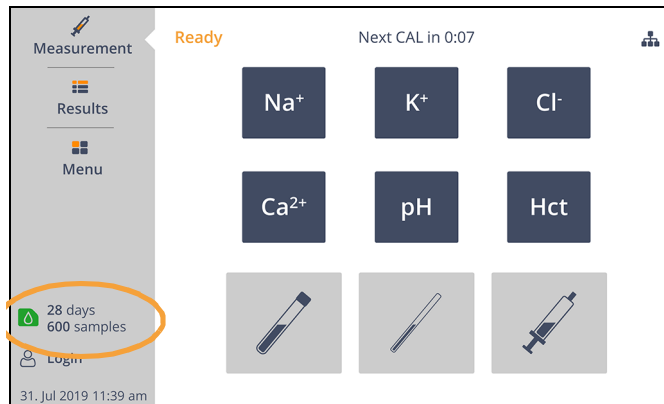


Figure 5-4

By pressing the icon, a detailed summary of the cartridge on-board is listed. This includes information like the serial and lot number, the expiration date, remaining in-use time, and remaining samples.

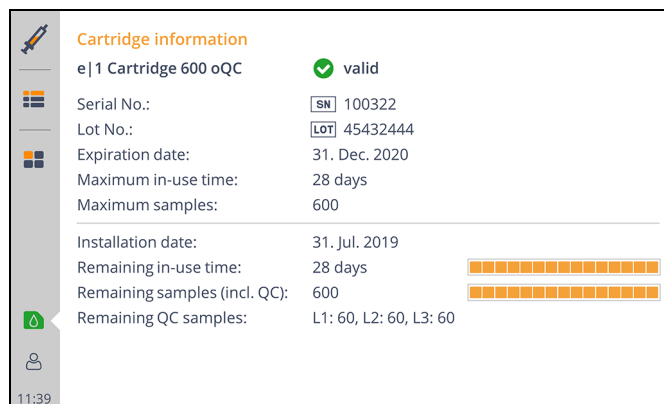


Figure 5-5

A warning is provided by the system either if the cartridge is only valid for two more days, or if only 20 more samples are left.



Note:

The installation date of the cartridge, any later removals, and re-insertions are stored on cartridge chip-data, and not on analyzer.

**Note:**

If removed from analyzer and stored outside, the active **e|1 Cartridge** is usable if re-inserted within 72 hours. After 72 hours the cartridge is invalid and has to be replaced.

If the analyzer is switched off (or has a power-fail) with the cartridge on-board, the cartridge is usable if analyzer's power is restored or switched-on within 72 hours.

If the analyzer has a system-stop with no actions, the cartridge is reusable if the last fluidic action has been less than 72 hours ago.

Customized settings

To configure the analyzer for your specific needs, the following settings should be made.

- Select the units for the measurement results.
- Add calculated parameters if required.
- Define input fields to be displayed and printed in the measurement results.
- Set automatic printout if required and layout.
- Configuring the interval of the automatic calibration.
- Set up the QC planner and automatic quality control measurements.
- Define QC consequences in case of failed QCs.
- To restrict device access for operator groups, set the authentication level and create operators.
- Activate patient management to be able to administer patients on the analyzer.
- Configure network and LIS settings if required.

**Note:**

For further information see chapter 9 **System Functions**.

5 System Installation

Customized settings

Sample Measurement

6 Sample Measurement

Preanalytics

Sample collection



Warning:

When drawing blood samples, the generally applicable safety precautions must be followed. When handling blood samples, the risk for transmission of HIV, Hepatitis B and C viruses or other blood borne pathogens exists. Appropriate blood sampling techniques must be used to minimize the risk for operating personnel.



Blood collection for analysis must be performed by qualified personnel.



To avoid direct contact with biological agents, wear suitable protective equipment, such as laboratory clothing, protective gloves, safety glasses and if necessary, surgical masks. In addition, a face shield is required, if there is a risk of splashing. Suitable disinfection procedures must be applied.



Guidelines and additional information about handling blood samples are provided in CLSI document M29-A3, "Protection of Laboratory Workers from Occupationally Acquired Infections; Approved Guidelines - 3rd edition 2005" and other documents.



Warning:

Under no circumstances pressure may be applied to the puncture site. If the blood sample is mixed with tissue, fluid coagulation may begin prematurely despite sufficient heparinization of the sample collection containers. Incorrect sample collection or the use of unsuitable sample collection containers can cause errors and interfere with measured values. The measuring of hemolyzed blood samples may lead to sustained deviations particularly of sodium and potassium.



For detailed information about drawing blood and storing and handling blood samples, refer to CLSI Document H11-A4, "Procedures for the collection of arterial blood specimens; Approved Standard (Fourth Edition 2004)".

Anticoagulants



Warning:

Only use Li-heparin or balanced heparin salts as anticoagulants for whole blood analysis in the **e|1 Analyzer**. Other anticoagulants such as EDTA, citrate, oxalates, fluorides and ammonium anticoagulants have a significant effect on blood pH, Na, K and Ca and must not be used.

Sample containers

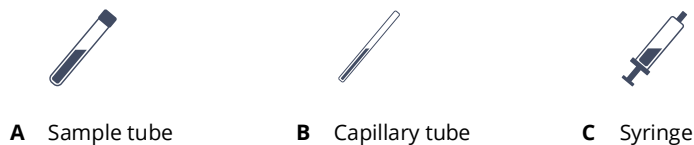


Figure 6-1

Sample tubes

Each laboratory should determine the admissibility of the sample containers used. These products vary from manufacturer to manufacturer and sometimes from lot to lot.

It is necessary that sample tubes are filled at least three cm below the rim.

Syringes

If products with liquid heparin as an anticoagulant are used, the sample container should not be larger than needed for the required blood volume to minimize the effects of blood thinning by the anticoagulant. Normally, plastic syringes are used.



Note:

To ensure safe operation, use only syringes with an inner luer diameter of at least 2 mm.

Capillary tubes



Warning:

It is strongly recommended to use the plastic capillary tubes offered by EXIAS. The capillary tubes are designed and tested to minimize risk of injury in case of possible foreseeable misuse.

If glass capillary tubes are used, there is a potential risk that the glass capillary could break, if it is not removed during the measurement procedure.

When using stirring bars these must be removed before sample input to prevent clogging the sample path of the **e|1 Analyzer**.

Sample handling

Whole blood

Whole blood samples should be taken with heparinized syringes, capillaries or with the sample tube and analyzed as soon as possible after collection. Immediately after removal, air bubbles must be removed from the sampling container.

Immediately after withdrawing the sample with syringes, it should be mixed thoroughly with anticoagulant by rolling the sample between both hands.

The samples must be marked correctly, observing the usual documentation procedures.



Caution:

Immediately before the measurement, a blood sample must be resuspended!

Within a few minutes sample can change significantly leading to incorrect Hct results.

Limitations of clinical analysis

The determined performance data can be influenced by known and unknown factors.

See section *Interference* in chapter 4 **Specifications** for more details about the influence of interfering substances.

General

Various substances are listed in the literature that may affect the measurement result of the sample material blood, plasma or serum.

For the **e|1 Analyzer**, an attempt was made to identify or assess these possible influences.

Since it is not possible to check all drugs or substances, the overall patient status must always be evaluated in case of abnormal deviations of the measurement results.

Electrolytes

It is known that the potassium value of a patient can vary by up to 20% compared to the normal state because of compression bandages. A blood sample should not be taken from patients wearing a pressure bandage. Generally, local hemolysis caused by pressure must be avoided before drawing blood.

Measuring procedure

The parameters that should not be measured can be deactivated temporarily by pressing the respective parameter before selecting a sample mode.

By selecting a sample mode (either sample tube, capillary tube or syringe) on the main screen, the measurement procedure is initiated.

123

The operator is guided by animated pictures through the procedure:

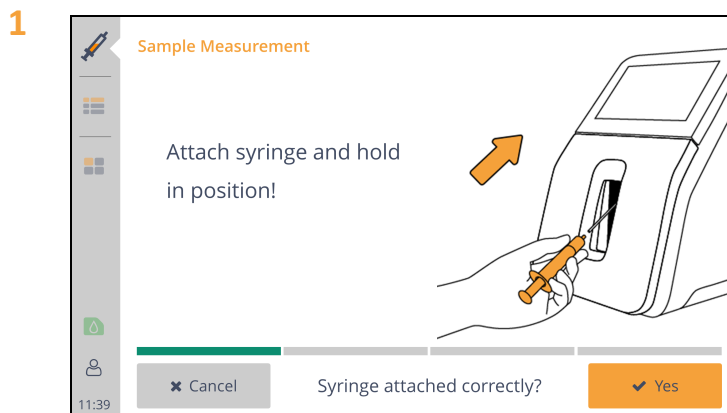


Figure 6-2

Attach sample container and hold it in place!



Warning:

In capillary mode, make sure that the capillary is not pressed too hard (danger of injury).

If the sample container is correctly attached, press **[Yes]** to start the aspiration process.

2 Aspirating sample.

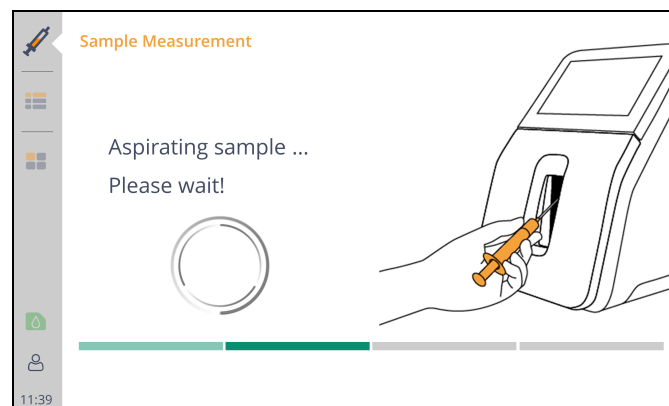


Figure 6-3

While the sample is being aspirated, the sample container must be held. It is important to avoid fractioning which might lead to incorrect or no results.

3 Remove the sample container.

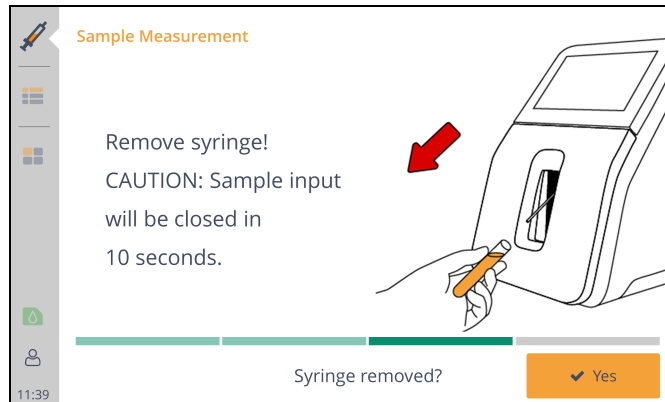


Figure 6-4



Caution:

The sample input closes automatically after ten seconds. The countdown is displayed accordingly.

Confirm with **[Yes]**, the measuring process is started.

4 Measurement in progress.

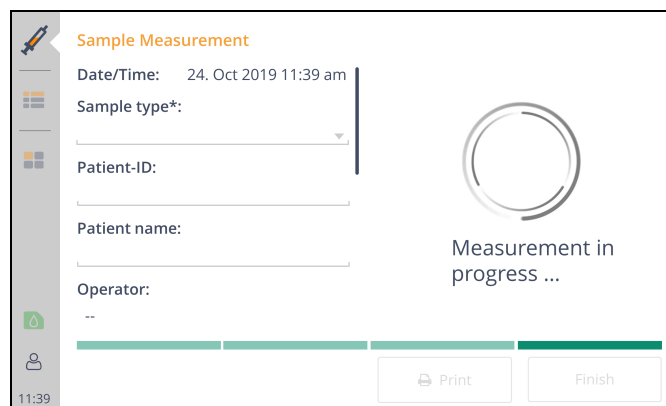


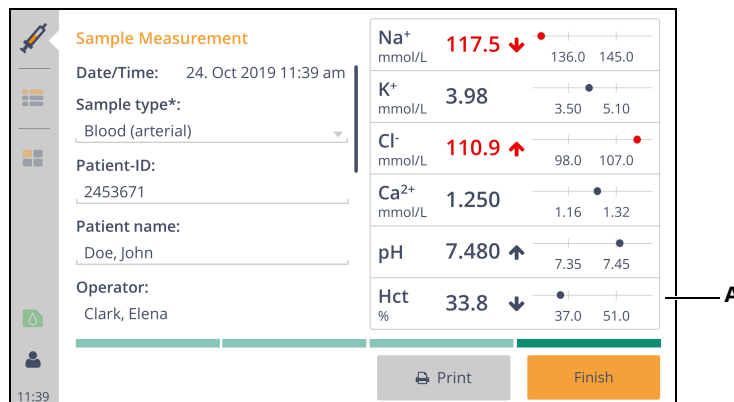
Figure 6-5

During the measurement process, the operator may enter additional information about the patient or the sample and an operator can be logged in (if not already logged-in). The editable fields are underlined in gray and dropdown fields (e.g. sample type) are marked accordingly.

6 Sample Measurement

Measuring procedure

5 The result screen appears.



A Standard values for the reference range - these can be configured in settings

Figure 6-6

After completion of the measurement, the previously selected parameters are shown on the display. If results are outside of the reference range, arrows indicate increased or decreased measurement results. If results are outside of critical limits, values are additionally colored red.

If a result correlation is applied to a result, it is marked using "c". For further information on result correlations, see section *Result Correlations* in chapter 9 **System Functions**.

Mandatory fields are marked with *. If these fields remain empty, the measurement will end automatically after five minutes. Instead of showing a result, the error message "Missing mandatory entries" will be displayed.



Note:

If errors occurred during the measurement, no or not all measured values could be determined. A corresponding error text is then displayed instead of measurement results and ranges.

If the sample type is changed after completion of measurement, so if the measurement results are already displayed, the measurement results will be recalculated. During this recalculation, the text "Calculation in progress ..." is displayed instead of the results.

Start printing by pressing **[Print]** if you need a printout.



Note:

If the "Auto-Print immediately" option is activated in *Settings*, a printout will be generated automatically, if the required fields are filled in and all results are available.

If the "Auto-Print when finished" option is activated in *Settings*, a printout will be created automatically, when **[Finish]** is pressed. For further information, see section *Printer* in chapter 9 **System Functions**.

The measuring procedure will be completed automatically after a timeout of 1 minute or by pressing **[Finish]**.

If sending the measurement results to a laboratory information system is activated, the result is sent by pressing **[Finish]**.

For further information, see section *Laboratory Information System* in chapter 9 **System Functions**.

Measurement evaluation



Warning:

Treatment to a patient should never be administered based solely on results shown on the device's display and printout. It is advised that a trained and knowledgeable medical professional checks the history and prognosis of the patient's condition, before proceeding with any treatment.

If the reported patient results do not reflect the patient's condition, the test should be repeated using a fresh sample. If results are still suspect, please run a liquid QC (oQC or Manual QC, see chapter 7 **Quality Control**) to ensure that the analyzer is performing according to specification. If the controls are within range, there may be an interfering substance in the sample.

Interfering substances in the patient's sample may cause erroneous results.

See also section *Interference* in chapter 4 **Specifications** for more details about the influence of interfering substances.

6 Sample Measurement

Measurement evaluation

Chapter **7**

Quality Control

7 Quality Control

Quality Control Concept

Quality Control, as part of an overall quality assurance program, consists of tests and procedures. The quality control monitors and evaluates the analytical performance of the system, to assure the reliability of patient's test results. EXIAS Medical recognizes the importance of effective quality control of the **e|1 Analyzer** and offers flexible and effective options to meet these needs.

The **e|1 Analyzer** offers two options for Quality Control measurements with aqueous based liquid QC materials, where the quality control material follows the same path through the analyzer as the patient sample:

- 1 Aqueous based QC material integrated within the e|1 Cartridge:** The **e|1 Cartridge** is available with integrated **on-board QC (oQC)**. These cartridges include three levels of QC material. The operator can program the **e|1 Analyzer** to run QCs automatically at fixed intervals. The oQC can also be **triggered manually** at any time as required. The target values of the parameters are included on the cartridge's storage and automatically uploaded when the cartridge is installed.
- 2 Aqueous based QC material offered as a package of 30 glass ampoules:** This material is offered in three levels packaged in a box of 30 ampoules (one box per level). The ampoules can be run **manually (mQC)** whenever necessary. Alternatively, the system is programmable to remind the operator at certain times to run the manual QC. The target ranges are provided as barcodes in the insert sheet and must be entered to the device once.

