Device Manual

BIOSYNEX Reader

Ref. 5060001

Contents

Symbols used in this manual and on the device

Symbol	Description
⚠	Caution! Important and security-relevant instructions.
🏭	Manufacturer
📖i	Please consult instructions for use.
IVD	*In vitro* diagnostic medical device
2004-06	Date of manufacture (year and month)
SN	Serial number
🗑	Do not dispose in domestic waste. Device contains Li-ion batteries. Dispose of the device only according to the regulations obtained in the country at hand.
+ ─)─ −	Polarity of power supply 5V DC
CE	CE emblem
IP 20	Protection class according to DIN 40050 respectively IEC 529

Field of application

The reader **BIOSYNEX Reader** is a mobile device for quantitative or qualitative evaluation of Lateral Flow Assays. The device is configured for special tests by the test manufacturer.

The accompanying tests come with an SD card containing data with information on the test type and lot number. Using this SD card the device is able to identify these attributes. Often there is a barcode attached to the back of every test cartridge which can be read by an internal scanner inside the reader and thereby used to identify the tests. For tests without barcode on the backside, the test identification can also be done manually with a test select menu on the reader. The reader must be configured accordingly in advance by the device manufacturer by deactivating the internal barcode scanner (on request).

The device is exclusively designed to be used by medical trained staff.

Attention:

All objects that can come into contact with blood or other body fluids constitute a potential source of infection.

At proper usage there are no biological hazards emanating from the device.

However the spreading of body fluids such as blood into the well is possible when the device is not used properly. These fluids can possibly be a risk for people working with the device. In case of such a contamination disinfection is necessary. Special protective equipment has to be used for this, please contact the manufacturer if further information is required.

In general please refer to standard lab practices concerning the disinfection and use a disinfection solution suitable for medical devices that does not affect the device housing material (for example *Mikrozid® AF Liquid* or comparable products).

Liability Exclusion

The devices are produced, calibrated and checked before shipping under strict quality control measures in order to guarantee a high degree of quality. However several test-specific configurations are made by third companies (test manufacturer) and provided via SD card for running the tests on the reader. For this reason, the device manufacturer is not liable for the correctness of test-specific measurement results for tests that have been installed on the device by a third company.

As a basic principle, results determined with the device should not be the sole base of a medical diagnosis. They should always be compared to reference values obtained from approved, comparable methods before a final diagnosis is made and a resulting therapy is initiated.

1   Shipment

Figure 1: Delivery condition of the device inside its transport case

(1)   Transport case
(2)   Device
(3)   Test cartridge adapter for test cartridge
(4)   Power supply unit 100V-240V AC / 5V DC and power cable
(5)   USB cable
(7)   Printer
(8)   Brush for cleaning optical parts of the device &
                    Quality control cassette (optional)
(9)   Screwdriver

(9)	Display
(10)	Keypad
(11)	Test cartridge adapter
(12)	Test cartridge
(13)	Printer (optional)
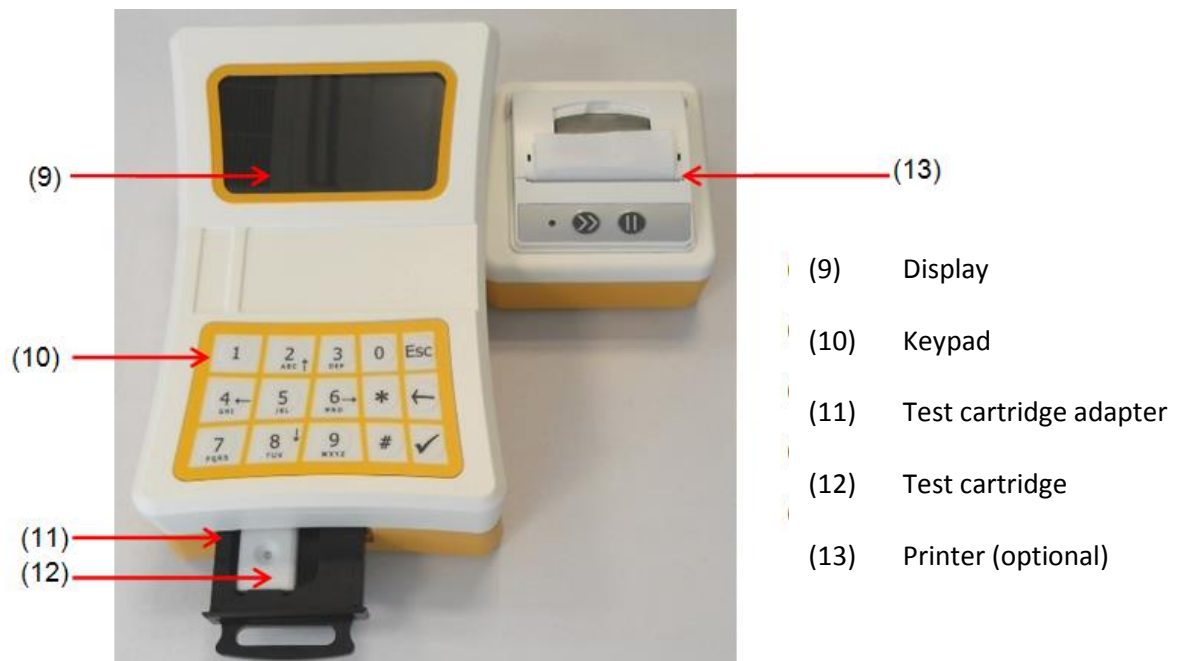
Figure 2: Front view of the device with a printer attached and the test cartridge adapter not inserted
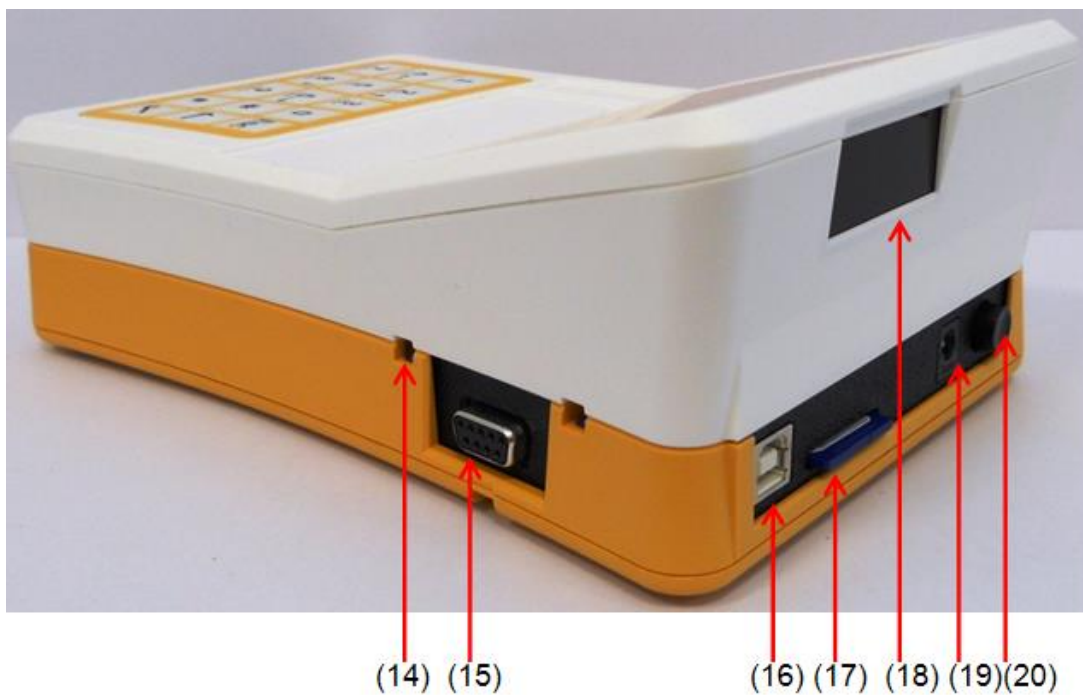
Figure 3: Connections on the rear side

14)	Guide contour for printer connection	(19)	Power connection
(15)	D-sub socket for printer connection	(20)	On/Off key
(16)	USB socket		
(17)	Slot for SD card		
(18)	Barcode scanner		
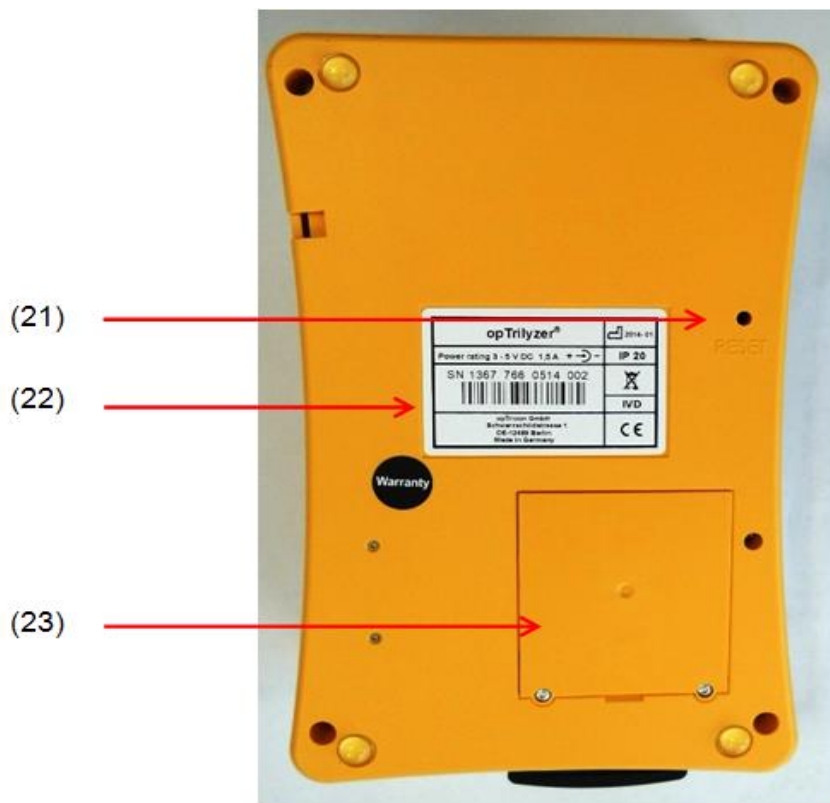
(21)	RESET-key
(22)	Type plate with serial number, barcode and date of manufacture
(23)	Cover for well

Figure 5: Printer
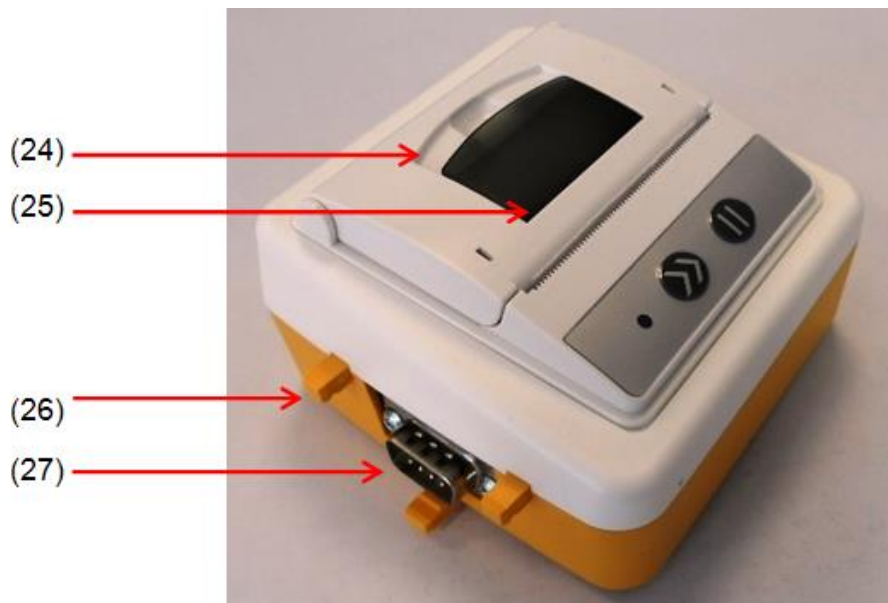
(24)	Printer lid
(25)	Shaft for print-out paper roll
(26)	Guide pins for printer connection
(27)	D-sub connector (cp. (15))

2 Commissioning and safety instructions

Please read the manual thoroughly through before putting the device into operation.

