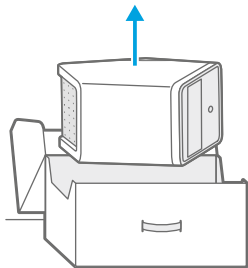# BOSCH

√ivalytic

Vivalytic

Instructions for use

Carefully read instructions for use

The user must consult and follow the instructions for use before using Vivalytic.
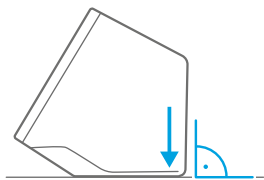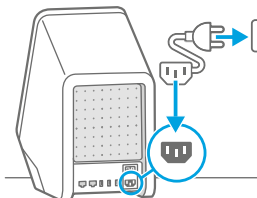
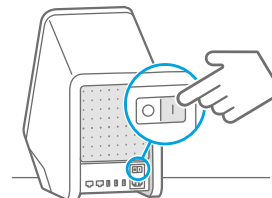## How to set up the analyser

① Unpack.

② Place on a **flat surface**.

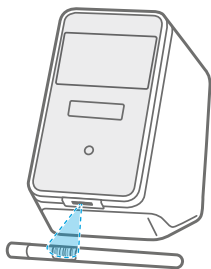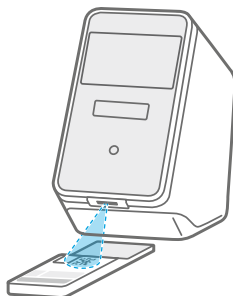③ **Connect** to a power source.

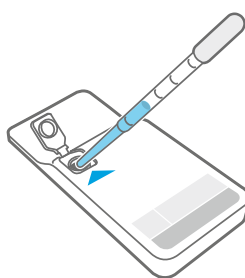④ Switch on.

How to perform a test

① Scan **sample** code.

② Scan **cartridge** code.

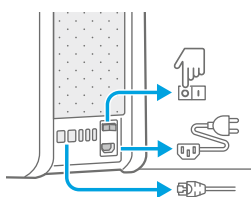③ **Insert** the sample and **close** cartridge lid.

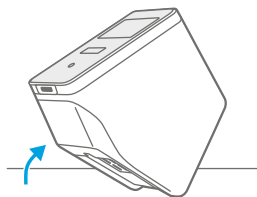④ **Insert** cartridge. The test **starts** automatically.

How to exchange the air filter

① Shutdown, turn off and unplug.

② Turn over.
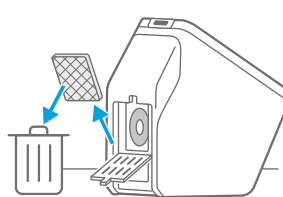
③ Remove used air filter.
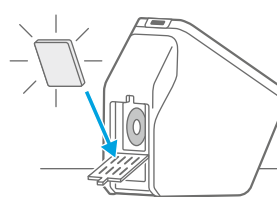
④ Insert new air filter.

Overview of functional parts

Analyser front

Analyser back

Analyser bottom

Cartridge
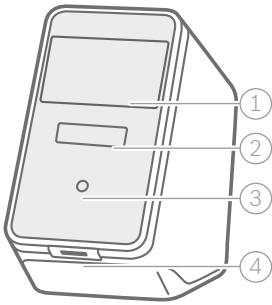
Analyser front
1. Touchscreen
2. Analyser slot with light bar
3. Front button
4. Scanner
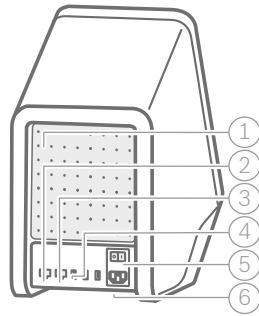
Analyser back
1. Air output
2. Ethernet 1
3. Ethernet 2
4. 3 x USB ports
5. Power switch
6. Power connection
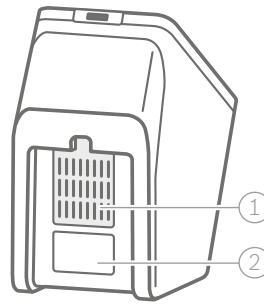
Analyser bottom
1. Air filter
2. Label with serial number
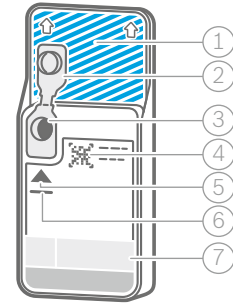
Cartridge
1. Detection area (do not touch or scratch!)
2. Lid
3. Sample input
4. Cartridge code
5. Sample volume
6. Expiry date
7. Test description