The laboratory must establish the number, type and frequency of testing control materials using. In deciding how much QC is necessary, the laboratory must strictly adhere to the minimum requirements of this instruction and, if applicable, any local regulation.

Recommended QC regime by EXIAS Medical

At least 2 levels should be run each day by the device. The levels should ideally be rotated over the entire week. The recommended oQC setting on the device is as shown below. This default oQC setting can be easily set by pressing **[Set oQC]** in the QC planner settings and changed by the operator based to local regulations and needs, see chapter 9 **System Functions**.

Time	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
06:10	Level 1	Level 3	Level 2	Level 1	Level 3	Level 2	Level 1
18:10	Level 2	Level 1	Level 3	Level 2	Level 1	Level 3	Level 3



Caution:

It is important and mandatory that quality control tests are performed immediately after replacing the **e|1 Cartridge** as this represents a complete change of analytical components like calibrating solutions and measurement sensors. This must be done before resuming patient testing.



Note:

The **e|1 Analyzer** has a setup possibility where all 3 Levels are automatically run (with oQC cartridge) as soon as the cartridge is replaced, see chapter 9 **System Functions**. For cartridges without integrated QC, the system alerts the operator to conduct quality control.

Important information for evaluating QC results

QC results are evaluated by examining whether the value of each parameter lies within an expected range or not.

- **Measured value is within the expected range**
 - o No follow-up action, the parameter is ok.
 - o The QC result is acceptable and the parameter remains enabled for patient measurements. The display and printout of the QC result shows the measured result in comparison to the target values.
- **Measured value is outside expected range**
 - o The QC result is not acceptable. Affected parameters will be locked, if the option "lock parameter in case of failed QCs" is activated in QC settings. The parameter may only be released for further patient measurements after the problem has been resolved and only after the same QC level has been passed again.



Caution:

If the error persists, replace the **e|1 Cartridge**. If the error remains after the cartridge replacement, please contact your local customer support.

QC measurement

The following QC options are offered by the system:

- automatic on-board QC measurement (optional),
- manual on-board QC measurement (optional),
- manual QC measurement with **e|1 Quality Control** ampoules (Level 1 - Level 3).

On-board QC measurement



Note:

An on-board QC measurement can only be performed if an **e|1 Cartridge** with on-board QC option is used.

An on-board QC measurement starts automatically at predefined times according to settings in the QC planner. Starting from the main screen, please call up the following function:



[Menu] > Administration > **[Settings]** > Quality control / Calibration > **[QC planner]**

Perform QC measurement

Starting from the main screen, call up the following function:



[Menu] > **[Actions]** > **[QC measurement]**

Manual on-board QC measurement



Note:

A manual on-board QC measurement can only be performed if an **e|1 Cartridge** with on-board QC is used.

The manual on-board QC measurement will be performed by pressing the desired level: **[Start oQC L1]** -, **[Start oQC L2]** - or **[Start oQC L3]**.

Manual QC measurement

The manual QC measurement must be performed using the **e|1 Quality Control** material.

Before use allow the ampoules at least four hours to equilibrate to room temperature.

Lot specific values printed on the insert sheet represent the mean values and the acceptable ranges of each parameter. Make sure, level and lot number on insert sheet and ampoules match.

Expected value ranges are provided as a guide for evaluating the performance of the analyzer. A laboratory may establish its own expected values and control limits. The established values should be within the expected ranges shown on the insert sheet.

QC Measuring procedure

Manual QC measurement is performed by pressing **[Start manual QC]**.

Please follow the instructions on the screen.



The operator is guided by animated pictures through the procedure:

- 1 Scan QC material barcode from ampoule (or from insert sheet) or enter it via the virtual keyboard.
If a new lot of QC material is used, scan the two range barcodes from the insert sheet or enter them via the virtual keyboard.

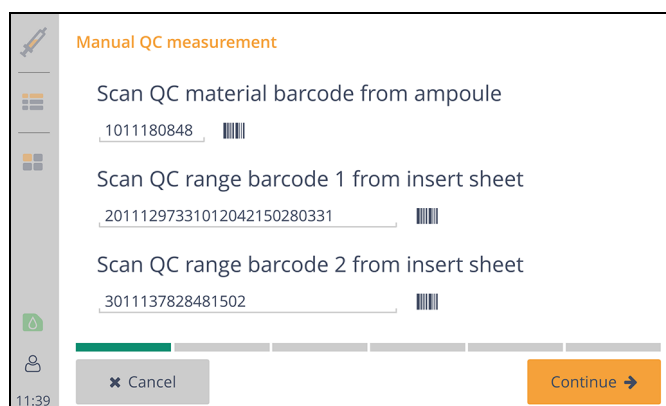


Figure 7-1

Press **[Continue]**.

If the QC material lot has already been used, the range barcodes are remembered by the analyzer and do not need to be scanned again.

- 2 Open ampoule.

7 Quality Control

QC measurement



Caution:

Before use, turn the ampoule three times upside down to mix the content. Tap the ampoule to make sure there is no liquid in the ampoule head. Protect fingers with gauze, tissue or gloves and carefully snap off the neck of the ampoule. Use the control material within half a minute after opening. Never use an ampoule twice.

- 3** Attach ampoule and hold it in place!
Press **[Yes]** to start the aspiration process.
- 4** Aspirating sample.
While the sample is being aspirated, the sample container must be held. It is important to ensure that no air bubbles occur because they could falsify the measurement result or an invalid measurement value could be calculated.
Please wait...
- 5** Remove ampoule.



Caution:

If the ampoule is not removed within five seconds, an acoustic signal will sound, **[Yes]** starts to flash and after another five seconds the sample input unit will be automatically closed. The measuring process is aborted.

By pressing **[Yes]** the measuring process will be started.

6 Measurement in progress.

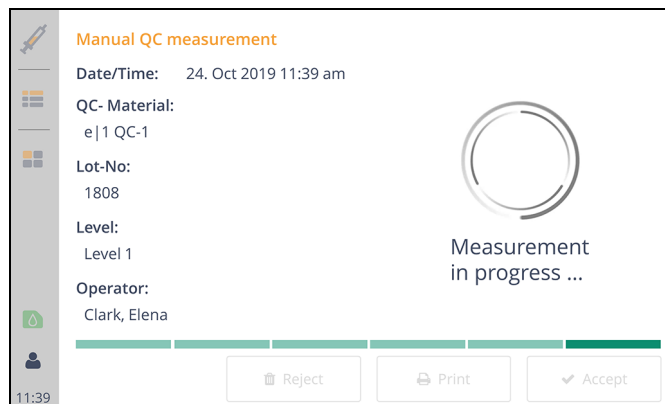


Figure 7-2

After completion of the measurement, the results will be displayed.

If the QC status of a parameter is within the expected range (QC range), the parameter is evaluated to be OK and displayed with a green checkmark. If the result is outside the expected range, the evaluation is nOK which is indicated by a red X.

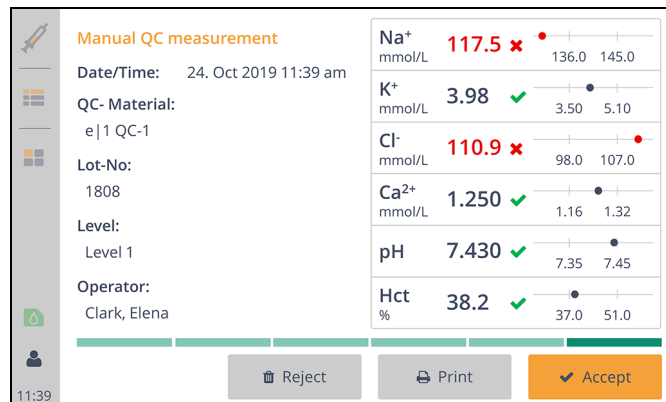


Figure 7-3

By pressing **[Print]** the results are printed out.

If any problems occurred during the measurement procedure (e.g. wrong material was used, air bubbles were aspirated) the result can be rejected by pressing **[Reject]**.

In that case the result will not be saved and the QC consequences will not apply.

The measuring procedure will be completed automatically after a timeout of one minute or by pressing **[Accept]**.

Afterwards the device is ready to measure.

QC consequences

If the QC result for a parameter is out of the expected range or a planned QC measurement was not performed and "lock parameter in case of fail QCs" is enabled in *Settings*, the affected parameter is marked as locked in the main screen.



If several QC measurements for different levels fail or are missing, the parameter will be locked for each level.

Additionally a QC alarm is displayed in the Alarms / Warnings screen.



Note:

A QC lock can be resolved by a manual or an on-board quality control of the corresponding level.



Note:

A QC warning can only be deleted if the QC consequences are disabled. A QC alarm cannot be deleted.

Levey-Jennings Chart

The Levey-Jennings Chart shows the trend of saved QC results in relation to the expected ranges. The chart can be accessed via a specific QC result or a saved QC material by pressing **[LJ chart]** and shows the QC results of the selected material in the specified time period for a selected measurement parameter. In addition to the material specific target and range, the calculated mean, standard deviation (SD) and coefficient of variation (CV) of the displayed QC results are presented.

The displayed parameter and the time period can be selected directly in the Levey-Jennings Chart. To display a specific QC measurement result, use the arrow buttons on the bottom of the chart, the selected result is indicated by a vertical line.

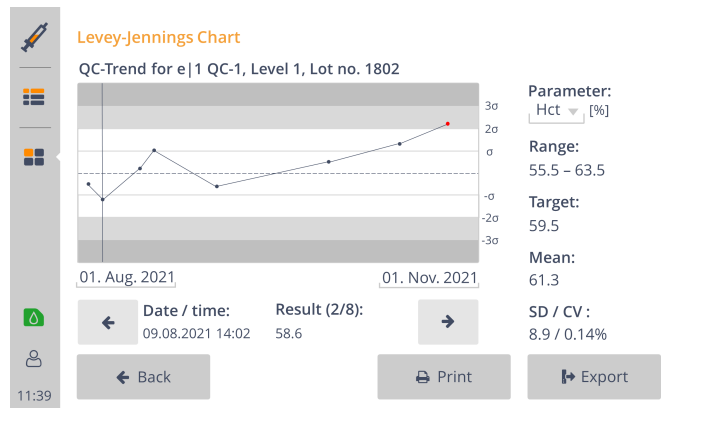


Figure 7-4

QC measurements outside the expected range are colored red. The presented chart can be printed, either for the selected parameter or for all parameters, and exported ("Portable Document Format").

External Quality Control

A guided workflow for external QC (eQC) allows the measurement of third party quality control materials for proficiency testing or other external quality control programs. The workflow is equivalent to the manual QC workflow, but without expected ranges and without result evaluation.

The workflow is started by pressing **[Start external QC]** in the QC measurement menu.

The results and the entered material specific data are stored in the QC results.

Replacement of Consumables

8 Replacement of Consumables

Replacement of e|1 Cartridge

The **e|1 Cartridge** needs to be replaced once the provided number of samples are run, or the maximum in-use time is reached, whichever comes first.



The counted samples include patient samples, as well as all QC samples run by the device within its in-use time.

Depending on the number of performed tests and the number of days the cartridge was used by the device, the analyzer detects that the **e|1 Cartridge** needs to be replaced.

A corresponding error message is displayed on the Alarms/Warnings Screen.



Caution:

Before inserting a new **e|1 Cartridge** it must be acclimatized to room temperature. If the cartridge was stored in a cooled environment (e.g. refrigerator), acclimatization can take up to two hours.



Press the **[Replace]** button from the Alarm/Warning Screen or press **[Cartridge Replacement]** from the Menu and follow the instructions shown on the screen. The operator is guided by animated pictures through the procedure:

- 1 Prepare a new **e|1 Cartridge**.
- 2 Remove cover and take out **e|1 Cartridge**.



Warning:

Dispose the **e|1 Cartridge** according to local regulations regarding disposal of biologically contaminated and hazardous waste.

- 3 Insert new **e|1 Cartridge**.

It is recommended to hold the analyzer with one hand, while inserting the **e|1 Cartridge** to prevent the analyzer from slipping backwards.

Insert the cartridge into the device until you hear a clear click sound.

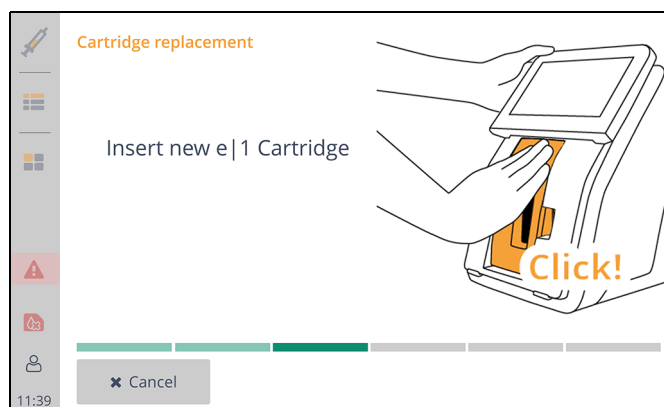


Figure 8-1

8 Replacement of Consumables

Replacement of e|1 Cartridge

4 The e|1 Cartridge data is read by the analyzer

The analyzer reads the cartridge-data out of the storage of the inserted **e|1 Cartridge** and displays it on screen.

If the cartridge has already been used, the remaining number of tests and the remaining in-use time are shown according to the read data.

Press **[Yes]** to confirm the usage of the inserted cartridge.

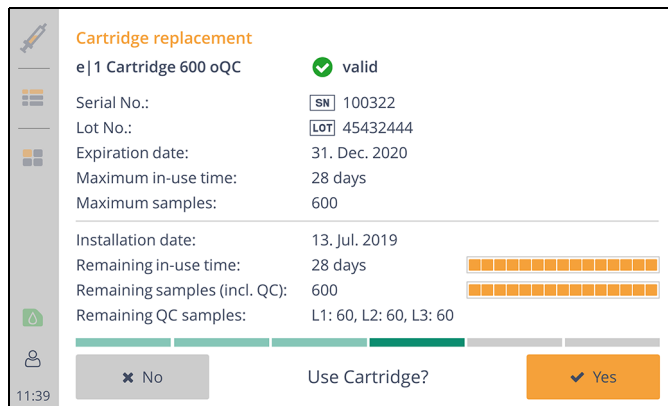


Figure 8-2

If the expiration date of the cartridge will lie before the time-of-use is reached, a warning and an info button is displayed. The usage of each cartridge is limited.

If there are no remaining samples left on the inserted **e|1 Cartridge**, this will be detected by the **e|1 Analyzer** and the inserted cartridge will no longer be usable:

This **e|1 Cartridge** cannot be used anymore.

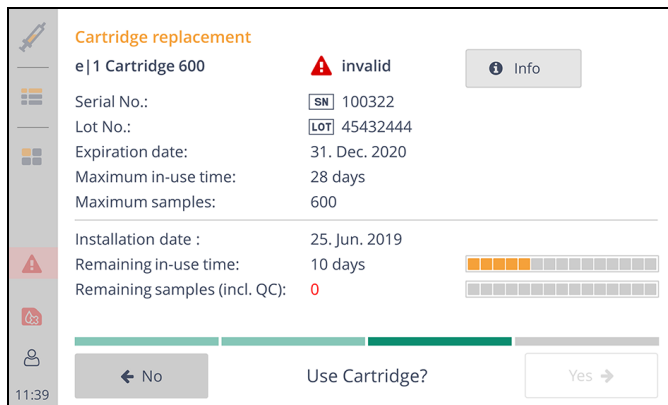


Figure 8-3

The exchange process must be terminated by selecting **[No]** and repeated with a new or suitable **e|1 Cartridge**.

- 5 Close cover and confirm with **[Continue]**.
- 6 The **e|1 Cartridge** initialization starts. Confirm with **[Yes]**.



Caution:

At the beginning of the initialization the sample input unit moves into the capillary position.

- 7 After the sample input initialization the **e|1 Cartridge** is checked. Please wait until the cartridge check is finished. In case of any error an information message appears.
- 8 After a successful cartridge check, the **e|1 Cartridge** initialization continues. The complete initialization takes 30 minutes for cartridges being used for the first time. If the cartridge has already been used, it only takes 15 minutes for the cartridge to initialize. Within this period of time also calibrations are conducted automatically.
The remaining time of the cartridge initialization is displayed in minutes.
After initializing the **e|1 Cartridge**, performs quality control measurements in all three levels (1 = low, 2 = normal, 3 = high).



Caution:

It is important and mandatory that quality control tests are performed immediately after replacing the **e|1 Cartridge** as this represents a complete change of analytical components like calibrating solutions and measurement sensors. This must be done before resuming patient testing.



