



Read this manual carefully before operating the *EasyReader+*<sup>®</sup> lateral flow immunochromatography analyzer.

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If this instrument is used in a manner differently than specified in this manual, the protection provided by the equipment may be impaired.

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# 1 Introduction

The goal of this manual is to help qualified operators of the *EasyReader+*<sup>®</sup> analyzer use the instrument effectively, with accurate results, and up to its full potential.

It provides information about every relevant aspect of the installation, use, and database management of the analyzer, as well as basic maintenance and troubleshooting information.

## 1.1 About *EasyReader+*<sup>®</sup>

The *EasyReader+*<sup>®</sup> instrument is a quantitative lateral flow immunochromatography analyzer. The *EasyReader+*<sup>®</sup> installation kit includes the analyzer and the software that lets the operator actuate the evaluation processes, regulate the functioning, storing and moving measurement results database.

## 1.2 Intended Use

The *EasyReader+*<sup>®</sup> analyzer is intended to provide a quantitative immunochromatography assay result for a wide range of otherwise purely qualitative rapid test devices to increase the accuracy and efficiency of the home, point of care, and laboratory testing of the relevant marker analytes.

## 1.3 Limitations of Use

- Any reactive specimen with any of the rapid test devices must be confirmed with alternative testing methods and clinical findings.
- The results obtained with rapid test devices should only be interpreted in conjunction with other diagnostic procedures and clinical findings.
- A negative result for an individual subject indicates that the level of the marker tested is not detectable. However, a negative test result does not preclude the possibility of one or more of the medical conditions associated with the given marker.

## 1.4 How to use this manual

This manual is intended as an instruction set and a reference guide for *EasyReader+*<sup>®</sup> operators. It provides all information needed to install, operate, maintain, and troubleshoot basic problems with the instrument, and lists service contact information.

### 1.4.1 Symbols and formatting conventions

This manual uses the following symbols to help you navigate the text:



**WARNING** This symbol indicates maintenance procedures, operations, and other processes that can cause personal injury or harm if the instructions are not followed carefully.

**This is an example of warning text.**



**CAUTION** This symbol indicates maintenance procedures, operations, and other processes that can cause equipment malfunction, equipment failure, or damage to the equipment if the instructions are not followed carefully.

**This is an example of caution text.**



**NOTE** This symbol indicates important information or useful tips for operating and handling the device.

*This is an example of note text.*

The manual uses the following formatting conventions to highlight important information and help you navigate the text:

- *Italic text in purple* indicates a cross-reference that points to a related subsection of the manual or to an external hyperlink.

- **Bold monospace type** indicates text that appears on a connected display.

- [Text in square brackets] indicates article numbers for parts and accessories that you can order for the device.

**1** numbering within procedures indicates steps that you need to perform in sequence.

- Bullet points (•) indicate items on a list or steps that you do not need to perform in sequence.

## 1.4.2 Acronyms and abbreviations

---

Abbreviation	Definition
AC	Alternating Current
LIS	Laboratory Information System
DHCP	Dynamic Host Configuration Protocol
csv	comma separated values
DC	Direct Current
EN	European Standard
ID	identification number
LED	Light Emitting Diode
CMOS	Complementary Metal-Oxide Semiconductor
EMC	Electromagnetic Compatibility
RF	Radio Frequency

## 2 System description

### 2.1 Theory of operation

*EasyReader+*<sup>®</sup> utilizes lateral flow immunochromatographic assay technology using -membrane rapid test assay devices.

#### 2.1.1 Rapid test device technology

The test specimen (type of sample that can be used on the instrument, as indicated in the corresponding device manual for each parameter) that the operator dispenses into the assay device migrates, with spontaneous capillary action, all through the membrane, and interacts with the particles and molecules placed at various parts of the membrane.

**1** It first interacts with the conjugate, where it binds with the color-coated bio-active particles. The specimen analytes that pass through the conjugate therefore become color-coated themselves.

**2** The specimen then passes through the Test Line (T) and the Control Line (C), where two types of capturing components are present in the membrane:

. The components in the Control Line capture every colored particle that passes through them, and indicate whether the assay device is functional: When an adequate number of colored particles, are captured, a colored band appears across the Control Line, which means that the test result is valid.

. The components in the Test Line are analyte-specific, and only capture test particles that bound to the analyte that the test detects. When an adequate number of analyte-bound colored particles are captured, a colored band appears across the Test Line, which indicates a positive test result.

#### 2.1.2 *EasyReader+*<sup>®</sup> assay device processing

**1** After the specimen is dispensed into the assay device, a device-specific incubation time must elapse before a reading can be made. You can time the incubation time yourself, or set the *EasyReader+*<sup>®</sup> device to count it down.

**2** When the incubation time elapses, the instrument shines a green LED light onto the surface of the membrane of the assay device. The green light is used for evaluation and serves to increase the contrast of the potential discoloration by effectively subtracting the white background from the image.

**3** A CMOS camera takes a picture of the oval test window of the device, using the light from the LEDs. The image processing software scans the resulting image, detects any discoloration, and calculates the average saturation of the colored area on the membrane.

**4** The microprocessor compares the average saturation value detected in the image to the preset device-specific cutoff ranges to arrive at a semi-quantitative test result.

### 2.2 Overview of operating elements

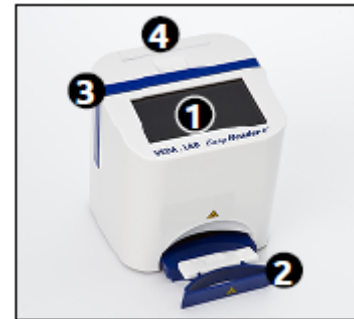


Figure 1: Front view of the *EasyReader+*<sup>®</sup> analyzer



Figure 2: Back view of the *EasyReader+*<sup>®</sup> analyzer with the bottom panel removed

1 Capacitive touch screen

2 Device holder

3 Carry handle

4 Printer compartment hinge

5 PS2 socket

6 Ethernet socket

7 USB Type B sockets

8 USB Type A socket

9. Control LED (red)

10 Power cable socket

11 Serial interface

12 Reset button

13 On switch





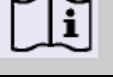



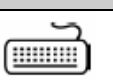

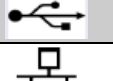

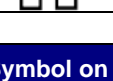


AA battery holder (bottom side, not shown in picture)









## 2.3 Technical specifications






Type	Reflectance photometer
Dimensions	Weight: 1500 g Height: 170 mm Width: 150 mm Depth: 180 mm
Throughput	In internal incubation (countdown mode): about 5 specimens/hour In external incubation (Immediate mode): about 50 specimens/hour
Power supply	External adapter: 100–240 Volt AC, 50–60 Hz, 7.5 Volt DC output Optional battery operation: 6 size AA battery/NiMH accumulator
Operational conditions:	Temperature: +15 to +40°C (optimal temperature 15°C to 30°C) Relative humidity: 30 to 80% (without condensation) Atmospheric pressure: 70 kPa to 106 kPa (corresponds to altitudes of 0–3000 above sea level)
Storage conditions::	Temperature: +5°C to +45°C Relative humidity: 10% to 85% (without condensation) Atmospheric pressure: 70 kPa to 106 kPa (corresponds to altitudes of 0–3000 above sea level)
Transportation	Temperature: -25°C to +60°C Relative humidity: 75% at 30°C (24h) Atmospheric pressure: 70 kPa to 106 kPa (corresponds to altitudes of 0–3000 above sea level)
Printer parameters	Thermal printer Maximum roll width: 60 mm
Database capacity	1000 measurement records
Display	Size: 4.3" Resolution: 480 x 272 pixels
Interfaces	Ethernet, PS2 port, Serial RS232, USB Type A, USB Type B





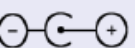









## 2.4 Instrument and labeling symbols





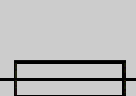




This section lists and describes all the symbols that appear on the analyzer, the power supply included with the instrument, or their packaging.

Symbol on the analyzer	Meaning	Symbol on the analyzer	Meaning
	The product conforms to the essential requirements in the European Medical Devices Directive.		Temperature limitation indicating upper and lower limits
	The product is an in vitro medical device.		Serial number
	Consult instructions for use		Humidity limitation indicating upper and lower limits
	Manufacturer details	7.5V  3A	Power requirements
	Catalog number		Biological hazard
	Keyboard port		Power on/off
	USB port symbol		DC Adaptor Polarity Centre Positive
	Ethernet port		

Symbol on the package	Meaning	Symbol on the package	Meaning
	Manufacturer details		Temperature limitation indicating upper and lower limits
	The product is an in vitro medical device.		Atmospheric pressure limitation indicating upper and lower limits
	Consult instructions for use		Humidity limitation indicating upper and lower limits
	The product conforms to the essential requirements in the European Medical Devices Directive.		Fragile

Symbol on the package	Meaning	Symbol on the package	Meaning
	Do not use if packaging is damaged		Keep away from direct sunlight
	This way up		Keep package out of rain and away from damp conditions
	Recycle material		

Symbol on the adapter	Meaning	Symbol on the adapter	Meaning
	The product conforms to the essential requirements in the European Medical Devices Directive.		Environmentally friendly period in year (ROHS)
	Use indoors		Waste Electric and Electronic Equipment
	DC Adaptor Polarity Centre Positive		Serial number
	The product conforms to the essential requirements of UL		Read manual
	The product conforms to the essential requirements of China Quality Certification Centre and Product Safety of Electrical Appliance & Materials		The product conforms to the essential requirements of Level V standard implemented by California Energy Commission
	Double insulation		Voluntary Control Council for Interference by Information Technology Equipment
	The product conforms to the essential requirements in Restriction of Hazardous Substances Directive		Tested to Federal Communications Commission requirements

Symbol on the adapter	Meaning	Symbol on the adapter	Meaning
	The product conforms to the essential requirements in Restriction of China Compulsory Certificate		Underwriters Laboratories Recognized Component certification mark in Canada and the United States
	Slovenian Institute of Quality and Metrology certification mark		The product conforms to the essential requirements of GOST standard implemented by Euro-Asian Council for Standardization, Metrology and Certification (EASC)
	Fuse		The product complies with the applicable EMC standard and establishes a traceable link between a product and the supplier responsible for placing it on the Australian or New Zealand market.
	TEST REPORT IEC 61558-2-16 Standard EN 61558-2-16:2009+ A1:2013 used in conjunction with EN 61558-1:2005 + A1:2009 (DIN EN 61558-2-16:2014-06)		Switch mode Power supply
	Ukraine UKR Sepro		

## 3 Quickstart



All components of the assay device analyzer may come into contact with human urine, blood or feces and are therefore possible sources of infection. These specimens should be handled at Biosafety Level 2. To prevent accidental contamination, always wear disposable surgical gloves when handling reagents, fluids, or any part of the analyzer. Use universal precautions, and consult your facility's infection control policy. See *Protecting yourself from biohazards* for more information.

1 Unpack the instrument and place it on an even, hard surface (for detailed unpacking and set up instructions see *Installation*).

2 Connect the power supply or insert batteries and switch the analyzer on with the On switch. After the first boot-up procedure the Start-Up Wizard will appear (See *Start-up Wizard*).



In the Start-up Wizard you can decide if you would like to use the Easy Mode which is emulating the functioning of the three pressing button operated old version of *EasyReader+*. For the ones who know the old menu might be easier to use it, although it has limited functionality compared to the new Plus Mode. For more information see *Easy Mode*.



After every further switching on the **Measurement** screen will show up on the display.



The analyzer runs a self check to test its hardware and software functionality at every switch on.

3 Select the assay device type you would like to use (see *7.1.2*).



The analyzer cannot recognize the type of assay device therefore it is very important to set the analyzer correctly. Using unmatching device type causes false results.

4 Perform a blank measurement (see *9.2.1*).



If **Autostart** is on, which is a default setting, you don't even have to tap the **START** button, the analyzer starts the measurement automatically. Works with regular measurement, too. To deselect it see *10.1*.

5 Prepare and apply the specimen to the sample well of the assay device.

6 Load the rapid test holder with the device and insert it into the analyzer.

7 The analyzer detects the assay device and waits for the assay device type-specific incubation time to elapse.



You can set the analyzer for external incubation by clicking in the **Immediate** checkbox on **Measurement** screen.



In case of choosing external incubation you have to follow the instructions of the package insert of the assay device type for the specified incubation time.



It is recommended to use internal incubation for the sake of accuracy, but there could be circumstances (e.g. large number of samples with same assay device type) when more convenient to do otherwise.

8 The analyzer starts the measurement and a few seconds later displays the result on **Measurement»Result** screen.

9 You can print , transfer , edit , delete  the result or go back  to **Measurement** screen.



If you pull out the rapid test holder and **Autostart** is enabled, the system goes back to **Measurement** menu.



With the default settings you can use the analyzer in a so-called Touchless operation mode, when you can analyze specimens without the need of touching the screen.




## 4 Installation


### 4.1 Preparation


#### 4.1.1 Installation site


Prior to unpacking, clear the area where the analyzer is to be operated. Check dimensions in Technical specification and add required space for any accessories, detachable parts and consumable materials needed for the operation of the analyzer. The table is needed to be is strong enough to support the weight of them.

 **Do not use the EasyReader+® analyzer outdoors.**

 **Make sure that you set up and operate the analyzer on a solid level surface in an environment without large variations in temperature or humidity. Do not operate the analyzer in temperatures below 15°C (59°F) or above 40°C (104°F). Do not expose the analyzer to strong light.**

 **Do not operate the analyzer in an enviroment with strong vibrations as it may influence the results and also could cause failures to the instrument.**

 **Do not operate the analyzer in close proximity to sources of intense electromagnetic radiation (such as unshielded intentional RF sources). The analyzer is certified to meet the EMC requirements of EN 61326-1:2007 and EN 61236-2-6:2007.**


 **Make sure that there is enough room behind the device for the easy access to cables, the main connector and the ON/OFF switch and also for the proper ventillation of the analyzer. The recommended safety clearance is 25 centimeters (9.8inches).**

 **Observe the safety labels on the analyzer and its packaging.**

#### 4.1.2 Unpacking and checking for completeness

**1** Check the package that the analyzer arrived in for visible signs of damage – if you find any, do not open the package, but contact the delivery service.

**2** If there is no visible sign of damage, open the package, and carefully remove its contents.

 *It is recommended that you keep the package and the package cushioning wrappers in case you would like to relocate the complete system in the future.*


**3** Check that the items in **Figure 3** are inside the delivered package, and that they are intact and in working condition.

**Figure 3 :** The contents of an EasyReader+® delivery package  
Key to the delivery package:

- 1** EasyReader+® analyzer or EasyReader+® analyzer (battery-operated)
- 2** A roll of thermal printer paper
- 3** Calibration rapid test
- 4** Rapid test holder
- 5** Blank card
- 6** Mains cable



- 7** AC adapter: Mains requirements: AC 100–240V, 50/60 Hz, 1.5 A; Output: DC 7.5V, 3.0 A (Manufacturer: GlobTek, Inc.; model: GTM91120-3007.5-T2)
- 8** Operator's manual CD

 **All parts and accessories of the analyzer listed in the packing list and all its rapid tests as well as available controls should be supplied by the manufacturer or by a distributor accepted by the manufacturer.**

## 4.2 Configuration

### 4.2.1 Power supply

1 Refer to 4.1.1 above and find a suitable installation site for the *EasyReader+*<sup>®</sup> analyzer. Insert the rapid test holder into the analyzer.

2 If you are using grid electricity to operate the analyzer, plug the mains cable into the grid electricity outlet and the AC adapter. Plug the AC adapter into the power socket at the back of the analyzer (Cf. *Figure 4*).

Figure 4 : Plugging the power supply into the analyzer



**⚠** Never use an AC adapter or power cord if it shows any signs of damage.

**⚠** The mains cable in the package has a CEE 7/16 (“Europlug”) plug that you can safely plug into any grounded CEE 7/4 socket. If your socket is incompatible with the power plug, use a plug converter. Use only the AC adapter supplied with the analyzer and always plug it into a grounded socket.

**i** If you are using grid electricity to operate the analyzer, make sure that the current and voltage is appropriate (Cf. 4.1.2), and connect the power supply to both the wall outlet and the analyzer.

### Optional

If you are using batteries to operate the analyzer, unscrew the Phillips screw that secure the metal plate over the battery compartment (Cf. *Figure 5*), open it, insert the six (6) AA batteries into the appropriate slots in the compartment (Cf. *Figure 6*), close the metal plate and secure it with the screw.

The printer is not working during battery operation. All data sent to print will be stored and printed automatically when returning to grid electricity

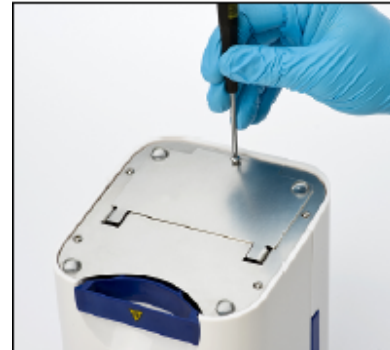


Figure 5: Unscrew the screws at the bottom of the analyzer to access the battery compartment



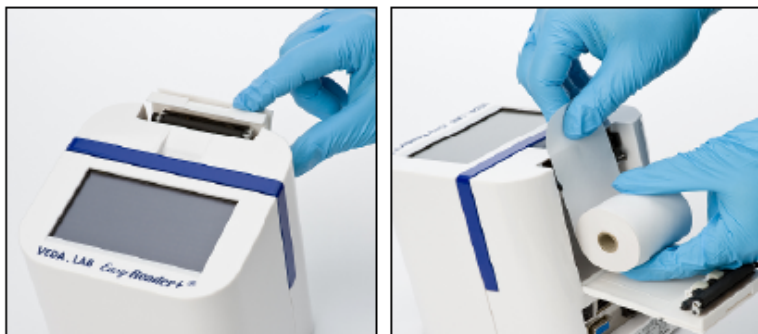
Figure 6: When you insert the batteries, always pay attention to the polarities

**⚠** Use only alkaline AA or NiMH AA batteries and pay attention to the right polarities, and make sure that all the batteries that you insert are the same type.

**⚠** Do not leave batteries in the analyzer for a long period of time to prevent unwanted leaking and warming up which can cause damage to the analyzer.

**⚠** Never use any metal items to pick batteries out of their compartment because it might harm the batteries and/or cause a short circuit.

## 4.2.2 Load the built-in printer



**Figure 7 :** Push back the printer compartment hinge to open it. Insert a roll of printer paper into the compartment so that it sits straight between the aligner ridges. Tap the **Paper Feed** button on the **Main** screen to make a few inches of paper hang out over the edge of the compartment hinge.

**i** Use a roll of maximum 60 millimeter wide thermal printer paper. The system displays a warning if it does not detect paper in the paper well.

**!** The edge of the printer compartment hinge is sharp. Handle it with care.

## 4.2.3 Interfacing with a computer

The instrument can send results to a computer via the serial port located on the back of the analyzer. This requires a D-sub,9-n serial cable (male on instrument side, female on PC side). It is even possible to transmit data via an Ethernet cable which connector is located on the back of the analyzer (labelled 6 in [Figure 2](#)).


## 4.2.4 Switching the analyzer on

**Figure 8 :** To switch the analyzer on, check that the power cord is connected, toggle the On/Off switch (labelled 11 in [Figure 2](#)) at the back of the analyzer on. Press on the switch for one second.



**i** If the analyzer does not start up, first check the AC adapter control LED.

## 4.2.5 Switching the analyzer off

Do not remove the power cable or turn the analyzer off while it is in operation, otherwise the data may be corrupted or the system may be compromised. Before turning the analyzer off, always ensure that there is no assay test in the rapid test holder and it is clean. The analyzer can be switched off by tapping the  power button on the **Main Menu**, the **Measurement** or on the **Login** screen.

**!** We recommend that you switch off the analyzer and unplug the mains adapter from the AC wall socket at the end of each day.

## 5 Interacting with the analyzer

### 5.1 Types of interaction

#### 5.1.1 Tapping the display

The primary user interface of the *EasyReader+*<sup>®</sup> analyzer is a capacitive touchscreen display, but you can also operate the instrument via a connected standard computer keyboard.

You can operate the display by lightly touching (“tapping”) it in a touch-sensitive area with your bare or rubber-glove covered fingers, or capacitive styluses.

**!** The display is made of glass. Do not touch the display if the glass is cracked or shattered. Glass screens are sensitive to drops and mechanical shocks.

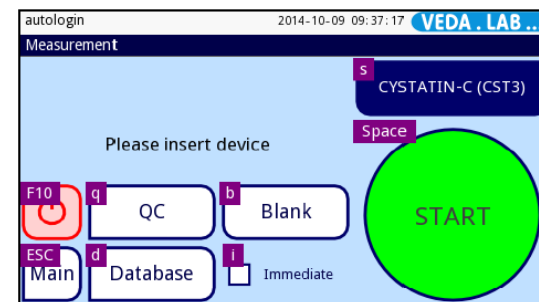
**!** Keep the display away from strong magnetic fields and heat sources.