2.1 First steps

Please check the contents of the package. **Figure 1** shows the complete shipment.

In case something is missing please contact the manufacturer. The contact information can be found on the shipping ticket or at page 47 of this manual.

The device contains lithium-ion batteries being charged by connecting the reader to the power supply and/or connecting it to a running computer using the USB port. The batteries are loaded upon delivery but may have partly or fully discharged during storage and transport.

Attention: The batteries should be charged for at least 4 hours before commissioning. In order to do so the power supply (5V DC - 4A) has to be connected to the socket on the rear side of the device housing and the power cable connected to the mains (**Figure 3**).

Attention: Please do not use any other than the provided power supply units for charging. Safety of the device cannot be guaranteed otherwise!

Attention: Do not use the power supply unit if it shows visible damages on the outside. Please contact the manufacturer in such a case.

Attention: The device is designed for use on flat and even surfaces. Please do not fitfully

move or bring the device into an uneven position during measurement!

When positioning the device on a workplace, please make sure that easy disconnection from the mains is not prevented by any obstacles.

Attention: At proper usage, there are no biological hazards coming from the device. However, when not handled properly, contaminations due to biological dangerous material are possible. Safety measures of the device can become ineffective at improper usage.

Therefore please follow the instructions in this manual in any case!

Attention In case of an impurity or contamination of the well the cover (

Figure 4) can be removed. Please use the required safety equipment for cleaning and see also **section 7.2** and **section 8** for more information.

Attention: When disposing the test cartridges please follow the instructions of the test manufacturer (see test IFU).

⚠ **Attention:** The quality control cassette included in delivery has to be stored under special conditions: lightproof wrapping, maximum relative humidity 40% (the provided wrapping containing a drying agent ensures these conditions), temperature 18 - 22°C.

Attention: Opening the device will void the manufacturer's warranty.

2.2 Turn on/Turn off and RESET

The on/off key is located on the back of the device housing (**Figure 3**).

Turn on	To turn the device on, press the button on the back of the device for **1s**.
Turn off	To turn the device off, press the button for **2s**. ⚠ In case it doesn't work press the button for longer than 10s.
Emergency off	Hold the switch down **for longer than 10s** to turn off the device.
Turn off automatically	If no entries are made on the device for longer than 20 min (with power connection 3 h) and the timer is not enabled, the device switches off automatically
RESET	⚠ RESET is only recommended if normal Turn-off – as described above – is not possible. Press the RESET button on the back of the device (see Figure 4) briefly with a pointed object (e.g. the provided screw driver or a ballpoint pen)

2.3   Accessories
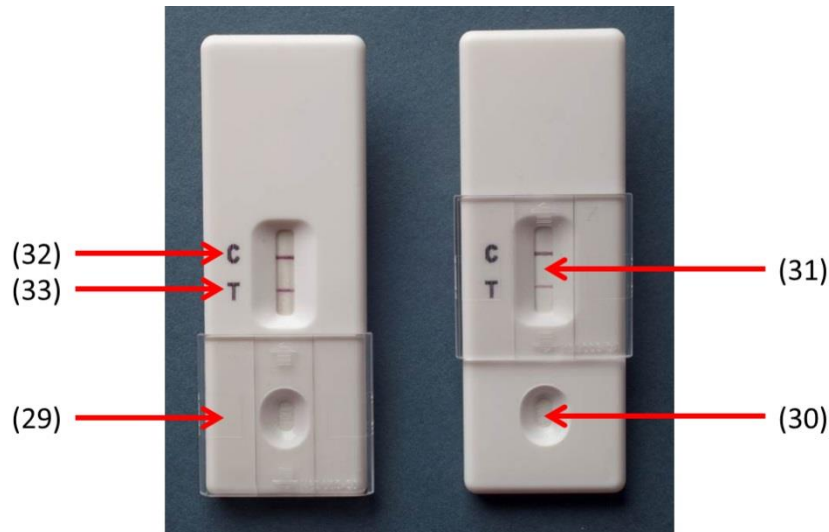
Figure 6: Example test cartridge

Figure 6 shows an exemplary test cartridge. The cartridges vary in their structural shape according to the test. Individual test cartridge adapters enable the device to analyze various differently shaped test cartridges.

The well for the blood sample (30) in the above illustrated cartridge can be covered by a transparent slide cover (29) after the application in order to protect the environment against possible infections emanating from the blood sample. Most test cartridges, as for instance visible in **Figure 2**, do not have such a slide cover.

There are two lines in the test area (31). Line C (32) is called the Control Line. Its purpose is to ensure the validity of the test. Line T (33) is the Test Line and holds information on the analyte concentration. The reader analyzes the intensity of the Test Line and provides a test result according to the test manufacturer's calibration.

If there is a barcode on the rear side of the test cartridge, a built-in barcode scanner can read it to identify the test.

Detailed instructions for the use of the test cartridge can be found in the corresponding test manual. If there are any doubts, please contact the manufacturer.

Delivery of the device, respectively the test kit includes an SD card. This card contains specific data important for running the test. Before starting a measurement the SD card is to be put into the according slot on the rear side of the device (

Figure 7), the electric contacts facing downwards. The reader autonomously identifies if SD card and test cartridge belong together for example by comparing the barcode on the back side of the cartridge and the data on the SD card. In case they don't fit an error message appears on the display.

In addition the SD card can contain a file with a language table which is loaded when the device is switched on.

Figure 7: Position SD card

2.4   Display

When the **BIOSYNEX Reader** is switched on, the manufacturer's logo appears and the device is initialized. The version number of the firmware appears briefly. After that the main menu is shown on the display (**Figure 8**).
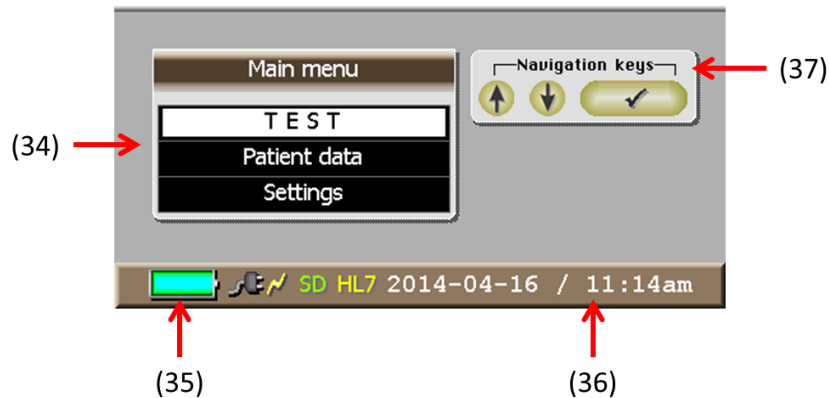
Figure 8: Main menu

The display shows the following information:

(34)   **Main Menu** window: Navigate with the cursor (see **section 2.5**) to select the menu items. The selected menu item appears against a white background. In **Figure 8** "TEST" is selected. Click *Enter* (√) to open the menu.

(35)   **Batteries' state of charge:** When the battery symbol is filled in green, the batteries are fully charged. During operation without a charger or power supply unit, the display bar will shrink down to empty when the batteries are discharged. The operating time is listed in the specification.

(36)   **Date/Time:** The first time operation is started this can be configured under the "Settings" menu and should be checked regularly for correctness afterwards.

(37)   **Navigation Help** window

Optionally the company logo and device name are shown at the top of the display.

Attention, energy saving mode: The display dims to around 50 % brightness 20 seconds after the last keypad entry, and then to 10 % after another 40 seconds. This is not an error, but a way of keeping the batteries charged longer. Pressing any key restores the display to full brightness.

2.5 Keypad and navigation

Figure 9: Keypad

Keys 0 to 9	Input keys for numerals and letters; Text is entered like on a mobile telephone. Each key represents multiple letters. Press the same key again to select the next letter.
	Use the * key to switch between numerals, upper-case letters and lower-case letters in the entry mode.
Key 0	Characters: ‚Space' 0 + : ; / ( ) *
Key 1	Characters: *1 . , - ? ! ' @*
Key 2/↑	Characters: *Aa Bb Cc Ää 2*
	Navigate "*up*" in the menu
Key 3	Characters: *Dd Ee Ff 3*
Key 4/←	Characters: *Gg Hh Ii 4*
	Navigate "*left*" in the menu / previous page in list
Key 5	Characters: *Jj Kk Ll 5*
Key 6/→	Characters: *Mm Nn Oo Öö 6*
	Navigate "*right*" in the menu / next page in list
Key 7	Characters: *Pp Qq Rr Ss 7*
Key 8/↓	Characters: *Tt Uu Vv Üü 8*
	Navigate "*down*" in the menu
Key 9	Characters: *Ww Xx Yy Zz 9*
Key Esc	"*Back*" in the menu
Key ←	Delete data (for instance patient data, or characters in the entry mode)
Key √	Confirm an entry ("*Enter*")
	Select a field in the navigation mode '*Nav*'
Key #	Edit data
	Print data
Key *	Switch between navigation mode '*Nav*' and entry modes '*ABC*', '*abc*' and '*123*'
	Re-sort data in the menu

3   HL7 - data transfer

3.1   In general

HL7, short for *Health Level 7*, is an approved protocol for medical data transfer to data processing systems in hospitals and doctor's offices. The data is sent to a defined Server belonging to the medical facility and is integrated into the system where it will be available for further processing.

The HL7 data transmission feature is an optional feature on the reader and can be activated by the device manufacturer. The connection of the device to a network is possible via USB or LAN and must be configured accordingly by the network administrator before it can be used to its full extend.

3.2   *opTrilyzer®* working principle

When the **BIOSYNEX Reader** is started, the HL7 symbol appears in the status bar of the device. Each time the reader is switched on, it is checked whether there is data stored that hasn't been sent yet. If so, the data is sent directly to the server (symbol *Yellow*; see below). Subsequently the data is synchronized every 5 minutes. If no new data has to be sent, the symbol appears in *Blue*.

Every data transfer is confirmed by the server afterwards. If the confirmation fails to appear, this will be indicated in the reader display (symbol *Red*).

Successfully transmitted measurement results are marked with a green check mark in the "Patient measurement results" menu. They will be recognized during future synchronizing and won't be sent to the server again.

If required, measurement results can be sent again manually. In order to do that the accordant result must be highlighted in the "Patient measurement results" menu and confirmed with √. The HL7 symbol in the status bar changes to *Yellow* right after that.

Data is <u>always</u> sent, when the reader is connected to a PC or network via USB or LAN, even if no server is in operating distance. However this doesn't affect the correct operation of the reader, the HL7 symbols just changes to *Red* after every data transfer because no confirmation could be received. The data remains in the memory and will be transmitted successfully as soon as the device is once again in operating distance to the server.