Note:

The **e|1 Analyzer** can be configured to perform automatic on-board quality controls (oQCs), or requests for manual quality control, after a cartridge replacement (see chapter 9 **System Functions**).



[Menu] > Administration > **[Settings]** > Quality control/Calibration > **[QC settings]**



Note:

If the new installed **e|1 Cartridge** does not contain on-board QC, external QC measurements must be performed (see chapter 7 **Quality Control**).

Current status of the e|1 Cartridge on-board

The current state of the **e|1 Cartridge** is depicted on the main screen next to the cartridge icon. Here left measurements and days the cartridge can be used are listed. By pushing the cartridge icon more details regarding the cartridge are shown. This information includes cartridge type, serial and lot number, expiration date, remaining in-use time and remaining tests.

8 Replacement of Consumables

Replacement of e|1 Cartridge

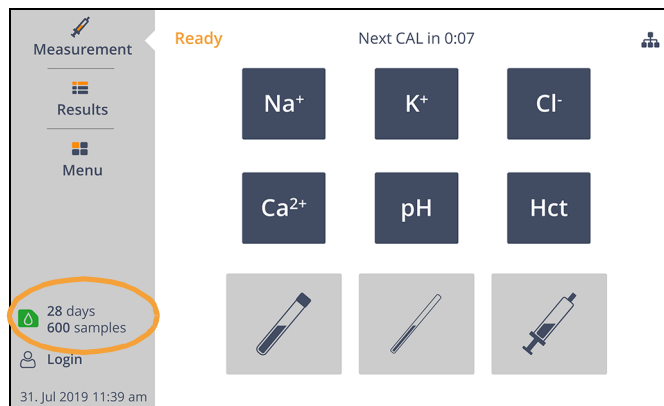


Figure 8-4

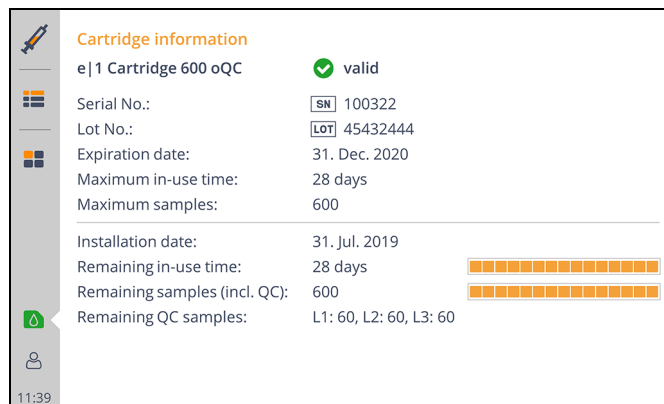


Figure 8-5



Note:

For an almost expired cartridge on-board, the analyzer gives a warning when three days are remaining, or 20 samples are remaining, whichever comes first.



Note:

- If removed from analyzer and stored outside, an active **e|1 Cartridge** is usable if re-inserted within 72 hours. After 72 hours the cartridge is invalid.
- If the analyzer is switched off (or has a power-fail) with the cartridge on-board, the cartridge is usable if analyzer's power is restored or switched-on within 72 hours.
- If the analyzer has a system-stop with no fluidic actions, the cartridge will be reusable if the last fluidic action has been less than 72 hours ago.

Removing and reinserting the e|1 Cartridge

It is possible to trigger the **e|1 Cartridge** replacement workflow with:



[Menu] > [Cartridge replacement]

This can be done to remove and re-insert the cartridge on-board.

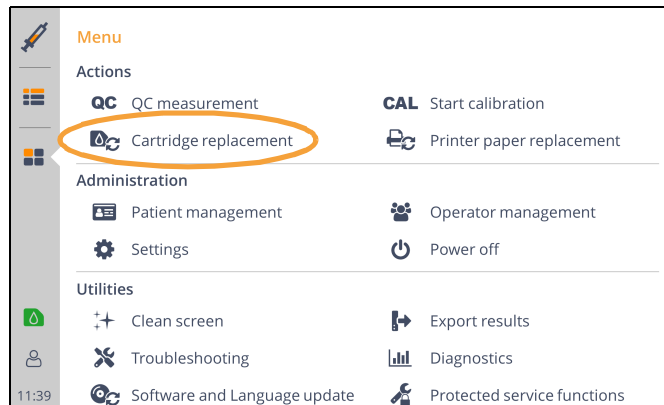


Figure 8-6

Replacement of e|1 Printer paper

If the printer paper is used up, the device will detect that a printer paper replacement is required. Therefore a warning is depicted.

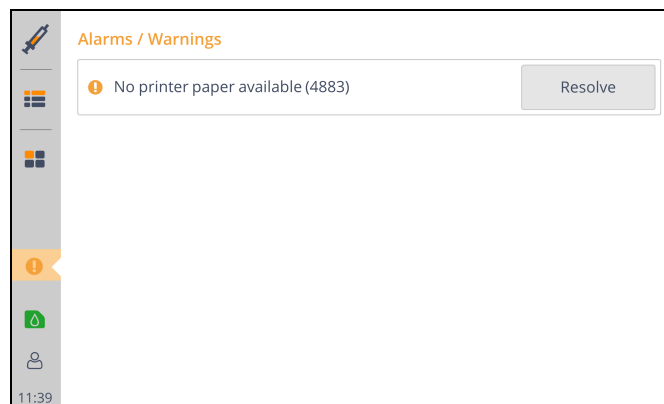


Figure 8-7

Press the **[Resolve]** button and follow the instructions on the screen!

8 Replacement of Consumables

Replacement of e|1 Printer paper

123

The operator is guided by animated pictures through the procedure:

- 1 Open shutter and printer cover.
- 2 Remove empty paper roll and recycle it.
- 3 Insert new paper roll correctly according to the screen animation.

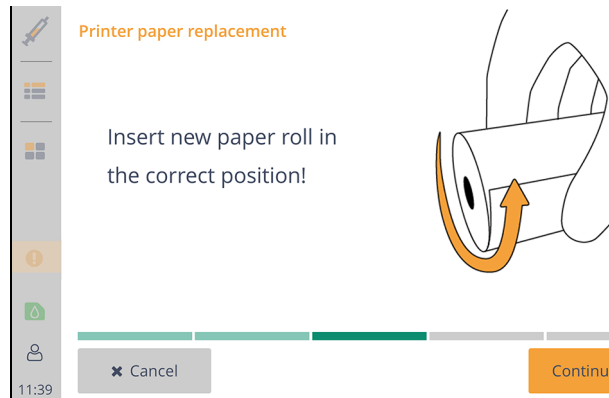


Figure 8-8



Note:

If the printer paper is inserted in the wrong direction, the print out will not be visible. The thermal paper can only be printed on one side.

- 4 Hold paper, close printer cover and shutter.
- 5 To make sure the paper replacement was successful, a test page can be printed.
- 6 Complete the process with **[Finish]**. The device will then return to the main screen.

System Functions

Main Screen



The main screen is displayed when the **e|1 Analyzer** is ready for measurement. The availability of all parameters is displayed and all device functions can be accessed from the Main screen.

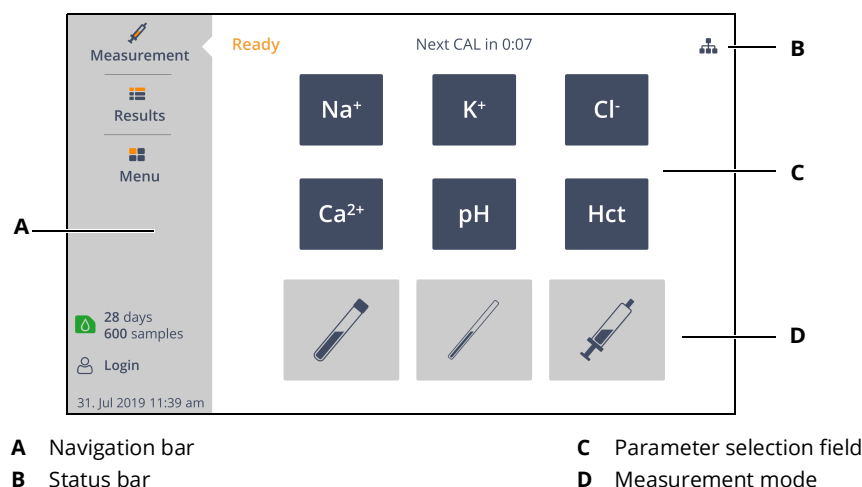


Figure 9-1

Navigation bar

A white arrow in the navigation bar indicates the section.

Icon	Description
	Measurement / Main Screen By pressing the syringe icon, the system switches to Main screen. A measurement can be started, and the status of the parameters is displayed.
	Results By pressing the result icon, an overview list of the sample measurements, quality control measurements and calibration results is displayed.
	Menu Via the menu icon further actions, the administration section incl. settings, utilities and system information can be accessed.
	Alarms / Warnings An alarm or warning icon is displayed, if an alarm or warning occurs. Pressing the alarm / warning icon shows more information and error resolving options.
	Cartridge information The cartridge icon shows the actual status of the currently inserted cartridge. Detailed information is displayed by pressing the cartridge icon.
	Login / logout Pressing the login icon, registered operators can login or logout.
	Actual date / time

Table 9-1 Navigation bar

Status bar

The status bar informs the operator about the current system status, upcoming calibrations or quality control measurements and the connectivity status.

Parameter selection field






Status	Description
	Parameter is activated and ready for measurement.
	Parameter is deselected for next measurement.
	Parameter is not ready for measurement since it is not calibrated.
	Parameter is not ready for measurement due to QC lock.
	Parameter permanently deactivated, see section <i>Parameter Settings</i> .

Table 9-2 Parameter selection field

Measurement modes




Mode	Description
	Sample tube
	Capillary tube
	Syringe

Table 9-3 Measurement mode

Results



By pressing the result icon, an overview list of the sample measurements, quality control measurements and calibration results sorted by date are displayed.

Press the patient, QC or CAL icon to switch between the lists.

By pressing a specific result, detailed information is displayed.

Use the press and hold gesture to select multiple results and print or delete them.



Note:

The export of measurement and QC results is possible by using the export result workflow, see section *Export results*.

Date / Time	Patient-ID	Patient name
24. Jul 2019 11:39 am	2453671	Doe, John
22. Jul 2019 02:34 pm	2743645	White, Andrew
22. Jul 2019 11:55 am	4755402	Miller, Joane
22. Jul 2019 06:22 am	5249632	Wilson, Susan
22. Jul 2019 05:23 am	9345345	Lee, Sarah
22. Jul 2019 04:56 am	8453762	O'Ryan, James

Figure 9-2

If sending to a Laboratory Information System is activated, the sending status is displayed in the result lists, see section *Laboratory Information System*.

9 System Functions

Results

Measurement results



Measurement results are shown in a list with Date/time of measurement, Patient-ID and Patient name. By pressing one record, detailed information of the selected measurement is shown. The result can either be printed or deleted.

Patient information can also be updated.

If a result correlation is applied to a parameter, it is marked using "c". For further information on result correlations, see section *Result Correlations*.



Note:

Changes do not affect measured or calculated results.

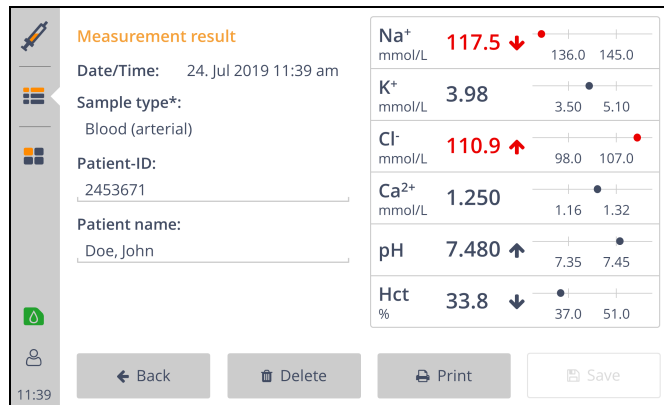


Figure 9-3

Quality control results and calibration results

CAL QC

The overview list shows the evaluation of quality control measurement and calibration results. QC results can be printed either by selecting several results in the overview list or in the detail view.

Quality control and calibration results cannot be deleted.

Date / time	QC type	Na	K	Cl	Ca	pH	Hct
22. Jul 2019 04:04 pm	oQC-1	✗	✓	✗	✓	✓	✓
22. Jul 2019 02:34 pm	oQC-2	✓	✓	✓	✓	✓	✓
22. Jul 2019 11:55 am	mQC-1	✓	✓	✓	✓	✓	✓
22. Jul 2019 06:22 am	eQC	-	-	-	-	-	-
22. Jul 2019 05:23 am	mQC-2	✓	✓	✓	✓	✓	✓
22. Jul 2019 04:56 am	oQC-2	✓	✓	✗	✓	✓	✗

Figure 9-4

Date / Time	CAL-Type	Na	K	Cl	Ca	pH	Hct
22. Jul 2019 04:04 pm	2P*-CAL	✓	✓	✓	✓	✓	✓
22. Jul 2019 02:34 pm	2P-CAL	✓	✓	✓	✓	✓	✓
22. Jul 2019 11:55 am	Post-CAL	✓	✓	✓	✓	✓	✗
22. Jul 2019 06:22 am	Post-CAL	✓	✓	✓	✓	✓	✓
22. Jul 2019 05:23 am	1P-CAL	✓	✓	✓	✓	✓	✓
22. Jul 2019 04:56 am	2P-CAL	✓	✓	✓	✓	✓	✓

Figure 9-5

Menu



Via the menu icon several system features are accessible.

- **Actions:** QC measurement, Start calibration, Cartridge replacement, Printer paper replacement.
- **Administration:** Patient management, Operator management, Settings, Power off.
- **Utilities:** Clean screen, Export results, Troubleshooting, Diagnostics, Software and language update, Protected service functions.
- **Information:** Instrument, Cartridge, Event log, Software, License information.

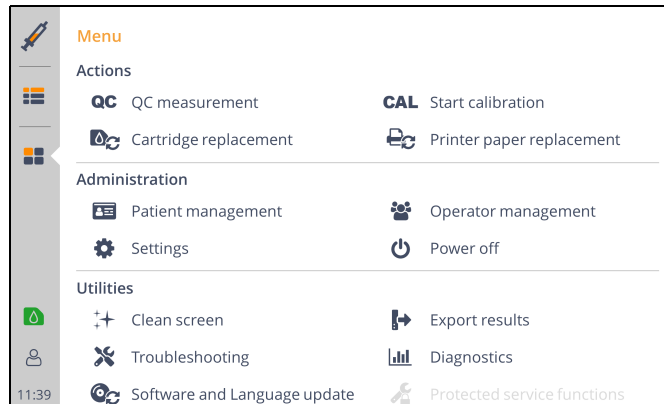


Figure 9-6

Menu > Actions

The Action section lists all actions that the operator may need to perform routinely:

- Performing on-board or manual QC measurements
For further instructions see chapter 7 **Quality Control**.
- Performing a calibration
By pressing **[Start calibration]**, a 2 point calibration is triggered which takes about 30 seconds.
- Replacing the **e|1 Cartridge**
For further instructions see chapter 8 **Replacement of Consumables**.
- Replacing the **e|1 Printer paper**
For further instructions see chapter 8 **Replacement of Consumables**.

Patient management



By pressing **[Patient management]** in the Administration section an overview of all patient data stored on the instrument can be displayed. Existing patients can be edited, and new patients added.

Patient ID	Patient name	Date of birth
2453671	Doe, John	16.Oct.1965
2743645	White, Andrew	28.Feb.1972
4755402	Miller, Joane	07.Jul.1989
5249632	Wilson, Susan	18.Sep.2002
9345345	Lee, Sarah	20.Mar.1978

Figure 9-7



Note:

The patient management feature is only accessible when the patient management is activated in the system settings. For further information see section *System settings*.

New patient:

Press **[New]** to create a new patient.

When creating a new patient, either the patient's last name or patient ID must be entered.

Edit patient:

Press the patient's name in the overview list to edit information or delete the patient.

Press **[Results]** to see all related results.

Patient information	
Patient-ID*:	<input type="text" value="2453671"/>
Last name*:	<input type="text" value="Doe"/>
First name:	<input type="text" value="John"/>
Middle name:	<input type="text" value="Andrew"/>
Title:	<input type="text" value="Prof"/>
Suffix:	<input type="text" value="PhD"/>
Maiden name:	<input type="text" value="Taylor"/>

Figure 9-8

Operator management



By pressing **[Operator management]** in the Administration section an overview of all operators stored on the instrument can be displayed. Existing operators can be edited, and new operators added.