**!** It is not possible to operate the capacitive touchscreen by touching it with non-conducting materials such as a pen or fingernails.

**!** The operating principle of capacitive touchscreens is based on conducting materials touching their surface. Do not let conducting materials such as grease and sweat from your fingers build up on the surface of the screen, as these can compromise the functionality of the display.

**i** Sound effect feedback is enabled by default, and the system confirms successful tap events with a short clicking sound.

### 5.1.2 Using a keyboard



**Figure 9** : The **Measurement** screen with the corresponding keyboard keys displayed over the touchscreen buttons.

If you have connected a computer keyboard via the USB-a or the PS2 socket (Cf. [Figure 2](#)), you can use it not only to enter text faster in text fields, but also to operate the *EasyReader+*<sup>®</sup> analyzer. Each button on each display screen has a specific keyboard key assigned to it.


Press the ‘Ctrl’ (Control) key on your connected keyboard to see which keyboard key corresponds to which button on the specific screen (Cf. [Figure 9](#)). Press the keyboard key that corresponds to the button that you would like to tap on the touchscreen.

**!** To avoid losing information or faulty functioning always connect the keyboard properly.


**!** Only connect devices that comply with the EN 60950 standard and all its extensions relevant to the type of the connected device.

## 5.1.3 Using a barcode scanner

You can use a barcode scanner to speed up patient and specimen data input, and to eliminate typing mistakes when you enter data into the analyzer. With a barcode scanner, you can enter the specimen ID, the patient ID, the assay device lot information, and even login information for operator accounts, if you save the user name and/or the password in a barcode.

 Consult the IT department of your facility for information about saving data in a barcode.

 **No external power supply, special software, or driver is necessary to operate the analyzer with a connected barcode scanner.**

 **Make sure that the barcode scanner that you are using supports ALT mode, and select this mode of operation before you start using it with the EasyReader+® analyzer.**

## 5.2 Elements of the user interface

### 5.2.1 The Status bar

The ribbon across the top of every screen on the EasyReader+® interface offers you some basic information about the analyzer.



Figure 10 : The Status bar is in the top of the EasyReader+ interface

Key to the status bar:






1 Operator's name


2 Date and time or queue information (to be seen alternately, only in case of below listed events). The four placeholders in square brackets, divided by commas, from left to right:

- the number of active errors;
- the number of records in the printing queue;
- the number of records in the transfer output queue;
- the number of items on the worklist.

3 Screen name, indicates the current section of the system you are working in.

4 Status icons:

- -  USB flash drive is connected.
- -  battery is full
- -  battery is 75% full
- -  battery is 50% full
- -  battery is 25% full.

 The background of the top of status bar changes to yellow if a warning message is active, and it changes to red if an error message is active. If a warning or error message is active, tap inside the status bar to view the details of the message.

## 5.2.2 Input screens

Whenever you need to enter some text on the display interface, text boxes are displayed. Tap inside text boxes to display an input screen that allows direct text input.

This section shows you how to use these screens.

### 5.2.2.1 Text input screens

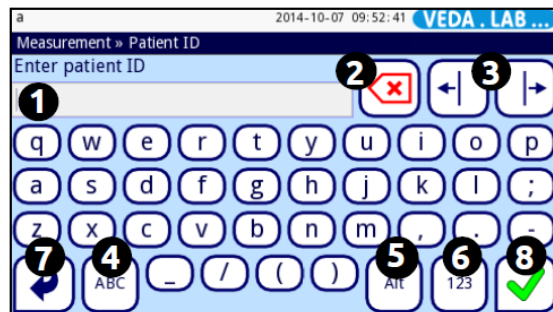


Figure 11 : An example of a text input screen with the special buttons marked

Key to Figure 11:

- 1 This is the text box that all the other buttons on the screen apply to. The string inside it will appear as the output text.
- 2 Tap this button to delete the character to the right of the cursor.
- 3 Tap these buttons to move the cursor inside the string in the text box left or right.
- 4 Tap the **ABC** and **A** buttons to toggle between upper and lowercase letter input.
- 5 Tap the **Alt** button to switch from letter input to additional character input.
- 6 Tap the **123** button to switch from letter input to numbers input.
- 7 To cancel the input press the **Back** button.
- 8 To save the text that you entered, tap the **Save** button.

### 5.2.2.2 The Birth date/Gender input screen

You can add the birth date and the gender of the patient who supplied the sample to each test result record. When you click inside the **Birth date/Gender** box on the **Result»Modify** screen (Cf. [Figure 31](#)), the **Birth date/Gender** input screen appears.

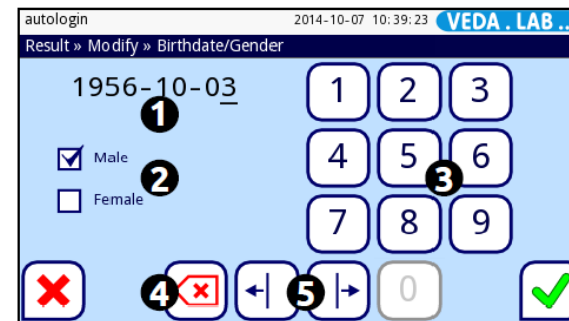


Figure 12 : The Birthdate/Gender input screen with its elements marked

Key to Figure 12:

1 A placeholder for the birth date that you are entering, that works like a text box. A cursor indicates the digit that you are changing.

*i* The default date format is Year-Month-Day. If you would like a different date format, consult with your system administrator.

2 The gender check box. Select Male or Female.

3 The number pad. Tap the numbers to enter a birth date for the patient.

*i* You cannot enter a birth date that is earlier than 1900.

4 The delete button. Tap this button to delete the digit in the birth date that the cursor indicates.

5 Cursor left and right buttons. Tap one or the other to move the cursor one digit to the left or right, respectively.

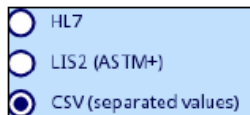
## 5.2.3 Special Buttons

When operating the *EasyReader+*<sup>®</sup> analyzer, you will encounter several buttons that have more than one state, and that provide information as well as functionality to the operator.

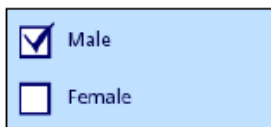
- The  **Save** button becomes active  only after you have modified at least one parameter on the screen: it indicates that you need to save the changes that you made before they take effect;
- The  **Back** button also changes to  **Back&Drop** when you have modified parameters on a screen: tap it to exit the screen and abandon the changes;
- The background color of a number of buttons changes to orange when you tap them: filter criteria , the **Select by movement** button (labelled 4 in *Figure 27*), the **Clear password** button. The orange background indicates that the button is now active.
- The Start button is green under normal circumstances, but its background color changes to orange when a blank measurement is required before a regular measurement (Cf. *Figure 18*).

## 5.2.4 Radio Buttons and Checkboxes

- Radio buttons are displayed when you can choose between options that are mutually exclusive. Whenever you tap inside a radio button to select it, all the other radio buttons on the screen become deselected. Selected radio buttons have a dot inside them; deselected radio buttons are empty



- Checkboxes are displayed when you can make one or more choices on a screen, and the choices do not cancel each other out. Tap inside a checkbox to toggle its selection on or off. Selected checkboxes have a check mark inside them, deselected checkboxes are empty.



## 5.3 Data input alternatives


### 5.3.1 Using a barcode scanner


For information see [5.1.3](#).

### 5.3.2 Using an USB flash drive

The USB port on the *EasyReader+*<sup>®</sup> analyzer (Cf. *Figure 2*) is mostly a channel for exporting and transferring data, but it can also serve as a data input port when you are updating the system software.

To mount a USB flash drive on the system, simply insert the drive into the Type A USB port on the back of the analyzer (Cf. *Figure 2*).

To remove a USB flash drive from the system, tap in the status icon area of the status bar, which displays "USB connected"  icon to unmount the drive and then remove it.

 **Do not remove a connected USB drive without first unmounting it, as this can cause data corruption on the drive.**

## 6 Start-up wizard

The first time your *EasyReader+*<sup>®</sup> analyzer is turned on, it will take you through a quick set up procedure. This procedure will allow you to select the basic functions of the analyzer so you can use the analyzer with your choice of settings.

**i** *It is recommended that a supervisor-level user should complete the Start-up Wizard and set up the system, so that all the features and functions can be customized.*

**i** *The supervisor password is 1234 by default which is recommended to be changed later.*

The **Start-Up Wizard** will allow you to select the following settings:

- ▶ Language (Cf. [11.1.Change the interface language](#))
- ▶ Date and time (Cf. [11.2.Set the date and time](#))
- ▶ System security (Cf. [11.3.Customize system security](#))

**i** *In this section you can select if you prefer to use the Easy Mode menu which is emulating the functioning of the push button operated old version of *EasyReader+*<sup>®</sup>.*

- ▶ Change 'supervisor' operator password (optional: depends on system security level)
- ▶ Printout (Cf. [11.4.Set up results printout](#))
- ▶ Output (Cf. [11.5.Configure results transfer](#))
- ▶ QC (Cf. [9.1.Quality Control settings](#))
- ▶ Add operators (Cf. [11.8.Manage operator accounts](#))

**i** *If you wish to skip the wizard after the language settings and configure them at a later date, tap Skip on the second screen.*

You can review all active settings on the **Main Menu » View settings** screen. All settings, including connectivity ('**Output**') can be modified on the **Main Menu » Settings** screen.



# 7 Analyzing specimens

## 7.1 Assay device management

The *EasyReader+*® analyzer is compatible with different assay device types each of which can detect a specific biomarker.

**!** The system cannot automatically detect the type of assay device that you insert using the device dock. Because of this, before you start a test, you need to check that the currently active assay device is the type that you are using, and, if necessary, manually select and activate the appropriate type.

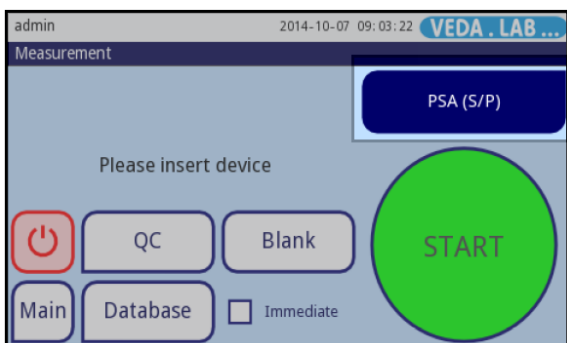


Figure 13: The device type indicator box (highlighted) has 2 functions: displaying actually selected device and as a button it takes you to **Select Device** screen.

### 7.1.1 Select a particular type of assay device

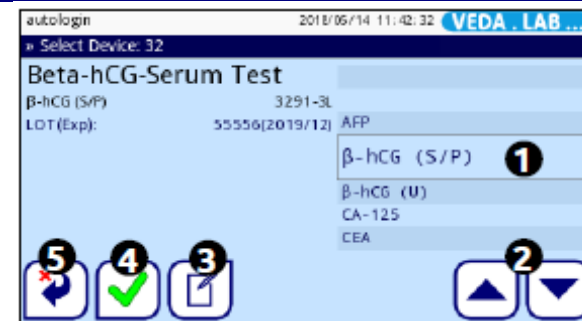


Figure 14 : The **Select Device** screen.

- 1 On the startup (**Measurement**) screen, tap inside the **device type indicator box**.
- 2 In the **Select Device** screen that pops up, use the up and down arrow keys (labelled 2 in *Figure 14*) to move the cursor bar over the assay device type that you would like to use.
- 3 Select assay device  or go back  to **Measurement** screen without selection.

Key to Figure 14:

- 1 Cursor bar
- 2 Up an Down buttons
- 3 Edit LOT and expiry date if QC lockout is checked in QC options menu
- 4 Select assay device type
- 5 Go back in menu hierarchy.

**i** The name and lot number of the assay device type that the cursor bar is currently over appears on the screen.

## 7.1.2 Excluding an assay device from selection

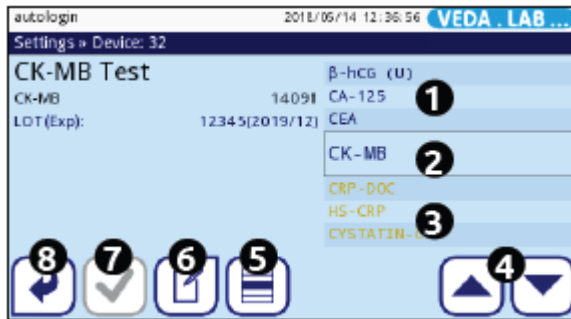







Figure 15: The Settings»Device screen

Key to **Figure 15**:

- 1 Available assay device types;
- 2 Cursor bar;
- 3 Unavailable assay device types (letters turned ochre);
- 4 Up and Down buttons;
- 5 Select or unselect the cursor-highlighted assay device;
- 6 Edit LOT and expiry date if QC lockout is checked in QC options menu;
- 7 Select assay device type;
- 8 Go back in menu hierarchy.

- 1 On the startup (**Measurement**) screen, tap the **Settings** button on the **Main** screen, and then the **Devices** button on the **Settings** screen;
- 2 In the **Settings»Device** screen that pops up, use the up and down arrow keys (labelled 4 in **Figure 15**) to move the cursor bar over the assay device type that you would like to exclude from the list of the **Select Device** screen.
- 3 Select assay device  and apply change  or go back  to Measurement screen without selection.

 On this screen you cannot actually select a device for measurement. You can edit the available device type list for the **Select Device** screen, where the selection is to be made.

 The name and lot number of the assay device type that the cursor bar is currently over appears on the screen.

## 7.1.3 Register assay device lots

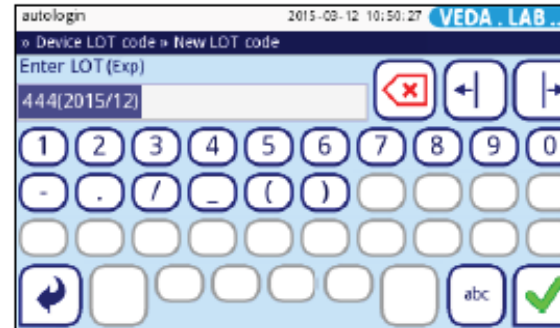



Figure 16: The LOT number with the expiry date in brackets.

You need to register the lot number of each batch of assay devices you would like to use before you can start a measurement for reasons of quality control:

- To make sure that the assay devices that you use to perform the measurements have not expired.
- To guarantee accurate measurement results and verify that you are using the assay devices that the analyzer was designed to process.

1 Access the **Select Device** by tapping the device indicator box on the **Measurement** screen or the **Settings»Device** by tapping **Devices** button on **Settings** screen

2 Use the up and down arrow keys to move the cursor bar over the assay device

type that you would like to register a lot for and tap **Edit**  button.

3 On the **Device LOT Code» New LOT Code** screen, enter LOT number, and lot expiry date in brackets (YYYY/MM) for the selected device type.

**!** **Make sure that you enter lot information for assay devices as it appears on the device packaging.**

4 Tap the **✓ Save** button to save the changes or the **↶ Back&Drop** button to cancel the changes and exit the screen.

## 7.2 Handling specimens

The collected samples must be stored until measurement in particular ways, that hospitals and laboratories have their regulations about them based on clinical experiments, WHO regulations, standards and patents. They must be stored in certain conditions until only certain period of time to suit the measurement method and the biomarker you want to detect. Therefore this manual do not give specified instructions about them. Every batch of assay device has package insert in them containing all necessary information of sample handling and preparation.

**Figure 17:** When you prepare specimens for analysis, always label or mark them individually.



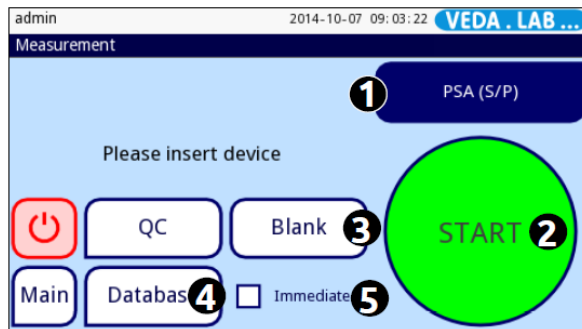
**!** **Specimens must be collected aseptically, under the standard laboratory conditions.**

**!** **Whole blood, plasma, serum, urine, and feces specimens are potentially infectious, and must be handled at Biosafety Level 2.**

**i** *The instructions for the use of the particular type of assay device you are using (package insert) always take precedence over the instructions in this manual. Consult the instructions for the use of the specific type of assay device that you are using before applying the test specimens.*

**i** *This format of test should not be used for visual reading.*

## 7.3 Start a regular measurement



**Figure 18 :** The Measurement screen with the assay device type indicator box and Select Device button (1), the START button (2), Blank measurement (3), the Database button (4), and the Immediate mode checkbox (5) indicated

Make sure that you prepare the following before you start using the *EasyReader+*<sup>®</sup> analyzer:

- the specimens that you would like to test (and that you handle and prepare according to best practices);
- assay devices (at least one for each of your specimens) for the semi-quantitative detection of the biomarker that you are testing;
- an *EasyReader+*<sup>®</sup> analyzer in working condition, complete with accessories (Cf. [Figure 3](#)).

**i** *Keep in mind that for the first measurement after system startup, the analyzer requires a blank reference measurement before you can start the testing procedure. Do not apply the test specimen to the assay device until you perform a valid blank reference measurement, and the analyzer is ready for a regular measurement.*

- 1 Switch the analyzer on and log in.
- 2 Perform a blank measurement.
- 3 Allow the test specimen and the wrapped assay devices to come to room temperature, and remove the wrapping of the assay device.

**i** *Read the package insert of the assay device type you are using to avoid mistakes what could lead to false results.*

- 4 Label each assay device with the name or identifier of the patient who provided the test specimen before you apply the test specimen to the device.

**Figure 19:** Mark or label each assay device individually



**i** *It is recommended that you clearly mark or label each specimen test tube and assay device individually so that you can identify them later (Cf. [Figure 17](#) and [Figure 19](#)).*

- 5 Follow the instructions on the package insert of the assay device when you apply specimens. Place the assay device horizontally and use the specimen dispenser provided with the assay device, and dispense the amount of specimen given in the package insert of the assay device into the sample well.

**!** **Avoid sampling air bubbles.**

- 6 If the package insert of the assay device requires it, add the amount and type of diluent that the instructions specify.

**!** **Wait for the complete absorption of the sample before adding the diluent.**

**!** **Avoid touching the assay device with the tip of the diluent bottle to prevent sample carryover.**

**Figure 20 :**  
Use a manual pipette to apply the amount of specimen that the package insert of the assay device requires into the sample well of the assay device.



**!** Do not use damaged, unclean, improperly stored, expired or already used devices.

7 If your assay device type is selected already, insert the assay device with the specimen and tap the **START** button to start a regular measurement (the 'Regular measurement status' of the **START** button is indicated by its green background color).

**!** The sample well of the assay device has to be on the right hand side when inserted in the analyzer. In case of inappropriate positioning the instrument gives an error message. When processing internal incubation (countdown mode), take care of inserting gently the cassette to avoid spill of reagents.

**!** Do not move assay device after the measurement started because it causes faulty reading of the device or the measurement will be deleted.

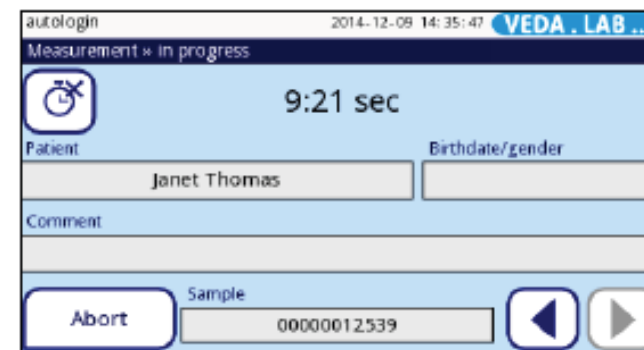
**i** If Immediate mode is enabled, make sure that you allow the device-specific incubation time to elapse before you insert the assay device into the analyzer. In this operation mode, the system will not count down the incubation time for the assay device but will immediately produce and evaluate an image of the device test area.

**i** If Autostart mode is enabled on the user account you currently logged in, you don't have to tap the **START** button.