3.3   Color codes

The current transfer status is indicated by the differently colored HL7 symbol in the status bar of the reader.

1. **Blue**   All data is synchronized with the server, there is no data left in the memory that hasn't been sent yet.

2. **Yellow**   Data is currently sent / was recently sent and the reader is waiting for the server confirmation (30 seconds).

3. **Red**   After 30 seconds no server confirmation was received, the data will be sent again during the next scheduled synchronization (in 5 minutes) / after restarting the reader / if selected manually. Then the HL7 symbol changes back to *Yellow*.

4. **Green**   Recently sent result was confirmed by the server.

This color does only occur rarely, because either the data transfer proceeds directly to the next result (*Yellow*) or the transfer is successfully completed after the last result (*Blue*).

The following image shows an exemplary screenshot of the reader main menu. In this case the symbol is *Yellow*, i.e. data was recently sent and the reader is waiting for the server confirmation for 30 seconds.
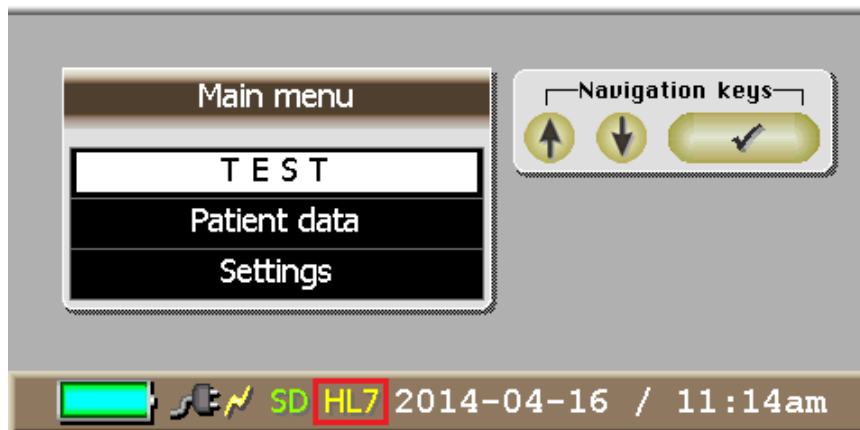

Figure 10: Display HL7

4 Menu

Advice:

As an orientation for the menu navigation there are short instructions integrated in every menu window as visible for example in **Figure 11** (marked in red). These instructions simplify the handling of the *BIOSYNEX Reader*.
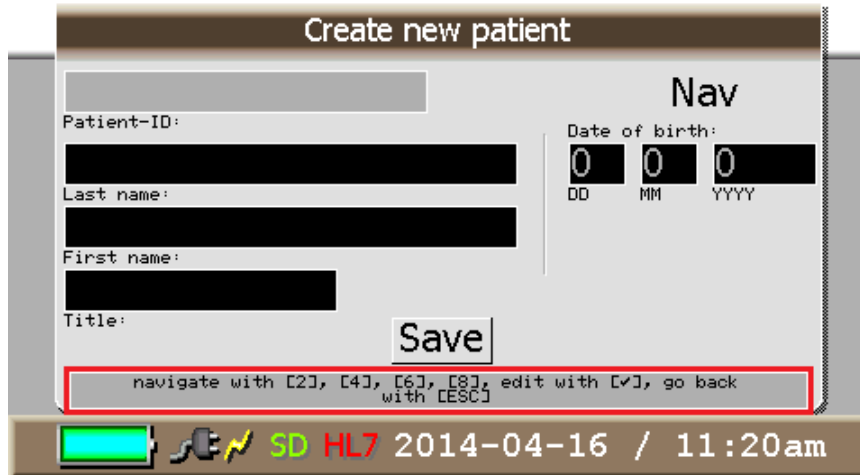
Figure 11: Example for menu navigation instructions

4.1 Settings

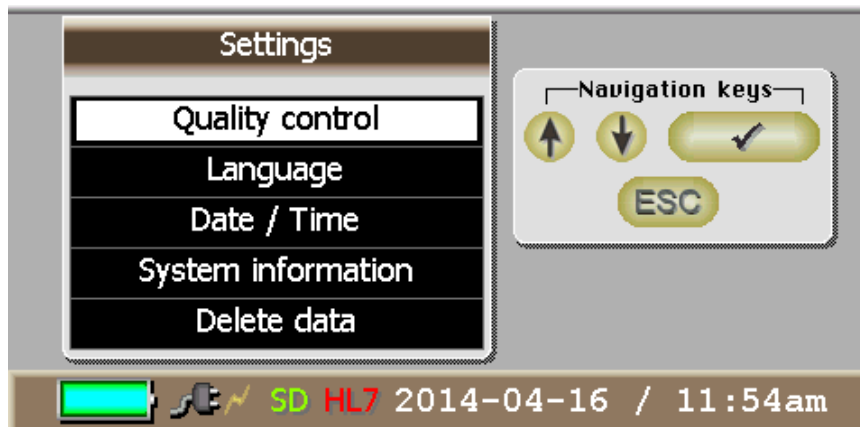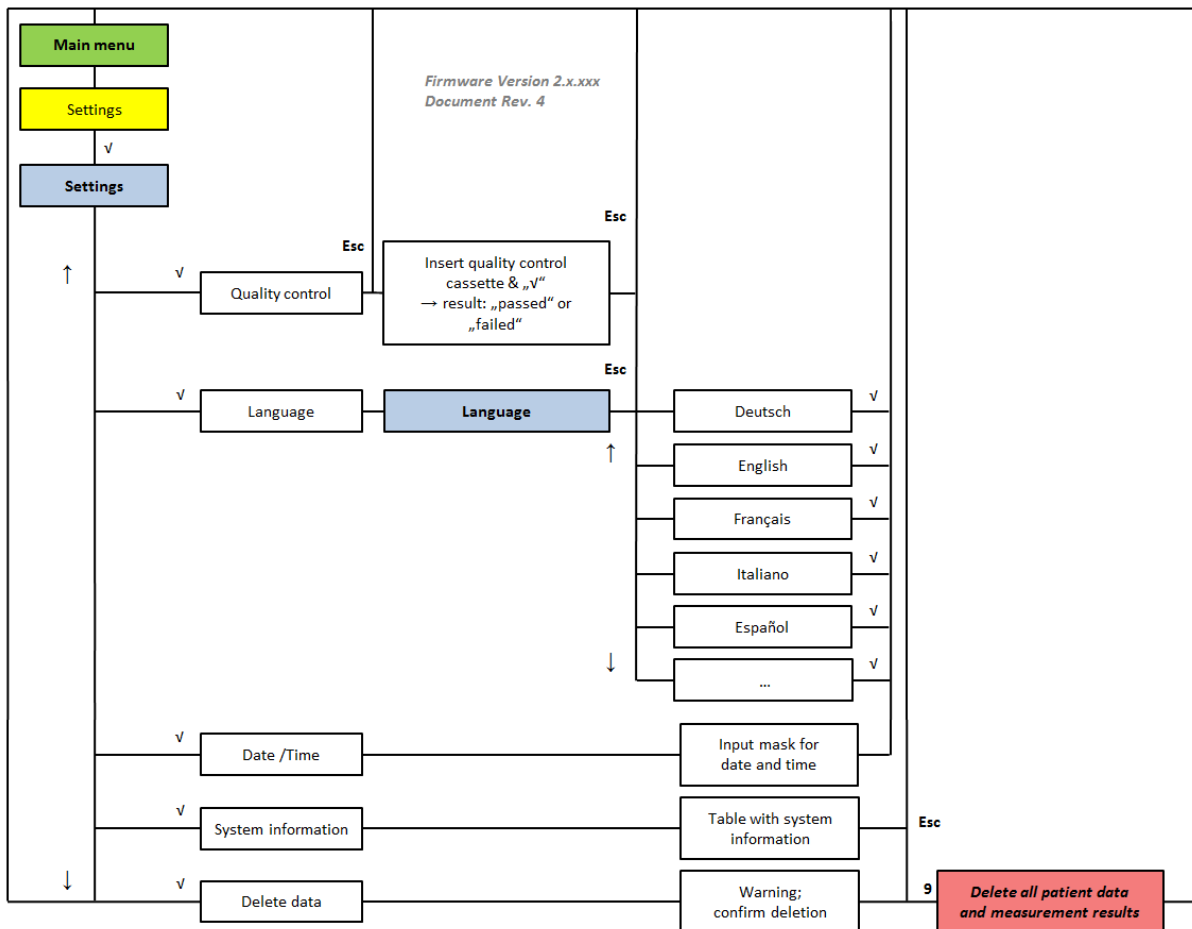Select "Settings" from the main menu and click √ to confirm. The following window appears.

Figure 12: Menu Settings

The structure of the menu is illustrated in the following flow chart.

Flow Chart 1: Menu "Settings"

The options available for selection in the "Settings" menu are "Quality control", "Language", "Date / Time", "System information" and "Delete data".

4.1.1 Quality control

To ensure the quality of the calibration there is the possibility for a quality control measurement. Therefore a quality control cassette is included in delivery (optional on request; figure 8 above).

To run a quality control measurement (**Figure**) put the quality control cassette into the test cartridge adapter and insert the adapter into the device until it snaps lightly into place (see also **section 4.3.7**). Make sure the corresponding SD card is also inserted in the accordant slot on the device. Start the measurement with √.
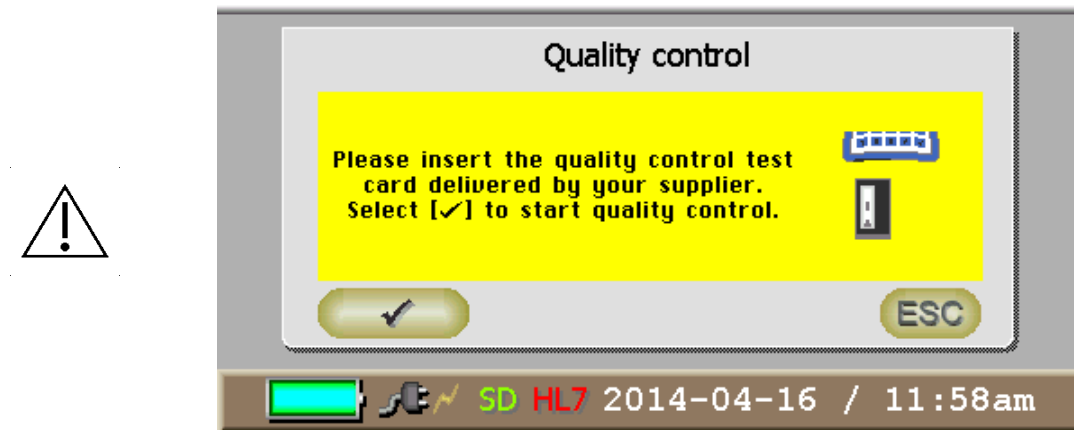

Figure 13: Quality control

The device produces a qualitative result, i.e. the quality control test will either have "passed" or "failed".

In case the measurement fails please ensure that the well and the approachable optical parts of the device are free of any visible contamination. Information on the cleaning of these components can be found in **section 7.2.**

If the purification doesn't improve the result of the quality control test please contact the manufacturer (see also **section 8**).

The results of the quality control measurements can be found and reviewed in the "Patient data" menu list. Please find more information on handling the "Patient data" menu and stored measurement results in **section 4.2**, more specifically in **subsection 4.2.4**.

Quality control measurements can be run ad libitum. It is recommended to perform a quality control measurement at least once a month in order to make sure the device works correctly.