Login name	Name	Profile	Enabled
smiths	Smith, Selina	User	✓
johnsd	Johnson, David	User	✗
tayloo	Taylor, Olivia	Administrator	✓
brownm	Brown, Megan	User	✓
davisj	Davis, Josef	Administrator	✓

Figure 9-9

New operator

Press **[New]** to create a new operator.

When creating a new operator, *Login name* and *Last name* must be entered, and the profile must be selected.

When saving a new operator, a password can be assigned. If a temporary password is used, the operator is reminded to change the password at the first login.

Edit operator

Press the operator's name in the overview list to edit information, reset the password or delete the operator.

If the password is reset, a temporary password can be defined. The operator is reminded to change the password after the first login. For further instruction see section *Login*.

Operator profile

The permission can be set to *User* or *Admin*. Operators with user permission cannot make any settings or changes in operator management and measurement results cannot be deleted.

Permission if no operator is logged in, see section *Authentication*.

Settings



The Settings are divided into the following sections:

Measurement

- Parameter settings
- Data input

Quality control / Calibration

- QC materials
- QC settings
- QC planner
- CAL planner

System

- Date / time
- Language
- System settings
- Network
- Display
- Printer

Security

- Authentication
- Remote access

Information System

- Laboratory Information System



Note:

After changing a setting, press **[Save]** to save the setting.

Parameter Settings



Press **[Parameter Settings]** in the measurement section to display parameter related settings.

Select a parameter from the list to enable/disable it, change the unit or press **[Ranges ...]** to change or redefine ranges.

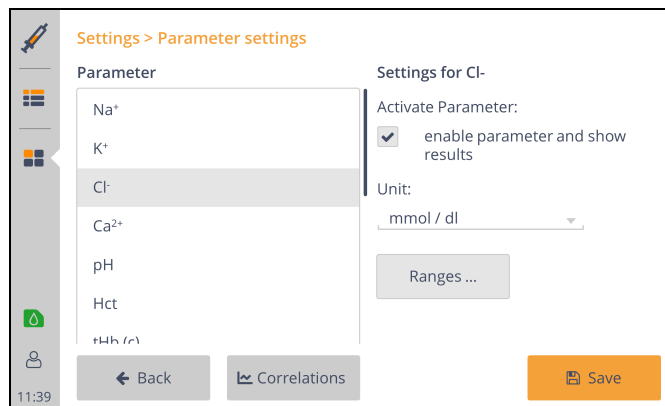


Figure 9-10

Activate / deactivate measured and calculated parameters

The calculated parameters tHb(c) and nCa²⁺ are deactivated per default.



Note:

To calculate tHb(c) the input of MCHC [g/dl] is mandatory. By activating tHb(c) the input field is selected automatically. The MCHC input field cannot be removed or set as not mandatory as long as the calculated value tHb(c) is active.



Note:

To calculate tHb(c) the parameter Hct must be activated.
To calculate nCa²⁺ the parameters pH and Ca²⁺ must be activated.



Note:

If a deactivated parameter is activated, a calibration is performed automatically.

Ranges and limits

By pressing [**Ranges ...**] the existing ranges and limits for the selected parameter can be edited or new ranges can be added.

Reference ranges and critical limits can be defined for all sample types in combination with the following age and sex categories:

- Unspecified
- > 1 year, female
- > 1 year, male
- <= 1 year

The ranges are used for the measurement if the input fields *Sample type*, *Gender* and *Age* are filled in.

For further information on reference intervals and critical limits, see chapter 11 **Theoretical Foundations**. For further information on input data see section *Data input*.

Press [**Reset**] to reset all ranges of a parameter to factory settings.

Result correlations



Warning:

By using result correlations, results can be significantly altered.

To prevent unauthorized changes, settings must be locked for different authorization groups, see section *Authentication*.

By pressing **[Correlations]** in the Parameter settings screen, correlations can be defined for combinations of parameter and sample type.



Note:

Correlations only affect sample measurement results.

QC measurement results are not changed by the application of correlations.

Measurement range limits are not changed by the application of correlations.

Press **[New]** to configure result correlations. To do this, parameter and sample type as well as the correlation factors offset and slope must be set.

The correlation factors are applied automatically on the parameter whenever the selected sample type is set.

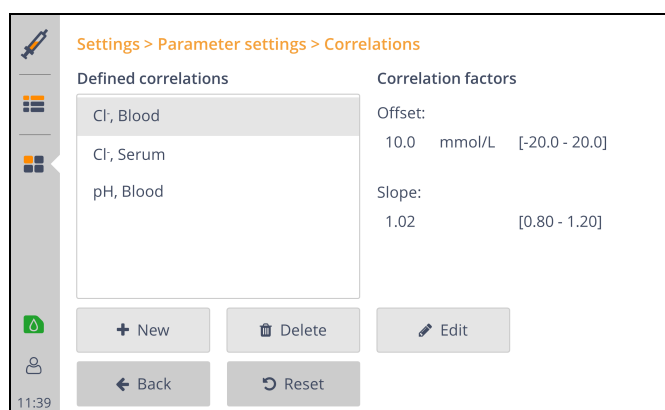


Figure 9-11



Note:

Only one correlation can be set for a combination of parameter and sample type.

To edit or delete a defined correlation, select the correlation entry and press **[Edit]** or **[Delete]**.

Parameter and sample type cannot be edited.



Note:

The correlation factors are automatically applied to the parameter when the corresponding sample type is set.

Data input



Press **[Data input]** in the measurement section to edit the input fields displayed during sample measurement and on the printout. Input fields can be rearranged and set as mandatory inputs.



Note:

During measurement, no measurement results are displayed as long as mandatory input fields are not filled in.

A mandatory input is also fulfilled by a default value.



Note:

The input field *Sample Type* always stays mandatory. This cannot be changed.

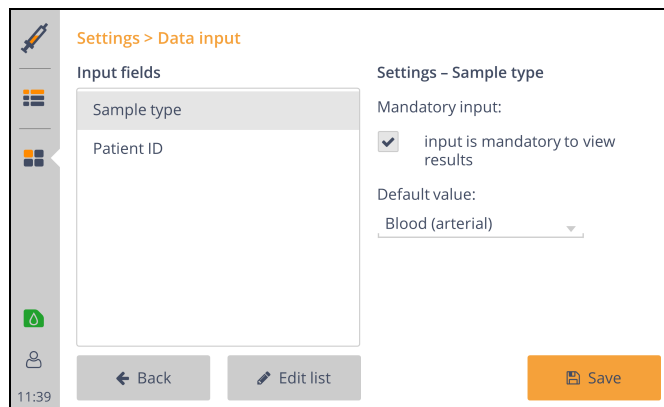


Figure 9-12

For some input fields a default value can be defined.

The following input fields are factory set:

- Sample type
- Patient ID
- Patient
- Operator.

Pressing **[Edit list]** allows to change input fields. The input fields can be easily dragged and dropped from **Available input fields** to **Selected input fields**.

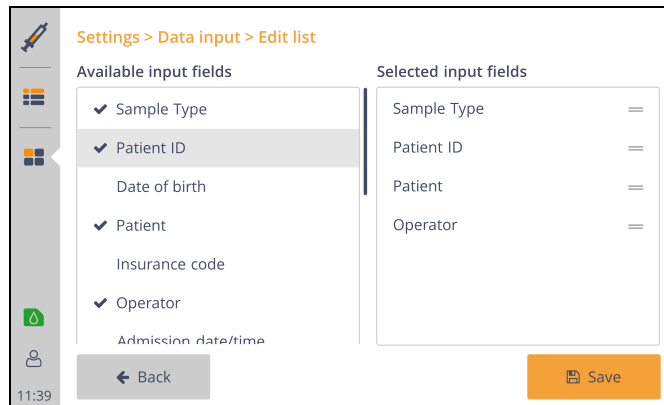


Figure 9-13



Note:

The input field **Sample Type** cannot be removed from the selected input fields, as the sample type affects measurement results.

Quality control materials



Pressing **[QC materials]** in the Quality control / Calibration section displays a list of quality control materials for manual and on-board quality control measurements stored on the instrument.



Note:

The expiry date of the on-board quality control material is not displayed, it corresponds to the expiry date of the cartridge.

For further information see section *Cartridge information*.

Material	Level	Lot No.	Expiry date
e 1 oQC-1	1	2018021800	--
e 1 oQC-2	2	2018021900	--
e 1 oQC-3	3	2018022100	--
e 1 QC-1	1	1802	29.02.2020
e 1 QC-2	2	1802	29.02.2020

Figure 9-14

By pressing a specific material, the ranges for this material are displayed. Use the press and hold gesture to select multiple materials and delete them.



Note:

Only materials that do not have an entry in the results can be deleted.

For further information on quality control results, see *Results*.

By pressing **[Add]** a new quality control material can be added manually by scanning the material and range barcode.



Note:

The on-board quality control material is automatically added by inserting the cartridge. Quality control material for manual quality control measurements can also be added using the quality control measurement workflow.

For further information on quality control, see chapter 7 **Quality Control**.

Quality control settings



Pressing **[QC settings]** in the Quality Control / Calibration section displays the following settings:

- Quality control mandatory after cartridge replacement

By selecting the check box, a quality control measurement level 1 to 3 is required after each cartridge replacement.



Note:

If a cartridge with on-board quality control material is used, one quality control measurement per level is performed automatically.

If a cartridge without on-board quality control is used, a warning or alarm corresponding to the setting of the QC consequences is displayed.

- QC Consequences

By enabling QC consequences, parameter will be locked in case of failed or missing quality control measurements. For further information see chapter 7 **Quality Control**.



Note:

A QC lock can be resolved by a manual or an on-board quality control of the corresponding level.

- oQC follow-up measurement(s) on failure

For cartridges with on-board quality control, up to two (2) automatically performed follow-up measurements can be set for failed on-board quality control measurements. This setting has no influence on manual quality control measurements.

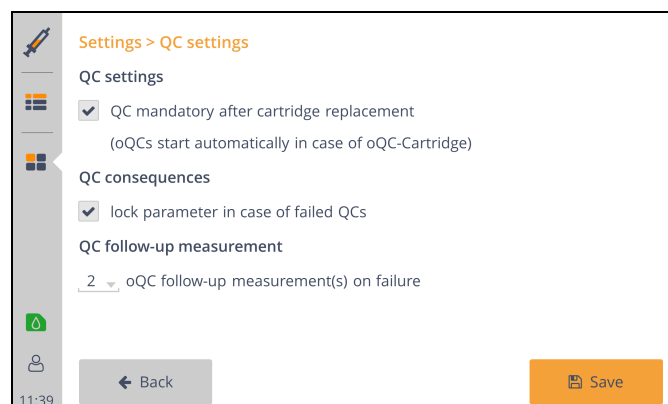


Figure 9-15

Quality Control planner



Pressing **[QC planner]** in the Quality control / Calibration section displays a list of all planned quality control measurement.

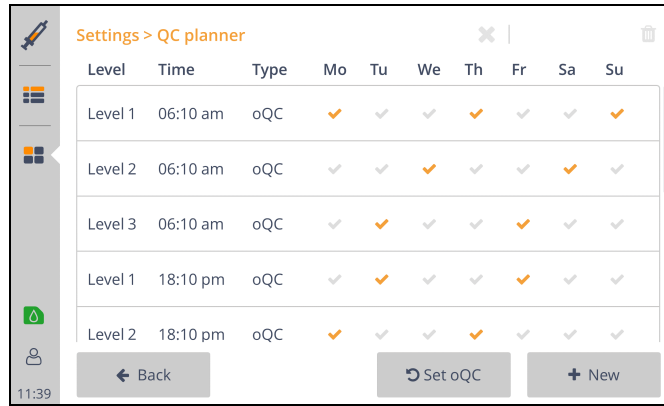


Figure 9-16

The factory settings do not provide any planned quality control measurements. Press **[Set oQC]** to load the recommended QC plan for on-board quality control cartridges. For further information, see chapter 7 **Quality Control**.

Press **[New]** to plan a new quality control measurement by entering level (1 to 3), type (on-board or manual), start time and weekdays.

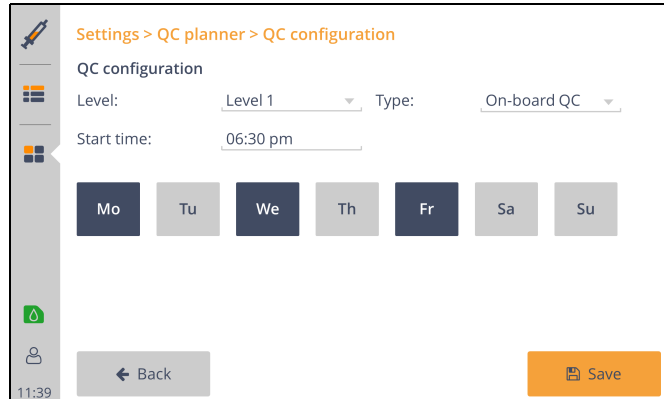


Figure 9-17

By pressing a specific planned quality control measurement, the configuration of level, type, start time and weekday can be changed.

Use the press and hold gesture to select multiple planned QCs and delete them.



Note:

If a planned QC is not performed, a warning will be displayed.

If the QC consequences are activated, an alarm will be displayed after 15 minutes and the parameters will be QC-locked.

Calibration planner



Pressing **[CAL planner]** in the Quality control / Calibration section displays settings for planned calibrations (start time and interval) and the current calibration interval.

For further information see chapter 11 **Theoretical Foundations**.

Date / time



By pressing **[Date / time]** in the System section the time and date as well as its layout, the region and time zone and a time server can be set.



Note:

The date can only be set by synchronizing with a time server. Manual setting is only possible for service technicians.



Note:

Time and date must be updated, and region and time zone must be set before installing any new software.

For further information see chapter 5 **System Installation**.

Depending on the region and time zone, the system automatically switches between summer and winter time.

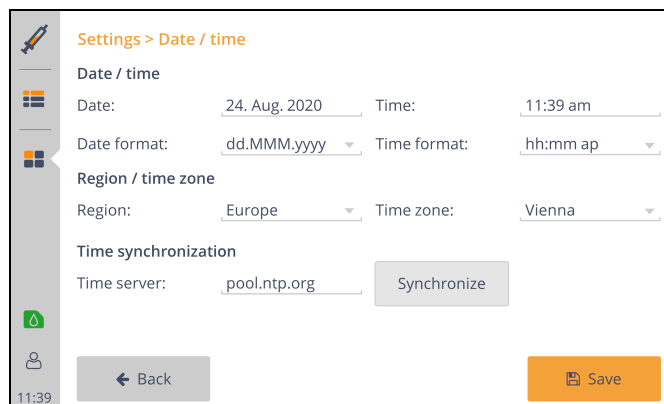


Figure 9-18

The time can be updated by pressing **[Synchronize]** if a time server is set and an internet connection is established.

For further information regarding network connection, see section *Network*.

Language



The language used on the device can be changed by pressing **[Language]** in the System section. To do this, select the desired language and save changes.

9 System Functions

Menu

System settings



By pressing **[System settings]** in the System section, the instrument name and the hospital information can be set, and the patient management can be activated or deactivated.

The device ID (consisting of “e1-“ and serial no.) is factory set as instrument name.

Instrument name and hospital information can be added to the printout. For further information see section *Printer*.

The patient management feature in the menu is only accessible if patient management is activated.

For further information on patient management, see section *Patient management*.



Note:

If patient management is activated, **Patient ID** is added as input field.

For further information on data input field, see section *Data input*.

Network



By pressing **[Network]** in the System section, general network settings, ethernet and wireless settings can be set.

General network settings

Press **[General]** to set gateway, search domain and host name, and add a new or delete a selected DNS name server.

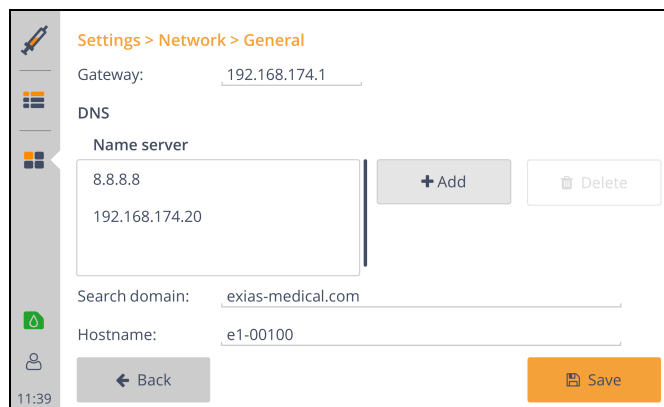


Figure 9-19

Ethernet settings

Press **[Ethernet]** to set IPv4 settings and display IPv6 address and MAC address.