Overview of the icons

Symbol	Function
<	Left arrow Goes back one screen
>	Right arrow Goes forward one screen
+	Add
×	Close, cancel
(!)	Check notice
🔓🔒	Activate/deactivate user
💡	Watch introduction video
☰	Menu

Symbol	Function
✎	Edit
🗑	Delete
🔍	Search Opens window to enter search criteria
↑	Export
🖨	Print
🔑	Enable/disable passcode protection
⏻	Shutdown/standby
📄	Joblist

Overview of the user interface

Home screen
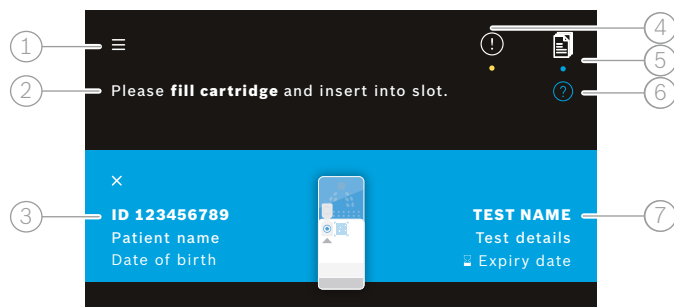
①	Menu
②	Information on what to do
③	Sample data
④	Notice
⑤	Joblist
⑥	Help
⑦	Test description

Analyser test screen
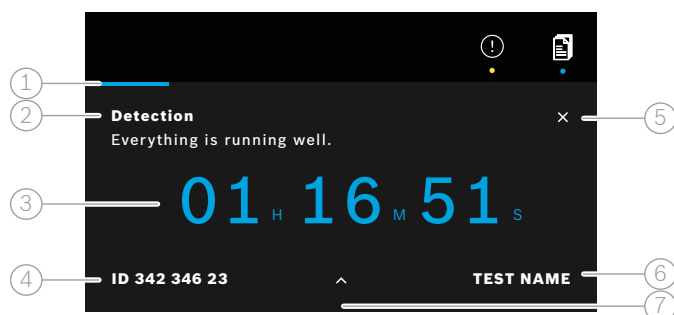
①	Progress bar
②	Test status information
③	Remaining test time
④	Sample data
⑤	Cancel test run
⑥	Test description
⑦	More detailed information

Analyser result overview screen
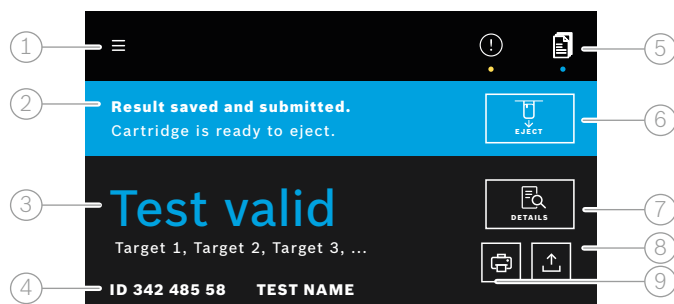
①	Menu
②	Status
③	Information about valid/invalid test
④	Sample data and test description
⑤	Joblist
⑥	Finish test run and eject cartridge
⑦	View details
⑧	Export
⑨	Print

Content

1 Initial information

1.1 Package contents

Prior to use, please check if all parts listed on this page are included and undamaged.