**Figure 21 :**  
Load the pipetted assay device into the rapid test holder, and insert the holder into the analyzer.



8 Enter some or all of the following data of the patient who provided the specimen on the series of screens that the system displays while the incubation time elapses: **ID**, **Name**, **Date of Birth**, and **Sex**. You can also add an optional comment to the measurement record. To do so tap inside one of the text boxes while the **Measurement»in progress** screen is displayed. Toggle between worklist items during incubation time with the left-right arrows in the bottom right corner.



**Figure 22:** The **Measurement»in progress** screen

**i** If Autotransfer and Autoprint is enabled, details cannot be modified after measurement is finished.

**9** The analyzer produces and evaluates the image of the device test area, and displays the results and data entered for the measurement record. If the measurement was successful, all data stored with the record in question is displayed. At negative result the text appears in black, at positive result the text is in red. If the measurement failed for some reason, only the reason for the failure is displayed (usually an error message), and the background of the menu is highlighted in yellow.

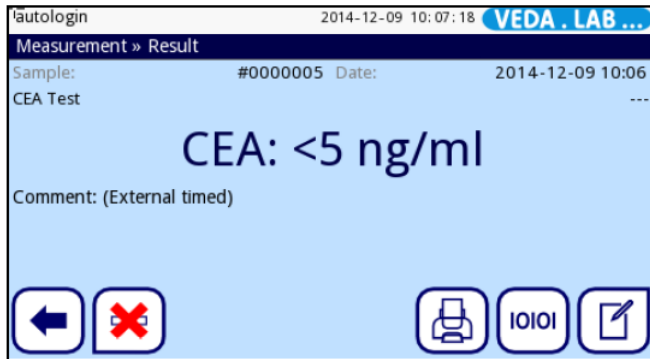


Figure 23: The Measurement » Result screen.

**i** The last result is displayed on the Measurement » Result screen after the analyzer finished evaluating the assay device. You can edit, delete, transfer, print or go back to Measurement screen from here.

**10** If Autostart enabled, the system goes back to Measurement menu when the rapid test holder is pulled out, and with a new assay device is inserted, a new measurement process will automatically start. If Autostart is disabled, you have to go back from the result window to the Measurement menu to start a new measurement by tapping Go back button.

## 7.4 Customizing workflow

With numerous possibilities in system settings and their combinations with user options allow you to design the workflow to the requirements of your laboratory, hospital or even every single labor assistant. (Cf. 11.Instrument settings).

### 7.4.1 Touchless operation

The default settings let you analyze samples without tapping the touch screen. All you need to do is apply your specimens to the assay devices, load the devices into the rapid test holder, and insert the holder into the analyzer (Cf. 14.1.Default Settings)

### 7.4.2 Immediate mode

To enable external incubation, select the **Immediate** checkbox on the **Measurement** screen (Cf. Figure 18). Due to different regulations in laboratories, EasyReader<sup>®</sup> lets operators choose this option only if Admin or higher level operators set it up on **QC settings** screen by checking **Immediate enable** checkbox. (Cf. Figure 32).

When this box is unchecked, the **Immediate** checkbox on the **Measurement** screen remains grey and out of operation.

**!** While Immediate mode is enabled, the analyzer starts the measurement process immediately after you insert an assay device into the device dock, without counting down the incubation time — make sure that you count down the incubation time for the particular assay device after you apply the test specimen.

## 7.5 Worklist

The worklist is a predefined sequence of samples and contains the sample IDs and patient IDs in the sequence of planned evaluation. Tap the **Worklist** button on the **Measurement** screen to go to worklist management.

The worklist can be generated manually through the touchscreen, or a connected external keyboard or barcode reader, or automatically by downloading the worklist items from the LIS.

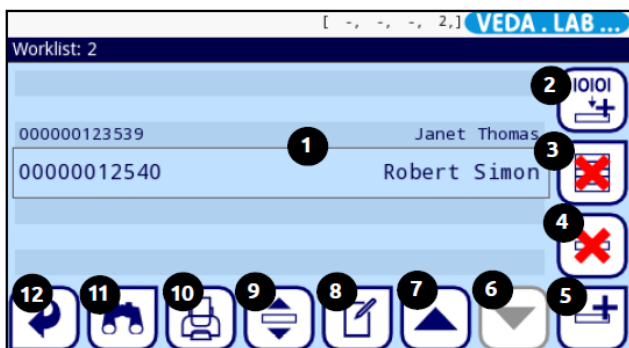


Figure 24 : The **Worklist** screen with the screen elements labelled

Key to **Figure 24**:

- 1 Worklist items
- 2 Download worklist from LIS
- 3 Delete all items
- 4 Delete active item
- 5 Add new item
- 6 Move down by one record in the list
- 7 Move up by one record in the list
- 8 Modify item
- 9 Action: select actual item
- 10 Print worklist
- 11 Search for sample ID
- 12 Return to Measurement menu

**Sample ID:** The sample ID is a maximum 15 character long numeric string. It can be generated by the analyzer, typed in or can come with the downloaded worklist from LIS.

*i* The system does not allow you to leave the **Sample ID** text box empty.

**Patient ID:** The patient ID is a maximum 33 character long string containing either numeric, alphabetic or special characters.

**In the Worklist menu you can:**

- manually add, modify or delete worklist items;
- download worklists from LIS;
- modify the sequence of the items;
- search for a sample ID in the worklist;
- print the worklist;
- delete the whole worklist


### 7.5.1 Creating worklist


1 Tap the **Main** button on the **Measurement** menu then **Worklist** button on the appearing **Main Menu** screen.

2 Use the  **Add new item** button to add a new entry to the list.

3 Set the sample and patient ID as described in the testing procedure.

*i* By using external keyboard or barcode reader the editing process can be speeded up considerably. The new item will be added to the end of the list.

4 Use the  **Modify item** button to modify an already existing record.

5 When you return the **Measurement** screen with the  **Back** button, the sample ID of the first worklist item will be shown in the list window.

*i* If the worklist is empty, only the  and  buttons are active. The other buttons are active if the worklist contains at least 2 items.


## 7.5.2 Worklist from LIS



1 Tap the **Main** button on the **Measurement** menu then **Worklist** button on the appearing **Main Menu** screen.

2 Use the  button to download worklist from LIS.


## 7.5.3 Worklist management

### 7.5.3.1 Modifying and deleting worklist items

Worklist items can be modified by moving the cursor bar over them using the Up and Down arrow buttons and tapping  Modify item button. The appearing input screens let operators making changes.

If a worklist item must be deleted, tap  Delete active item button when the cursor bar is over it. Tapping  Delete all items button erases every item on the worklist.

### 7.5.3.2 Changing the worklist order

New items always added to the end of the list notwithstanding the possible numeric order of the sample IDs. The sequence can be changed with one item at a time. First go to worklist. Using the **Up** and **Down** arrow buttons place the cursor bar over the item you would like to move. Select item by tapping  Select actual item button. The button turns orange indicating that the selection has been made and you can move the item. Using the **Up** and **Down** arrow buttons move the item on the list notwithstanding the possible numeric order.

If measurement is already started, change the sample ID during incubation time on the **Measurement»in progress** screen. To go through the sample IDs, use the Right and Left arrow buttons next to **Sample** textbox.

### 7.5.3.3 Working outside worklist

When there are items on the worklist, the analyzer recording measurement results using the list, starting with the first sample ID and going down the list. If there is an urgently needed results and items are on the worklist, *EasyReader+*<sup>®</sup> still able to evaluate the new sample. Simply start a new measurement using the assay device prepared with the new sample. Rewrite the sample ID of the worklist item during incubation time by tapping in **Sample** text box on the **Measurement»in progress** screen. If there are other details, change them, too.

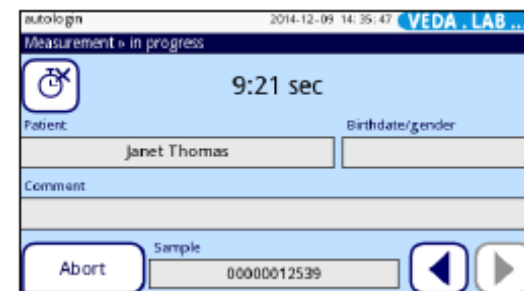


Figure 25: The Measurement»in progress screen when working from worklist



## 8 Managing test results

*EasyReader+*® can store up to a thousand (1000) measurement records in its fully searchable database. To access the database, tap the **Database** button on the **Measurement** screen (Cf. [Figure 18](#)).

### 8.1 Finding and selecting test results

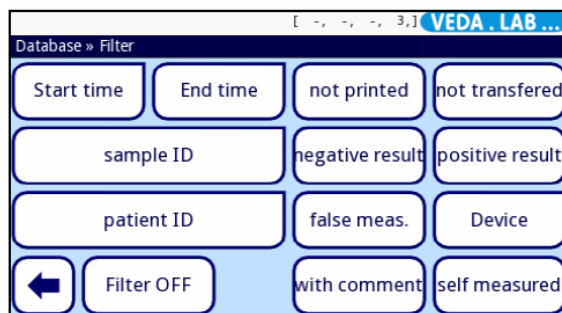
#### 8.1.1 Finding specific test result records

The *EasyReader+*® database includes a robust and customizable search engine to help you find the specific test result records that you are looking for.

##### 8.1.1.1 Turning on a filter parameter


1 To access the database, tap the **Database** button on the **Measurement** screen (Cf. [Figure 18](#)).


2 To display the **Filter** screen, tap the  filter button on the **Database** screen (labelled 3 in [Figure 27](#)).






**Figure 26:** The **Filter** screen. Tap the **Filter OFF** button to cancel result filtering.

3 On the **Filter** screen, tap the filter parameter that you would like to search for in the database. The background of the filter parameter that you selected will turn orange to indicate that it is active. To deactivate a filter parameter, tap its button a second time.

4 If the filter parameter that you selected requires additional data input, enter the details using the the input screen. When you tap the  OK button on the input screen, you will return to the **Database»Filter** screen.

5 Tap the  **Back** button to see only the measurement records that the filter returns.

 If a filter parameter is active, the background of the filter icon will become orange  until you turn the filter off (Cf. [8.1.1.2](#)).

 You can combine filter parameters for increased search efficiency. However, you cannot combine incompatible filter criteria (such as searching for positive and invalid measurements).


##### 8.1.1.2 Turning off result filtering

If you want to see all the test result records that are in the database, you need to turn off filtering completely. To do this, tap the **Filter OFF** button on the **Database »Filter** screen (Cf. [Figure 26](#)).

##### 8.1.1.3 Automatic result filtering

The *EasyReader+*® system has a special automatic result filtering feature to help you focus on the most recent test result records in the database.

When you access the **Database** screen from the **Measurement** screen, and you have started at least one measurement since you switched on the analyzer, the system automatically applies a **Start time** filter parameter on the database, and only displays the records that you have created since you turned on the analyzer.

The background of the filter icon changes to green  to indicate that automatic filtering is active.

To turn off automatic filtering, access the **Filter** screen (Cf. [Figure 26](#)), and tap the **Filter OFF** button.

## 8.1.2 Selecting test result records

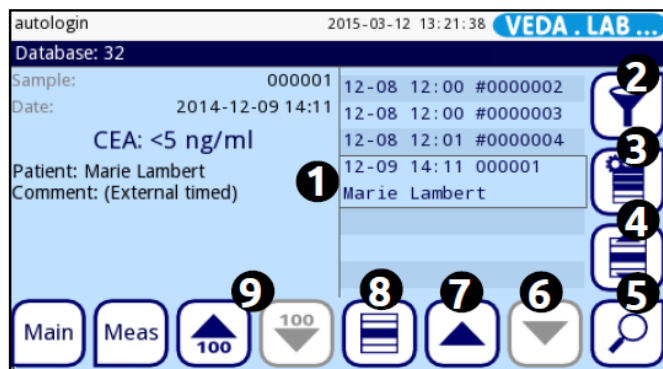


Figure 27: The Database screen with the screen elements labelled

### 8.1.2.1 Selecting a single test result record in the database

Tap the up and down arrows (labelled 6 and 7 in [Figure 27](#)) to move the cursor bar (labelled 1 in [Figure 27](#)) in the list of result records over the analysis record that you would like to select, and tap the selection button (labelled 8 in [Figure 27](#)). To cancel the selection of a previously selected record, tap the selection button a second time, or see [8.1.2.4](#).

The background of the result record will turn blue to indicate that it is selected.

If there are more than one hundred result records in the database, the **100 up/100 down** buttons (labelled 9 in [Figure 27](#)) become active. Tap these buttons to move the cursor one hundred records up or down in the database list.

### 8.1.2.2 Selecting more than one test result in the database

To select more than one record at the same time, do one of the following:

- Using the up and down arrows (labelled 6 and 7 in [Figure 27](#)), move the cursor over each record that you would like to select, and tap the **Select** button (labelled 8 in [Figure 27](#)).

The measurement records that you select do not need to be next to each other in the list. The result records that you selected will stay selected.

- Using the up and down arrows (labelled 6 and 7 in [Figure 27](#)), move the cursor over the first or last record in the list that you would like to select, and then tap the selection by movement button (labelled 4 in [Figure 27](#)). When you tap the up or down buttons, you will select a result record that is above or below the starting record in the database list.

To disable selection by movement, tap the button a second time.

The background of the selection by movement button will become orange to indicate that it is activated.

The measurement records that you select in this way need to be next to each other in the list.

### 8.1.2.3 Using the record details screen for selection

After you have selected a test result record, you can also use its detailed result screen to select further test result records. To do this, complete the following steps:

**1** Select a record in the database (Cf. [8.1.2. Selecting test result records](#)), and tap the **Review the selected record** button (labelled 5 in [Figure 27](#)).

**2** On the record details screen (Cf. [Figure 30](#)), use the **Up** and **Down** arrows (labeled 5 in [Figure 30](#)) to cycle through the details of the other records in the database list.

**3** When you find a test result record that you would also like to select, tap the **Selection** button. When you return to the database screen with the **Back** button, all the test result records that you selected in the record details view will remain selected.

### 8.1.2.4 Cancelling the selection of measurement records

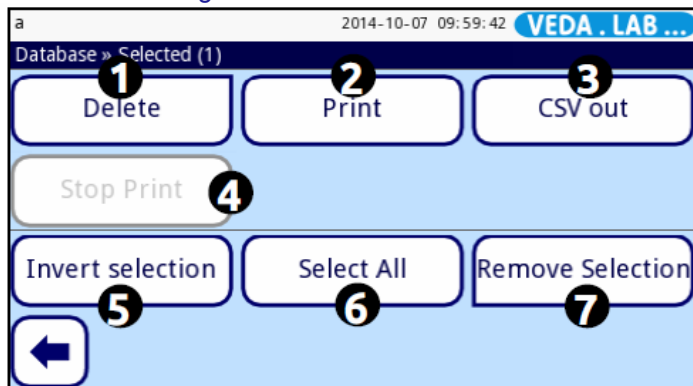



Figure 28: The Database » Selected screen with the screen elements labelled.

To invert the selection that you made (de-select previously selected records and select previously unselected records), tap the  **Actions with selected records** button (labelled 3 in Figure 27) and then, on the Database » Selected screen, the **Remove Selection** button (labelled 7 in Figure 28).

## 8.2 Further actions with test results


### 8.2.1 Reviewing selected test result records

Tap the view selected record button on the **Database** screen (labelled 5 in Figure 27). The **Database » Result** screen (Cf. Figure 30) will be displayed, that lists all the data available for the test result record that was supplied by the operator or measured by the analyzer. You can modify but cannot delete the data here.

### 8.2.2 Deleting selected test result records

To delete one or more test result record:

1 Select the record or records in the database (Cf. 8.1.2.1. *Selecting a single test result record in the database* and 8.1.2.2. *Selecting more than one test result in the database*).

2 Tap the  **actions with selected records** button (labelled 3 in Figure 27), and on the **Database » Selected** screen, tap the **Delete** button (labelled 1 in Figure 28).

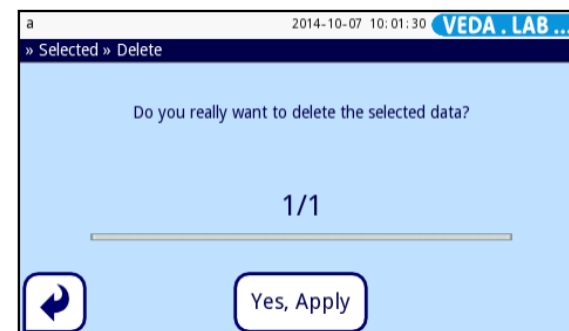



Figure 29: The system prompts you to confirm that you want to delete one or more test result records.


3 To permanently delete the selected test result records from the database, on the confirmation screen that appears, tap the **Yes, Apply** button.

 *You cannot undo this action.*

## 8.2.3 Editing the details of test result records

When you access the database, you have the option to modify the automatically generated Sample ID and add further data to the test result record: the name, gender, and birth date of the patient who supplied the blood specimen, or a text comment.

You even have the option to edit the details of a test result record while the test is still going on.

 You can only edit the details of a test result record if you have not yet printed or transferred it.

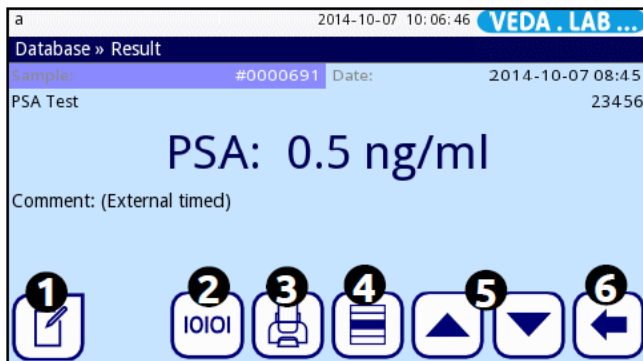



Figure 30: The Database»Result screen, with the buttons labelled.

To modify the details of a test result record, complete one of the following set of steps.

- To edit the details of a test result that is already in the database:
  - 1 Select the record in the database (Cf. [8.1.2.Selecting test result records](#)).

 With wide filtering options the desired results can be easily found.

2 Tap the  review the selected record button (labelled 5 in [Figure 27](#)).

3 Tap the  Edit button (labelled 1 in [Figure 30](#)), and on the Result»Modify screen (Cf. [Figure 31](#)) tap inside the text boxes to start editing the data.

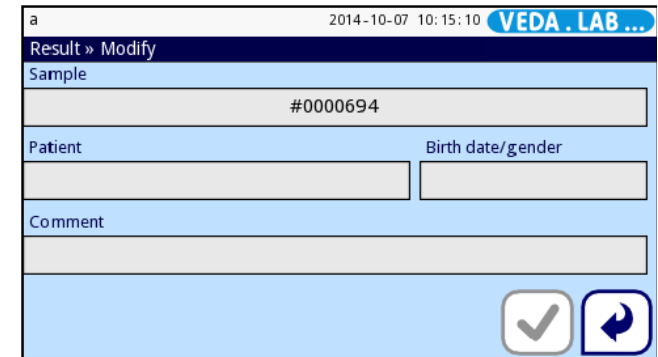







Figure 31: To add details to the test result record, tap inside the text boxes on the Result»Modify screen

4 To save or discard the change and return to the Result»Modify screen, tap the  OK or the  Cancel button.

5 To save or discard the change to the test result record, tap the  OK or the  Cancel button on the Result»Modify screen.


## 8.2.4 Transferring test result records


 After you transfer a test result record, you will not be able to edit its details.

To transfer one or more test result records in plain text format to a connected USB flash drive, complete one of the following sets of steps:

### 8.2.4.1 To transfer one or more test result records from the database:




1 Select the record or records in the database (Cf. [8.1.2.Selecting test result records](#)).

2 Tap the  actions with selected records button, and then the Text out button (labelled 3 in [Figure 28](#)).

 The label of the button changes with the output settings: HL7, LIS2, CSV out or Text out.


3 The .txt file for the selected record will appear in the root folder of the connected USB flash drive.


#### 8.2.4.2 To transfer one test result record from the record details screen:


- 1 Select the record in the database (Cf. [8.1.2.Selecting test result records](#)).
- 2 Tap the  review the selected record button (labelled 5 in [Figure 27](#)).
- 3 Tap the  Transfer button (labelled 2 in [Figure 30](#)). The .txt file for the selected record will appear in the root folder of the connected USB flash drive.
- 4 Tap the  back button to return to the database.


### 8.2.5 Printing test result records


You can use the built-in thermal printer or a connected external printer to print off one or more test result records.

 *If the default settings are active, the system automatically prints off each test result at the end of the analysis process. To change the default print setting, see [10.1 User options](#).*


 *After you transfer a test result record, you will not be able to edit its details.*  
To use the built-in thermal printer to print off one or more test result records, complete one of the following sets of steps:


- To print one or more test result records from the database:
- 1 Select the record or records in the database (Cf. [8.1.2.Selecting test result records](#)).
  - 2 Tap the  actions with selected records button, and then the **Print** button (labelled 2 in [Figure 28](#)).
  - 3 The system displays the I105 information message: **Selection was sent for printing**, and the built-in printer prints off the record or records.