By selecting manual (static), IPv4 Address and subnet mask can be set.

Wireless settings

Press **[Wireless]** to enable wireless, select a network, set IPv4 settings and display IPv6 address and MAC address.

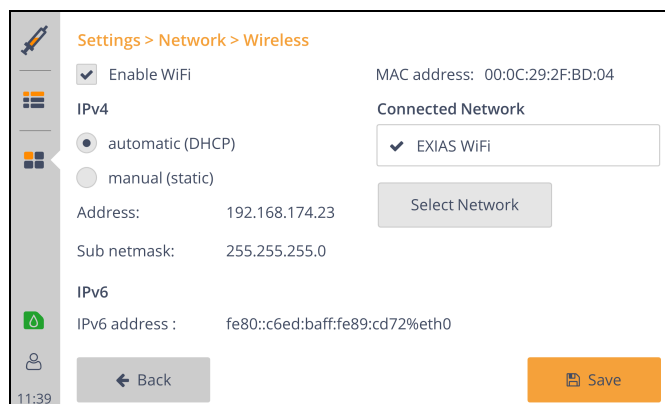


Figure 9-20

To establish a wireless connection, follow the steps below:

123

- 1 Connect a WiFi dongle and enable Wireless connection.
- 2 Press **[Select Network]** and **[Scan]** to display available networks.
- 3 Select available network, enter network key and press **[Connect]**.



Note:

To enable a wireless connection, a WiFi dongle must be connected to the device. In case of problems with the dongle used, contact your local representative of EXIAS Medical.

Display



The brightness of the display can be adjusted to the ambient conditions.

Printer

By pressing **[Printer]** in the System section, automatic printout of sample and quality control measurement results and layout settings can be adjusted.

- Auto printout off:
During a sample or quality control measurement printouts can be generated by pressing **[Print]**.
- Auto printout immediately:
As soon as mandatory inputs have been made and the sample measurement results have been derived, a printout is generated. Each time an input is changed, a printout will be made.
- Auto printout when finished:
During a sample or quality control measurement, by pressing **[Finish]** or **[Accept]**, a printout is generated.

9 System Functions

Menu

**Note:**

The serial number of the instrument and the cartridge are always printed.

**Note:**

All mandatory input fields must be filled-in to view and print the results.

Authentication



By pressing **[Authentication]** in the Security section, a logout time can be set to automatically log out the operator.

The authentication level can be set to:

- No login required:
No operator must be logged in to use all functions.
- Login required for extended functions:
To use extended functions, such as Settings and Operator management and deleting measurement results, operators with admin permissions must be logged in.
If no operator is logged in, the access rights correspond to those of an operator with user permissions.
- Login required for basic and extended functions:
An operator must be logged in to perform basic functions like measurements, view results or enter the menu. To perform extended functions such as Settings and Operator management, an operator with admin permission must be logged in.

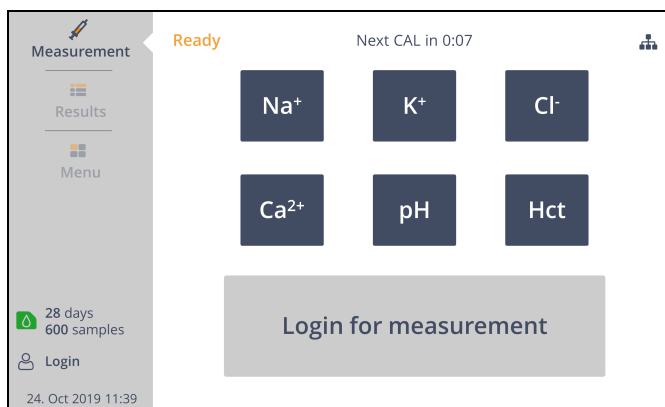


Figure 9-21

Remote access



Press **[Remote access]** in the security section to enable or disable screen sharing and external connection.

**Note:**

If a screen sharing connection is active, a screen symbol is shown at the right bottom of the display. In this case patient and user data are not displayed in plain text to fulfill data protection requirements.

**Note:**

An Internet connection must be established to perform remote access.
For further information see section *Network*.

LIS Settings



By pressing [**Laboratory Information System**] in the Information System section, LIS can be enabled and transmission settings can be configured.

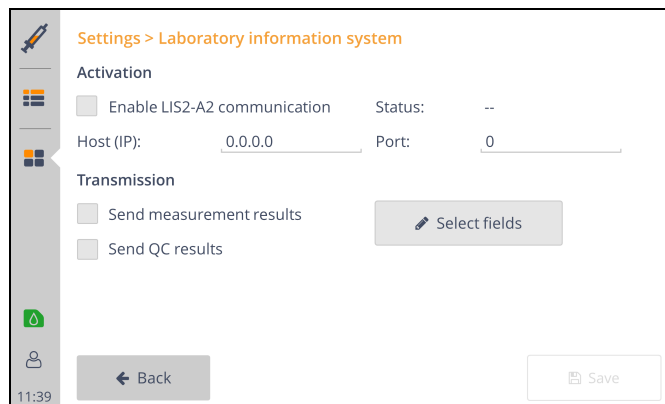


Figure 9-22

Before LIS can be enabled, host IP and port must be filled in.

The Status of the LIS communication is also displayed on the Main Screen using the following icons:

Icon	Description
no LIS Icon	LIS is disabled
	LIS enabled, but no connection can be established (status "connection failed", and "disconnected")
	LIS is activated and a connection can be established successfully

Table 9-4 LIS status icons Main screen

**Note:**

If the connection fails or if the connection is interrupted, a new connection is automatically established every 2 minutes.

To send results automatically after sample measurements or QC measurements, activate the sending option.

The fields sent to LIS can be adjusted by pressing [**Select fields**].

**Note:**

For further information on the protocol, see **LIS Interface Description**.

9 System Functions

Menu

Power off



Press **[Power off]** in the administration section to shut down or reboot the analyzer.



Note:

If the analyzer is switched off for more than 72 hours, the cartridge can not be used any more.

Menu > Utilities

The utilities section includes the following features:

Clean screen, export of results and log files, troubleshooting, software and language update and protected service functions.

For further instructions on troubleshooting see chapter 10 **Troubleshooting**.

[Protected service function] can only be accessed by service personnel.

Clean screen



Pressing **[Clean Screen]** in the utilities section deactivates the touch display for 30 seconds to clean the surface.

For further instructions on disinfection see chapter 2 **Safety Information**.

Export results



Warning:

The USB ports must not be used in connection with devices, that use their own power supply. A failure of the power supply could cause severe damage to the **e|1 Analyzer**.



To export measurement and/or QC results to USB flash drive, press **[Export results]** in the utilities section. The result period can be set.

The guided export workflow is started by pressing **[Export]**.



Note:

All common USB 2.0 sticks that use FAT32 formatting can be used.

Troubleshooting and Diagnostics



Note:

See chapter 10 **Troubleshooting**.

Software and language update



Warning:

The USB ports must not be used in connection with devices, that use their own power supply. A failure of the power supply could cause severe damage to the **e|1 Analyzer**.



A guided workflow for updating software or language can be performed by pressing **[USB Update]** or **[Network Update]**.

If network update is used, an internet connection must be established, for further instructions see section *Network*.

When using USB update, a bootable stick must be used, contact your local representative of EXIAS Medical for further instructions.



Note:

After the update, the instrument is restarted.

After the restart, QC measurements Level 1, 2 and 3 must be performed.

For further instruction see chapter 7 **Quality Control**.

Menu > Information

Instrument information



Press **[Instrument]** in the Information section to display the following information about the instrument:

- Instrument type and Serial no.: e|1 Analyzer and Serial no.
- Instrument name: Can be set, see section *System settings*.
- Hospital info: Can be set, see section *System settings*.
- Service info: Is set by your local representative of EXIAS Medical.
- Patient samples: The patient sample counter represents all sample measurements performed on this instrument. In case of a leasing contract, this counter can be reset by the local representative.
- QC samples: The quality control sample counter represents all quality control measurements (on-board and manual) performed on this instrument. In case of a leasing contract, this counter can be reset by the local representative.




Network

- Hostname: Can be set, see section *Network*. The device ID (consisting of "e1-" and serial no.) is factory set as host name.
- LAN IP address and MAC address: see section *Ethernet settings*
- WiFi IP address and MAC address: see section *Wireless settings*

Cartridge information



Press **[Cartridge]** in the Information section to display the following information about the cartridge:

- Cartridge Type: example given "**e|1 Cartridge 600 oQC**"
- Status of the Cartridge: valid  or in case of a cartridge warning  or invalid . The Status equals the colour of the Cartridge icon in the navigation bar, see section *Cartridge*.

9 System Functions

Menu

- Serial no. and Lot not.
- Expiry date and maximum in-use time
- Maximum samples: depending of the **e|1 Cartridge** type 600, 300 or 150 samples, including QC measurement.
- Installation date: Date of first installation of this cartridge.
- Remaining in-use time and remaining samples (incl. QC)
Remaining QC samples: Displayed only when a cartridge with on-board QC is inserted.
- Details: Additional information concerning cartridge validity including performed and max. urine samples

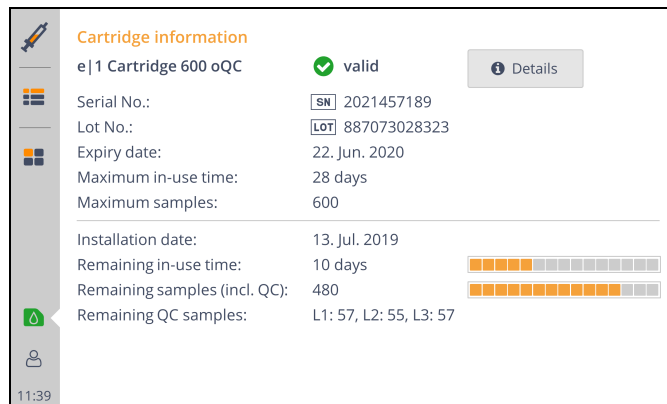


Figure 9-23

Event log



Press **[Event log]** in the information section to display all events listed by date.

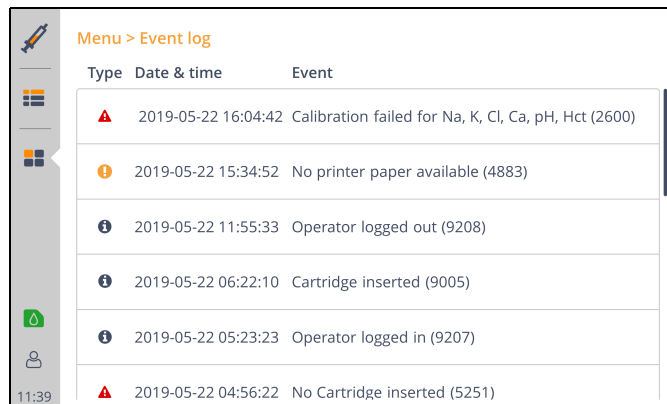


Figure 9-24

Detailed information can be displayed by pressing the event.



Note:

Each alarm, warning or information contains an error number. This number enables a more precise error analysis. In case of contacting your local representative of EXIAS Medical, please provide the error number.

For further instruction see chapter 10 **Troubleshooting**.

Software



Pressing **[Software]** in the Information section displays the installed software. If packages are installed, they are listed as modifications.

License information



All licenses are displayed in the information section when pressing **[License information]**.

Alarms / Warnings



In case of an alarm or warning, an alarm or warning icon is displayed in the navigation bar.



By pressing the alarm or warning icon, all events are listed, and a corresponding resolving action is offered.

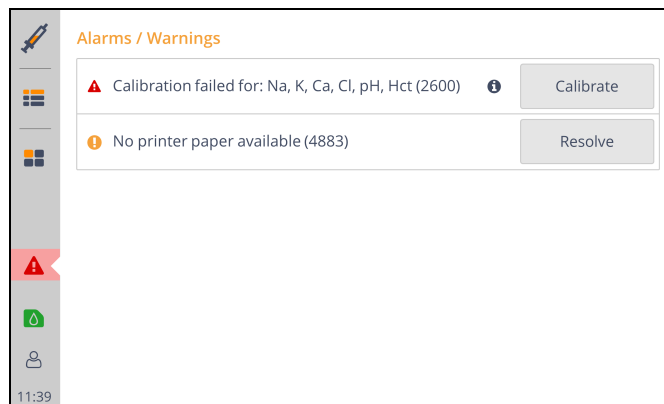


Figure 9-25

If detailed information is available for an event, an information icon is displayed next to the text. The detailed information can be displayed by pressing on the event.



Note:

Each alarm or warning contains an error number. This number enables a more precise error analysis. In case of contacting your local representative of EXIAS Medical, please provide the error number.

For further instructions see chapter 10 **Troubleshooting**.



Note:

All events that have occurred can also be viewed in the event log.

For further instructions see section *Event log*.

Cartridge



By pressing the cartridge icon detailed cartridge information is displayed, see section *Cartridge information*.

The cartridge icon changes the color according to the cartridge status:




Icon	Cartridge status	Description
	Valid	Cartridge valid
	Warning	<ul style="list-style-type: none"> • Remaining in-use time <=3 days • Expiry date <= 3 days • Remaining samples <= 20 samples
	Alarm	<ul style="list-style-type: none"> • Cartridge invalid • No cartridge inserted

Table 9-5 Cartridge status

In case of a cartridge alarm or warning, an alarm or warning icon is displayed, and the cause is listed in the Warnings / Alarms, for further information see section *Alarms / Warnings*.

Login



An already created operator can log in by pressing the login icon.

To log in, the login name must be entered or selected in the drop down list.

If an operator is logged in, the first and last name will be displayed next to the icon on the Main Screen.

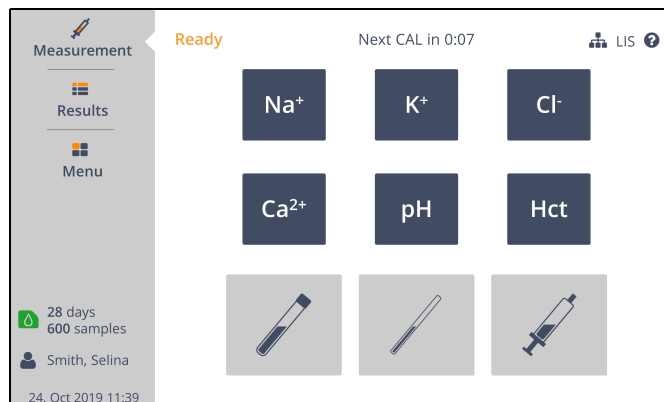


Figure 9-26

If an operator is logged in and the login icon is pressed, the operator will be able to be logged out, or the operator's password changed. Further instructions on creating an operator see section *Operator management*.

Laboratory Information System

The **e|1 Analyzer** offers the possibility to transfer results of sample measurements and QC measurements to a laboratory information system (LIS) using the CLSI LIS2-A2 standard protocol.



Note:

For further information on this protocol, see **LIS Interface Description**.

The results can be sent either automatically after the measurement or manually via the Results screen.



Note:

For further information on enabling LIS and settings, see section *LIS Settings*.

If the laboratory information system is activated, an additional column is displayed in the measurement and QC results.

Date / Time	Patient-ID	Patient name	LIS
24. Jul 2019 11:39 am	2453671	Doe, John	
22. Jul 2019 02:34 pm	2743645	White, Andrew	
22. Jul 2019 11:55 am	4755402	Miller, Joane	
22. Jul 2019 06:22 am	5249632	Wilson, Susan	
22. Jul 2019 05:23 am	9345345	Lee, Sarah	
22. Jul 2019 04:56 am	8453762	O'Ryan, James	

Figure 9-27

The status of the transmissions is indicated by the following icons:

Icon	Description
	Not send, LIS not enabled during measurement
	Successfully send
	Unable to send, LIS enabled during measurement

Table 9-5 LIS status icons results

If sending fails, a warning is displayed.

Open Results view by pressing **[Results]** in the navigation bar or by pressing the resolving action button of the warning to resend unsent results.

Resend

To resend a result to the laboratory information system use the press and hold gesture to select multiple results and press the send icon.

Result Correlations



Warning:

By using result correlations, results can be significantly altered.

To prevent unauthorized changes, settings must be locked for different authorization groups, see section *Authentication*.

The configuration of correlations allows to adapt the measured values of the **e|1 Analyzer** to results of other measuring instruments.