Bosch Vivalytic *one* analyser
(F 09G 300 061)

Ethernet cable
(F 09G 300 111)
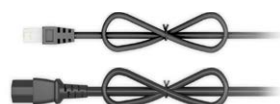
2 Power supply cables
(DE: F 09G 300 109)
(UK: F 09G 300 179)

Spare air filter
(F 09G 300 107)

Instructions for use
(F 09G 300 066)

i	• USB or flash drive not included. • Any changes or modifications made to Vivalytic that are not approved by the manufacturer will invalidate the warranty. • Please keep these instructions for use for future reference. • Make sure to use the correct and updated version of these instructions for use. To check, please visit www.bosch-vivalytic.com. • For more information about reordering of accessories please refer to chapter 8.1.

1.2 Before using Vivalytic

Welcome to Bosch Vivalytic.

Vivalytic consists of a universal analyser and application-specific cartridges. The cartridge is scanned, loaded with a sample and inserted into the analyser slot. The test then runs automatically. The results are presented to you at the end.

These instructions for use, together with the application-specific instructions for use, that come with each test will provide all the information needed to set up the system and perform a test.

Please consider the following notes before using Vivalytic:

• Only operate Vivalytic if you are a healthcare professional and trained on the analyser.
• Take enough time to read these instructions for use and the application-specific instructions for use.
  You must understand the functions, warnings, displays, and operations for safe and reliable use.
• Do not use the analyser or cartridges if you notice any damage.
• Use Vivalytic only as described in these instructions for use to assure performance and safety.
• Report any serious incident that has occurred in relation to the analyser to the manufacturer and the competent authority of the member state in which the user and/or the patient is established.
• Control, manage and update the analyser by using the Vivasuite-connectivity-solution at www.bosch-vivasuite.com.

If you require any support or have additional questions, please visit the Bosch Vivalytic website at www.bosch-vivalytic.com or contact your sales partner.

i	SN	Have the serial number available when contacting the customer service. The eight-digit serial number is located on the bottom of the analyser.
WARNING ⚠		Not following the instructions for use or improper handling can lead to malfunction, damage to the equipment and person, hazardous situations or incorrect results.

1.3 Device safety information

Please follow the instructions to ensure safe and reliable measurements. The results from Vivalytic should not be used as a sole parameter for a diagnosis or screening. Only operate Bosch Vivalytic after you have read and understood **these instructions for use** and the corresponding **application-specific instructions for use**. Not following the instructions may cause damage to the analyser and the disposable cartridge and can result in misleading measurement results.

WARNING ⚠	• **Do not** expose the analyser to **vibrations, shocks, hot surfaces** or strong electric or electromagnetic fields (see chapter 8). • **Do not disassemble** the analyser or its components or try to **repair** it yourself. Do not change the fuse by yourself. Any changes or modifications to Vivalytic that are not approved by the manufacturer will **impair safety**. • **Do not** attempt to **remove the cartridge** until it has been fully ejected. • **Do not turn off** the analyser **during a test**. • **Do not** attempt to open the door of the analyser slot manually. • **Do not** use under conditions with high humidity, extreme temperatures, direct sun radiation or high exposure to dust (see chapter 8).

1.4 Data security information

Bosch privacy statement: This product stores measurement data as well as user and patient information.

WARNING ⚠	• Data protection is under the responsibility of the organisation using Vivalytic. • Make sure to protect the analyser against unauthorised access. • Only use the analyser in a protected area. • Protect user name and passwords as well as network credentials. • Only use **trusted USB devices.** • Only use **trusted and protected networks.** • Note that data transfer via a network or to an external device (e.g.: printer, USB device, HIS/LIS) is unencrypted with the risk of unauthorised data access. • Delete the personal data on the analyser prior to disposal or service returns.