 *You can abort the printing process by tapping the **Stop Print** button.*

- 4 Tap the  back button to return to the database.

- To print one result record from the record details screen:
- 1 Select the record in the database (Cf. [8.1.2.Selecting test result records](#)).

- 2 Tap the  review the selected record button (labelled 5 in [Figure 27](#)).

- 3 Tap the  print button (labelled 3 in [Figure 30](#)). The system displays the I105 information message: **Selection was sent for printing**, and the built-in printer prints off the record.

- 4 Tap the  back button to return to the database.


To use a connected external printer to print test result records:

- connect an SII Smart Label Printer 440 or an SII Smart Label Printer 450 device to the USB type A interface, and follow the steps for using the built-in printer.

 *The system is not compatible with any other external printer.*

### 8.2.6 Rerun failed measurements

The operators can transfer the records of failed measurements to the worklist, to run new test with them.

1. Select the record or records in the database (Cf. [8.1.2.Selecting test result records](#)).
2. Tap the  review the selected records button and then tap the **To worklist** button.

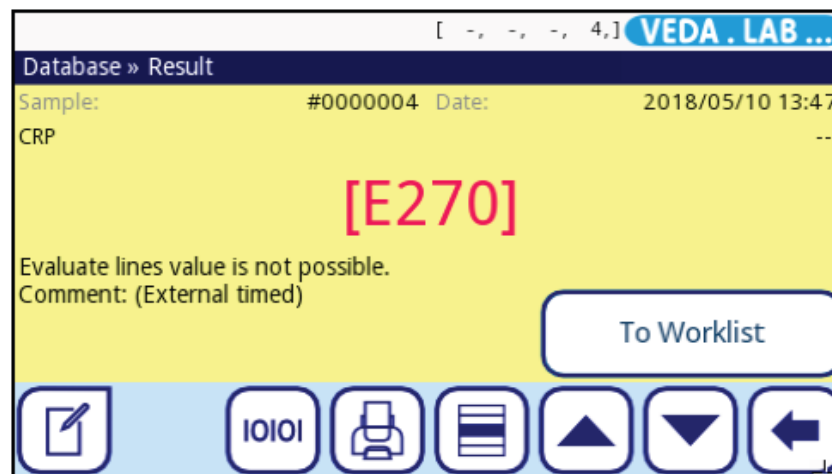


Figure 32: Send record of failed measurements back for a repeated test with the **To worklist** button

## 9 Quality control

The performance of the system (analyzer and assays) should be monitored regularly to ensure reliable results are obtained. Determining the frequency of quality control, consult your facility's quality control policy.

To make sure of the reliability of the measuring you can check the analyzer three ways:

- Blank measurement with blank device
- Check measurement with calibration device

Proper quality control is a three-phase process:

**1** Configuring the system: setting QC lockout on the **Settings » QC Options screen**. See [9.1.1.QC lockout](#).

**2** Setting the calibration device range code. See [9.2.2 Check measurement](#).

**3** Performing QC testing at regular intervals.

The analyzer uses color coding on the buttons of the **QC measurement** screen:

**QC lockout** is disabled:

- grey: not measured,
- green: valid measurement was performed while in the **QC Measurement** menu
- red: invalid measurement was performed while in the **QC Measurement** menu

**QC lockout** is enabled:

- grey: not measured,
- green: valid measurement was performed within the time limit
- red: invalid measurement was performed within the time limit or the time limit passed

### 9.1 Quality control settings

You can configure quality control settings for the device on the **Settings»QC Options** screen. QC settings available only with Admin or higher level operator accounts.

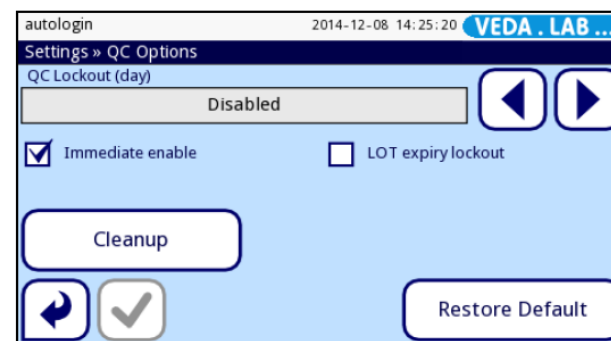


Figure 33: The QC Options screen.

The screen offers the following options:

- enabling/disabling QC lockout
- setting the QC lockout interval in days
- restore default options
- delete previous QC measurement records
- enabling/disabling Immediate mode

### 9.1.1 QC lockout

The lockout mode offers the opportunity to ensure a QC check latest at every determined interval. If the lockout mode is activated, the instrument will be released for measurements for the determined timeframe once a successful QC check has been performed.

To enable the QC lockout and set the interval use the right and left arrows on the **Settings»QC Options** screen. The remaining lockout time and the date is displayed in the information windows of the **Main** screen.

**i** If you apply changes to the QC lockout period, a popup window appears with the modified lockout time. When the period passed, the system displays a warning message and the status bar background is changes to yellow. Measurements still can be done.

### 9.1.2 LOT expiry lockout:

- If ON, the previously set expiry interval is going to trigger an error message , changes the status bar background to red and prevents performing new measurement, until new QC measurement is done.
- It works with assay device LOT, too. When the previously set expiry date passes, the system sends an error message and locks you out, until new assay device LOT registered.

**i** If strong user security is applied the normal users are not able to modify the QC settings, so the QC policy determined by the system administrator will be forced. However if the analyzer is locked out and you need to make a measurement immediately without performing the QC check first, the lockout mode can be switched off only by an administrator.

## 9.2 Quality control measurements

### 9.2.1 Blank measurement

Blank measurement used in order to equalize the slight non-uniformities of the optics of the instrument. This procedure needs to be performed for the proper operation of the *EasyReader+*<sup>®</sup>, that is why the operator is forced to repeat it regularly.

Use a special, completely white ('blank') assay device to perform a blank measurement.

The blank assay device is part of the *EasyReader+*<sup>®</sup> delivery package.

Blank measurement is needed in the events of:

- after every powering on (the analyzer prompts for it);
- after every 24 hours continuous use;
- if the detected temperature changes  $\pm 5^{\circ}\text{C}$  to what it was during last measurement.

To perform a blank measurement do one of the following:

- If you are performing the first measurement since you switched on the analyzer, tap the **START** button on the **Measurement** screen to start a blank measurement, and then follow the displayed instructions.

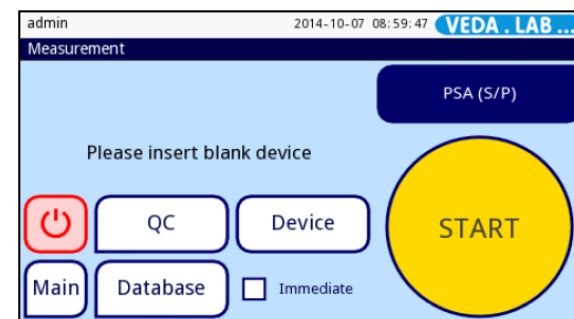


Figure 34: The starting screen prompts you to perform a blank measurement

- When you have already performed measurements with the analyzer since you switched it on, go to **Measurement** screen, tap **Blank** button, insert a blank device and tap **START** or tap through in the interface to **QC Measurement** insert a blank device and tap **Start:Blank**.

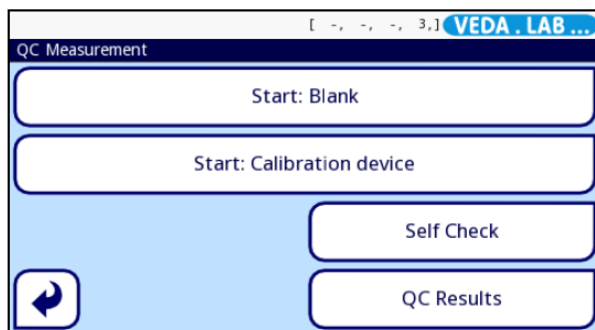


Figure 35: The QC Measurement screen

**i** If the test performed successfully the background of the **Start:Blank** button turns green. If the test fails the button turns red.

**!** Using damaged or dirty blank assay device results in analyzer reduced capability of prompt measurement.

**i** The analyzer automatically asks for a blank device after powering on.

## 9.2.2 Check measurement

The measurement with the calibration device can be used as a mechanism to confirm the functionality of the analyzer. Its purpose is to check and control the performance of the optic system. The lines on the calibration device have saturation values which the analyzer measures. The packing insert of the device contains the range limits in between the measured values should be.

### ProceSSION of check measurement:

- 1 Go to **QC Measurement** screen.
- 2 Tap **Start:Calibration device**.
- 3 With new calibration device first you have to type in the range code. It is the identifier of the calibration device and it is printed on the label of the calibration device package. Save it with .
- 4 Tap button to start the check measurement.

**i** If the quality check is successful, the system displays 'PASSED' next to the QC result ID. The button background for passed QCtests changes to green. If the QC measurement has failed, red FAILED text is displayed after the QC result Id. The button background for failed QC tests changes to red.

**!** Verify the performance of the reader with the calibration device every 2 weeks and after every accident (drops, spills, splashes), even if visible damage was not done.

**!** Using damaged or dirty calibration device results in analyzer reduced capability of prompt measurement.

## 9.2.3 Self Check

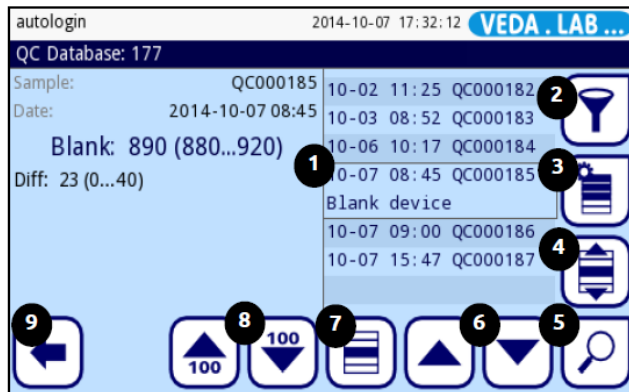
The analyzer runs a series of checks to make sure all components and the software work properly. The self check is the same as it is run after every switch on.



## 9.3 Quality control record management

### 9.3.1 Select and review QC records

The *EasyReader+*® analyzer can store up to 5000 measurement records in its fully searchable database. You can access the QC database by tapping the **QC Measurement** button on the **Main** screen, and then the **QC Results** button on the **QC Measurement** screen.



**Figure 36** : The QC Database screen with the functional elements indicated: Cursor bar (1), Filter (2), Further actions with selected records (3), Select by movement (4), View (5), Up and Down (6), Select (7) Up and Down by 100 (8), Back to QC Measurement (9).

#### 9.3.1.1 Select a single QC record in the database

On the **QC Database** screen, tap the **Select** button (labelled 7 in *Figure 36*) when the cursor bar is over the QC measurement record that you would like to select, as it is displayed in the list (labelled 1 in *Figure 36*).

#### 9.3.1.2 Select multiple QC records

To select more than one QC record at the same time, do one of the following:

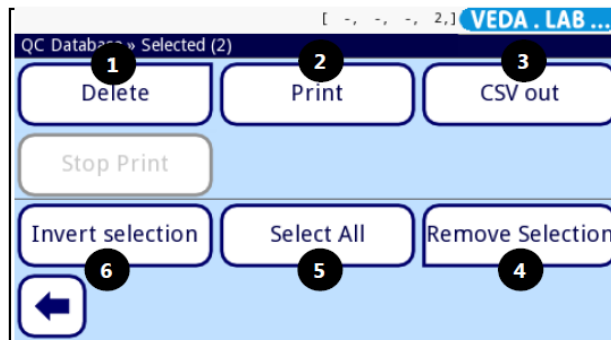
- On the **QC Database** screen, use the  arrows (labelled 6 in *Figure 36*) to move the grey selection bar over each record that you would like to select, and tap the **Select** button.

*i* In this way, you can select QC records that are not next to each other in the list (non-contiguous selection). Records that you selected previously will stay selected.

- On the **QC Database** screen, use the up and down arrows (labelled 6 in *Figure 36*) to move the cursor bar over the record that is the first or last record that you would like to select, and then tap the **Select by Motion** button (labelled 4 in *Figure 36*). The background color of the button changes to orange to indicate that the 'select by movement' option is active. Tap the up and down buttons to extend the selection from the record that you selected to one or more records above or below the first one.

*i* You can only select QC records that are next to each other in the list (contiguous selection).

### 9.3.1.3 Invert the selection of QC records



**Figure 37 :** The QC Database » Selected screen with the function buttons indicated: Delete (1), Print (2), Transfer (3), Remove selection (4), Select all (5), Invert selection (6)

To invert the selection that you made (de-select previously selected records and select previously unselected records), tap the **Action** button (labelled 3 in [Figure 36](#)) on the **QC Database** screen, and then, on the **QC Database » Selected** screen, the **Invert Selection** button (labelled 6 in [Figure 37](#)).

#### 9.3.1.4 View the details of selected QC records

On the **QC Database** screen, tap the **View** button (labelled 5 in [Figure 36](#)) The **QC result** screen (Cf. [Figure 38](#)) will be displayed, that lists all the data associated with a particular QC record.

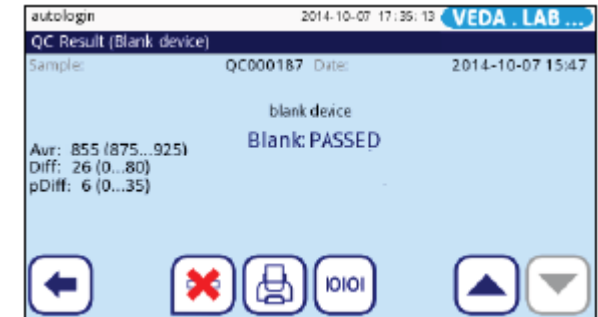
#### 9.3.1.5 Cancel the selection of QC records

On the **QC Database** screen, tap the **Action** button (labelled 3 in [Figure 36](#)), and then, on the **Selected** screen, the **Remove Selection** button (labelled 4 in [Figure 37](#)).

### 9.3.2 Delete QC records

To delete one or more QC record from the database, select the record or records on the **QC Database** screen, and do one of the following:


- Tap the **View** button (labelled 5 in [Figure 36](#)), and then, on the **QC result** screen, tap the **Delete**  button (Cf. [Figure 38](#)).



**Figure 38:** The QC Result screen.

- Tap the **Action** button on the **QC Database** screen (labelled 3 in [Figure 36](#)), and then, on the **QC Database » Selected** screen, tap the **Delete** button (labelled 1 in [Figure 37](#)).

The system prompts you to confirm the deleting of the selected record or records.

 *Deleting QC records is a permanent, irreversible action.*

### 9.3.3 Find specific QC records

The *EasyReader+*® database includes a robust and customizable search engine to help you find the specific record you are looking for.

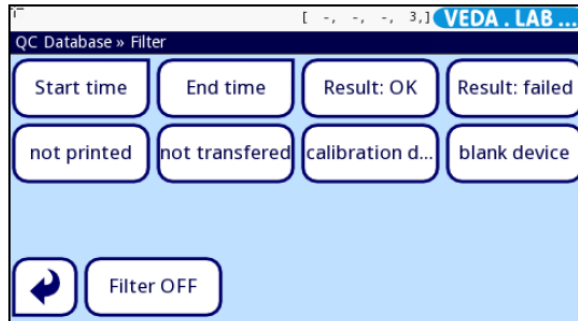


Figure 39: The QC Database»Filter screen

#### 9.3.3.1 Filter QC records by certain criteria

1 Tap the **QC Measurement** button on the **Main** screen, and then the **QC Results** button on the **QC Measurement** screen to access the QC database.

2 Tap the **Filter** button on the **QC Database** screen (labelled 2 in [Figure 36](#)).

On the **QC Results»Filter** screen, tap the filter parameter that you would like to apply in the database.

#### 9.3.3.2 Find QC records by date and time of measurement

The **Start Time** and **End Time** parameters require that you enter a specific date and time — if you tap either of them, a date picker screen will display.

- Use the buttons to move the selection cursor among the date and time components, and the **+** and **-** buttons to set the year, day, month, or time, in hours and minutes of the first or last QC measurement that you would like to see.

- Tap the **Today** button to see only QC results that were performed after midnight the previous night.
- Tap the **Switch on** button to see only QC results that were performed since the last time you switched on the analyzer.
- Tap the **Clear** button to reset the date counters on the screen.

Tap the **Back** button to abandon the changes, or the **Save** button to store the edits.

### 9.3.4 Print and transfer QC records

To print or transfer one or more QC records, select the record or records on the **QC Database** screen, and do one of the following:

- Tap the **View** button (labelled 5 in [Figure 36](#)), and then, on the **QC result** screen, tap the **Print** or the **Transfer** button.
- Tap the **Action** button on the **QC Database** screen and then, on the **QC Database » Selected** screen, tap the **Print** or the **Transfer** button

The function of the **Print** and **Transfer** buttons depends on the currently active printout and transfer settings (Cf. [11.4.Set up results printout](#) and [11.5.Configure results transfer](#)).

# 10 Main menu

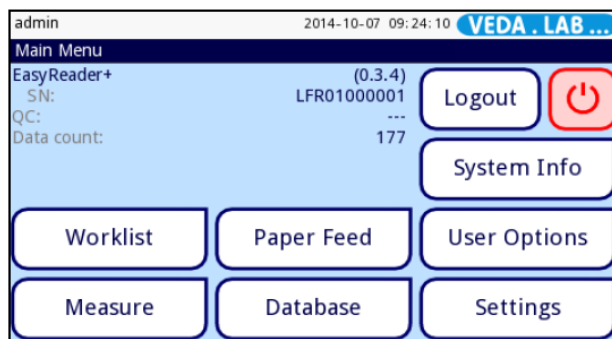


Figure 40: The Main Menu

The **Main menu** displays the following information:

- software version number;
- analyzer serial number;
- next QC measurement in days;
- number of results in database

The screen also contains buttons to reach the following functions and screens with:

- worklist (Cf. [7.5.Worklist](#));
- measurement screen;
- paper feed;
- measurement results database (Cf. [8.1.Finding and selecting test results](#), [8.2.Further actions with test results](#) and [11.9.Database management](#));
- instrument settings (Cf. [11.Instrument settings](#));
- user options;
- system info;
- logout;
- switch off

## 10.1 User options

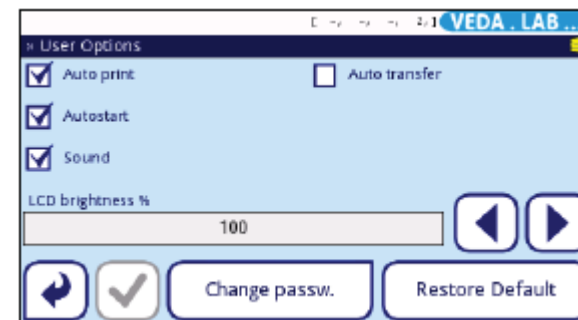


Figure 41: The User Options

You may want to exit the default options, or customize the interface of the *EasyReader+*® analyzer. To access the **User Options** screen, tap the **Main** button on the starting (**Measurement**) screen, and then the **User Options** button.

The operator accounts that the *EasyReader+*® system stores not only include the user name and the password associated with the account, but also a number of user preferences that each operator can customize for him- or herself. These user preference settings are saved and stored as part of the operator's account, and will be automatically enabled every time the operator logs in.

**!** The system stores the customized settings on this screen as part of the operator account that is currently logged in. Each operator can configure their own user preferences.

**i** To revert back to the default options, tap the **Restore Default** button.

**i** To save or discard your changes and return to the **Main Menu**, tap the **OK** or the **Cancel** button.

- Refer to the following table for a description of the various options on the screen.

Auto print	If you select this option, the built-in printer will print off every test result as soon as a measurement is finished.
Autostart	If you select this option, you do not need to tap the <b>START</b> button on the <b>Measurement</b> screen to start a measurement or a blank reference measurement. If you insert the device dock and the system detects that there is an assay device it starts the measurement process.
Sound	If you select this option, the system will give off a brief beep every time you tap a button on the screen.
Auto transfer	If you select this option, the system transfers every test result using the transfer type that you set up (Cf. <b>11.5</b> ).
LCD brightness %	To adjust the brightness of the LCD display, tap inside the <b>LCD brightness%</b> text box and enter a percentage or use the left and right arrows to lower or increase the brightness.

## 10.2 System info

### 10.2.1 Alarm & Warning

In the content navigation bar, after the name of the screen there is the number of error and warning messages. The message IDs and status line texts are listed in the display area. Use the **Up** and **Down** arrow buttons to scroll through them. When the cursor bar is over one of them, below the list the related full text and recommended action is shown.