Attention: The quality control cassette has a limited durability in order to maintain the same level of quality. It has to be replaced before the expiring date. Please contact the test manufacturer before the date is expired.

Please also note the following storage conditions for the quality control cassette! The card has to be stored in lightproof wrapping at a maximal relative humidity of 40%. The provided package ensures these conditions. The storage temperature should be between 18 and 22°C.

4.1.2 Language

Figure shows the menu for selecting the language. The selected language is designated by a white background. The entry must be confirmed with √. After that the main menu will appear in the selected language.
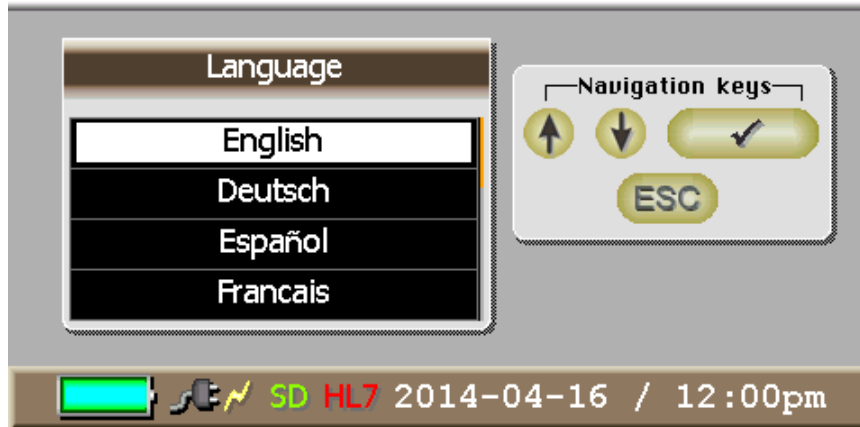

Figure 14: Language selection

4.1.3 Date and time

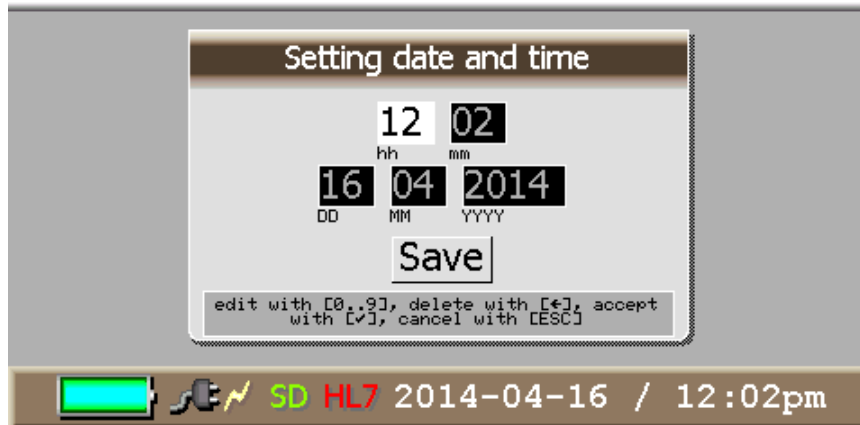When "Date / Time" is selected, the following input mask appears.

Figure 15: Setting date and time

Date and time can be entered consecutively in the input mask. The first filed ("hours") is automatically activated after selecting the menu item "Date / Time" (white background = input mode). After the correct value has been entered it can be confirmed with √ and the next field ("minutes") is selected automatically. If data is already entered in a field and must be corrected it has to be erased with the ← key before new data can be entered. Using ESC the input mode can be left (grey background = navigation mode) the initial value is preserved in the accordant field in this case. A new field can be selected for data input with the arrow keys and activated with √.

If the entered values are incomplete or do not make sense, the entry is displayed in red.

4.1.4 System information

The menu "system information" shows information on the system that is important for the manufacturer in maintenance cases.

Figure 16: System information
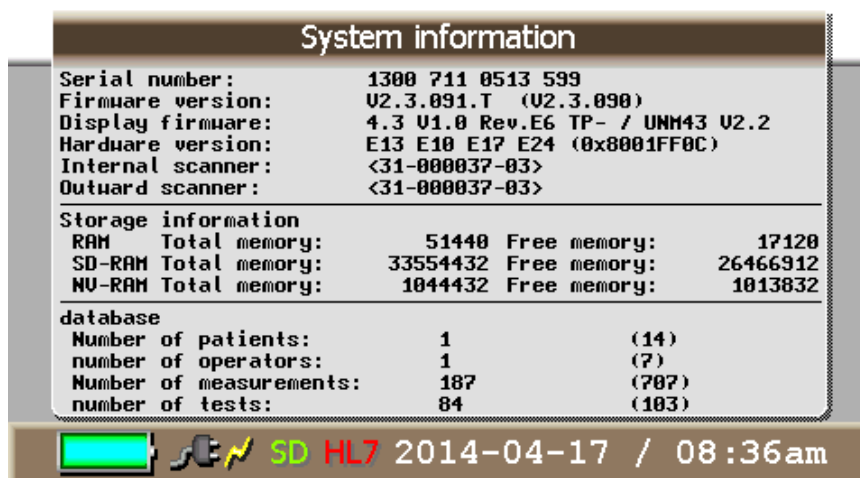
4.1.5 Delete data

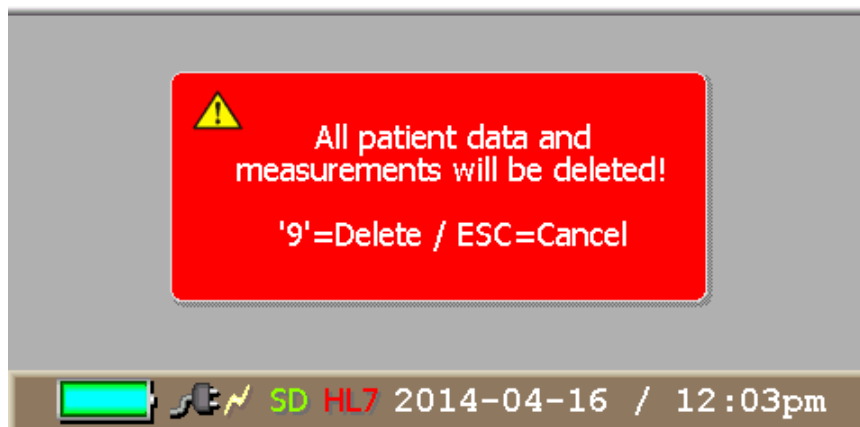The following window appears in the "Delete data" menu.

Figure 17: Delete data

It indicates that pressing the '9' key will delete all data. Entering ESC cancels the deletion and returns the display to the main menu.

⚠ **Attention: Once records have been deleted they cannot be restored! All patients and measurement results will be permanently deleted!**

4.2 Patient data

In the "Patient data" menu storage information about the memory of the reader can be found. Furthermore it is possible to create and edit patient data as well as to show and sort patient data, their measurement results and quality control measurements. Patient data of interest and their results can be sorted, printed or deleted in the end. The following flow chart shows the entire menu and its possible options.
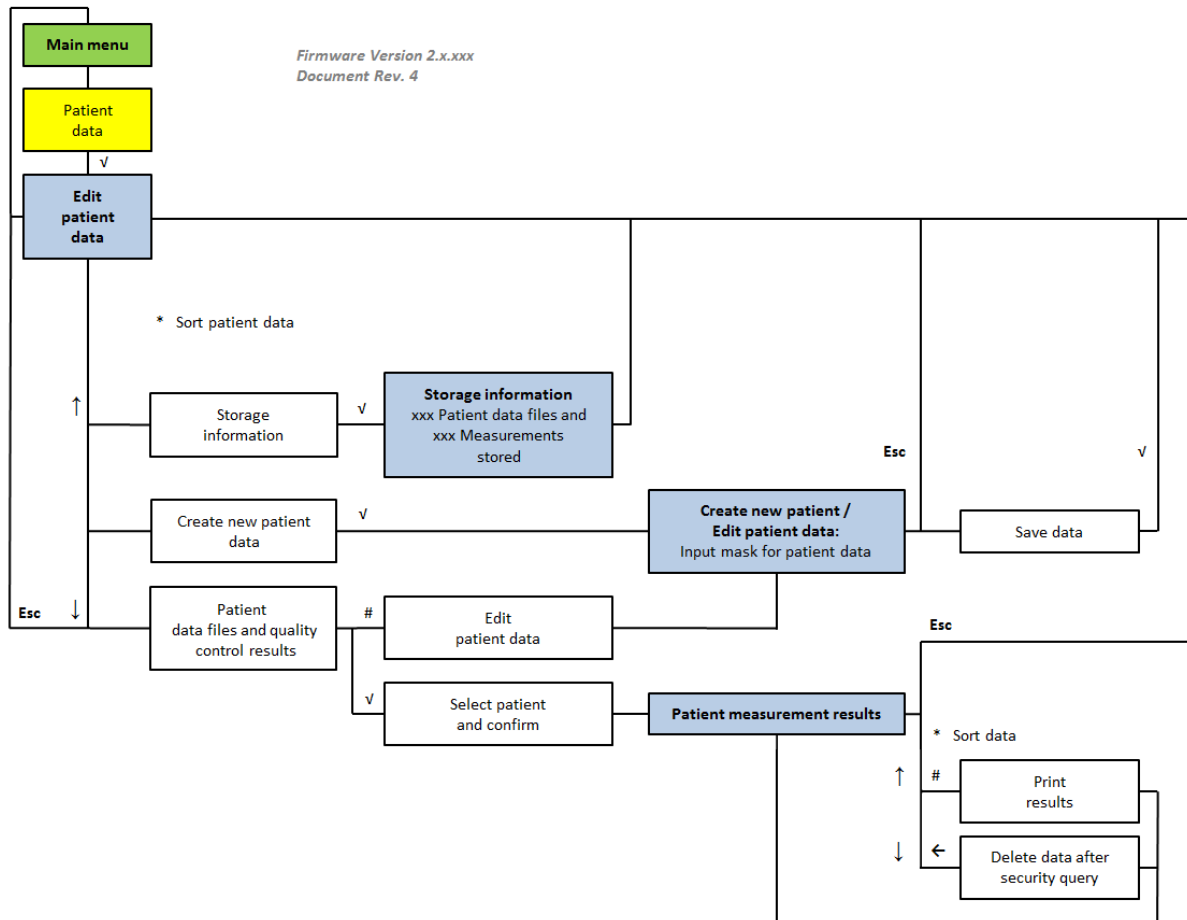
Flow Chart 2: Menu "Patient Data"

When the "Patient data" menu is selected, the display shows the "Edit patient data" selection menu (**figure 18**). The options available for selection here are the following:

- Storage information
- Create new patient data
- Quality control results
- List of all the patient data (sortable with *)
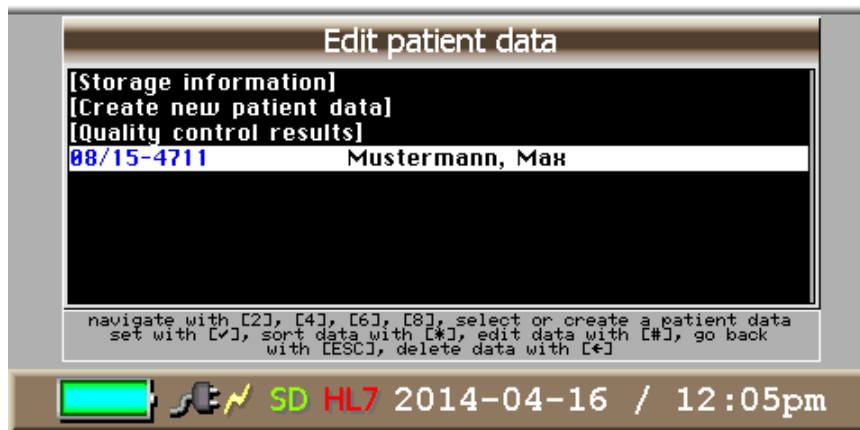
Figure 18: Patient data

By using the * key it is possible to switch between sorting the list according to last name or patient-ID. By pressing # the editing mode is activated where patient data can be changed or added, see also **section 4.2.3** for more information on that. For further information about the measurement results of each patient, select the patient by using the arrow keys and press the √ button.