1.5 Cartridge safety and handling information

Only use Vivalytic application-specific cartridges and accessories approved for the analyser. Using other may produce incorrect results. For cartridge safety and handling information please refer to the application-specific instructions for use delivered in paper format in each packaging box.

1.6 Intended use

The Vivalytic application-specific cartridges contain quantitative or qualitative nucleic acid-based in vitro diagnostic tests intended for use with a Vivalytic analyser.

Vivalytic automates single and multiplex detection and identification of nucleic acids from bacteria, viruses, parasites or eukaryotic cells from different sample types.

2 Installation and setup

2.1 Installing the analyser
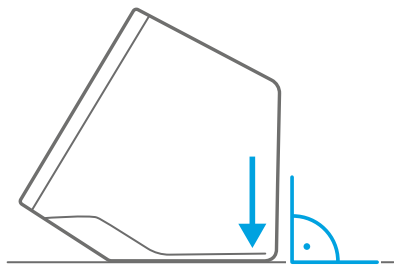
Carefully unpack the analyser from its box.

Place the analyser on a **flat surface**. Consider the operating conditions described in chapter 8.

Remove the adhesive film pulling upwards from the front of the analyser.

Connect to a power source.

Make sure to use the correct power supply cable for your country.

After plugging in, **switch on** using the **power switch** on the back.

The analyser will start up.

Please wait until onboarding **starts automatically**.

i	• The analyser is for indoor-use only. • Make sure that the power switch is accessible. • Make sure to leave sufficient space for adequate air circulation. • Do not grab or touch the scanner of the analyser.

2.2 Setting up the software – onboarding

When you start the analyser for the first time, you will be guided through a setup procedure.

Please follow the instructions displayed on the screen.
• Select the desired **language** by scrolling through the list of available languages.
• Continue to set the **date and time**.
• Afterwards set up an **administrator account**.
• Continue to set up a connection to **Vivasuite** for device management and software updates.
• At last press **finish** to **complete** the onboarding procedure.

2.3   User concept

User accounts protect patient data by controlling access to the system. When passcode protection is enabled, access is protected by a username and a numeric passcode. You can also use the analyser when passcode protection is disabled.

i	• Using the analyser without passcode protection is only recommended if you do not use patient records. • Every user has access to the analyser with his credentials regardless which user is logged in.

The analyser supports the following levels of user account:

	Administrator	Professional
Edit own account	✓	✓
Perform a test	✓	✓
Manage and print measurement data	✓	✓
Change display brightness	✓	✓
Change language, date and time	✓	
Edit or reset passcode for other accounts	✓	
Add/delete and activate/deactivate other accounts	✓	
Enable/disable passcode protection	✓	
Configure network	✓	
Configure order/result interface (HIS/LIS)	✓	
Set export configuration	✓	
Install and configure printers	✓	
Approve/schedule software updates	✓	
Passcode	8 digits	4 digits

2.4   Status of the analyser

The light bar and the front button indicate the current activity or status of the analyser.

Front button
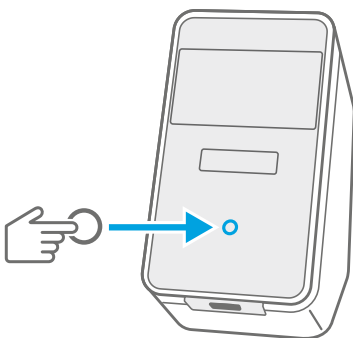
Press

to enter **standby** or **wake up**.

to **lock** the analyser during a test.

Light modes

On	Analyser is in standby mode.
Off	Analyser is on.
Dimmed	Analyser is in energy saving mode.

Light bar

Light modes

On	Cartridge is inside.
Blinking	Insert or remove the cartridge.
Pulsing	New test results are available.