For the list of messages see [13.4.Error messages](#).

## 10.3 Version

Tap **System Info** button on **Main Menu** screen, then **Version** button on the **Alarm & Warning** screen. The list on the appearing **System info (versions)** screen displays details of the analyzer. Version numbers of the software and its components, device version numbers, MAC address, hardware number and source codes.

Scroll through the list with **Up** and **Down** buttons. The list can be printed by tapping **Print** button.

# 11 Instrument settings

Your *EasyReader+*® analyzer allows you to change settings to suit your workplace requirements.

Instrument settings can be reached from **Main Menu » Settings** screen.

For default settings see 14.1.

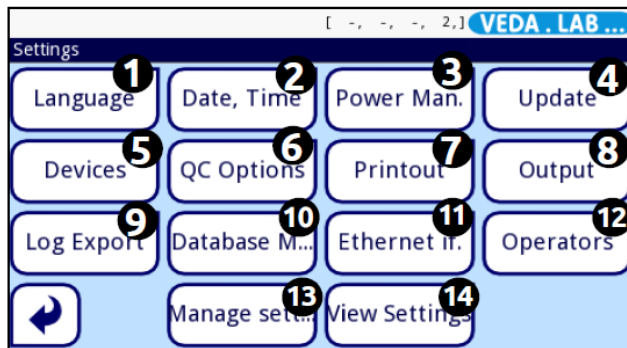






Figure 42: The **Settings** screen with the function buttons labelled

To review active instrument settings tap the **Settings** button (Figure 40) on the **Main Menu** screen, and then the **View Settings** button (labelled 14 in Figure 42) on the **Settings** screen to review the currently active settings. Tap the **Print** button to print off the active settings as a list.

*i* You cannot modify any of the settings on this screen.

• Confirming Changes:

You always have to confirm any changes to have it saved by tapping **Apply**  button, then when it turns grey , you can leave the screen with **Back**  button.

To cancel modifications tap  **Back&Drop** button.

*i* The list of available settings may vary from authenticated user level.

*i* If you do not want to modify the existing default settings, you can start to operate the analyzer without further setup.

• Restoring default values

On each settings screen there is a button (named Restore Default or DEF.), which can be used to restore the default value(s) for that screen. To restore ALL settings on the system level go to Manage Settings.

*i* At system level the settings cannot be restored while printing or transfer is in progress.

The settings can be restored based on the settings of supervisor user, if the 'Default by "supervisor" settings' switch is active on Manage settings page.

## 11.1 Change the interface language

You do not need to understand English to use the analyzer — the user interface is available in several world languages, with more options on the way.

1 Go to the **Settings** screen,

2 On the **Settings** screen, tap the **Language** button (labelled 1 in Figure 42), and then on the **Language** screen, select the radio button for your preferred language.

3 Tap the  **Save** button to store your changes.

## 11.2 Set the date and time

The accurate date and time settings are important because the system stores, prints, and transfers measurement records with the date and time when they were performed.

1 To access the **Settings** screen, tap the **Settings** button on the **Main Menu** screen,

2 On the **Settings** screen, tap the **Date & Time** button (labelled 2 in Figure 42) to start setting the date and time.

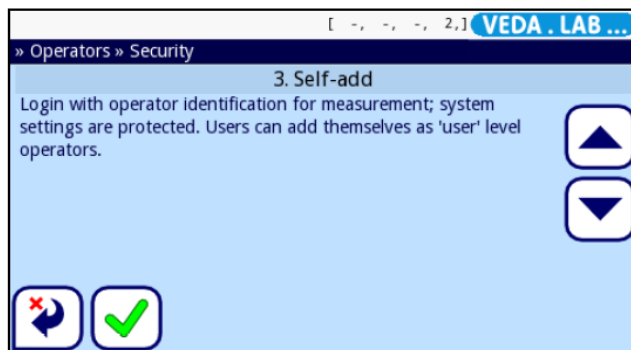
3 On the **Date & Time** screen, use the   buttons to cycle through the date, time, date format, and date delimiter options.

*i* Available date delimiters are "-", ".", and "/".

4 Tap the  **Save** button to store your changes.

## 11.3 Customize system security

The *EasyReader+*® system offers five (5) preset security levels, but a slot is provided for a fully customizable additional security level. You can configure the security settings to allow free access to all, implement full security where only pre-registered operators are allowed password-protected and audit-trail–enable access to the analyzer and the database, or any level of security in between.



**Figure 43:** The **Operators>Security** screen. Use the arrow buttons to cycle through the preset system security levels and tap your preferred level.

**i** Regardless of the active security level, system security settings are available only to operators with Supervisor– or higher category operator accounts.

**i** Easy mode has the same security level as Open system.

### 11.3.1 System security levels

The following table summarizes the preset security levels that you can select on the **>Operators>Security** screen.

	0. Easy Mode	1 Open system	2 Anonymous usage	3 Self-add	4 Self-add with password	5 Secure
Autologin operator account	Enabled with Admin category	Enabled with Admin category	Enabled with User category	Disabled	Disabled	Disabled
option to add new accounts	Disabled	Disabled	Enabled. New accounts have User category	Enabled. New accounts have User category	Enabled. New accounts have User category	Disabled
Login without password access option	Available	Available	Available	Available	Not available	Not available
Login restrictions	None (autologin)	None (autologin)	None (autologin)	User name required Password not required	User name and password required	Only pre-registered operator accounts
audit trail	Disabled	Disabled	Disabled	Disabled	Enabled	Enabled

## 11.3.2 Set up a custom security level

 It is not recommended to allow more than one (1) Supervisor-category operator account (used by the laboratory or department head, usually) on your system.

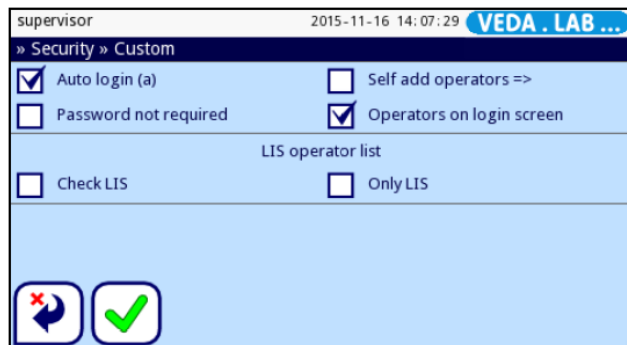



Figure 44: The Security>>Custom screen


1 Access the **Settings>Operators>Security** screen: go to the **Main** screen, then tap the **Settings** button, on the **Settings** screen, tap the **Operators** button (labelled 12 in [Figure 42](#)), then on the appearing **Operators** screen tap .

2 Use the arrow buttons on the **>Security** screen to find the **Custom** security slot, and tap the slot to select it.


3 Tap the **Customize** button and configure the security level settings by selecting one or more of the following checkboxes on the **>Security>Custom** screen:

- **autologin**: select to enable the preprogrammed autologin operator account.


 When you select this option, the system prompts you to specify the operator category of the autologin operator account.

 Keep in mind that if you enable the autologin operator account and grant it a category of Administrator or higher, you override every other security setting, and effectively create an Open system security regime.


- **self add operators**: select to enable operators to add new operator accounts.



 When you select this option, the system prompts you to specify the operator category of newly-created accounts.

- **password not required**: select to make the access option of disabling passwords available for newly-created operator accounts.

 If you leave this checkbox unchecked, the **Password not required** checkbox is not displayed on the **Settings>Operators>Rights** screen.

- **operators on login screen**: select to make the access option of including operator accounts on the login screen available for operator accounts.

 If you leave this checkbox unchecked, the **Display on login screen** checkbox is not displayed on the **Settings>Operators>Rights** screen.

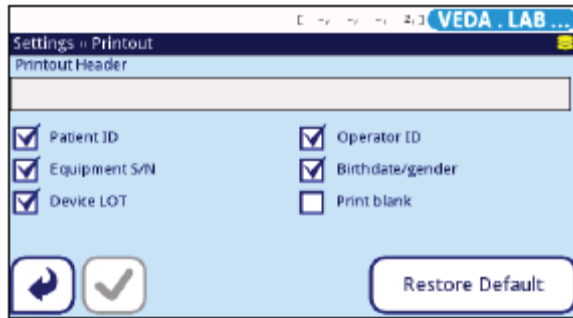
- 4 Tap the  **Save** button to save your changes, or the  **Back&Drop** button to cancel them.



## 11.4 Set up results printout

When you print out measurement records, you can decide if you would like to review all the available patient data for a given measurement record, or if you would only like to see the most important details. *EasyReader+*® gives you full control of what is included on the printout.

- 1 Go the **Settings** screen,
- 2 On the **Settings** screen, tap the **Printout** button (labelled 7 in *Figure 42*).  
On the **Printout** screen, select the checkboxes of the data categories that you would like to include on measurement records printouts.



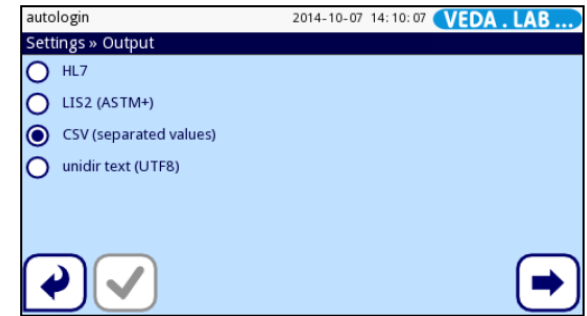
**Figure 45 :** The **Printout** screen. Select the checkboxes of the data categories that you would like to include on measurement record printouts.

**i** Select the **Print blank** checkbox to include a line for each of the selected data categories on the printout even if no data is supplied for the category.

- 3 Tap the  **Save** button to store your changes.

## 11.5 Configure results transfer

You can transfer any *EasyReader+*® measurement record to other systems or storage devices using the serial or Ethernet interface, or the USB connection. You can finetune data transfer configuration to best suit the host device, including the baud rate and, in case of unidirectional data export, all the details of the measurement records file you would like to create.



**Figure 46:** The **Settings>Output** screen

The system support two protocols to transfer data trough interface:

**1** bidirectional (two-way) protocols:

- LIS2-A2 standard protocol,
- HL7 protocol

**2** unidirectional protocol, when the data are sent out as a one-way data flow, either formatted:


- as comma-separated values (CSV),
- or as UTF8 text.

The **Output type** text box (available after you select any output protocols excluding HL7) is used to define the communication port. Available options are based on the output protocol.

	Serial (RS232)	TCP/IP Ethernet	File	USB B
Bidir:LIS2 (ASTM+)	⊕	⊕	/	⊕
Bidir: HL7	/	⊕	/	/
Unidir: CSV	⊕	/	⊕	⊕
Unidir: UTF8 text	⊕	/	⊕	⊕

For the serial port the selectable baud rates are 2400, 4800, 9600, 19200, 38400, 57600, and 115200 bits per second. The value defines the speed of the serial communication. The serial interface specification is 1 (one) stop-bit, no parity.

If you select the **Output: file** option, the transferred data will be saved directly into a file on the root folder of a **USB flash** drive connected via a Type A USB port. The default file name is `udir2(%Y%m%d-%H%M%S)`. (The placeholder string in parentheses indicates the time of measurement where %Y stands for the year, %m for the month, %d for the day, %H for the hour, %M for the minute, and %S for the second.) The file extension is either .csv or .txt, depending on the output protocol you selected.

**i** The default measurement transfer option is CSV unidirectional text, with the specific default options listed in [11.5.3.Set up comma-separated values-based transfer \(CSV\)](#). If you modify the default settings, the  **Save** button becomes active, indicating that you need to save the modification to activate it.

**!** When you transfer or export measurement records, all data associated with the selected records will be transferred, regardless of the data categories that you set up for the printout (Cf. [11.4.Set up results printout](#)).

**i** Once you transfer a measurement record, you will not be able to modify any of its details in the *EasyReader+*® database.

**i** Make sure that you configure the communication ports properly, otherwise data transfer will not work.

## 11.5.1 Set up bidirectional transfer (LIS2)

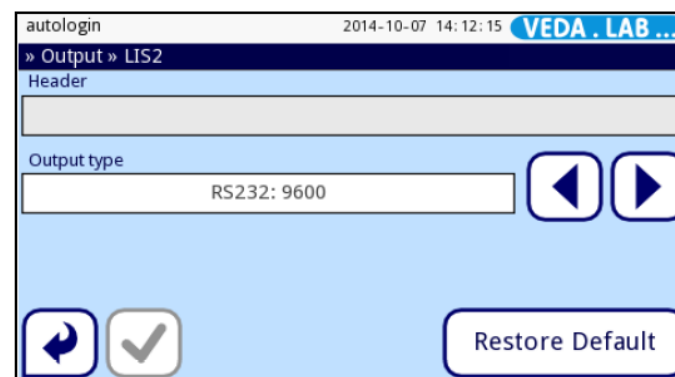




Figure 47 : The Transfer>LIS2 screen

You can set up a two-way data transmission between the analyzer and any system that conforms to the NCCLS LIS2-A2 information transfer standard.

- 1 Go the **Settings** screen,
- 2 On the **Settings** screen, tap the **Output** button (labelled 8 in [Figure 42](#)), and select the **LIS2** radio button. Tap the **Next** button to configure the selected transfer.
- 3 On the **Output > LIS2** screen, tap inside the **Header** text box for an input screen (Cf. [Figure 46](#)), and enter the text that you would like to be the header for the transferred data.
- 4 Use the arrow keys next to the **Output type** box to determine the type of data transfer you would like to have, by scrolling through the following options:
  - transfer through the RS-232 serial port (available baud rate options: 1200, 2400, 4800, 9600, 19200, 38400, 57600, and 115200);
  - transfer through the Type B USB port;
  - transfer using an Ethernet connection (TCP/IP)

**!** If you would like to use an Ethernet connection for data transfer, in the **Server** text box, you need to specify the IP address and the port of the server you would like to connect through.

5 Tap the  **Save** button to store your settings and move back to the **Settings** screen.

 Tap the **Default** button to revert to the following settings: conventional units transferred through the RS-232 port at a baud rate of 9600.

## 11.5.2 Set up bidirectional transfer (HL7)

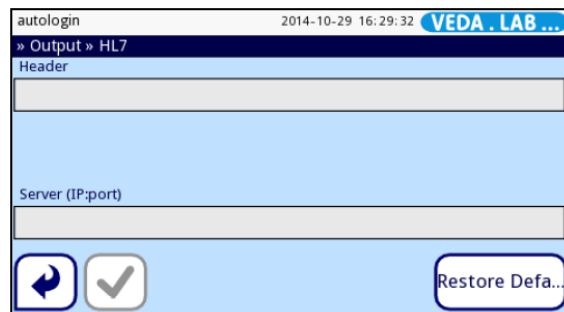



Figure 48 : The Output >HL7 screen

HL7 stands for Health Level Seven; it is a collective of healthcare informatics standards that allow exchange, integration, sharing, and retrieval of the measurement data over the *EasyReader+* analyzer and a suitable network.

On this screen, you can set up a custom header and the preferred units for the output, and enter the IP and the port of the server that you are using.

 Support for the HL7 protocol is in its introductory phase. Contact the manufacturer for the details of the specific HL7 standards that the analyzer supports.

## 11.5.3 Set up comma-separated values–based transfer (CSV)

Comma-separated output is a one-directional transfer that transfers the measurement records as plain text. The data categories within records are separated by a separator character that you select, and the records themselves are separated by line breaks in the transferred output. You have the option to export the plain text output as a .csv file.

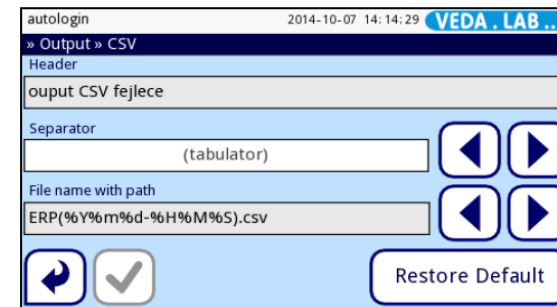




Figure 49 : The Output >CSV screen

 CSV transfer is not supported through the Ethernet connection.

- 1 To access the **Settings** screen,
- 2 On the **Settings** screen, tap the **Output** button (labelled 8 in *Figure 42*), and select the **CSV** radio button. Tap the **Next** button to configure the selected transfer.
- 3 On the **Output>CSV** screen, tap inside the **Header** text box for an input screen (Cf. *Figure 49*), and enter the text that you would like to be the header for the transferred data.
- 4 Use the arrow buttons next to the **Separator** box to scroll through the following separators: a tab character, a semicolon, or a comma.
- 5 Use the arrow keys next to the **Output type** box to determine the type of data transfer you would like to have, by scrolling through the following options:

- transfer through the RS-232 serial port (available baud rate options: 1200, 2400, 4800, 9600, 19200, 38400, 57600, and 115200);
- transfer through the Type B USB port;
- export to a .csv file.

**i** If you would like to export the data as a .txt file, you have the option of specifying the file name. Tap inside the **File name with path** text box to display an input screen (Cf. [Figure 49](#)), and enter your preferred file name. If you do not specify a file name, the system generates a file name using the date and time of the creation of the file.


6 Tap the  **Save** button to store your settings and move back to the **Settings** screen.

**i** Tap the **Default** button to revert to the following settings: tabulator-separated values in conventional units transferred through the RS-232 port at a baud rate of 9600.

## 11.5.4 Set up unidirectional text-based transfer (UTF-8)

Unidirectional text output is a one-directional data transfer that transfers the measurement records as plain text using Unicode characters with UTF-8 encoding. Unidirectional text output is similar in format to a printout. To ensure that the potential errors that can appear in the text strings during transfer can be easily detected, you can configure the transfer so that the system adds a start text character (STX) at the beginning, and an end text character (ETX) at the end of a transferred string, as well as a two-digit checksum, so that the transferred data can be verified. You also have the option to export the plain text output as a file..txt.

**i** Unidirectional text transfer is not supported through the Ethernet connection.

- 1 Go to the **Settings** screen,
- 2 On the **Settings** screen, tap the **Output** button (labelled 8 in [Figure 42](#)), and select the **UTF8** radio button. Tap the  button to configure the selected transfer.

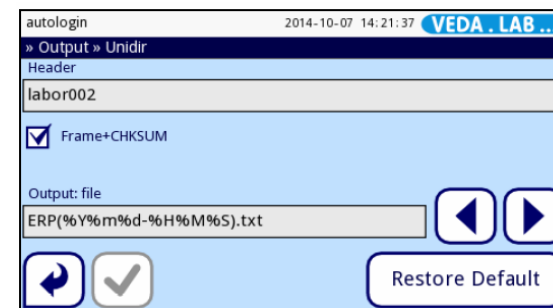


Figure 50 : The Output>UTF8 screen

3 On the **Output>UTF8** screen (Cf. [Figure 50](#)), tap inside the **Header** text box for an input screen, and enter the text that you would like to be the header for the transferred data.

4 Select the **Frame+CHKSUM** checkbox to enable adding the start text and end text characters and the two-digit verification checksum to the transferred records.

5 Use the arrow keys next to the **Output type** box to determine the type of data transfer you would like to have, by scrolling through the following options:

- transfer through the RS-232 serial port (available baud rate options: 1200, 2400, 4800, 9600, 19200, 38400, 57600, and 115200);
- transfer through the Type B USB port;
- export to a .txt file.

**i** If you would like to export the data as a .txt file, you have the option of specifying the file name. Tap inside the **File name with path** text box to display an input screen, and enter your preferred file name. If you do not specify a file name, the system generates a file name using the date and time of the creation of the file.

6 Tap the  **Save** button to store your settings and move back to the **Settings** screen.

**i** Tap the **Default** button to revert to the following settings: a text string in conventional and arbitrary units transferred through the RS-232 port at a baud rate of 9600.

## 11.6 QC settings

The detailed description of QC settings is in [9 Quality Control](#).

## 11.7 Configure the Ethernet connection

Before you can connect the *EasyReader+*<sup>®</sup> analyzer to an external host via TCP/IP, you need to set up the Ethernet connection on the analyzer to match the settings of your host.