By pressing ← a complete patient file can be deleted.
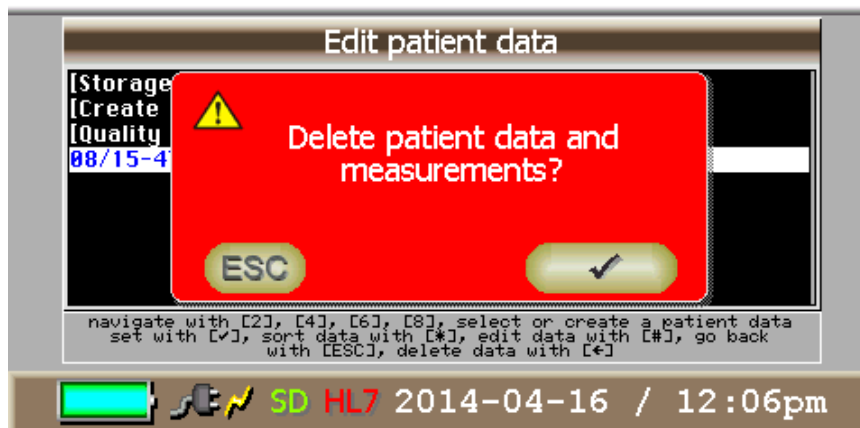
Figure 19: Delete patient

Attention: By pressing the ← key all selected data will be deleted and cannot be restored afterwards!

4.2.1   Storage information

When the "Storage information" command is selected, the following window appears.
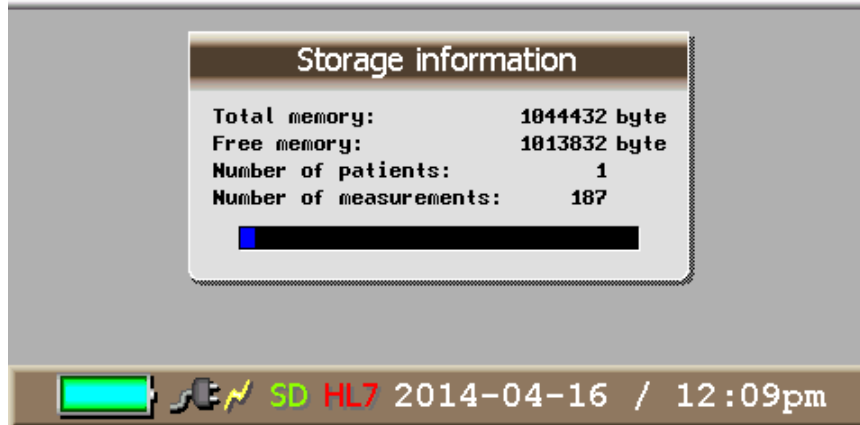
Figure 20: Storage information

The window (**figure 19**) shows the total memory which is available, how much memory is still free and how many patients and measurements have been stored already. In **Figure 20**, for instance, 1 patient and 187 measurements have been stored.

4.2.2   Create new patient

Selecting the "Create new patient" submenu opens the input mask for patient data (**figure 21**).
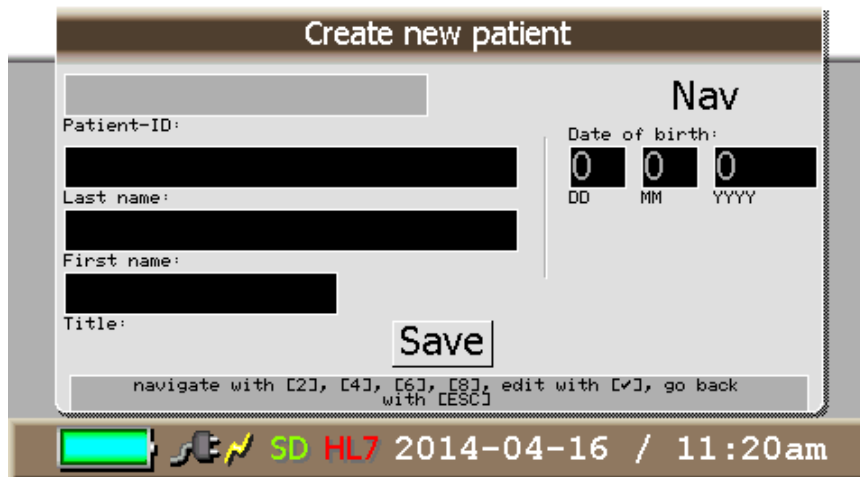

Figure 20: Create new patient

The mask visible in **figure 21** requests the input of several patient data.

Step through the separate input fields by activating them with the √ key. The selected field is marked in grey (navigation mode '**Nav**') and can be changed by navigating the cursor with the 2 and 8 keys. To begin entering data the √ key must be pressed a second time, then the field is marked in white (input mode). Data is entered using the alphanumeric keys on the keypad.

Data can be entered in three entry modes: upper-case letters ('**ABC**'), lower-case letters ('**abc**') or characters/numerals ('**123**'). Since each key is assigned multiple characters (like on a mobile tele-

phone), press each key as often as needed to step through to the character needed for entry. See also the table in **section 2.5** for detailed information on the keypad.

The entry mode is displayed at the top right of the mask. It can be switched by using the ***** key while data is being entered in a window.

Patient data can be created and stored without entering data in every field. Only the patient-ID (name or number) is absolutely necessary, otherwise the new patient file cannot be saved. The entry of last name and first name can be omitted. Make corrections within a window using the ← key and confirm an entry with ∨.

A total of approximately 1.000 patients can be created (exact number depends on number of measurements per patient).

4.2.3   Edit patient data

By selecting a patient from the list of patient data with # the editing mode is activated and the patient data of this file can be changed if necessary. The input mask is similar to the one for creating a new patient (**figure 21**), new data can be entered, and data can be deleted or changed (see previous section). Only the patient-ID cannot be changed for safety reasons. After selecting "Save", all changes are saved and the menu "Edit patient data" appears again.

Figure 21: Edit patient data

4.2.4 Patient measurement results

In the "Edit patient data" menu the sorted patient files can be viewed by pressing the **v** key. The window "Patient measurement results", shown in **22** appears.
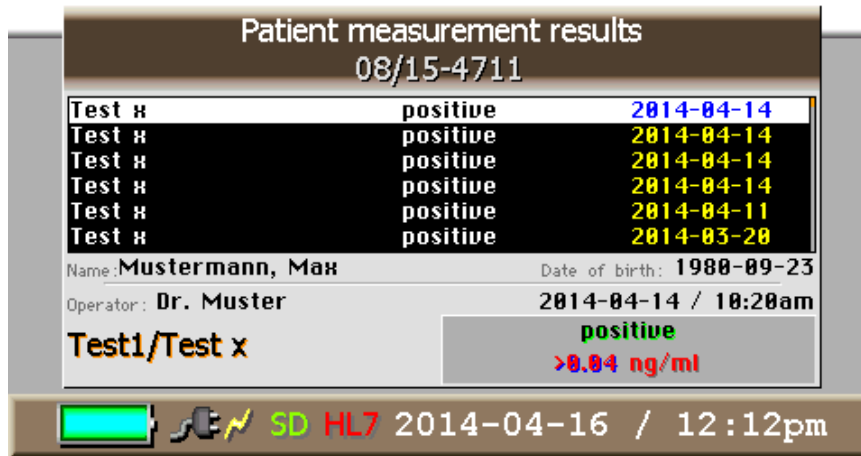
Figure 22: Patient measurement results

The window shows the measurement data of each patient, listed according to the type of test and sorted by the measurement result, date of measurement or by operator (sortable with *).

In the upper part of the display above the list of measurement results the patient-ID of the patient is shown. The lower part holds information on both the saved data of the patient (name, date of birth, time of measurement, operator) and details on the selected measurement, like type of test and measurement result.

A selected item can be printed by pressing the # key. If no printer is connected or the printer is not ready, an error message is displayed.

By navigating with the 2 und 8 keys individual measurement results can be selected for showing, printing or for deletion with ←.
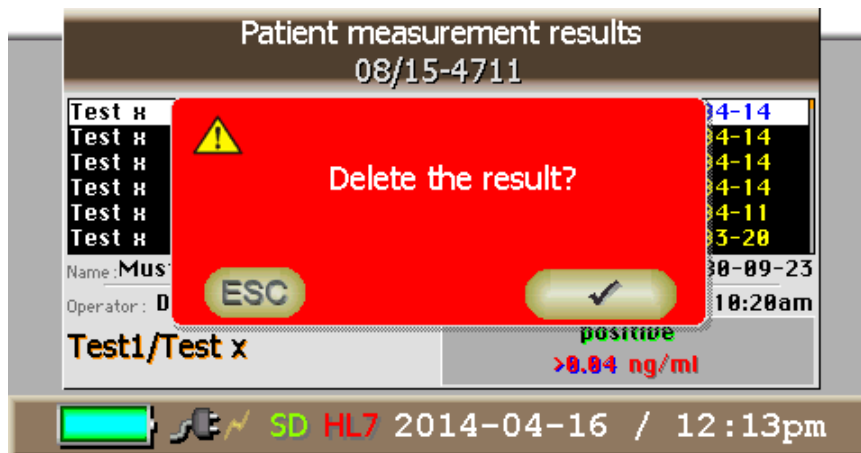
For faster navigation it is also possible to scroll through the list page by page with the keys 4 and 6. With Esc the screen returns to the patient data menu.

4.3 TEST

4.3.1 Test menu

The Test menu is shown in the following flow chart.

Flow Chart 3: Test menu

4.3.2   Measurement preparation

- For a fast test sequence the patient data should be created beforehand (see **section 4.2.2**) if they are not scanned from a barcode (optional).
- The appropriate SD card with the lot-specific data on the test (included in the test package) must be inserted in the device (
-
-

- Figure 7).

   ⚠   **Attention:** With every new test lot usually a new SD card with new calibration data is enclosed in delivery. Do not forget to dispose of the old SD card in order to avoid a mix-up of the cards.