This is achieved by defining offset and slope for combinations of parameter and sample type.



Note:

Correlations only affect sample measurement results.

QC measurement results are not changed by the application of correlations.

Measurement range limits are not changed by the application of correlations.

If correlations are applied, the corresponding parameters are marked with a "c" during measurement, in the results and on the printout.



Figure 9-28



Note:

For further information on correlation setup, see section *Parameter Settings*.

Chapter **10**

Troubleshooting

Troubleshooting concept

The Navigation bar on the left side of the main screen has an **Alarm / Warning** indicator icon, which is visible as soon as an issue occurs. Press the icon to show all current alarms or warnings.

For each alarm or warning, there is an action demanded by the device to resolve the issue.

Examples:

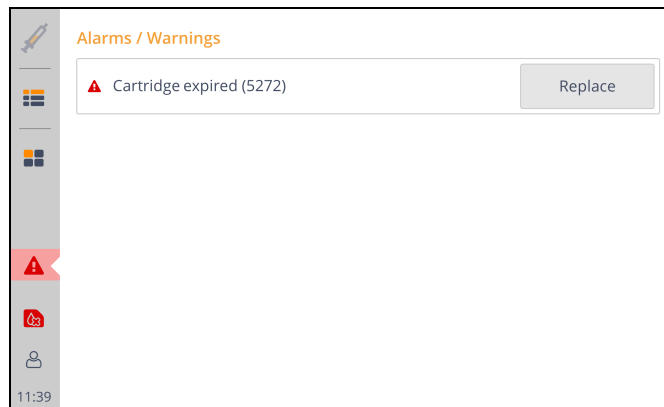


Figure 10-1 Selecting alarm icon

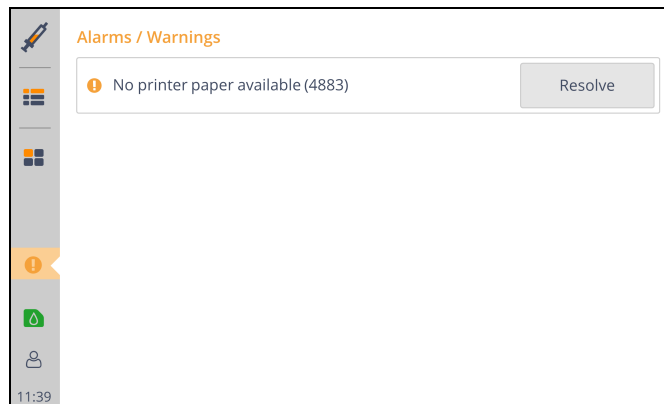


Figure 10-2 Selecting warning icon

Dependent on the situation the screen may display more than one alarms and/or warnings. Some displayed errors may be shown only as consequence of the main alarm, as seen below.

10 Troubleshooting

Troubleshooting concept

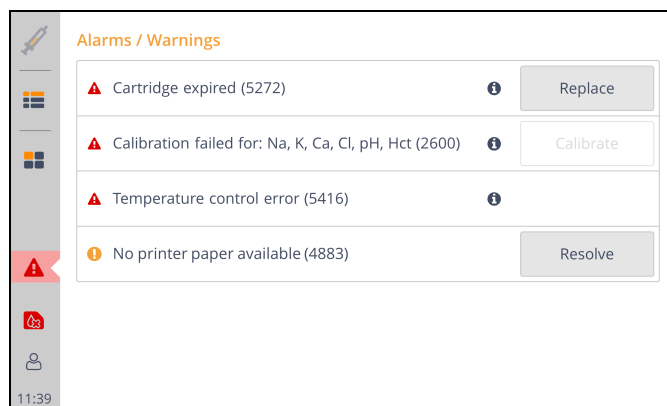


Figure 10-3 Analyzer may show more than one alarm and/or warning

The **Info** icon may also be displayed, depending of the error. By pressing that icon, additional relevant information concerning the alarm or warning is shown.

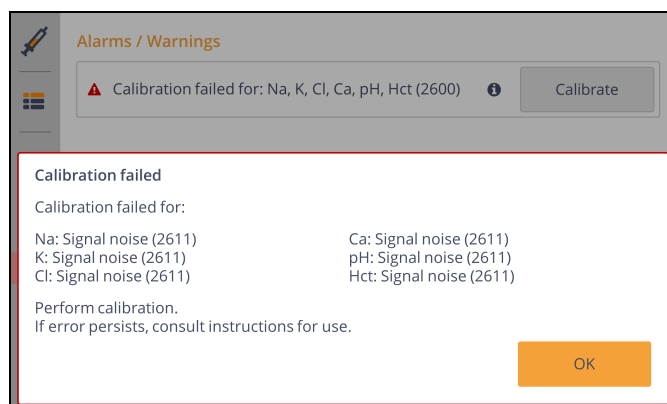


Figure 10-4

If a parameter is not available, it will be shown on main screen by the crossed-out parameter. By pressing the crossed-out parameter, the reason is shown.

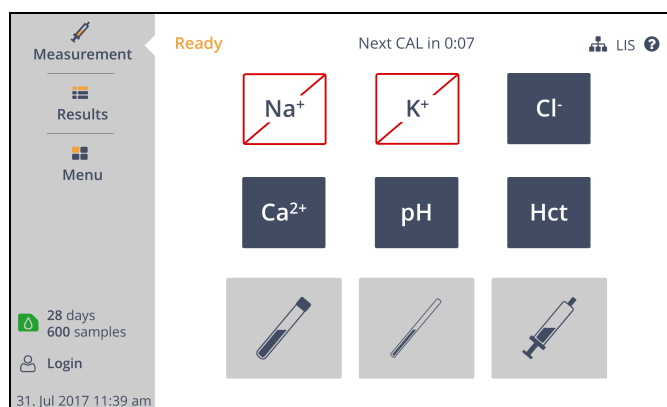


Figure 10-5 Main screen with crossed parameters

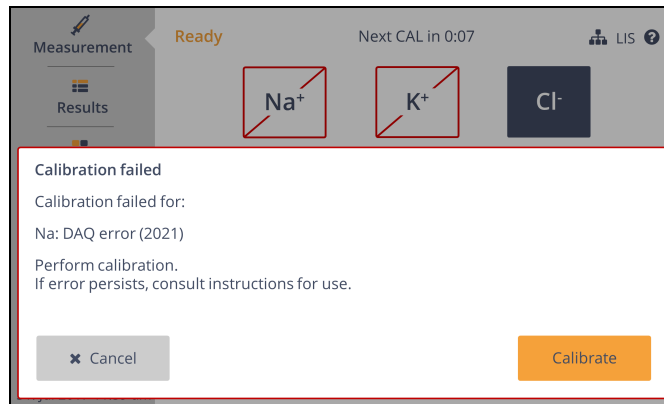


Figure 10-6 Pressing a crossed out parameter

Self-diagnosis and self-checks

The **e|1 Analyzer** continuously monitors all analytical, fluidic and thermal processes in the background. If a problem is detected, a system check is started and the analyzer tries to fix the problem automatically. If the system check fails, an alarm will be displayed.

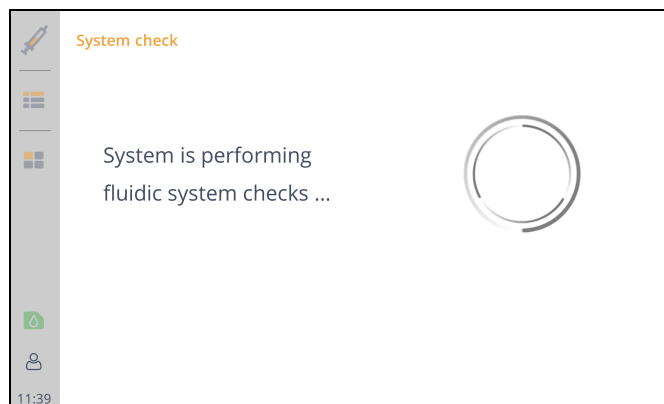


Figure 10-7

Automatic clot-detection and declotting routines

The **e|1 Analyzer** includes a built-in clot detection. If a patient sample has a clot, this will automatically be detected by the system and a “declotting” routine is started to remove the clot out of the sample path.

Troubleshooting routines



The troubleshooting routines can be performed by the user himself, or in conjunction with telephone support from your local representative of EXIAS Medical.

Press **[Troubleshooting]** in the Utilities section to access the following routines:

- Declotting
- Intensive wash
- Aspirate
- Clean sample input
- Export log files
- Debug level

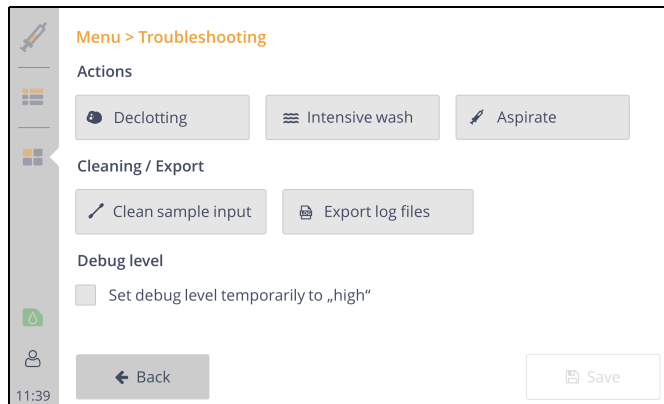


Figure 10-8



Note:

If troubleshooting routines are performed, measurement readiness is restored after leaving the troubleshooting screen. This can take several minutes.

Declotting

Perform the declotting routine by pressing **[Declotting]** to remove minor blockage of the sample input, causing sample aspiration or fluidic errors.

This manually started routine is equivalent to the automatic declotting triggered by the analyzer when a clot is detected during sample measurement.

During this action a waiting loop animation is displayed.



Note:

If this troubleshooting routine does not solve the problem, repeat the procedure. Contact your local representative of EXIAS Medical if the problem persists.

Intensive wash

Perform an intensive wash to remove minor deposits and blockages in the sensor and sample input, causing sample aspiration or fluidic error.

Press **[Intensive wash]** to start this routine.

During this routine, a waiting loop animation is displayed.

Clean sample input



Warning:

Whenever the sample port and the probe are cleaned, there is always a risk of infection, since both are used to aspirate biological samples. Always use protective gloves during the cleaning process.



Warning:

The sample input will be opened automatically to enable cleaning.

With the guided cleaning workflow, the sample input is moved to different positions to clean the sample port and the probe and to remove contaminations. Contaminations can lead to leakage problems and other types of aspiration errors.

Press **[Clean sample input]** to start the cleaning workflow.



Note:

Use cotton swabs and tissues moistened with water to clean sample port and probe.

Export log files



Warning:

The USB ports must not be used in connection with devices, that use their own power supply. A failure of the power supply could cause severe damage to the **e|1 Analyzer**.

To export logfiles to USB flash drive or upload to customer support press **[Export log files]**. The period can be set.

The guided export workflow is started by pressing **[Export]** or **[Upload]**.

If Upload is used, an internet connection must be established, for further instructions see chapter 9 **System Functions**.



Note:

All common USB 2.0 sticks that use FAT32 formatting can be used.

Debug level



Warning:

Do not activate the high loglevel permanently. This can lead to unnecessary memory usage.

In order to facilitate error analysis with the help of log files, it is recommended to set the log level to "high" for a period of 48 hours using the checkbox.

Diagnostic functions



The Diagnostics functions provide further details in case of problems.



Note:

Diagnostic functions should only be performed in consultation with your local representative of EXIAS Medical.

Press **[Diagnostics]** in the Utilities section to access the following checks:

- Fluidics Check
- Positioning Check
- Electronics Check
- Signal Quality Check
- Temperature Check
- Contacting Check
- Touch Screen Check

The parameters of the individual checks are determined either immediately on entering the check or after pressing **[Start]**. The status is displayed using the following icons.

Icon	Description
—	Not yet determined
✓	Status is valid
✗	Status is invalid

Table 10-1 Status checks



Note:

If diagnostics functions are performed, measurement readiness is restored after leaving the diagnostics screen. This may take several minutes.

System recovery



The system recovery screen is displayed, if severe software problems occur.

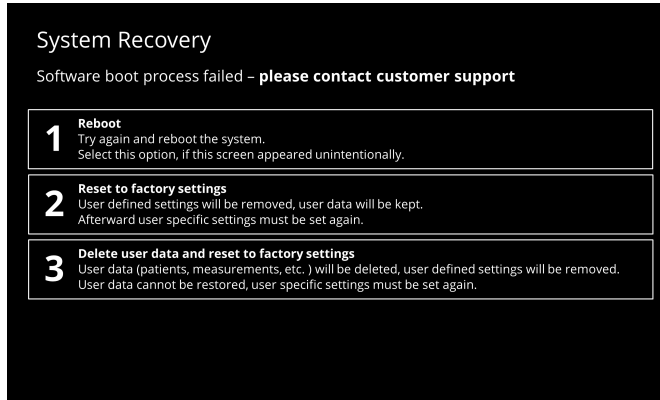


Figure 10-9



Caution:

In case the recovery screen is displayed, contact your local EXIAS Medical representative and determine the correct action before performing any action.



Caution:

Deleted user data cannot be restored. Try other options first and contact your local representative of EXIAS Medical.

Following recovery actions are offered:

- **Reboot:**
Try again and reboot the system.
- **Reset to factory settings:**
User defined settings will be removed, user data will be kept.
Afterward user specific settings must be set again.
- **Delete user data and reset to factory settings:**
User data (patients, measurements, etc.) will be deleted, user defined settings will be removed.
User data cannot be restored, user specific settings must be set again.

Error Messages

Sampling errors during Patient Measurements

Sampling Error codes: 1301, 1302, 1304, 1305, 1309
<p>Check the last patient sample</p> <ul style="list-style-type: none"> • Ensure sample is adequately heparinized. • Ensure sample is presented to device on time. • Check available sample volume. • Ensure sample is homogeneous, without fragmentation, foam or air-bubbles. • For Neonatal samples, ensure capillary used contains enough heparin. • For syringe samples, ensure adequate volume. The aspiration probe should not touch the piston while aspirating sample.
Repeat the patient sample
“Clot in Path” System Stop. Error codes: 5301, 5302, 5304, 5305
Error indicates that the automated de-clotting routine of the system attempted to clear the clot / blockage in the measuring path, was not successful.
<p>Go to Menu – Troubleshooting – Declotting</p> <p>Run the de-clotting once or twice.</p>
<p>Go to Menu – Troubleshooting – Clean sample input</p> <p>Check the sample-input for visible clots/contamination. Clean it with an cotton swabs and tissues moistened with water to clean sample port and probe.</p> <p>Caution Biohazard. Please take precautions and wear gloves.</p>
Replace e 1 Cartridge if this does not resolve the problem.

Parameter/s not calibrated

Sensor Drift Error Nos: 2623, 2624, 2641
Sensor Slope Error Nos: 2621, 2622
Sensor Noise error Nos: 2610, 2611, 2612, 2613
Check if an improper (unspecified) sample was recently run on device.
Go to Menu – Start calibration to run a full 2pt calibration.
Remove and re-insert the e 1 Cartridge.
<p>Go to Results – Cal results.</p> <p>Select the last 2 point calibration in the list, and check the slope value of the parameter. If the slope value is on borderline, repeat the calibration, and if possible, wait two hours for the parameter to stabilise again.</p>
Replace the e 1 Cartridge if the slope is falling distinctly outside the range, even after waiting.

QC results out of range (for on-board as well as manual QC)

<p>Go to Menu – Start calibration</p> <p>This triggers an automatic 2 point calibration. Repeat in case of an error message.</p>
<p>Rerun QC again and check, if ranges are met.</p>
<p>Go to Results – Cal results.</p> <p>Select the last 2 point calibration in the list, and check the slope value of the parameter. If the slope value is borderlining, repeat the calibration, and if possible, wait two hours for the parameter to stabilise again.</p>
<p>For On-board QC measurements of Cartridge</p> <p>Go to Menu – Troubleshooting – Clean sample input</p> <p>Check the sample-input for visible clots or contamination. Clean it with an cotton swabs and tissues moistened with water to clean sample port and probe.</p> <p>Caution biohazard. Please take precautions and wear gloves.</p>
<p>Replace e 1 Cartridge if this does not resolve the problem.</p>

Fluidic and aspiration errors



Note:

These errors may occur after a calibration, measurement sample or QC sample.