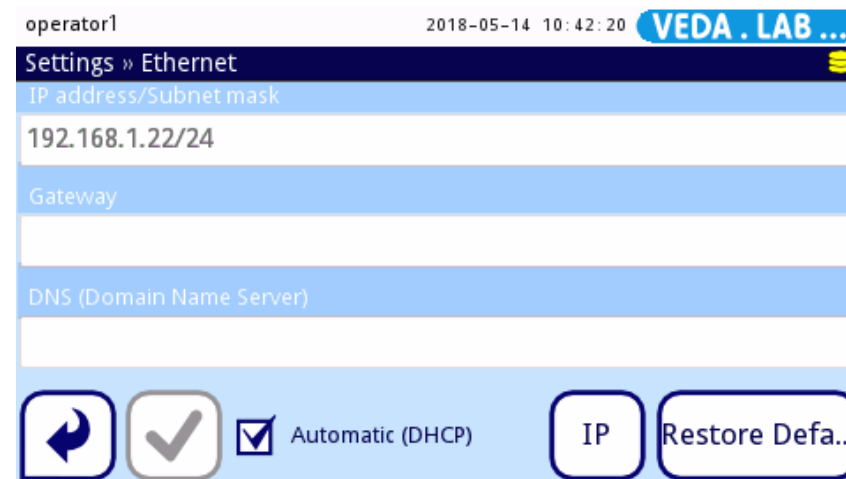


Figure 51: The **Settings>Ethernet** screen. See section [11.7](#) for details

**!** Consult the IT system administrator for the valid Ethernet settings on your network.

- 1 Go to the **Settings** screen, .
- 2 On the **Settings** screen, tap the **Ethernet** button (labelled 11 in [Figure 42](#)) to access the Ethernet settings (Cf. [Figure 51](#)).

**i** If you would like to manually set up the connection, skip step 3 below and go directly to step 4.

- 3 If you would like to configure your Ethernet connection automatically, select the **Automatic (DHCP)** checkbox.

**!** Automatic network configuration is only available if your network has a properly configured DHCP server.

- 4 Tap inside the **IP address**, **Mask**, **Gateway**, and **DNS** text boxes, and enter the appropriate values using the input screen that displays.

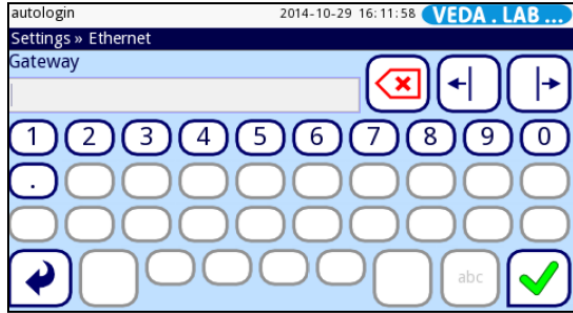





Figure 52: The Gateway input screen

5 Tap the  **Save** button to store your settings and move back to the **Settings** screen.

 **To connect the analyzer to any peripherals use only undamaged properly functioning cables and plugs.**

## 11.8 Manage operator accounts

 By default, the level of system security is set to “Open system” (Cf. [11.3.1.System security levels](#)), which means that all operators use the same non–password-protected Administrator type **autologin** operator account.

### 11.8.1 Operator accounts overview

*EasyReader+*<sup>®</sup> operator accounts offers system administrators control over system security, traceability of operator activity, and can significantly speed up the workflow of the operators of the analyzer.

Operator Category	Roles and Permissions
Disabled	Operators cannot log in or perform any tasks using a disabled operator account.
User	This is the default operator account operator category. Operators with user-category operator accounts can perform the following routine tasks: <ul style="list-style-type: none"> <li>• testing</li> <li>• quality control</li> <li>• printing and exporting measurement records</li> <li>• modifying user preferences.</li> </ul>
Admin	Operators with Admin-category operator accounts can perform all the tasks that a User-level operator can, plus the following: <ul style="list-style-type: none"> <li>• editing settings</li> <li>• editing operator accounts</li> <li>• installing software updates.</li> </ul>
Supervisor	Operators with supervisor-category operator accounts can perform all administrator-rights tasks, and can also modify system security settings.
Service	Operators with service-category operator accounts can perform all of the above actions, and have access to the <b>Service</b> screen.

Operators of the analyzer need an operator account, and they need to log in with this operator account on the system, before they can start using the analyzer. Operators with administrator– and higher type operator accounts can create operator accounts for new operators by entering a user name and a password. The new operator, depending on the active system security level, (Cf. [11.3.1.System security levels](#)) can further customize the operator account by modifying the access options (Cf. [11.8.5.Edit operator account access option settings](#)) and user preferences (Cf. [10.1.User options](#)). The database stores the user name, password, access option information, and the user preference settings associated with each operator account.

The following table summarizes the types of operator accounts available on the *EasyReader+*® system, in order of ascending user rights.

**i** Operator account and system security management are topics that concern system supervisors and service personnel only. Basic operators do not have access to these settings.

**i** Operators with User-level operator accounts can modify the user preferences settings, but do not have access to the system settings.

## 11.8.2 Add an operator account





Figure 53 : The **Settings>Operators** screen with the function buttons indicated.

Operators with Administrator– or higher category operator accounts can create new operator accounts of a category below their own.

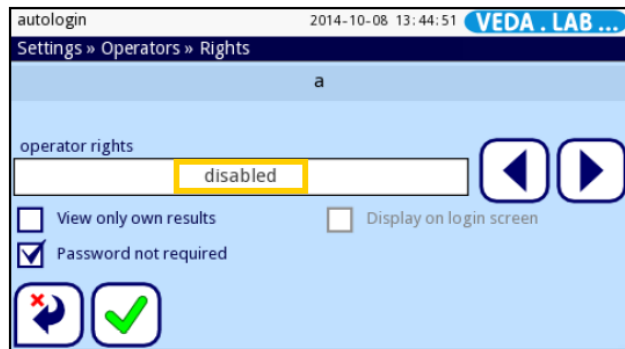
**1** Tap the **Add** button on the **Settings>Operators** screen (labelled 4 in [Figure 53](#)), and on the input screen that displays, enter the preferred user name for the new operator account that you are creating.

**2** Tap the **Next** button on the input screen to access the **Settings>Operators>Rights** screen (Cf. [Figure 54](#)), and tap the options in the **Operator rights** column to select the category of your new operator account.

**3** Select the checkboxes on the right to customize account access options for the new operator account (Cf. [11.8.5.Edit operator account access option settings](#)). Tap the **Edit device list** button to set what assay devices the new operator account will have access to.

**4** Tap the  **Save** button to save the new operator or the  **Back&Drop** button to revert to the operator account defaults.

### 11.8.3 Delete or disable an operator account





**Figure 54 :** The **Settings>Operators>Rights** screen. You can find available operator account categories on the left, and operator account access options on the right side of the screen.

- 1 Go the **Settings** screen,
- 2 On the **Settings** screen, tap the **Operators** button (labelled 12 in [Figure 42](#)). On the **Operators** screen, select the operator account you would like to delete or disable, then do one of the following:
  - To delete the selected operator account, tap the **Delete** button (labelled 2 in [Figure 53](#));

- i** A confirmation dialog displays when you tap the **Delete** button.
- To disable the selected operator account, tap the **Edit** button (labelled 3 in [Figure 53](#)), and then select the **Disabled** operator category on the **Settings>Operators>Rights** screen (indicated by an orange rectangle in [Figure 54](#)).

### 11.8.4 Reset or change an operator account password

If an operator forgets the password to his or her operator account, or if he or she would like to speed up the login process and disable the associated password completely, the first necessary step is to clear the password that is associated with the account.

- 1 Go to the **Main Menu**,
- 2 On the **Main Menu**, tap the **User Options** button ([Figure 40](#)). On the **User Options** screen, tap **Change password** button.
- 3 On the **Change password** screen type in the old password and tap **Go forward and Save** button  then type in and save the new password on the following screen. To cancel the password reset, tap the  **Abandon changes** button.




**!** Unless the system does not require a password when a user logs into the operator account (Cf. [11.8.5](#)), the system will prompt the operator to enter a new password the next time that he or she attempts to log in to the account.

**i** If you reset the password so that the operator can enter a new password, no further action is necessary. If you reset the password because you would like to disable passwords completely for the operator account, Cf. [11.8.5](#) and enable the “login without password” access option setting for the account.



## 11.8.5 Edit operator account access option settings

The following table summarizes all the account access options available to further customize operator accounts.

Access Option	Description of Option
Account is displayed on login screen	<p>If enabled, operators who would like to log in using this account do not need to enter the user name of the account, but can simply select the user name from a list.</p> <p> <b>This option can speed up the login process for operators using this operator account, but can compromise system security, especially if one or more of the operator accounts listed on the login screen have disabled passwords.</b></p> <p> <i>The system can display up to six (6) user names on the login screen.</i></p>
Login without password is allowed	<p>If enabled, the system does not prompt operators who are logging in using this account to enter a password.</p> <p> <b>This option is only functional for newly-created operator accounts. If you would like to disable the password of an existing operator account, reset the password of the account first (Cf. 11.8.4), and then enable this access option.</b></p>
View only own results	<p>If enabled, the operators can see only the records made under their accounts.</p>

## 11.9 Database management

### 11.9.1 Configure Database preferences

You can determine whether items in the analyzer database are automatically overwritten when the memory runs out, and whether and when the system will warn the operator that free disk space in the database is running out.

- 1 Go to the **Settings** screen,
- 2 On the **Settings** screen, tap the **Database Management** button (labeled 10 in [Figure 42](#)).
- 3 Select the **Circular memory** checkbox if you would like to overwrite old records in the database with new ones when the database is full, on a first in–first out basis. If you select the checkbox and the prewarning is OFF, the **Warning at circular memory limit** checkbox becomes active, and you can decide whether you would like the system to prompt you when memory in the database is running out.

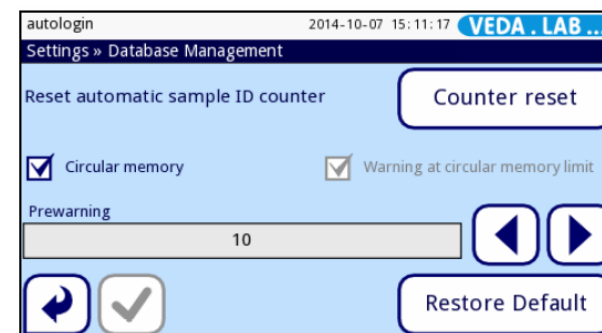



Figure 55 : The Settings>Database screen.

 *The **Circular memory** is disabled by default.*

Tap the - or + buttons next to the **Prewarning limit** text box, or tap inside the text box to display an input screen, and enter how many measurement records below the memory limit the system will warn the operator when the memory in the database is running out.

The buttons increase and decrease the limit by 10, but you can enter any positive number using the input screen if you tap inside the text box. This setting is independent of whether the Circular Buffer is enabled or not.

**i** The default prewarning limit is 30 records.

4 Tap the  **Save** button to store your settings and move back to the **Settings** screen.

### 11.9.2 Reset the sample ID counter

The *EasyReader+*® system assigns an automatically generated sequence number to each and every test specimen that you measure with the analyzer. This sequence number never starts over unless you manually reset the test specimen counter.

1 To reset the specimen ID counter, go to **Settings** screen.

2 On the **Settings** screen, tap the **Database Management** button (labeled 10 in *Figure 42*), and then the **Counter reset** button.

3 On the confirmation dialog that is displayed (“Do you really want to reset the automatic **Sample ID counter**?”), tap the **Yes, Apply** button to reset the counter, or the **No** button to cancel the operation.

### 11.10 Manage power settings

You can choose to conserve energy, extend battery life, or increase operator account security by controlling how long the LCD is active, the current operator stays logged in, and the power stays on when the system does not detect a touch event on the display.

**i** You can modify the power settings in increments of 5 minutes at the LCD off time, 10 minutes at the logout time and 20 minutes at the Power off time by the left-right buttons. If you decrease any of the settings below these threshold values, they become disabled. This means that no matter how long the display is inactive, the system never takes the particular action.

1 Go the **Settings** screen.

2 On the **Settings** screen tap the **Power Management** button (labelled 3 in *Figure 42*),



**Figure 56** : The **Power Settings** screen with the function buttons labelled.

3 Use the forward-back buttons (labelled 4 in *Figure 56*) or tap into the textboxes and type in manually in the appearing textboxes to set the number of minutes that will pass without operator activity before the LCD display switches off (labelled 1 in *Figure 56*), the current operator is logged out (labelled 2 in *Figure 56*), or the system shuts down (labelled 3 in *Figure 56*). You can set the three power settings separately.

**i** You can revert to the default power scheme at any time by tapping the **Restore Default** (labelled 5 in [Figure 56](#)) button. The defaults for power supply operation are summarized in the following table.

	Power supply default power scheme	Battery-operation default power scheme
Power off time	60 minutes	60 minutes
LCD off time	5 minutes	5 minutes
Log out time	10 minutes	10 minutes

## 11.11 Manage settings

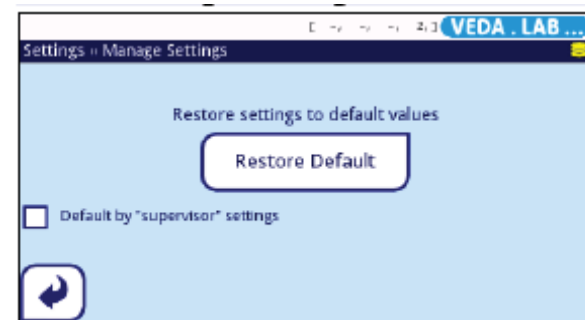


Figure 57: The **Settings > Manage Settings** screen

### 11.11.1 Restore default settings

You can bring back factory settings (see [14.1](#)) by tapping **Restore Default** button and confirm the changes on the next screen by tapping **Yes, Apply** button. This will change every single settings. If you would like to change back specific settings only, go to the screen applied to them within **Settings** menu and press **Restore Default** on that screen.

### 11.11.2 Default by "supervisor" settings

You can customize default settings to the needs of your laboratory and save it as default by "supervisor".

To be able determine and save these settings you have to log in using the predefined account named "supervisor".

After login, make the changes in all settings you need, go to **Manage Settings** screen and save them by checking the **Default by "supervisor" settings** checkbox. As long as this checkbox is checked every action to restore default settings leads to "supervisor" settings.

**i** You cannot set supervisor settings with a normal supervisor level operator account, it only can be done with the predefined supervisor account.

## 12 Easy Mode

The Easy Mode menu is inherited from the predecessor of *EasyReader+*<sup>®</sup>.

It is imitating the pressing buttons of the previous model on the touchscreen and the working principle is the same. After every logging in the user arrives to this menu but can decide to choose the Plus Mode, which will be described later throughout the user manual. The idea behind the two kinds of menu is that the ones who know the previous model are more familiar with this 'three button' operation.

To set up Easy mode you have to tap through to **Operators»Security** screen.

Use the arrow buttons to cycle through the preset system security levels and select **0.Easy mode**.

### 12.1 The Easy Mode menu detailed description

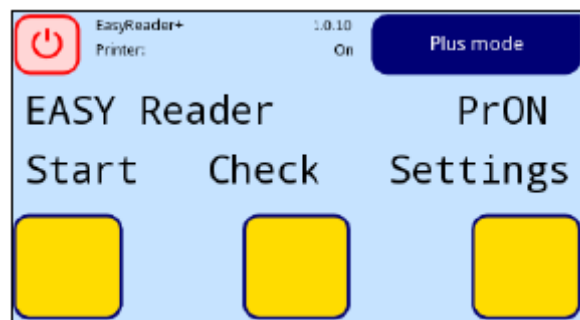


Figure 58 : The Easy mode menu

The user can choose from the sub-menus by tapping one of the three buttons on the display. The current function of the buttons is indicated on the top of them. Right above there are the user information and the present state of the analyzer. To leave the current sub-menu and return to the Main Menu, press the **Quit** button.

To return to the previous screen/menu press **Back** button

#### 12.1.1 The START menu

Tapping **Start** a routine measurement can be carried out under this menu. The screen displays the type of assay device is actually set..

**OK**

Accepting the type of assay device.

**<<<**

Go to previous type of assay device.

**>>>**

Go to next type of assay device

**BLANK STRIP**

Blank assay device has to be loaded into the rapid test holder and inserted into the analyzer.

**Back**

Cancel blank measurement and go back to previous screen.

**PLEASE WAIT...**

The analyzer is checking the positioning of the assay device. If correct next menu appears.

**Back**

Goes back to previous screen.

**BLANK IN PROGRESS**

As soon as the *EasyReader+*<sup>®</sup> recognises the blank device, starts to calibrate automatically.

**Back**

Goes back to previous screen

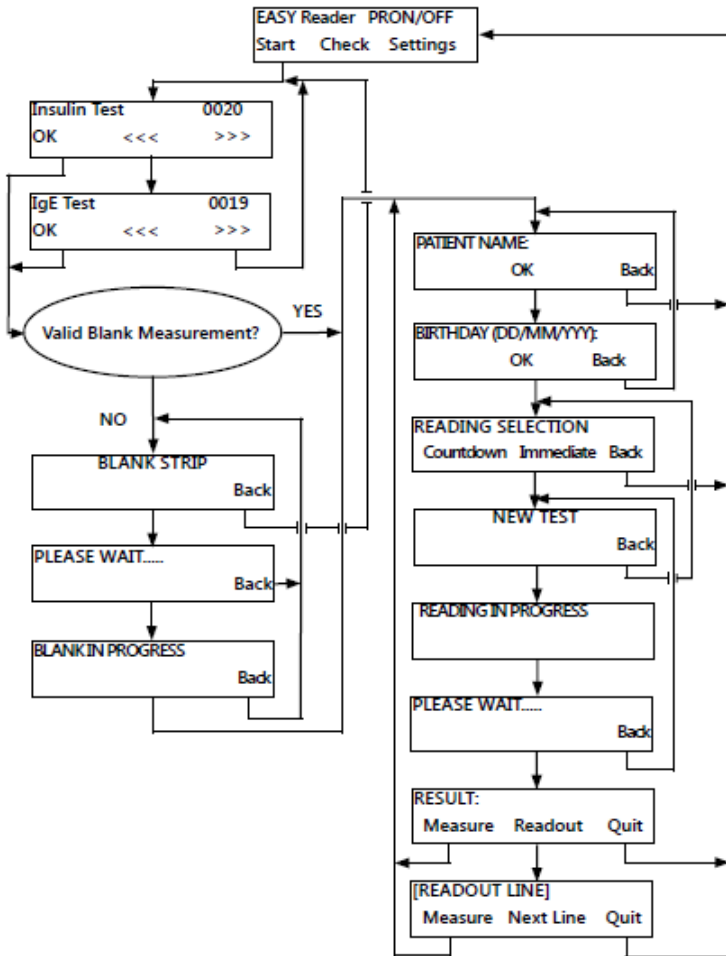
**PATIENT NAME**

Type in the patient name/sample ID. You can leave it blank

**OK**

**Back**

Goes back to Welcome screen.



**BIRTHDAY (DD/MM/YYYY):**

Type in the patients birthday accordingly. You can leave it blank.

**OK**

**Back**

Goes back to Welcome screen.

**READING SELECTION**

**Countdown**

The analyzer starts to count down incubation time.

**Immediate**

The analyzer starts evaluation immediately.

**Back**

Goes back to previous screen.

**NEW TEST**

Place the next assay device with specimen into the analyzer. Make sure it is positioned right. *EasyReader+*<sup>®</sup> recognises and starts measurement automatically. Next menu appears.

**Back**

Stops waiting for an assay device and goes back to START menu.

**PLEASE WAIT...**

The analyzer is checking the positioning of the assay device. If correct next menu appears.

**Back**

Cancel measurement and goes back to previous screen.

**READING IN PROGRESS**

As soon as the *EasyReader+*<sup>®</sup> recognises starts to measure automatically. Evaluating assay device based on pre-defined features of the assay device type. Wait until the next screen appears.

**RESULT:**

The result is displayed.

## Measure

Carry out a new measurement again.

## Readout

The report can be displayed line by line.

## Quit

Return to Main Menu

## [READOUT LINE]

Displaying the lines of the report printout in the upper row of the display.

Carry out a new measurement again.

## Next Line

Display the next line of the printout report. At each button press the next line is displayed. After the last line the first one is displayed again.

## Quit

Return to Main Menu.

## 12.1.2 The CHECK menu

The check measurement can be done in this menu.

### BLANK STRIP

Blank assay device has to be loaded into the rapid test holder and inserted into the analyzer. Make sure its placed in correctly.

*EasyReader+*<sup>®</sup> recognises and starts to measure automatically. Next step appears..

### Back

Stops waiting for an assay device and goes back to previous menu.