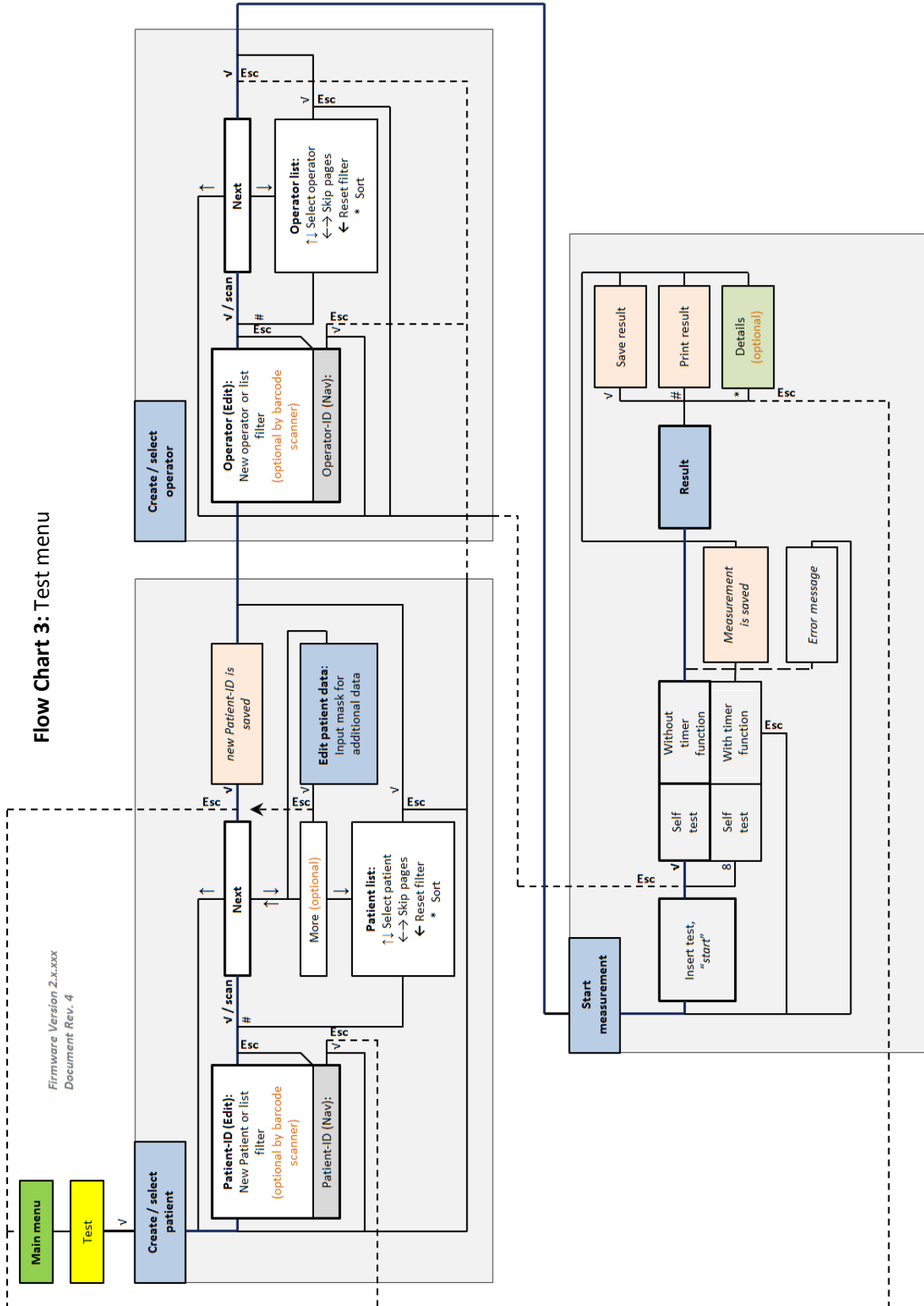- It is recommended to not run the test until all the important inputs and adjustments on the device are executed. Otherwise the prescribed specific incubation time of the test can be exceeded by accident which can lead to faulty results in the measurement. Concerning the test execution please regard the instruction sheet provided by the test manufacturer.

4.3.3   Select test

Please select the "TEST" option from the main menu. The "Test Selection" window (Figure 23) is displayed and the test can be selected with the √ key.

Figure 23: Select test

4.3.4   Select patient

After selecting "TEST" from the menu the window "create / select patient" (**figure 24**) appears. A new patient can be created here just by entering the patient-ID. More information on this patient can be added directly afterwards by choosing "more" or added later on in the "Patient data" menu (see **section 4.2.**). Data is entered by using the alphanumeric keypad. The input mode (upper-case

letters, lower-case letters or numerals) can be changed with * and is displayed in the upper right hand corner of the display window.
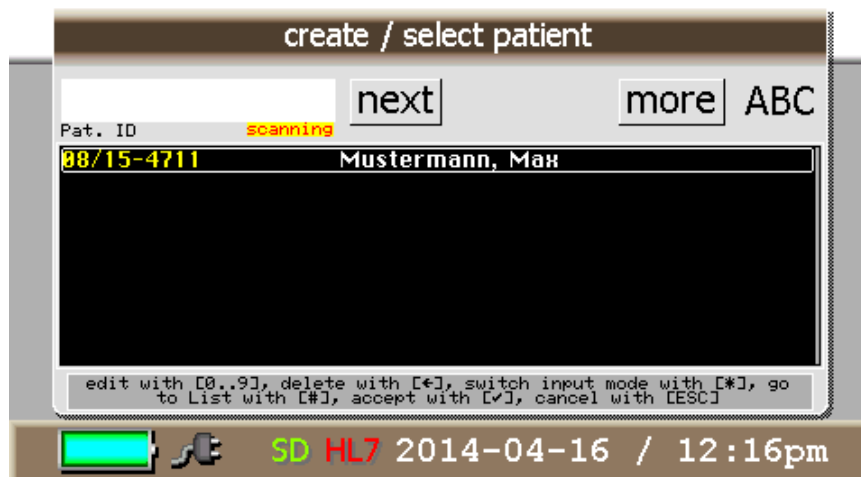

Figure 24: Select patient

Instead of creating a new patient it is also possible to choose an already existing one from the list in the lower half of the menu window. In order to do this the integrated filter function can be used. By entering the first letters or numbers of the favored patient's ID the list automatically shows only the applicable patients.

By pressing # the cursor goes to the list and one of the patients can be selected with √. In the list mode the filter can be reset with ← so that all stored patients are displayed again.

Even if the filter function is not used, the # key can be pressed to enable the list selection. It is possible to sort with * and to navigate up and down the list with 2 and 8. 4 and 6 can be used to switch whole pages of the list for faster navigation. To select a patient from the list press √ and then choose "next". To edit patient data of the selected patient choose "more".

Optionally there is an additional barcode scanner on the rear side of the reader available (cp. **Figure 3** above) which can be used to scan the patient information from a barcode instead of entering the data by hand. Thus the encoded information from the barcode is automatically entered into the device. In case there is a scanner integrated in the system it is activated as soon as the patient-ID input field is selected and the entry mode is active. This can be recognized by the blinking display "*scanning*" underneath the input field for the patient-ID. The barcode can be scanned without any further ado. If there is no barcode available or if the scanning function is not required the patient can be selected or created as described above.

4.3.5   Scan the barecode

Once the patient is selected, the test kit barcode containing the lot information should be scanned. The "scan barcode - test" window appears (Figure 25). This involves scanning the barcode supplied

with the test kit. At the back of the reader, the barcode scanner can directly scan this barcode which has two functions:

- It makes it possible to check the compatibility between the SD card and the nature of the test used.
- It identifies the batch of the test used.
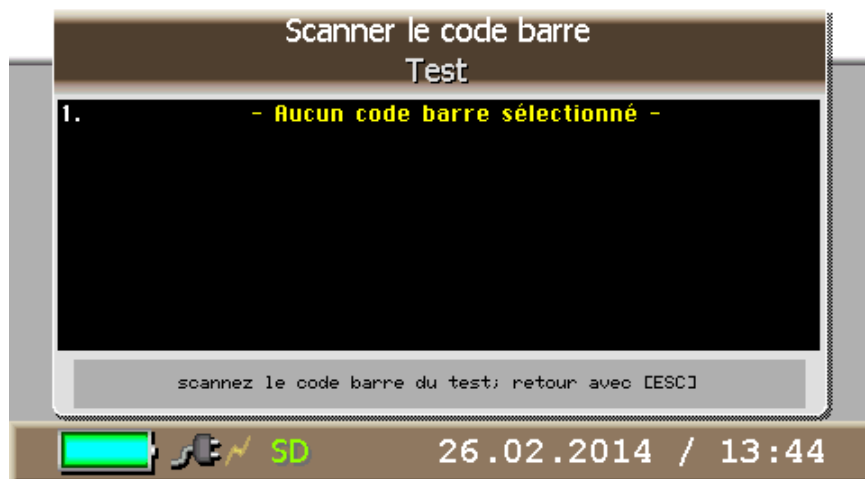
Figure 25: Scan the barecode

The data recorded in this barcode is then automatically entered into the reader. The barcode can be scanned without having to select other options

4.3.6   Create/select operator

After the patient is selected the window "create / select operator" appears on the display (**figure 26**).
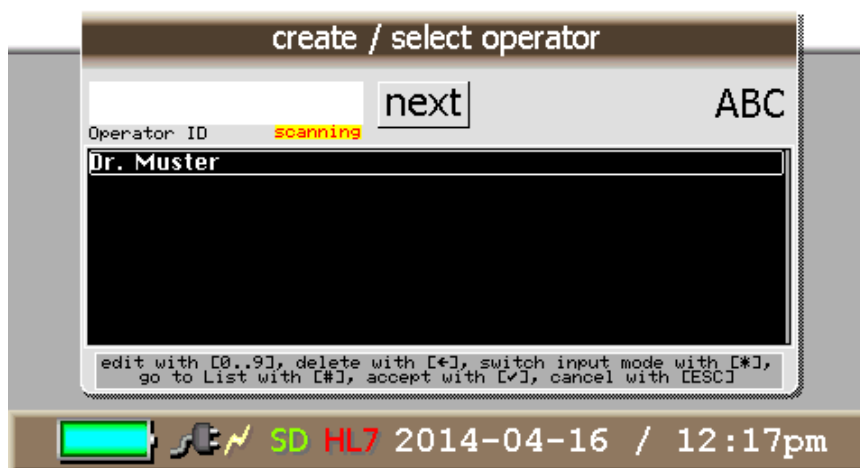
Figure 26: Create/select operator

A new operator can be created here by using the functions of the alphanumerical keypad. Alternatively it is also possible to select an already existing operator from the list (operators alphabetically sortable with *; ascending or descending order). Press # to switch from the input field to the list selection and use the filter function as described in **section 4.3.4**. The keys 2 and 8 can be used to navi-

gate up and down in the list as well as 4 and 6 can be used to skip through the pages for faster navigation.

The selected operator is marked in white and can be confirmed with √.

If the reader has an additional barcode scanner on the rear side (optional) the operator can be entered by scanning a corresponding barcode. The procedure is the same as the one for selecting a patient via barcode scanner which is described above.

⚠️ **Attention:** The manual creation of an operator without a measurement as well as the manual deletion of an operator is not possible! Measurement results have to be explicitly attributable to the accordant operator. Therefore an operator can only be created in the menu item "TEST" in correlation with a measurement.

To delete an operator all the measurement results stored under his name have to be deleted. When all the results are gone the operator disappears automatically from the list after the device has been switched off and on again.

After confirming the operator with √ the next window appears which prompts the user to insert the test cartridge and start the measurement (**figure 27**).
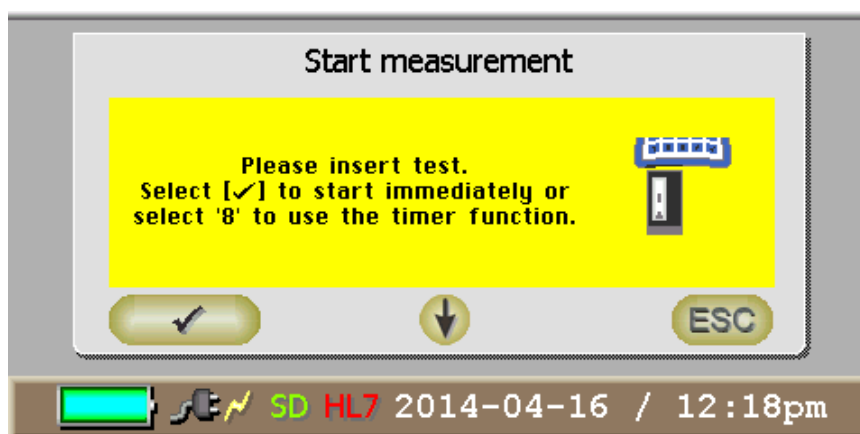

Figure 27: Start measurement

Advice:

In order to achieve an exact test result the samples should be applied to the test cartridge just before the measurement is started so the prescribed reaction time of the test doesn't get exceeded. Otherwise it is possible that the data input unintentionally prolongs the incubation time of the test.