<p>Rinse error No: 1321, 1322, 1324, 1325, 1329</p> <p>System stop: Rinse error No: 5321, 5322, 5324, 5325, 5329</p>
<p>Internal fluidic error Nos: 1311, 1312, 1314, 1319</p> <p>System Stop: Internal fluidic Error Nos: 5311, 5312, 5314, 5319</p>
<p>Go to Menu – Start calibration</p> <p>This triggers an automatic 2 point calibration.</p> <ul style="list-style-type: none"> • Rerun Patient Sample / QC if error occurred after measurement / QC
<p>Go to Menu – Troubleshooting - Intensive wash</p> <p>Press [Start] to run routine 2-3 times to prime all the solutions.</p>
<p>Go to Menu – Troubleshooting – Clean sample input</p> <p>Check the sample-port for visible clots or contamination. Clean it with an cotton swabs and tissues moistened with water to clean sample port and probe.</p> <p>Check the probe to see if it is damaged or bent. Replace e 1 Cartridge if probe is bent or damaged.</p> <p>Caution Biohazard. Please take precautions and wear gloves.</p>
<p>Remove and re-insert the e 1 Cartridge</p>
<p>Replace e 1 Cartridge if test shows repeated not ok.</p>
<p>Call Service if replaced e 1 Cartridge fails to resolve the problem.</p>

Errors related to e|1 Cartridge

No e|1 Cartridge Inserted: Error No: 5251

Error indicates that the **e|1 Cartridge** has been removed / is not inserted in the system.

e|1 Cartridge removed: Error No: 5252

Error indicates that the **e|1 Cartridge** was removed suddenly, without using the predetermined workflow to do so.

Insert the e|1 Cartridge using the predetermined workflow

If the system still depicts this error message

Reboot the System

Remove and re-insert the e|1 Cartridge

Replace e|1 Cartridge if this does not resolve the problem.

Call Service if replaced **e|1 Cartridge** fails to resolve the problem.

e|1 Cartridge Data invalid: Error No: 5253

Reboot the System

Remove and re-insert the e|1 Cartridge

Replace e|1 Cartridge if this does not resolve the problem.

Call Service if replaced **e|1 Cartridge** fails to resolve the problem.

Insert e|1 Cartridge correctly: Error No: 5254

Error indicates that the **e|1 Cartridge** was inserted incorrectly, outside the dedicated workflow to do so.

Remove and re-insert the e|1 Cartridge, using the dedicated workflow.

Reinsert e|1 Cartridge: Error No: 5255

Error indicates that the **e|1 Cartridge** was inserted correctly, but did not contact the measuring cell heating circuit.

Reboot the System

Remove and re-insert the e|1 Cartridge

Replace e|1 Cartridge if problem persists.

Call Service if replaced **e|1 Cartridge** fails to resolve the problem.

Cartridge was out of power for more than 72 h: Error No 5259

Error indicates that the system was switched off, or was in a system stop, or the Cartridge was removed and left outside the analyzer for more than 72 hours.

Replace e|1 Cartridge

e|1 Cartridge depleted: Error No: 5261, 5262

Error indicates that the Cal or standby solution inside the **e|1 Cartridge** is empty

Replace e|1 Cartridge

e|1 Cartridge Onboard expiry: Error No: 5271

Error indicates that **e|1 Cartridge** has been on board longer than the maximum in-use time.

Replace e|1 Cartridge

e|1 Cartridge samples used up: Error No: 5272

Error indicates that the specified number of tests (600, 300 or 150) of the **e|1 Cartridge** have been used up.

Replace e|1 Cartridge

e|1 Cartridge Shelf life: Error No: 5274

Error indicates that the **e|1 Cartridge** is old in terms of shelf-life. It has exceeded the expiry date.

Replace e|1 Cartridge

e|1 Cartridge Rotary valve: Error No: 1340**System Stop: 5340**

Error indicates that the rotary valve on the **e|1 Cartridge** is worn-out.

Clean sample input

Run fluid Check

Reboot the System

Remove and re-insert the e|1 Cartridge

Replace e|1 Cartridge

Call Service if replaced **e|1 Cartridge** fails to resolve the problem.

e|1 Cartridge Priming error (after insertion of Cartridge) Error No: 1350, 1351, 1352, 1353, 1354, 1355, 1356, 1357**System Stop: 5350, 5351, 5352, 5353, 5354, 5355, 5356, 5357**

Error indicates the system detected aspiration issues from the Cartridge, at the aspiration after inserting a **new** cartridge.

Check if the new cartridge was stored too cold before inserting (moisture and condensation)

Go to Menu - Troubleshooting - Intensive wash

Press **[start]** to run routine 3 times to prime the solutions.

Remove and re-insert the e|1 Cartridge

Replace **e|1 Cartridge** if this does not resolve the error.

Temperature errors related to e|1 Cartridge

<p>Temperature control error: Error No: 1212, 1213</p> <p>System Stop Error code: 5212, 5213</p> <p>Error indicates that the temperature measured by the new cartridge is completely outside (below or above) the specified electronic range.</p>
<p>Remove and re-insert the e 1 Cartridge</p>
<p>Go to Menu - Diagnostics - Electronics Check and check value Sensor NTC.</p> <p>If not OK, reboot the System</p> <p>Remove and re-insert the e 1 Cartridge again</p>
<p>If still not OK, replace the e 1 Cartridge</p>
<p>Call Service if replaced e 1 Cartridge fails to resolve the problem</p>
<p>Check Cartridge Temperature: Error No: 1214, 1215</p> <p>System Stop Error code: 5214, 5215</p> <p>Error indicates that the system has measured the current temperature of newly inserted e 1 Cartridge to be too low or too high.</p>
<p>Remove the e 1 Cartridge</p> <p>Check if the e 1 Cartridge was stored in the refrigerator and inserted without acclimatization or too warm (in non air-conditioned room with ambient temp. above 31°C).</p> <p>The recommended storage temperature for the e 1 Cartridge is from 15 - 25°C and 25...30°C for 48h.</p> <p>Keep the cartridge ~40min outside the analyzer to acclimatize.</p> <p>Reinsert the e 1 Cartridge after its temperature has returned within specified range.</p> <p>Or, use a different e 1 Cartridge from stock that was stored according to specifications.</p>
<p>Temperature Control Error: No: 1216</p> <p>System Stop Error code: 5216</p> <p>Error indicates that the calibration of the temperature measurement circuit / coil failed.</p>
<p>Reboot the Analyzer</p>
<p>Remove and re-insert the e 1 Cartridge</p>
<p>If still not OK, replace the e 1 Cartridge</p>
<p>Call Service if replaced e 1 Cartridge fails to resolve the problem.</p>

Check room temperature: Error No: 1217, 1218, 1219

System Stop Error code: 5217, 5218, 5219

Error indicates that the system has measured the ambient room temperature to be too cold or too warm.

Remove the e|1 Cartridge.

Switch off the e|1 System.

Error 1217 / 5217: Check if the room temperature is too cold. Is the System placed directly under the draft of air conditioning? Is the window close to the system opened during cold weather period?

Error 1218 / 5218 and 1219/5219: Check if the room temperature is too warm. Is the air condition of the laboratory / hospital working properly? Is the system placed in direct sunlight? Is there enough space on both sides of the instrument?

The recommended ambient room temperature for the analyzer is from 15 - 32°C.

Wait for the room temperature and system temperature to return within specified range.

Switch-on the system and reinsert the e|1 Cartridge

If still not OK, replace the e|1 Cartridge

Internal Temperature errors

Internal Temp error: Nos: 1400,1407, 1408, 1409, 1411, 1412, 1413, 1415, 1440, 1441, 1442, 1443, 1444, 1445

System Stop Error code: 5400, 5417, 5408, 5409, 5411, 5412, 5413, 5415, 5440, 5441, 5442, 5443, 5444, 5445

Error indicates that the System experienced issues with the control function of the internal temperature

Remove the e|1 Cartridge.

Switch-off the system. Disconnect the power supply pin on the back panel.

Wait about 2 minutes and then switch-on.

Reinsert the e|1 Cartridge in the designated workflow, if the analyzer will not detect that there is a cartridge.

If still not OK, replace the e|1 Cartridge

Call Service if replaced e|1 Cartridge fails to resolve the problem.

10 Troubleshooting

Error Messages

Chapter

11

Theoretical Foundations

Reference intervals and critical limits



Warning:

The reference intervals presented in this chapter are for general information purposes only. Individual laboratories should generate their own set of reference intervals.

Sodium

Reference intervals

Blood / Plasma / Serum	> 1 year (female / male)	135.0 - 145.0 mmol/l
	≤ 1 year	133.0 - 142.0 mmol/l
Urine	unspecific	40.0 - 220.0 mmol/l

Table 11-1 Reference intervals^{(1) (2)}

Critical limits	Lower limit	Upper limit
Blood / Plasma / Serum	120.0 mmol/l	155.0 mmol/l

Table 11-2 Critical limits⁽³⁾

Potassium

Reference intervals

Blood / Plasma / Serum	> 1 year (female / male)	3.50 - 5.10 mmol/l
	≤ 1 year	3.50 - 6.10 mmol/l
Urine	unspecific	25.00 - 125.00 mmol/l

Table 11-3 Reference intervals^{(4) (2)}

Critical limits	Lower limit	Upper limit
Blood / Plasma / Serum	2.50 mmol/l	6.20 mmol/l

Table 11-4 Critical limits⁽³⁾

- (1) L. Thomas, Labor und Diagnose, Elektronische Auflage ed., TH-Books-Verlags-Gesellschaft Frankfurt/Main, 2016, Tab. 8.2-1
- (2) N. Rifai, A. R. Horvath and C. T. Wittwer, Tietz Textbook of Clinical Chemistry and Molecular Diagnostics, 6. ed., Elsevier, 2017
- (3) C. A. Campbell, A. Georgiou, J. I. Westbrook and A. R. Horvath, "What Alert Thresholds Should Be Used to Identify Critical Risk Results: A Systematic Review of the Evidence," Clinical chemistry, vol. 62, pp. 1445-1457, 2016, Tab. 3
- (4) L. Thomas, Labor und Diagnose, Elektronische Auflage ed., TH-Books-Verlags-Gesellschaft Frankfurt/Main, 2016, Tab. 8.7-1

11 Theoretical Foundations

Reference intervals and critical limits

Ionized calcium

Reference intervals			
Blood / Plasma / Serum	> 1 year (female / male)	1.120 - 1.320 mmol/l	4.49 - 5.29 mg/dl
	≤ 1 year	1.100 - 1.300 mmol/l	4.41 - 5.21 mg/dl

Table 11-5 Reference intervals ⁽⁵⁾

Critical limits	Lower limit	Upper limit
Blood / Plasma / Serum	0.821 mmol/l or 3.29 mg/dl	1.549 mmol/l or 6.21 mg/dl

Table 11-6 Critical limits ⁽⁶⁾

Chloride

Reference intervals		
Blood / Plasma / Serum	> 1 year (female / male)	98.0 - 107.0 mmol/l
	≤ 1 year	96.0 - 110.0 mmol/l
Urine	unspecific	110.0 - 250.0 mmol/l

Table 11-7 Reference intervals ^{(7) (8)}

Critical limits	Lower limit	Upper limit
Blood / Plasma / Serum	80.0 mmol/l	120.0 mmol/l

Table 11-8 Critical limits ⁽⁶⁾

(5) K. Dörner, Klinische Chemie und Hämatologie, 8. Auflage, Thieme, Stuttgart-NewYork, 2013, p. 533

(6) C. A. Campbell, A. Georgiou, J. I. Westbrook and A. R. Horvath, "What Alert Thresholds Should Be Used to Identify Critical Risk Results: A Systematic Review of the Evidence," Clinical chemistry, vol. 62, pp. 1445-1457, 2016, Tab. 3

(7) L. Thomas, Labor und Diagnose, Elektronische Auflage ed., TH-Books-Verlags-Gesellschaft Frankfurt/Main, 2016, Tab. 8.3-1

(8) N. Rifai, A. R. Horvath and C. T. Wittwer, Tietz Textbook of Clinical Chemistry and Molecular Diagnostics, 6. ed., Elsevier, 2017

Hct

Reference intervals		% Packed cell volume (red blood cells)	Packed cell volume (l/l)
Blood	> 1 year (male)	40.0 - 53.0	0.40 - 0.53
	> 1 year (female)	36.0 - 48.0	0.36 - 0.48
	≤ 1 year	30.0 - 43.0	0.30 - 0.43

Table 11-9 Reference intervals ⁽⁹⁾

Critical limits	Lower limit	Upper limit
Blood	20.0%	60.0%

Table 11-10 Critical limits ⁽¹⁰⁾

pH

Reference intervals		
Blood, arterial	> 1 year (female / male)	7.350 - 7.450
	≤ 1 year	7.090 - 7.500
Blood, venous	> 1 year (female / male)	7.320 - 7.430
	≤ 1 year	7.320 - 7.430
Blood, mixed venous ^(a)		7.350 - 7.430

(a) L. Thomas, Labor und Diagnose, Elektronische Auflage ed., TH-Books-Verlags-Gesellschaft Frankfurt/Main, 2016, Tab. 9-2

Table 11-11 Reference intervals ⁽¹¹⁾

Critical limits	Lower limit	Upper limit
Blood, arterial or capillary	< 7.200	>7.600

Table 11-12 Critical limits ⁽¹⁰⁾

(9) L. Thomas, Labor und Diagnose, Elektronische Auflage ed., TH-Books-Verlags-Gesellschaft Frankfurt/Main, 2016, Tab. 15.4-2

(10) C. A. Campbell, A. Georgiou, J. I. Westbrook and A. R. Horvath, "What Alert Thresholds Should Be Used to Identify Critical Risk Results: A Systematic Review of the Evidence," Clinical chemistry, vol. 62, pp. 1445-1457, 2016, Tab. 3

(11) N. Rifai, A. R. Horvath and C. T. Wittwer, Tietz Textbook of Clinical Chemistry and Molecular Diagnostics, 6. ed., Elsevier, 2017

Calculated values

Calculated values based on measurement results of the **e|1 Analyzer**



Warning:

The validity of calculated results of the **e|1 Analyzer** must be carefully examined by a clinical-medical specialist before any clinical decision is reached based on these values.

nCa²⁺

Ionized calcium value standardized to pH = 7.40 ion concentration units [mmol/l]⁽¹²⁾

$$nCa^{2+}(pH = 7.40)[mmol/L] = Ca^{2+}[mmol/L] \cdot 10^{k \cdot (pH - 7.40)}$$

whole blood: $k=0.22$

plasma/serum: $k=0.24$



Note:

No calculation without valid Ca²⁺ and pH-value.

The equation is applicable for $7.2 \leq pH \leq 7.6$

tHb(c)

tHb (total hemoglobin) as a function of Hct⁽¹³⁾

$$tHb_c [g/dL] = HCT [\%] \cdot \frac{MCHC [g/dL]}{100}$$



Note:

No calculation without valid Hct value.

Input range based on adult reference range⁽¹⁴⁾ $30 \leq MCHC [g/dL] \leq 38$

By activating tHb(c) the input field is selected automatically. For further information on parameter settings and input field configuration see chapter 9 **System Functions**.

24h Urine

Na⁺ 24h Urine, K⁺ 24h Urine and Cl⁻ 24h Urine for pooled urine samples (24 h collection)

$$analyte\ 24h [mmol/24\ h] = \frac{analyte [mmol/l]}{1000} \cdot \frac{V_{Urine} [ml]}{t_{collection\ period} [h]} \cdot 24[h]$$

V_{Urine} : Collected urine sample volume

T_{Collection time} : Time period of collected urine (if collection time differs from 24h)

(12) Thode, J.; Fogh-Andersen, N.; Wimberley, P.D.; Moller Sorensen, A.; Siggaaard-Andersen, O.: Relation between pH and ionized calcium in vitro and in vivo man. Scand. J. clin. Lab. Invest., 43, Suppl. 165, 79-82, 1983

(13) Schmidt Robert, Thew Gerhard. Physiologie des Menschen, 26. Auflage. Springer-Verlag (p.607f)

(14) Thomas, Lothar: Labor und Diagnose: Indikation und Bewertung von Laborbefunden für die medizinische Diagnostik; 7. Auflage. Frankfurt am Main: TH- Books- Verl.- Ges., 2008, S. 677 f.

Measuring principle

Measuring principle for Electrolytes and pH

The **e|1 Analyzer** measures sodium (Na⁺), potassium (K⁺), ionized calcium (Ca²⁺), chloride (Cl⁻) and pH (pH) using potentiometric electrode technology. The potential of each electrode is measured relatively to a mathematically stabilized reference electrode, whereat the measured potential varies with a specific ion dissolved in the sample. The voltage is theoretically dependent on the logarithm of the ionic activity, as described by the Nernst equation.