### PLEASE WAIT...

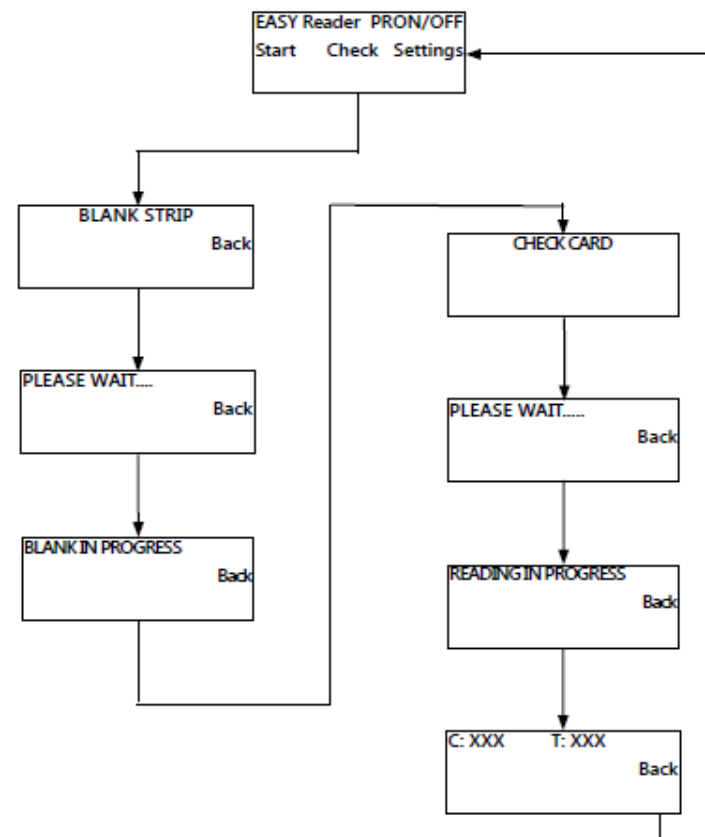
The analyzer is checking the positioning of the assay device. If correct next menu appears.

### Back

Cancel measurement and goes back to previous screen.

### BLANK IN PROGRESS

As soon as the *EasyReader+*<sup>®</sup> recognises starts to calibrate automatically.



## CALIBRATION DEVICE

Insert calibration device for measurement. Make sure its positioned right. *EasyReader+*® recognises and starts to measure automatically. Next menu appears.

### Back

Goes back to previous screen.

## PLEASE WAIT...

The analyzer is checking the positioning at the assay device. If correct next menu appears.

### Back

Cancel measurement and goes back to previous screen.

## READING IN PROGRESS

As soon as the *EasyReader+*® recognises starts to measuring and evaluating check assay device based on pre-defined features of the check assay device. Wait until the next screen appears.

## C: XXX T1: XXX T2: XXX

Check line values.

### Quit

Back to Main menu.

## 12.1.3 The SETTINGS menu

Setups and settings of the analyzer and reading memory recall/transfer can be done under this menu.

### SETTINGS

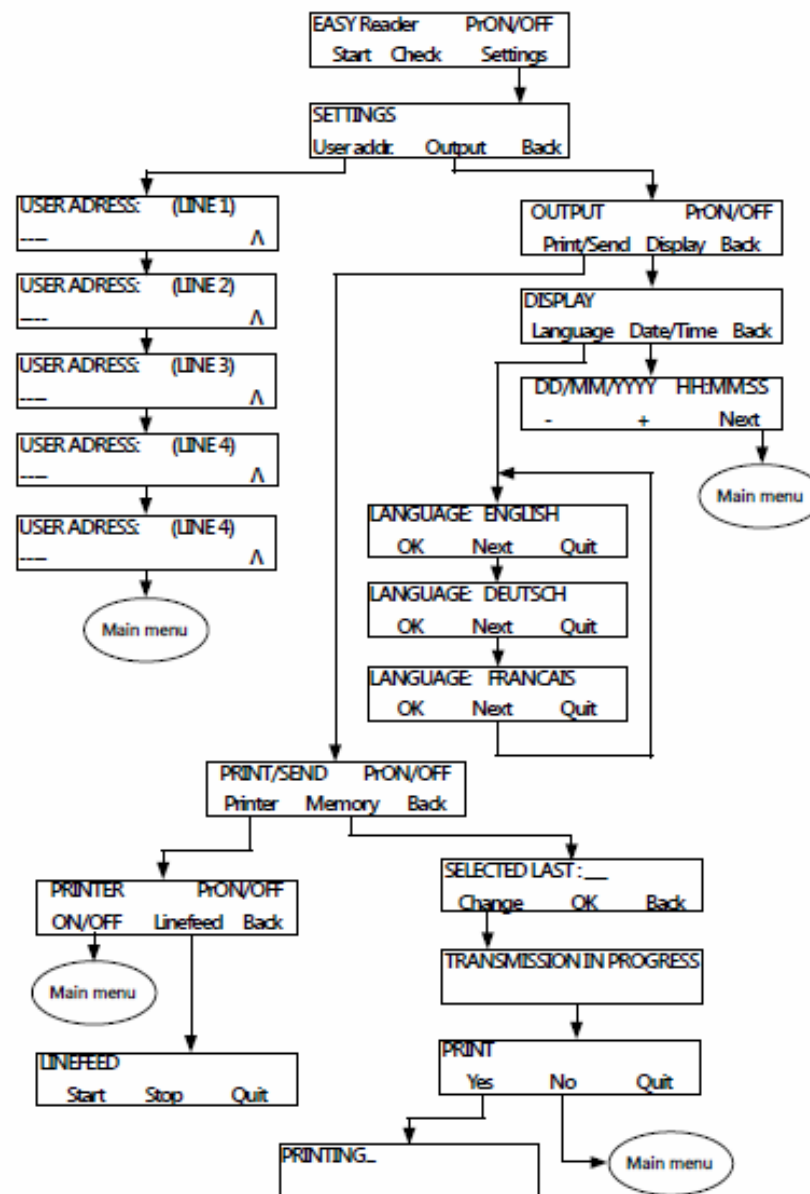
#### User Adr.

The user adress can be typed in in 5 lines. It could be information about the place of measurement, the patient or any other information about the measurement.

#### Output

Output settings

### Back



### **USER ADRESS: (LINE X)**

Type in the X line of user adress. Use external keyboard or text input screen by tapping the keyboard icon in the top right corner of the screen. 23 characters can be typed in one line.

Press 'enter' to insert the line. The information stays after shutdown.

^

Back to **SETTINGS**

### **OUTPUT**

Output features of the reader can be set under this sub-menu.

#### **Print/Send**

Printer settings and memory access for printing out and sending to a host PC.

#### **Display**

Display (date/time and language) settings.

#### **Back**

Return to the previous screen.

### **PRINT/SEND**

Printer settings and memory access to printouts and sending to a host PC.

#### **Printer**

The online printing (reports are printed out immediately after the measurement) can be switched on or off.

#### **Memory**

Memory access for printing or sending.

#### **Back**

Return to the previous screen.

### **PRINTER PrON / PrOFF**

The indicator is displayed according to the current setting on the upper right corner of the display.

#### **OFF/ON**

Alter the printer setting and return to the Main Menu.

#### **Linefeed**

Access of the Linefeed control

#### **Back**

Return to the previous screen.

### **LINEFEED**

Paper forwarding control.

#### **Start**

Start the paper forwarding.

#### **Stop**

Stop the paper forwarding.

#### **Quit**

Return to Main Menu.

### **SELECTED LAST = xx**

Select the number of reports to be printed out and sent to the PC.

Type the number in using the keyboard. The details of sending to PC can be found in the chapter PC CONNECTION. Press <ENTER> on the keyboard or press OK button to enter the number. The displayed number after entering this menu can be accepted by pressing <ENTER> or OK.

#### **OK**

Enter the number of the reports to be printed out and sent.

#### **Back**

Return to the previous screen.

### **PRINT**

It can be chosen whether the reports should be printed and sent out, or only should be sent out.

#### **Yes**

Print out the reports, and send to PC.

#### **No**

Do not print out the reports, only send to PC.

#### **Quit**

Return to Main Menu.



## PRINTING

Printing is in progress.

### Quit

Cancel printing and return to Main Menu.

## DISPLAY

Display (date/time and language) settings.

### Language

Language selection.

### Date/Time

Date and time setting.

### Back

Return to the previous screen.

### DD/MM/YYYY HH:MM:SS

The currently set date and time are displayed. All fields can be set, from year to seconds.

+

Increase the current field.

-

Decrease the current field.

### Next

Step to the following field.

### LANGUAGE: X

The language of the display and the report printouts can be selected.

### OK

Select the currently displayed language.

### Next

Skip to the next language.

### Quit

Return to Main Menu without changing the current language setting.

## 12.1.4 Error messages

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The Easy mode menu has the following error messages:

### E06: SAMPLE INVALID

It means the measurement can't be evaluated, for example there was no Test or Control line or the assay device was dirty. Repeat the measurement with a new assay device.

### E20: WRONG DATE

Invalid date typed in. Check the date and type in again.

### E28: BLANK/OPTIC FAULT


Measurement of blank device failed. The blank device can be scratched or discoloured or the optic system got dirty. Check the blank device and/or replace it with a new one, if error still exist, call service to check the optic system.

### E30: WRONG FORMAT

The typed in date has less, than 8 character. Type it in again.


# 13 Cleaning and maintenance

## 13.1 Cleaning and disinfection

 While cleaning the analyzer never tilt or turn it upside down, wash it with large amount of liquid or spray on it directly with disinfectant.

### 13.1.1 Cleaning the touchscreen display

1 Switch off the *EasyReader+*<sup>®</sup> analyzer.


 Do not use paper towels or tissue paper to wipe the touchscreen, because these can cause scratches on the surface of the display.


 Do not use chemicals to clean the touchscreen.


2 Dampen a corner of a microfiber cloth, and wipe across the whole display until you clean the entire display surface. Wipe over stubborn stains repeatedly, but do not use pressure, because this can damage the touchscreen.

3 Use the dry parts of the microfiber cloth to dry the water on the display surface before you switch on the analyzer.

### 13.1.2 Cleaning the analyzer

 Always switch off the analyzer and unplug the AC adapter before you clean the analyzer.

 Make sure that no liquid enters the analyzer. Do not immerse in water even when it is switched off.

 Do not use any type of solvent, oil, grease, silicone spray, or lubricant to clean the analyzer.

 Make sure that no liquid enters the printer compartment.

1 Switch off the analyzer and remove the rapid test holder. Pull the carrier handle up to access the surface underneath it.

2 Use a lint-free cloth that you dampened with a solution of 70% (V/V) isopropyl alcohol to wipe the surface of the analyzer clean. Keep clear of the electronic parts and sockets at the back of the device, but make sure that you go over the entire surface of the analyzer.

 Do not switch the device on before it is completely dry.

3 Dry the analyzer with the dry parts of the lint-free cloth.


### 13.1.3 Cleaning the rapid test holder

Keep the *EasyReader+*<sup>®</sup> analyzer's rapid test holder clean and free of obstructions.

Complete the following steps to clean the device dock at least once a day:

1 Switch off the analyzer and remove the device dock.

2 Rinse the bowl of the dock in running water. Wipe the tray with a lint-free cloth that you dampened with a 70% (V/V) isopropyl alcohol solution.

 Make sure that the rapid test holder is completely dry before you reinsert it into the analyzer.

3 Dry the rapid test holder with the dry parts of the disposable towel, and reinsert it into the analyzer.

### 13.1.4 Cleaning the printer roller

The printer roller can pick up grease and dirt that can cause non-printing white spots or streaks on the printout. It is recommended that you clean the printer roller at least every six months of operation.

1 Switch off the analyzer and open the printer compartment (Cf. *Figure 7*) to expose the printer roller.

 Do not attempt to remove the printer roller from its hinges.

2 Hold a lint-free cloth that you dampened with distilled water to the surface of the roller, and use the roller's cogwheel on the left end to turn it. Make sure that you wipe the entire surface of the roller.

### 13.1.5 Dispose of used assay devices



The bodily fluids that came into contact with assay devices make them infectious waste (biomedical waste). Always handle them as potentially infectious.



When you dispose of a used assay device, always follow the package insert for the particular device. Most guidelines for the handling of biomedical waste recommend that you incinerate used assay devices. Before you dispose of them completely, use color-coded waste bags with the word 'BIOHAZARD', and the biohazard symbol clearly printed on them to store used assay devices.



Unused expired assay devices can be disposed as municipal waste.

## 13.2 Preventive maintenance

The *EasyReader+*® analyzer is not a high-maintenance medical device. If you keep it and its touchscreen clean, and handle it with care so that none of its internal parts are damaged, the *EasyReader+*® analyzer provides continued efficient and accurate operation. The system database and the system software, however, sometimes require special attention for full functionality.

### 13.2.1 Software update



The update process described in this section does not overwrite or delete the existing database or the active settings on the analyzer.


The manufacturer is continuously upgrading the *EasyReader+*® system software, adding new features and functions, and improving usability. From time to time, the manufacturer will notify you that a software update package is ready for you to download and install on your *EasyReader+*® analyzer.

Complete the following steps to install the latest version of the system software:




You will need a USB flash device, a PC or a Macintosh computer to connect it to, and some basic computer skills.

- 1 Create an 'update' directory (without the quotes) in the root folder of your USB flash drive.
- 2 Unzip the software update package that you received or downloaded and copy the files that it contains into the 'update' folder that you created in step 1.
- 3 Switch on the analyzer and wait until the system is ready. Plug in the USB flash drive that contains the update package into the Type A USB port of the analyzer. Wait for the USB icon to appear on the display in the status icon area of the status bar (Cf. [5.2.1.The Status bar](#)).
- 4 To access the **Settings** screen, tap the **Settings** button on the **Main** screen. On the **Settings** screen, tap the **Update** button to start the automatic software update process.

 The system detects and verifies the software update package before starting the update process. If it cannot detect a USB flash drive or an update package, the **Update** button changes to **Refresh**. Tap the refresh button to force the system to check the peripherals again for updates.

5 Tap the **Restart** button that is displayed when the update process finishes, and remove the USB flash drive (Cf. [5.3.2.Using an USB flash drive](#)).

 **Do not remove a connected USB drive without first unmounting it, as this can cause data corruption on the drive.**

## 13.3 Troubleshooting

Your *EasyReader*<sup>®</sup> analyzer will operate properly if you follow the directions for using and cleaning the instrument. Advisory messages will be displayed when your attention is required on any disorder or result of a performed action.

The user interface messages can be categorized into the following groups:

- Error messages
- Warning messages
- Information messages

The active errors and warnings can be listed by tapping the status bar area on any screen or the **System Info** button on **Main Menu**.

### Error messages

If an error prevents the instrument from being used, certain selection areas on the screen will be disabled and testing procedure cannot be started. The background of the status bar changes to red. Performing the displayed corrective action will remove the error and allow you to use the instrument and enable testing.

### Warning messages

Less severe errors trigger warning messages. These kinds of errors do not prohibit testing, but may limit certain functionality (i.e. transfer, printing) of the system. The background of the status bar changes to yellow. These errors do not compromise the testing and the measurement performance of the system. The resolution of these errors may include the restart of the system. When you have taken the corrective action, the message will be removed from the system.

### Information messages

Provides a feedback about the successful execution of an action and/or provides additional information for the operator.

Based on the presentation the display type of the messages are the following:

- Status line: appears permanently in the status bar
- Timed pop-up window: a pop-up window is displayed only for a few seconds, then disappears automatically without operator interaction
- Pop-up window: a pop-up window disappears after the confirmation of the operator
- Result view: message appears on the standard content area.

## 13.4 Error messages

In case of an error, try to solve it according to the troubleshoot guide first. The lists of this section help you diagnose the problem and give you advices to sort them out. If the failure remains, please contact your service representative. The certified service personnel is allowed to perform further troubleshooting, repair serviceable parts, and configure the system according to the service manual.

### 13.4.1 Lists of error messages

Legend for the table of Error messages	
Categories (Message ID)	Type (T)
Error message (E)	Status line (S)
Warning messages (W)	Timed pop-up window (TP)
Information messages (I)	Pop-up window (P)
	Result view (R)

### 1 General error messages

Message ID	T	Status line text	Full text	Recommended action
E99	S	Image HW error	Image capture HW error. Please call Service.	Contact your service representative
E98	S	Printer HW	Printer hardware error. Please call Service.	Contact your service representative
E97	S	Calibration	Calibration data are out of acceptable range or lost. Please call Service.	Contact your service representative
E96	S	Power voltage	Power voltage value is out of range. Please call Service.	Contact your service representative
E95	S	Mechanic HW	Mechanical hardware error. Please call Service.	Contact your service representative
E94	S	Image environment error	Image capture environment error (external light high or HW error). Please put in rapid test holder, shade equipment or call Service.	Follow instructions or contact your service representative.
E90	S	Reference pad	Failure of reference pad check. Reference pad value of the tray is out of range. See User's Manual for further instructions.	The photometry reference pad is contaminated or damaged. Contact your service representative to replace the reference pad, and recalibrate the analyzer.
E89	S	QC lockout	Go to "QC measurement" to perform QC check.	Perform QC check measurements to remove the QC lockout.
E88	S	Memory limit	Database limit exceeded, please delete results to free up space.	Free up memory by erasing old data!

Message ID	T	Status line text	Full text	Recommended action
W69	S	Output port	Output port not open. Please restart the system!	Restart the analyzer.
W68	S	Output internal	Output internal error. Please restart the system!	Restart the analyzer.
W67	S	Output init	Output not initiated. Please restart the system!	Restart the analyzer.
W66	S	Output closed	Output closed. Please restart the system!	Restart the analyzer.
W65	S	Output memory	Not enough memory for output. Please restart the system!	Restart the analyzer.
W64	S	Output write	Cannot write output. Please change file name or (re)insert USB pendrive.	Use alphanumeric characters only, and ensure that the USB flash drive is connected properly and recognized by the system. If required, re-initialize the USB port by tapping the VEDALAB logo in the top right corner.
W63	S	Output aborted	Output aborted. Please start again.	Restart transfer.
W62	S	Output limit	Output reached internal limit. Please check protocol.	Check and verify output settings.

Message ID	T	Status line text	Full text	Recommended action
W61	S	Output protocol	Protocol failure. Please check connection type.	Check and verify output settings.
W60	S	Output failure	Output failure. Please wait and try again in a minute. In case of repeated failure please check connection type.	The system continuously tries to deliver the output. If it succeeds, the error will automatically disappear. If the error persists, check and verify output settings.
W59	S	Output busy	Output line busy. Please wait and try again in a minute.	The system continuously tries to deliver the output. If it succeeds, the error will automatically disappear. If the error persists, check and verify output settings.
W58	S	Output file	Output file not open. Please change file name or insert pendrive.	Change the file name / destination and ensure that the USB flash drive is connected properly and recognized by the system. If required, re-initialize the USB port by tapping the VEDALAB logo in the top right corner.
W57	S	Output link	Output link lost. Please wait a minute. In case of persistent failure please check connection and connection parameters.	The system continuously tries to deliver the output. If it succeeds, the error will automatically disappear. If the error persists, please verify the connections and the presence/status of the destination
W56	S	Output connect	Output port cannot connect to server. Please check Ethernet cable, Ethernet configuration in settings and server IP address and port number.	

Message ID	T	Status line text	Full text	Recommended action
W56	S	Output connect	Output port cannot connect to server. Please check Ethernet cable, Ethernet configuration in settings and server IP address and port number.	The system continuously tries to deliver the output. If it succeeds, the error will automatically disappear. If the error persists, please verify the connections and the presence/status of the destination
W38	S	Head version	Measure head SW version is unknown. Please call Service.	Contact your service representative.
W37	S	Temperature	Temperature out of allowed range.	Ensure the proper environmental conditions.
W35	S	Data lost (limit)	Database limit exceeded. Earlier results will be dropped.	To free up memory in the database, delete unused data. (Circular memory is active, so old data will be overwritten by new data).
W34	S	Memory near full	Database counter is reaching its limit. Please delete some results.	To free up memory in the database, delete unused data.
W33	S	QC lockout	Go to "QC measurement" to perform QC check.	Perform QC check measurements to remove the QC lockout.
W31	S	Door open	Printer door is open. Please close it!	Check if the paper roll is correctly loaded in the printer bay and close the printer door.
W30	S	Paper out	Paper out. Please replace the printer paper!	Open printer door and load a fresh paper roll in the printer.
E199	P		DB failure: cannot write result. Please call Service.	Contact your service representative.

Message ID	T	Status line text	Full text	Recommended action
E198	P		DB failure: cannot modify result. Please call Service.	Contact your service representative.
E197	P		DB failure: cannot delete result. Please call Service.	Contact your service representative.
E196	P		DB failure: configuration is corrupted. Please check the configuration settings.	Contact your service representative.
E195	P		Worklist DB failure: cannot write new item.	Contact your service representative.
E194	P		Worklist DB failure: cannot insert or modify item.	Contact your service representative.
E193	P		Worklist DB failure: cannot delete item.	Contact your service representative.
E181	P		Load config error: read details from "wpa_suppllicant.conf.err" file on PENDRIVE	The system encountered a problem in the wpa_suppllicant.con.zip file, and has saved an error report on the connected USB stick. Refer to <a href="#">the WPA Suppllicant documentation</a> to deal with the issue.
E180	P		Load config error: USB drive or wpa_suppllicant.con.zip file not exists.	Make sure that the wpa_suppllicant.con.zip file is properly saved on the connected USB flash drive.
E177	T P		Length of password must be between 8 and 63 characters.	The password that you entered is too long or too short. Enter a new password.
E175	T P		Length of LOT+expiry is more than 32 character.	Enter a LOT expiry shorter than 32 character.