4.3.7 Insertion of the test cartridge

Figure 28: Position of the test cartridge in the test cartridge adapter

After applying the test sample the test cartridge must be inserted into the test cartridge adapter. **Figure 28** shows the correct positioning. As a guideline there is a pictogram at the bottom right of every test cartridge adapter showing how the according cartridge should be positioned.

Note the following instructions before inserting the test cartridge:

- The sample (for example serum) must be applied to the sample well.
- The sample well must be pointing forward.
- The viewing panel must be on top.
- If a test cartridge with slide cover is used this must be pushed back from the viewing panel (snaps into place in the test cartridge adapter).

⚠ **Attention:** There are test cartridges without slide cover which are symmetrical. Therefore they can be put into the test cartridge adapter back to front. Please make sure the sample well is always pointing towards the operator and not into the device, as it is illustrated in the pictogram.

After that the test cartridge adapter is inserted into the well (**Figure 2**) until it snaps lightly into place.

4.3.8 Starting the measurement

After choosing the patient and the operator press the √ key to open the "Start measurement" window.
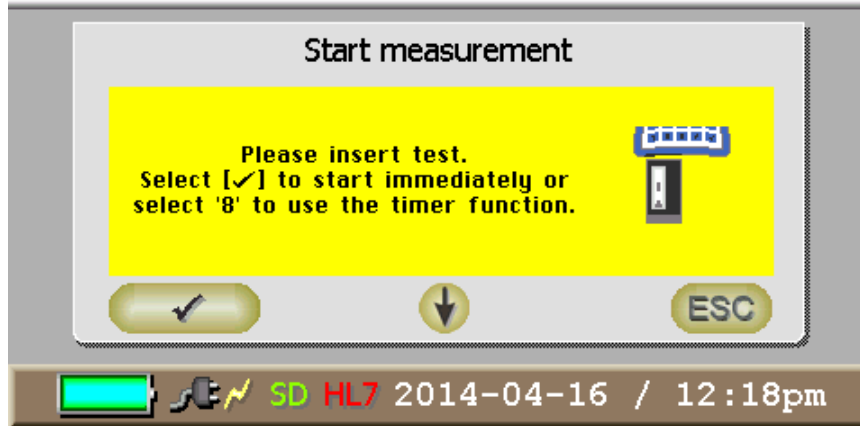
Figure 29: Start measurement

By now at the latest, the test cartridge must be inserted in the test cartridge adapter and the test cartridge adapter inserted all the way into the well of the device.

There are two possibilities for performing a test:

- **Instant measurement:** Press √ and the measurement starts immediately.
  Attention: This form of measurement engages the operator to manually time the test specific incubation time and start the measurement with √ not until the time is up. Otherwise the measurement results may be faulty. It is possible to interrupt the measurement with ESC, however the interruption is delayed. Without interruption the result is shown in the display after around 15 seconds (**figure 30**).

- **Measurement with timer function:** Press 8 to start the measurement after a test-specific incubation time configured in the test-specific data on the SD card, for instance after 15 minutes. The time period is displayed in the menu with a spinning hourglass and the remaining time. The measurement procedure can be interrupted by pressing ESC. After the configured time the measurement is taken and the result is shown (**figure 30**).

Before evaluating the actual measurement result an internal self-test is run by the device in order to check the current calibration quality of the reader. If there are unusually high deviations from the standard values deposited in the reader software a message is displayed. In this case it is not possible to output an authentic measurement result value. Please contact the manufacturer since a new calibration of the device is necessary to solve the problem.

If no measurement is possible for another reason, an according error message appears. Possible messages are (see also **section 6**):

- Test inserted incorrectly, if for instance the test cartridge adapter is not inserted all the way
- Barcode not read: (no barcode found)
- Control line not found

4.3.9 The measurement result

The measurement result is displayed as shown in **figure 30**.

Figure 30: Display measurement result

The display shows the patient data, the name of the test and the measured result value with units.

The measurement can be saved with √ and printed with #.

5 Printing

An optional printer is available for the device, which is connected directly to the reader as shown in **Figure 2** . The printer is detected by the device automatically. Press the # key to print a result right after a measurement or from the "Patient measurement results" menu if you want a printout. An exemplary printout is shown in **figure 31**.
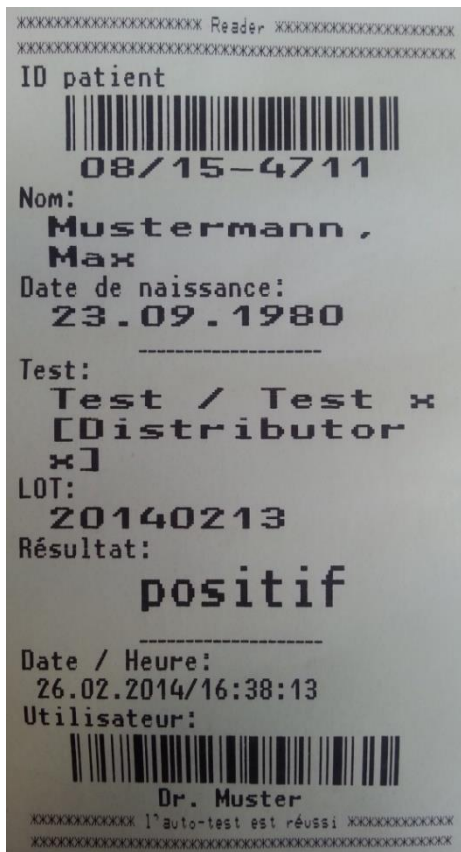
Figure 31: Exemplary printout

Continuous form paper is delivered with the printer. Self-adhesive stickers are also available as an option; please contact the manufacturer (see also **section 10**).

To insert or replace the printer roll, stick an index finger in the depression on the printer lid (see

Figure 5: Printer) and pull it back. Then the lid can be lifted and a new roll placed into the tray.

> ⚠️ **Attention:** The thermal paper of the printer roll can fade gradually (within several days or weeks in direct sunlight!) so the printout cannot be read anymore after some time. If the storage time is longer than 2 years it is recommended to copy the printouts before they fade.

6 Error messages

6.1 In general

During operation the device emits audio signals (beeps) which symbolize the current operating condition. For instance, a single beep occurs when the device is initialized, after a measurement or when the SD card is inserted or removed.

However the device can output more complex audio sequences if there is a serious error in the operating system that cannot be displayed in the display. These sequences consist of several audio signals output at short intervals and they represent an error code which can be interpreted by specialists to solve the problem. Please contact the manufacturer in such a case and arrange a remote diagnostics session by phone.

If the "Save Mode" error occurs (**figure 32**), the device has experienced an initialization error. The reader goes into a save operating mode in this case where an error diagnosis can be made if necessary. This error is very rare, but does occur occasionally. Usually it can be remedied by switching the device off and back on. If this does not solve the problem, please contact the manufacturer.
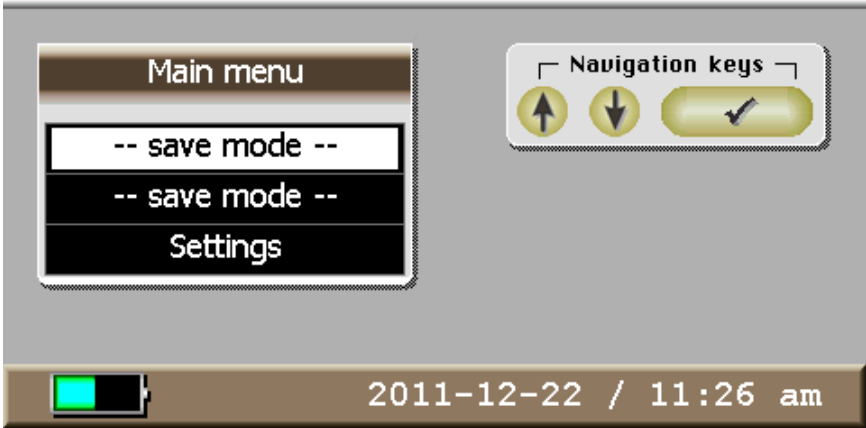
Figure 32: Save Mode Error

Some typical error messages caused by faulty handling and their according correction will be described in the following section.

6.2   Typical error messages
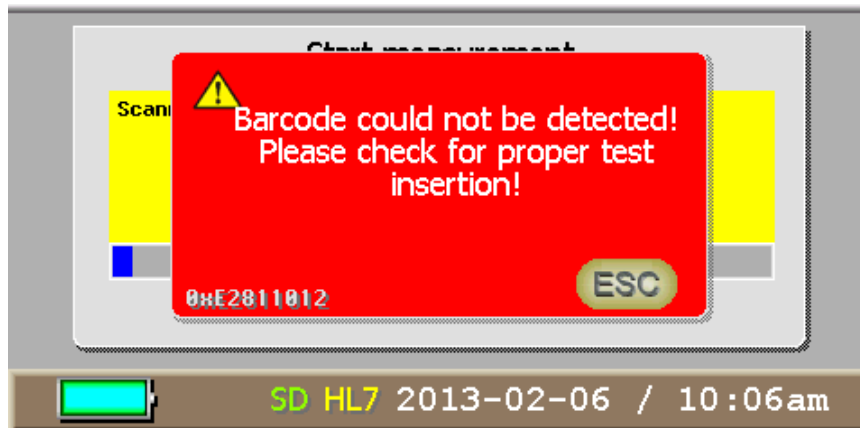
Figure 33: Barcode not detected

Possible reasons and correction:

- No barcode on the test → Check test

- Test not inserted correctly, barcode not readable → Check test

- Faulty barcode or scanner

   → Check with different test if problem still occurs

   → If yes, contact manufacturer if necessary

Figure 34: Configuration file not found

Possible reasons and correction:

- Configuration file belonging to the barcode/test is not on the SD card

   → Check SD card (SD card belonging to the test lot is required)
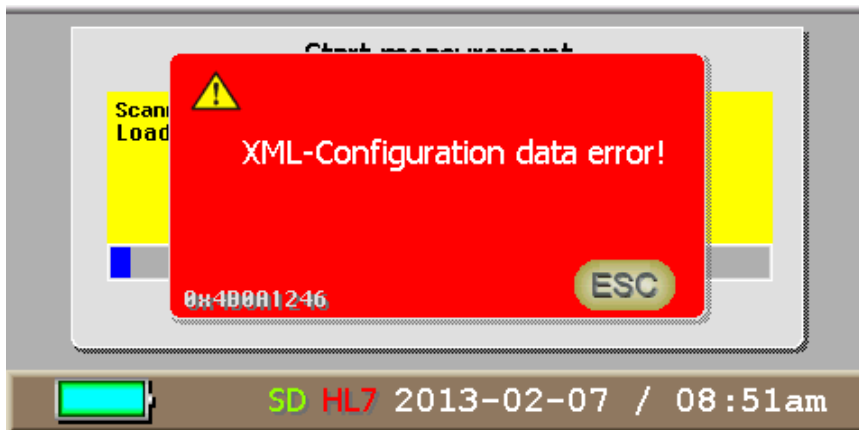
Figure 35: Configuration data error