Equation 1 Nernst-equation

$$E_i = E_{0,i} + \frac{RT}{z_i F} \ln(a_i)$$

with

E_i	electrical potential (EMF) of ion i
$E_{0,i}$	Standard Potential
R	Gas Constant
T	Absolute Temperature
F	Faraday constant
z_i	charge number of ion i
a_i	activity of ion i

The ideal ion-selective electrode would be ion specific, i.e. it would respond only to the ion to be detected and not react to other ions. In practice, ion selective electrodes often have cross sensitivity to other ions. Thus, an ion-selective electrode is rarely completely ion-specific, and potential cross-influences of other ions must therefore be taken into account for accurate analysis. A quantitative description can be made with the Nikolsky-Eisenman equation

Equation 2 extended Nernst-Equation (Nikolsky-Eisenman)

$$E_i = E_{0,i} + \frac{RT}{F z_i} \cdot \ln(a_i + a_{i,j,QE}) \quad \forall j: j \neq i$$

with

$$a_{i,j,QE} = \sum_j K_{ij} \cdot a_j^{\frac{z_i}{z_j}}$$

K_{ij} cross-sensitivity – factor for ion i , sensitivity for ion j

11 Theoretical Foundations

Measuring principle

A comparative measurement method is used to determine the analytes' concentrations. This means that the solution to be analyzed (sample) and the operating solution "SBY" are measured sequentially in succession. The difference between the two measured potentials is related in the direct (logarithmic) context, or in the extended context of Nikolsky-Eisenman to the activities of the sample. Since the activities are known for the operating solution "SBY", the activities $a_{i,Sample(n)}[mmol L^{-1}]$ (respectively the concentrations $\gamma \cdot a_{i,Sample(n)}[mmol L^{-1}]$) of the ions in the sample can be calculated as

$$a_{i,Sample(n)}[mmol L^{-1}] = (a_{i,Sby,QE}[mmol L^{-1}]) \cdot 10^{\frac{E_{Sample}[mV] - E_{Sby}[mV] + E_{Ref}(a(n-1))[mV]}{S[mV dec^{-1}]} - a_{ij,Sample,QE}(n-1)[mmol L^{-1}]}$$

with

$E_{Sample}[mV]$	EMF potential developed in sample solution
$E_{Sby}[mV]$	EMF potential developed in operating solution "SBY"
$E_{Ref}[mV]$	mathematical stabilization of reference electrode
$S[mV dec^{-1}]$	electrode slope
$a_{i,Sby,QE}[mmol L^{-1}]$	activity of the ion in operating solution "SBY" compensated for cross-sensitivity-activity
$a_{ij,Sample,QE}[mmol L^{-1}]$	cross-sensitivity-activity of sample
$a_{i,Sample}[mmol L^{-1}]$	activity of ion in the sample

The electrode slope $S[mV dec^{-1}]$ is calculated in the course of 2P-CAL (respectively 2P*-CAL) using calibrant "CAL" and operating solution "SBY", which both have known activities for the analytes.

Measuring principle for Hct

The Hematocrit (Hct) measurement is based on the conductivity measurement. The lowering of the plasma conductivity is determined by the displacement of the plasma by cellular components (erythrocytes). The conductivity measuring section for hematocrit measurement is regularly checked based on the known conductivity of the operating solutions.

Limitations of the measurement technology

The reported patient result can be influenced by various factors. The influence of a large number of substances were investigated and documented for the **e|1 Analyzer**. For details see chapter 4 **Specifications**, section *Interference*.

However, it is not possible to evaluate all interfering substances (drugs and their degradation products in the samples). In the event of abnormal deviations of the measurement results, the operator must evaluate the entire clinical picture of the patient and, if necessary, carry out extended measurements.

Calibration principle

All necessary calibrations to maintain the availability of the **e|1 Analyzer** are done automatically by the system and include transport of calibration solutions to the sensor according to defined patterns as well as detection and evaluation the electronic signal outputs.

For this purpose, two calibration solutions are used, which are integrated in pouches, made of water vapor-tight material, and are integrated into the **e|1 Cartridge**. Both solutions are aqueous buffered saline solutions with fixed values for the parameters Na^+ , K^+ , Ca^{2+} , Cl^- , pH and Hct.

- SBY** The operating solution "SBY" has mid-level analyte activities (corresponding to normal physiological values) and ensures rapid readiness of the sensor. The solution is used in a 1P calibration and serves as a reference point after each measurement.
- CAL** The calibrant "CAL" has analyte activities that are different from the operating solution and allows the system to determine sensor-specific properties (i.e. mainly electrode slope S)

Calibration types

There are different types of automatic calibrations done by the system, depending on the requirement at a specific time:

- Post-CAL** The "Post-CAL" is performed as part of all measurement and quality control measurement workflows.
- 2P-CAL** The electrode slope $S [mV \text{dec}^{-1}]$ is calculated in the course of 2P-CAL (respectively 2P*-CAL) using calibrant "CAL" and operating solution "SBY", which both have known activities for the analytes. (duration: 30sec)
- 2P*-CAL** If the system detects deviations (due to e.g. sample induced drift or insufficient wetting) in the signal quality of the sensors, additional 2P-calibrations will be carried out automatically (shown as 2P*-CAL, duration: 30sec)
- 1P-CAL** The "1P-CAL" will be triggered by the system to maintain operational readiness only if no other system actions (measurement, QC-measurement, 2P-CAL, 2P*-CAL) are performed for more than 4h.

Cartridge phases

Depending on the life cycle of the **e|1 Cartridge**, the calibration scheme is adapted to corresponding operational modes:

- Initializing** When inserting a new cartridge, the cartridge is initialized and a system calibration is performed. This takes about 30 minutes.
- Stabilizing** Within the first 6 hours of operation of the **e|1 Cartridge**, the system is in the so-called "stabilizing" phase. In this phase, a tighter calibration scheme (a 2P-CAL is triggered every 30 minutes) is necessary to maintain readiness for measurement and to provide accurate results.
- Stable** By default, a 2P-CAL is performed every 12 hours, but the user can shorten the interval to 4 or 8 hours. For further information on calibration settings, see chapter 9 **System Functions**.

Metrological Traceability

The traceability of measurands in the calibration solutions to accepted standards is done according to EN ISO 17511:2021. All analyte concentrations are traceable to certified reference materials (SRM) that are obtained from the National Institute of Standards and Technology (NIST, Gaithersburg, Maryland USA). The assessment of uncertainty was done according to EP32-R (CLSI 2006), considering all influencing factors, such as substance specifications, uncertainties for gravimetry and the commutability of procedures. The resulting uncertainties of measurands are calculated as expanded measurement uncertainty with a coverage factor $k=2$ covering a confidence level of 95%.

Calibration solutions (Sby and Cal)

The following tables show the measurands of the calibration solutions and the ranges für lot specific Values. The numbers of NIST materials listed as well as the reference methods and the accompanied uncertainties:

Traceability and Uncertainties for Solution "Sby":

Analyte	Range	NIST SRM No.	Reference Method	Uncertainty
Na ⁺ [mmol/l]	143.0 - 147.0	2192a, 723, 2201	Gravimetry	±1.1
K ⁺ [mmol/l]	3.90 - 4.10	918c	Gravimetry	±0.03
Ca ²⁺ [mmol/l]	1.196 - 1.316	682	Gravimetry/Chelatometry	±0.023
Cl ⁻ [mmol/l]	102.5 - 107.5	2201, 682	Gravimetry	±1.0
pH [1] ^(a)	7.352 - 7.412	2181, 723	Gravimetry/Calculation	±0.009
HCT [%]	17.05 - 17.65	999	Gravimetry/Conductometry	±0.26

(a) pH-value is calculated using the Henderson-Hasselbalch equation

Traceability and Uncertainties for Solution "Cal":

Analyte	Range	NIST SRM No.	Reference Method	Uncertainty
Na ⁺ [mmol/l]	98.0 - 102.0	2192a, 723, 2201	Gravimetry	±1.0
K ⁺ [mmol/l]	9.80 - 10.20	918c	Gravimetry	±0.06
Ca ²⁺ [mmol/l]	0.345 - 0.395	682	Gravimetry/Chelatometry	±0.017
Cl ⁻ [mmol/l]	58.0 - 62.0	2201, 682	Gravimetry	±0.9
pH [1] ^(a)	6.870 - 3.930	2181, 723	Gravimetry/Calculation	±0.009
HCT [%]	11.79 - 12.36	999	Gravimetry/Conductometry	±0.25

(a) pH-value is calculated using the Henderson-Hasselbalch equation

Na⁺: The concentration of sodium is traced to the standard reference materials NaCl and Na₂CO₃, (both obtained from NIST SRM 2201 and SRM 2192 and to sodium hydroxide solution with a concentration of 1 mol/L (titrisol ®). The value for sodium hydroxide solution is given by the supplier which ensures a traceability to the NIST substance Tris(hydroxymethyl)aminomethane (SRM 723).

K⁺: The concentration of Potassium is traced to the standard reference material KCl (obtained from NIST SRM 918c)

Ca²⁺: The concentration of Calcium is measured and appointed using complexometric titration. The titration is carried out using 0,1 mol/L EDTA solution (titriplex ®). The value is given by the supplier which ensures a traceability to High-Purity Zinc (NIST SRM 682).

Cl⁻: The concentration of Chloride is traced to the standard reference materials NaCl and KCl (both obtained from SRM 2201 and SRM 918c). For the contribution of CaCl₂, and its traceability, see complexometric titration for Ca²⁺ above.

pH: The concentration of all substances that establish the pH value are standard reference materials (obtained from NIST, HEPES: SRM 2181, Na₂CO₃: SRM 2192a) or can be traced to NIST (NaOH 1 mol/L titrisol ®)

HCT: Electrical conductivity (used for hematocrit measurement) reflects the concentrations of contributing ions. However, it also depends on matrix effects that can not be exactly calculated. So direct comparisons of the solutions with conductivity standards where carried out. The conductivity standards, based on KCl solutions where traced to the standard reference material from NIST (SRM 999, KCl)

Quality control material (on-board QC and manual QC)

The quality control material is provided to detect malfunctions of the system, with the measuring performance in focus. It is according to EN ISO 17511:2021 “supplied with intervals of suggested acceptable values that are not metrologically traceable to higher order reference system components”. Consequently, the material is traceable to the manufacturers selected measurement procedure that consists of the procedure of target value assignment on the e|1 Analyzers. Considering the specifications of the system and the transfer protocol for the measurements, the following uncertainties for the QC-Material (both manual QC and on-board QC) are calculated:

Analyte	QC – Level 1		QC – Level 2		QC – Level 3	
	Range ^(a)	Uncertainty ^(b)	Range	Uncertainty	Range	Uncertainty
Na ⁺ [mmol/l]	112 - 124	±1.7	133 - 141	±1.7	157 - 165	±1.7
K ⁺ [mmol/l]	1.50 - 2.30	±0.17	4.10 - 4.90	±0.17	6.1 - 6.9	±0.17
Ca ²⁺ [mmol/l]	1.40 - 1.60	±0.07	1.00 - 1.20	±0.07	0.43 - 0.67	±0.07
Cl ⁻ [mmol/l]	78.0 - 86.0	±3.0	97 - 105	±3.0	127 - 135	±3.0
pH [1]	7.11 - 7.17	±0.018	7.37 - 7.45	±0.018	7.62 - 7.70	±0.018
HCT [%]	55 - 65	±2.0	39 - 49	±2.0	18 - 28	±2.0

(a) Ranges for lot-specific variations

(b) The uncertainty is expressed as expanded measurement uncertainty with a coverage factor k=2 covering a confidence level of 95%.

11 Theoretical Foundations

Metrological Traceability

Chapter **12**

Appendix

Order list

EXIAS Medical offers different products for the in-vitro diagnostic measurement. The following Table 12- 1 lists the names of the products as well as their associated reference-/ material numbers.

Product name	Catalogue No.	Units/Quantities
Instrument		
EXIAS e 1 Analyzer	M000204	1 piece
Consumables		
EXIAS e 1 Cartridge 150	M000338	1 piece
EXIAS e 1 Cartridge 150 oQC	M000339	1 piece
EXIAS e 1 Cartridge 300	M000137	1 piece
EXIAS e 1 Cartridge 300 oQC	M000138	1 piece
EXIAS e 1 Cartridge 600	M000139	1 piece
EXIAS e 1 Cartridge 600 oQC	M000140	1 piece
e 1 Printer paper	M000322	1 box à 5 rolls
Accessories		
EXIAS e 1 QC-1 Quality Control	M000293	1 box à 30 ampoules
EXIAS e 1 QC-2 Quality Control	M000294	1 box à 30 ampoules
EXIAS e 1 QC-3 Quality Control	M000295	1 box à 30 ampoules
Barcode scanner 1D	M000323	1 piece
Barcode scanner 2D	M000453	1 piece
Plastic Capillaries for Blood Gas	107076	1 box with 10 dispenser boxes à 100 pcs. Capillaries (50µL)

Table 12-1 Order List of EXIAS Medical

12 Appendix

Order list

Index

A

Abbreviations, 1-7
Accessories, 3-8
Accuracy of measurement, 4-4
Analytical Sensitivity, 4-13
Analytical Specificity, 4-14
Authentication, 9-22

B

Barcode scanner, 3-9
Biohazard, 2-3

C

Calculated Parameters, 4-4
Calculated values, 11-6
Calibration planner, 9-19
Calibration principle, 11-9
Calibration results, 9-7
Capillary tubes, 3-10, 6-4
Cartridge replacement, 8-3
Clot-detection, 10-5
Consumables, 3-5
Copyright, 0-4
Critical limits, 11-3

D

Data input, 9-14
Declotting, 10-5
Diagnostic functions, 10-8
Disinfection, 2-6
– Device surfaces, 2-6
– Touch-Display, 2-6
Disposal, 2-3
Document history, 0-3

E

e|1 Cartridge, 3-5
e|1 QC material, 3-8
Edition notice, 0-4
Electrical safety, 2-8
Electromagnetic compatibility, 2-5, 2-8
Error Messages, 10-10
Export results, 9-24

I

Important information for evaluating QC results, 7-4
Inserting the e|1 Cartridge, 5-5
Intended use, 3-3
Interference, 4-14
– Substances with effect, 4-16
– Substances without effect, 4-15
IT security advisory, 2-7

L

Laboratory Information System, 9-23, 9-29
Language setting, 9-19
License information, 9-27
Limitations of clinical analysis, 6-5
– Electrolytes, 6-5
– General, 6-5
Linearity, 4-17
LIS Settings, 9-23

M

Main screen, 9-3
– Navigation bar, 9-3
– Parameter selection field and information, 9-4
Manual on-board QC measurement, 7-5
Manual QC measurement, 7-5
Measurement evaluation, 6-9
Measurement modes, 9-4
Measurement Parameters, 4-3
Measurement results, 9-6
Measuring principle, 11-7
Measuring procedure, 6-6
– Auto-Print, 6-8
– Capillary mode, 6-6
– Measurement results, 6-8
– Remove sample container, 6-7
Metrological Traceability, 11-10

N

Network settings, 9-20

O

On-board QC measurement, 7-4
Operating conditions, 4-18
Operator management, 9-10
Order list, 12-3

P

Parameter Settings, 9-11
Patient management, 9-9
Perform QC measurement, 7-4
Preanalytics, 6-3
Precision, 4-4
Printer, 3-4
Printer paper, 3-7
Printer paper replacement, 8-7
Printer settings, 9-21
Purpose and use of this document, 1-3

Q

QC consequences, 7-7, 9-17
QC material, 7-3
QC measurement, 7-4
QC regime, 7-3
QC results, 7-4
Quality control, 7-3
Quality control materials, 9-16
Quality Control planner, 9-18
Quality control results, 9-7

R

Rear panel, 3-4
Reference intervals, 11-3
Remote access, 9-22
Replacement of e|1 Cartridge, 8-3
Replacement of e|1 Printer Paper, 8-7
Result Correlations, 9-30
Results, 9-5
– Calibration results, 9-7
– Measurement results, 9-6
– Quality control results, 9-7

S

Sample containers, 6-4
Sample modes, 3-6
Sample tubes, 6-4
Sample types, 4-3
Settings, 5-7, 9-11
Software and language update, 9-25
Specifications, 4-19
Storage and transport conditions, 4-18
Symbols, 1-5
Syringes, 6-4
System recovery, 10-9

T

- Text convention, 1-4
- Touch display, 3-3
- Troubleshooting concept, 10-3
- Troubleshooting routines, 10-6
- Trueness of measurement, 4-8