Message ID	T	Status line text	Full text	Recommended action
E174	TP		Format of entered expiry is failed.\nFormat of expiry is 'YEAR/MONTH'.	Enter expiry in format: 'YEAR/MONTH'.
E173	TP		Format of entered LOT is failed.\nFormat of expiry is (YEAR/MONTH) with brackets.	Enter LOT expiry in format: '(YEAR/MONTH)' with brackets.
E172	TP		Time is expired.	Start it again.
E171	TP		Cannot export log.	Ensure the USB flash drive is connected properly and recognized by the system. If required, re-initialize the USB port by tapping the VEDALAB logo on the top right corner.
E170	TP		Sample ID already exists, please change it.	Verify and repeat the input or use another Sample ID!
E169	TP		Registration Code is already used.	Verify and repeat the input or use another RegCode.
E168	TP		Format of date is failed.	
E167	TP		Operator ID already exists, please change it.	Enter another Operator ID.
E166	TP		Password check failed, please try again.	Enter the valid password.
E165	TP		Password is too short, please try again! (minimum length is 3 characters)	Enter a new password that is at least 3 characters long.
E164	TP		Password does not match, please try again.	Re-enter the password.

Message ID	T	Status line text	Full text	Recommended action
E163	TP		Operator does not exist, please try again.	The operator name that you entered is not on the operator list. Enter another Operator ID.
E162	TP		Password check failed, please try again.	Enter the valid password.
E161	TP		Sample ID required. Please set it.	Enter a Sample ID.
E160	TP		LOT Code required. Please set it.	Enter a LOT Code.
W169	TP		Cannot open serial port for output!	Check the serial port connection.
W158	TP		Cannot open file for output!	Check the output port and that the output storage is present.
W156	TP		Cannot connect to server for output.	Check output server settings.
W140	P		Due to changes lockout time was decreased to %d day(s). (Touch to confirm.)	Tap inside the message window to confirm the new QC lockout period.
W139	TP		Paper detected.	Touch to confirm.
W138	P		Server IP address or mask format not right. (ex.: 192.168.1.12:4130)	Check and correct server IP address or mask input.
W137	P		IP address or subnet mask format is not correct. (i.e. 192.168.1.5/24 or 192.168.5/255.255.255.0)	Check and correct the analyzer's IP address or mask input.



Message ID	T	Status line text	Full text	Recommended action
W136	P		IP address format is not correct. (i.e. 192.168.1.12)	Check and correct the analyzer's IP address.
W135	TP		Cannot export log, because USB drive does not exist. Please insert it.	Make sure that the USB flash drive is connected properly and recognized by the system. If required, re-initialize the USB port by tapping the Vedalab logo in the top right corner.
W134	P		Worklist DB failure: possible data loss! Trying to repair. May take some minutes, please wait.	Database failure. The system is trying to repair itself. This may take a few minutes.
W134	P		Worklist DB failure: possible data loss!	Possible data loss, check worklist. If problem occurs multiple times, contact your service representative.
W133	P		Config DB failure: possible data loss! Trying to repair. May take some minutes, please wait.	Data loss probably occurred. The system is trying to repair itself.
W133	P		Config DB failure: possible data loss!	Possible configuration loss, check database. If problem occurs multiple times, contact your service representative.
W132	P		Config DB is recreated. Previous configuration is lost!	System settings are regenerated. Set the configuration options again. If problem occurs multiple times, contact your service representative.
W131	P		DB failure: possible data loss! Trying to repair. May take some minutes, please wait.	Data loss probably occurred. System is trying to repair itself.

Message ID	T	Status line text	Full text	Recommended action
W131	P		DB failure: possible data loss!	Possible data loss, check database. If problem occurs multiple times, contact your service representative.
W130	P		DB is recreated. All previous data is lost!	All existing data was lost. If problem occurs multiple times, contact your service representative.
I117	P		Due to changes lockout time was increased to %d day(s). (Touch to confirm.)	You have successfully increased the active QC lockout time.
I117	P		Successful QC check. Lockout time was increased to %d days(s). (Touch to confirm.)	The QC lockout time was restarted because of the successful QC measurement.
I116	TP		Reminder: Last day before lockout.	There is only one day left to perform a successful QC measurement before the QC lockout is activated.
I115	TP		Measure head SW update in progress. May take some seconds, please wait.	N/A
I114	TP		Connection is in progress. Please wait.	N/A
I113	TP		Output is paused while in "Settings>Ethernet" screen.	N/A
I112	TP		Log is exported.	N/A
I111	TP		Log export in progress. Please wait.	N/A

Message ID	T	Status line text	Full text	Recommended action
I110	TP		Output paused while navigating in settings menu.	N/A
I109	TP		Unused QC LOTS and limits deleted.	N/A
I107	TP		No password set. Please set your password on login!	N/A
I106	TP		Operator added.	N/A (Applicable in 'self-add' and 'self-add with password' system security levels.)
I105	TP		Selection was sent for printing.	N/A
I104	TP		Selection was sent for output.	N/A
I103	TP		Selection is inverted.	N/A
I102	TP		All samples are selected.	N/A
I101	TP		Sample ID was not found, please try again or cancel the search.	N/A

2 Testing and measurement result errors

ID	T	Status line text	Full text	Testing: Error Source & Action
E299	R	Head HW error: defective LEDs	Head HW error: some LEDs may be defective. Please call Service.	Head hardware error. Contact your service representative.
E298	R		Internal error: system configuration corrupted. Please call Service.	Contact your service representative.
E297	R		HW error: software check failed. Please call Service.	Head hardware error. Contact your service representative.
E296	R	Head communication error	Head communication failed. Please restart the system.	Communication with the head failed after the measurement. Restart the analyzer and repeat the test with a new test strip. If the error persists, contact your service representative.
E282	R	DB error: corrupted item	Database error. Stored item is corrupted. Please delete item from database.	Corrupted data. Restart the analyzer and repeat the test with a new test strip. If the error persists, contact your service representative.

ID	T	Status line text	Full text	Testing: Error Source & Action
E281	R	DB error: missing configuration data	Database error. Missing strip configuration data. Please delete item from database.	Corrupted data. Restart the analyzer and repeat the test with a new test strip. If the error persists, contact your service representative.
E280	R	DB error: configuration corrupted	Configuration error. System configuration (or database) failed.	Corrupted data. Restart the analyzer and repeat the test with a new test strip. If the error persists, contact your service representative.
E270	R	Measurement error: reference pad out of range	Strip tray reference pad error. Measured value is out of acceptable range.	Repeat the last measurement. If the error persists, contact your service representative.
E269	R	Measurement error: too strong backlight	Backlight is too strong. Measurement is not possible!	External light was too strong during testing. Reduce the intensity of the external light or do not expose the tray directly with a strong light source (i.e. direct sunlight or lamp). Repeat the test with a new test strip.
E268	R	Measurement error: Blank device value out of valid range	Blank device value out of valid range	
E267	R	Measurement error: Device is not blank or dirty.	Device is not blank or dirty.	

ID	T	Status line text	Full text	Testing: Error Source & Action
E266	R	Measurement error: device type mismatch	Device type mismatch while calculating the results of measurement (no control line).	Not the proper test device type was used. Make sure that the device used was of the type that was set. Repeat the test with a new test device.
E265	R	Measurement error: line values are out of range	Measured value out of valid range for one or more lines	
E264	R	Measurement error:		
E263	R	Measurement error: temperature out of range	Temperature was out of allowed range during measurement.	Test was performed outside the operation range. Ensure the proper environmental conditions. Repeat the test using a new test strip
E262	R	Measurement error:		
E261	R	Measurement error: dry strip	Strip is (partially) dry.	Strip was (partially) dry. Repeat the test ensuring that the new strip including the pad closest to the handle (the last pad) has been in contact with the sample
E260	R	Measurement error: no device	No device is present. Storing commented item without real values.	No device was detected during measurement. The result is only saved to enable comment input.

### 3 Software update:List of error and information messages

SW Update ID	T	Full text	Corrective action
E596	U	Update was failed.	Check and verify the software update sources on the media. Restart update.
E597	U	Internal configuration failure!	Restart update.
E572	U	Failed install: .....	Corrupted or missing files. Check and verify the software update sources on the media. Restart update.
E562	U	Failed backup: .....	Restart update.
E561	U	Missing: .....	Corrupted or missing files. Check and verify the software update sources on the media. Restart update.
I502	U	The system is already up to date.	N/A
I503	U	SW update is not found. Please insert USB drive with SW package.	Follow the message text instructions.
I504	U	Software update package was found. Tap "Update" button to start process.	Follow the message instructions.
E5XX	U	Package error: .....	Corrupted or missing files. Check and verify the software update sources on the media. Restart update.
E5XX	U	Internal error: .....	Restart update.
E5XX	U	Missing source: .....	Check and verify the software update sources on the media. Restart update.
E5XX	U	Source check failure: .....	Corrupted or missing files. Check and verify the software update sources on the media. Restart update.

### 13.5 Trouble shooting with problem occurrence


Error description	Recommended action
1. Printer paper is rolling out of the instrument during printing, but characters or any sign of printing are not present on the paper, it remains empty (no external printer attached)	<ul style="list-style-type: none"> <li>- Check whether correct type of paper is used (see Operator's Manual)</li> <li>- Check whether the paper is placed in the reader with the correct side inside, and try reversing it.</li> <li>-Check for mispositioned or damaged cover or printer paper holder door.</li> <li>- If error persists, call your distributor.</li> </ul>
2. Measurement does not start when the button is pushed.	<ul style="list-style-type: none"> <li>- Please enter the LOT code of the used test device LOT on the Measurement &gt; [device name] screen (see Figure 16).</li> <li>- Please check that the assay device has not expired.</li> <li>- Please check if the expiry date is in the correct format.</li> <li>- Please check the date on the instrument. If it is not suitable, correct the date, or ask your administrator to do it (see 11.2).</li> <li>- If error persists, call your distributor.</li> </ul>
3. The reader cannot be switched on and does not have any reaction (LEDs on the back of the reader or display lighting up and beeping sound) to pushing the power button when trying to use with a power supply adapter or batteries.	<ul style="list-style-type: none"> <li>- Check whether the correct type of external power supply is used with the reader. Replace, if necessary.</li> <li>- In case of battery operation, make sure that the six size AA batteries / NiMH accumulators in the reader are correctly positioned (see Figure 6). Replace or reposition, if necessary.</li> <li>- Reset the reader with the reset button: Remove power cable and/or batteries and push the reset button on the back of the reader for at least 30 seconds. Plug in power cord or replace batteries. The time and date need to be set after switch on.</li> <li>- If error persists, call your distributor.</li> </ul>
4. During start-up, the LCD display stays back, and no image appears.	<ul style="list-style-type: none"> <li>- Make sure that during start-up, the power LED next to the power button lights up (first with red, then with green color), and a short beeping sound can be heard. If this is not the case, follow the steps of error 3.</li> <li>-If error persists, call your distributor.</li> </ul>


## 13.6 Log file export

The log files of *EasyReader+*® function as a sort of ‘flight recorder’ or ‘black box’ for the analyzer: the system is continuously monitoring every process and sub-process that starts during normal operation, and stores them in its log files. When a software error occurs, these log files are often helpful to software developers when they try to determine the source of the error.

When you report a problem to the manufacturer’s service personnel (Cf. [13.6.Servicing Contact Information](#)), they can ask you to send them the log files from your *EasyReader+*® analyzer. To do this, you will need to export the log files to a USB flash drive first.

### Export log files:

 You can only export log files from the analyzer to a connected USB flash drive. You cannot transfer log files via the serial port or through an Ethernet connection.

 Unless the USB flash drive that you are using is completely full, you do not need to delete files from it to store the analyzer log files. Log files normally take up less than half a megabyte (about 300 kilobytes) of data.

**1** Plug a USB flash drive into the Type-A USB port on the back of the analyzer (Cf. [Figure 2](#)), and wait for the USB drive icon to appear in the status icon area of the status bar (Cf. [Figure 10](#)).

**2** To access the **Settings** screen, tap the **Settings** button on the **Main Menu** screen, and then tap the **Log Export** button (Cf. [Figure 42](#)) to start the export process. An information message will display (**Log exporting is in progress. Please wait.**).

 **Do not remove the USB flash drive before the log file export finishes.**

**3** The message disappears when log export is finished. In this special case, you can immediately remove the USB flash drive, without unmounting it first (Cf. [5.3.2.Using an USB flash drive](#)).

**4** Plug the USB flash drive into a PC or Macintosh computer. Find the zipped folder with the name ‘log\_[Date of creation].tar’ on the flash drive, and send it to the manufacturer’s service personnel.

## 13.7 Servicing Contact Information

The manufacturer offers complete service support for its products. If you encounter problems with the *EasyReader+*® analyzer that you cannot, or can only partially solve by consulting this manual, feel free to contact your local distributor who supplied you with this equipment:

# 14 Appendices

## 14.1 Default Settings

### User options:

Auto print: ON  
Auto transfer: OFF  
Sound: ON  
LCD brightness(%): 100

### Device:

VedalabMiniClip-CRP-HS  
VedalabMiniClip-CHECK  
VedalabMiniClip-BLANK

### Printout:

Header: (empty)  
Operator ID: ON  
Patient ID: ON  
Equipment S/N: ON  
Strip LOT: ON  
Print blank: OFF

### Output:

unidir text (UTF8)  
Header: (empty)  
Frame+CKHSUM: ON  
Output type: RS232: 9600

### QC options:

QC Lockout (day): 0  
Mode: Check device  
Lot expiry lockout: OFF

### Power management options:

LCD off time (min.): 5  
Logout time (min.): 10  
Power off time (min.): 60

### Database management options:

Circular memory: OFF  
Warning at circ.mem. limit: OFF  
Prewarning: 30

### Ethernet:

Automatic (DHCP): ON

### Authent. general settings:

Mode: Custom  
Auto login: Supervisor  
Self add operators: OFF  
Password not required: ON  
Operators on login screen: ON  
LIS operator list check: OFF  
LIS operator list only: OFF



*Authentication general settings do not change when you restore the default settings.*

## 14.2 Safety information

*EasyReader+*<sup>®</sup> was designed and manufactured to comply with the international regulations listed in this section, and left the factory in a safe condition. To keep the analyzer in a safe condition, you must observe all instructions and warnings included in this manual.

The instrument complies with the protection requirements of IEC 61010-1:2010, IEC 61010-2-101:2002 and IEC 61326-1:2005, IEC 61326-2-6:2005.

The instrument is certified as meeting the EMC requirements and safety specifications of the In Vitro Diagnostic Directive (98/79/EC). Per IEC 61326-2-6 it is the user's responsibility to ensure that a compatible electromagnetic environment for this instrument is provided and maintained in order that the analyzer will perform as intended. Do not use this analyzer in close proximity to sources of strong electromagnetic radiation (e.g. unshielded intentional RF sources), as these may interfere with the proper operation. The electromagnetic environment should be evaluated prior to operation of analyzer.

This equipment has been designed and tested to CISPR 11 Class A. In a domestic environment it may cause radio interference, in which case, you may need to take measures to mitigate the interference.

The analyzer must be operated only with the prescribed power supply unit (Class II protection).

Opening covers or removing parts of the instrument, except where this can be achieved manually without the use of any tools, may expose voltage-carrying components.

Connectors can be live, too.



**Do not attempt to maintain or repair an open instrument which is carrying voltage.**

If you suspect that the instrument can no longer be operated safely, turn it off and take steps to ensure that no one will subsequently attempt to use it. Make sure that only trained members of staff operate the *EasyReader+*<sup>®</sup> analyzer.

Any personal computer to which the analyzer is connected must meet the EN 60950, UL 60950/CSA C22.2 No. 60950 requirements for data processing equipment.

Only connect the intended external analyzers with safety low voltages to the corresponding interfaces (serial, PS2, USB, Ethernet) to avoid the risk of electrical shock or the risk of damaging the analyzers or the analyzer.

If the instrument is to be taken out of operation entirely and disposed of, it must be disposed of in conformity with the relevant legal regulations and in co-ordination with your local authority, if appropriate.



**Please note that the instrument may potentially be infectious. Equipment must be decontaminated before repair, maintenance, or removal from the laboratory.**



*The data and information contained in this manual are accurate at the time of printing. Any substantial changes will be incorporated in the next edition. In case of conflict between this manual and information given in package inserts, the package inserts shall take precedence.*

### 14.2.1 Disposal of the analyzer

The instrument must be treated as biological contaminated-hazardous waste. Without disinfection or sterilization, the device and any of its parts are considered infectious clinical waste (EWC code 180103\*). Untreated infectious waste is typically incinerated but proper disposal of the old appliances (including its plastic parts, electrical components) prevents potential negative consequences for the environment and human health. All electrical and electronic products and other components of the analyzer should be disposed separately from the municipal waste system. Final disposal must be organized in a way that does not endanger waste handlers. As a rule, such equipment must be fertilized before it is passed for final disposal.

These are common guidelines only, please apply the relating regulations of your laboratory or hospital. For more information about disposal of such product, please contact your city office, waste disposal service or your Local Safety Officer.

## 14.2.2 Recycling

Making sure that unwanted, old instruments do not pollute the environment more than is unavoidable is very important.

Parts and components of the analyzer could be sent to recycling after proper disinfection:

- the AC adapter and power cable: contact the manufacturer for disposal information or find a recycling center online
- the electrical wires: find a recycling center online
- the casing panels: follow the local guidelines and regulations for Acrylonitrile butadiene styrene (ABS) disposal
- the printed circuit boards (PCBs): find a specialized recycling firm
- the CR2032 real-time clock battery on the Mainboard: follow local regulations and guidelines for lithium battery disposal
- metallic elements: follow local guidelines and regulations for metal disposal
- silicone supports: dispose of these as municipal waste

Vedalab will accept *EasyReader*<sup>®</sup> devices that you no longer want to use, if you disinfect or sterilize the device before mailing it.

## 14.2.3 Protecting yourself from biohazards


This information summarizes the established guidelines for handling laboratory biohazards. Use this summary for general information only. It is not intended to replace or supplement your laboratory or hospital biohazard control procedures.

Blood specimens should be handled at Biosafety Level 2 as recommended for any potentially infectious material in the Centers for Disease Control and Prevention manual, Biosafety in Microbiological and Biomedical Laboratories, 20091. Universal (or standard) precautions may apply if required by the infection control policy of your facility<sup>1</sup>.

To prevent accidental contamination in a clinical laboratory, strictly adhere to the following procedures:

- ▶ Wear gloves to protect hands from exposure to hazardous materials. Change gloves when contaminated, glove integrity is compromised, or when otherwise necessary. Do not wash or reuse disposable gloves.
- ▶ Remove gloves and wash your hands after working with potentially hazardous materials and before leaving the laboratory.
- ▶ Wear personal protective laboratory equipment, such as coats, gowns, smocks, or uniforms when working with possible hazardous contaminants. Remove protective clothing before leaving for non-laboratory areas.

- ▶ Wear eye and face protection when splatter or aerosol formation are possible.
- ▶ Do not eat, drink, smoke, handle contact lenses, apply cosmetics or store food while in the laboratory.
- ▶ Do not pipette any liquid by mouth; use only mechanical pipetting analyzers.
- ▶ Always handle sharp items with precautions.
- ▶ Perform procedures carefully to minimize the creation of splashes or aerosols.
- ▶ Decontaminate work surfaces after completion of work and after any spill or splash of potentially infectious material with appropriate disinfectant.
- ▶ Dispose of contaminated materials including used personal protective equipment according to your laboratory's biohazard control procedures. Potentially infectious materials must be placed in a durable, leak proof container during collection, handling, processing, storage, or transport within a facility.
- ▶ The laboratory supervisor must ensure that laboratory personnel receive appropriate training regarding their duties, the necessary precautions to prevent exposures, and exposure evaluation procedures.
- ▶ During service work, keep your hands and fingers away from your mouth, nose and eyes.
- ▶ Wash your hands after working.
- ▶ Waste material should be handled or disposed of in accordance with the local safety regulations.

 *Be sure to read and understand the safety warnings and symbols in this manual.*

<sup>1</sup> <http://www.cdc.gov/biosafety/publications/bmb15/>