Possible reasons and correction:

- Test specific configuration file found but faulty

    → Check file if possible

    → If not, request new SD card with intact file from test manufacturer

Figure 36: SD card not found

Possible reasons and correction:

- No SD card inserted in the device → Insert SD card
- SD card error, SD card not found → Remove SD card and insert again
- SD card defect → Request new SD card from test manufacturer
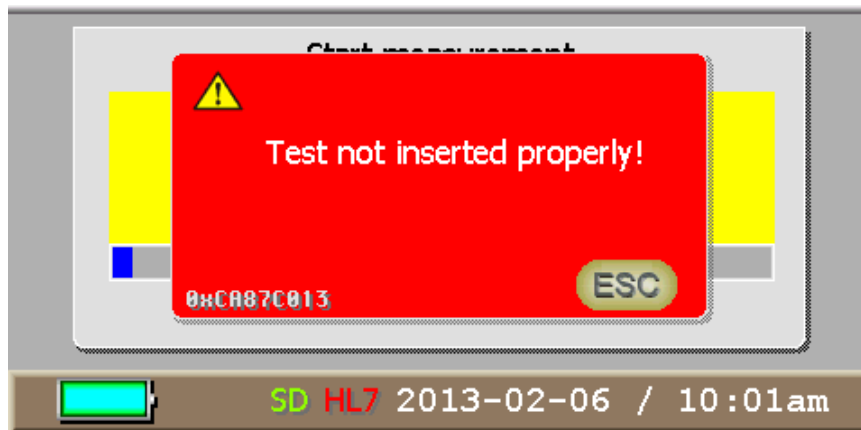
Figure 37: Test not inserted properly

Possible reasons and correction:

- Test cartridge adapter not inserted completely

→ Insert adapter completely until it snaps into place and start the measurement again
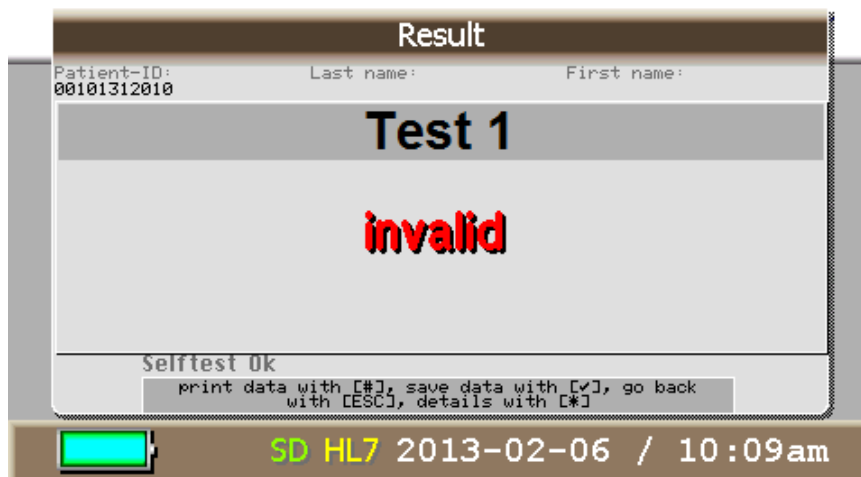
Figure 38: Test invalid

Possible reasons and correction:

- Test invalid because control line too weak

- Test did not run correctly → Check test for correct C-line, repeat test if required

- Test not conducted (no lines) → Run test before starting the measurement

7 Maintenance

7.1 Checking calibration

The device is calibrated upon delivery. It is recommended to have the calibration checked every other year and have the device re-calibrated if necessary. Please contact the manufacturer in this case because the device needs to be sent in for that (for transmittal see **section 8**)

7.2 Cleaning the well

On the back panel of the device (see

Figure 4) there is a cover for the well. The well and the optical unit are separated by a glass plate, which may have to be cleaned if the device becomes polluted with particles or is not used properly.

<u>Note:</u>
The cleaning of the optical parts according to the following description is recommended <u>twice a year</u> to guarantee a flawless performance of the device.

Proceed as follows to clean the well.

(39)

(38)
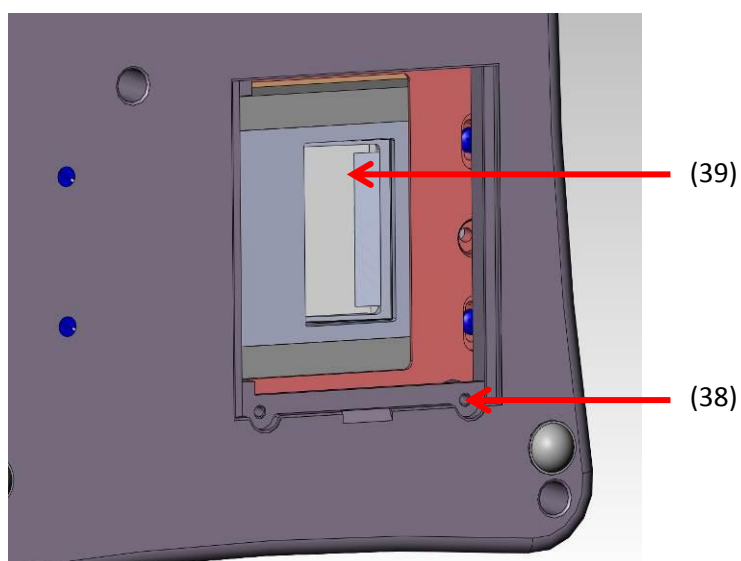
Figure 39: Underside of the device with open cover

- Remove the test cartridge adapter if it is inside the well.

- Loosen the screws (38) and remove the cover (**Figure**).

Figure 39 shows the well with the cover open. Also visible is the glass plate (39) at the end of the optical unit.

⚠ **Attention:** Please do <u>only</u> use the brush included in delivery (**Figure 1**) to clean this glass plate!

On the back of the cover there is a mirror mounted on a slope (optional if internal scanner is installed on the reader, **figure 40**).

Figure 40: Cover

This mirror is used to read the barcode on the back of the test cartridge with the internal barcode scanner. It may also have to be cleaned from time to time.

⚠ **Attention:** This mirror as well has to be cleaned only by using the brush included in delivery!

After cleaning, replace the cover and tighten the screws. Now the device is ready for operation again.

## 8	Transmittal of the device

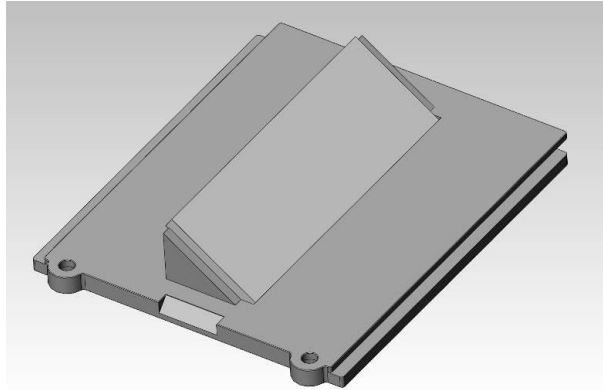In case of a defect it may be necessary to send the device back to the manufacturer. Due to contact with infectious material while using the device, disinfection is required to prevent infections or other contaminations.

For disinfection every surface of the device as well as the test cartridge adapter need to be cleaned with a suitable disinfection solution. That solution should be approved for medical devices and should not affect the device housing material. The disinfection spray *Mikrozid® AF Liquid* is for instance a suitable solution. Comparable products can also be used.

The customer has to give a receipt for the disinfection of the device. Therefor the form on the following page can be used.

Then the device has to be send to the manufacturer together with the signed form.

Please do not send the form within the device case, but for example with the shipping note so that it is directly available in the manufacturer's incoming goods department. The device case will not be opened until the disinfection receipt is on hand.

⚠ **Attention:** Please note that a transmitted device without a disinfection receipt cannot be accepted by the manufacturer and will be returned to the sender without being opened!

Disinfection Receipt

Attention: **A transmitted device won't be accepted by the manufacturer without this receipt! It will be returned to the sender without being opened!.**

Device type: *Biosynex Reader*

Reason for transmittal:

Customer/company:

Date of disinfection:

Disinfection operator:

The following device(s) was/were disinfected (Serial numbers):

The following disinfecting measures were executed on the above mentioned devices: (please checkmark):

☐   Cleaning of every surface of the device with paper tissue and disinfection solution suitable for medical devices
(for instance *Mikrozid® AF Liquid* or comparable product*)*

☐   Cleaning of both sides of the test cartridge adapter with paper tissue and disinfection solution suitable for medical devices
(for instance *Mikrozid® AF Liquid* or comparable product)

Place and date   Signature

9 Disposal of the device

During its operating time the device gets in contact with infectious material, for example blood. Therefore a used device can constitute a possible source of infection. Hence a disinfection using the according safety equipment is necessary before disposing of the device.

Dispose of the used reader according to the regulations obtained in your country after removing the batteries from inside. Please contact the manufacturer for instructions concerning the dismounting of the batteries. Manufacturer's contact information can be found at the end of this manual.

The device does not fall within the scope of the EG directive 202/96/EG (directive for old electronic devices).

10 Replacements

	Reference number
BIOSYNEX Reader	5060001
Printer stickers (self-adhesive)	5060002
Printer	01083
Power supply unit with cable	01086
USB cable	01087
Screwdriver	01088
Brush	01090
Quality control cassette	01084
Transport case	01091
Test cartridge adapter	01092

Specification

Users	Medical trained staff
Purpose	Quantification of *Lateral Flow Assays* Mobile and clinical usage
Measuring time	around 15 seconds per measurement
Timer function	Adjustable during calibration; default setting 15 min.
Dimensions	210mm x 130mm x 50/70mm (length x width x height)
Weight	800g
Display	4,3" TFT graphic color display
User interface	Flat-sheet keypad, 10 alphanumeric keys, 5 function keys
Power supply	Li-ion rechargeable batteries, mains adapter 100 - 240 V; 47 - 63 Hz; 0,6 A
Internal power supply	DC 5V
Power consumption	1,5A
Protection class	IP 20
Battery service life	> 8h
Interfaces	USB port D-sub socket for printer connection SD card slot LAN port (optional)
Memory capacity	Integrated Flash ROM >1.000 patient files
Language	German, English, French, Italian, Spanish, …
Barcode reader	Integrated: Plausibility test for identifying test lot and calibration Optional: additional scanner for scanning patient and operator IDs
LOT-specific calibration	via external SD card
Printer	optional
Ambient temperature	10°C … 35°C (during operation)
Ambient humidity	20 % … 85 % (during operation and storage)
Storage temperature	-30°C … 80°C
Storage quality control cassette	Storage in lightproof wrapping storage temperature 18°C … 22°C maximal relative Humidity 40 %
Shipment	Case with accessories

Distributeur and manufacturer information:

If there are questions or problems of any kind that cannot be solved with the aid of this manual, please contact your distributor

Contact person: BIOSYNEX S.A.

22 Boulevard Sébastien Brant   Tel: +33 (0)3 88 78 78 87

67400 Illkirch-Graffenstaden   Fax: +33 (0)3 88 77 90 68

FRANCE   Internet: www.biosynex.com

This product is manufactured and marketed by Optricon under the trade name opTrilyzer®

Manufacturer's information

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