> **i**
> • After **5 minutes** the screen is dimmed to **save energy**.
> • After **20 minutes** of inactivity the analyser automatically switches to **standby**

3 Performing a test

3.1 How to find application-specific instructions for use

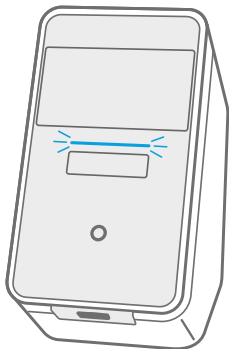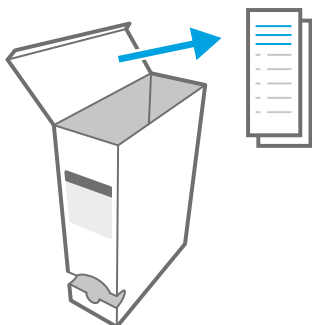The application-specific instructions for use for each test can be found in paper format in each packaging box.

Before you start to perform a test on the analyser, please make sure you have **read** and **understood** the **application-specific instructions for use** for the test you want to perform.

3.2 Login

If passcode protection is enabled, the analyser requires authentication before a test can be started.
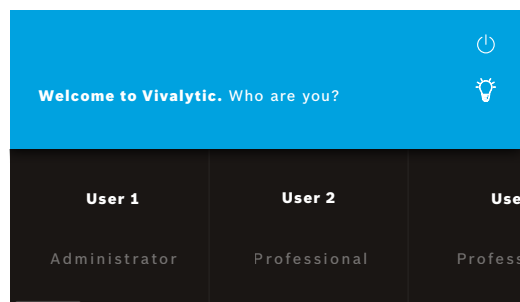
The welcome screen opens automatically when you turn on the analyser. A list of available users appears.

You can search for a username by scrolling left or right. Select your **user account** from the user list.

Enter your **passcode**:
• Professional account: 4 digits
• Administrator account: 8 digits

> **i**
> In case of a forgotten passcode, press **forgot** and follow the instructions displayed on the screen or go to chapter 6.6 for troubleshooting.

3.3 Starting a test

Scanning the sample

Place the **barcode** of the sample underneath the scanner.

A white light beam with a red dot indicates that scanning is in progress.

The sample data will be **displayed** on the screen.

✎ Alternatively press **edit** to enter the sample data manually.

i	• Please check **scanned ID** and **displayed ID** to ensure they match. • **Check** that no other test is running or check the estimated remaining test time **before opening** the cartridge pouch. • Sample data will be matched automatically when connected to an HIS/LIS. • Alternatively enter sample data manually**.**

Scanning the cartridge
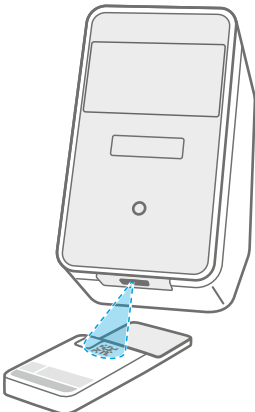
Place the **cartridge code (DMC)** underneath the scanner.

A white light beam with a red dot indicates that scanning is in progress.

The **test description** and further **data** will be displayed on the screen.

i	• When scanning the cartridge, the analyser will check the expiry date of the cartridge. It will only accept cartridges that have not expired. • If cartridge scanning fails, follow the instructions displayed on the screen.

Inserting the sample
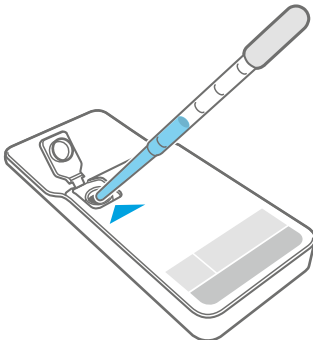
Place the cartridge on a flat surface.

Insert the **correct sample type** as described in the corresponding application-specific instructions for use.

The necessary **volume** is indicated on the cartridge label.

After inserting the sample, **close** the cartridge lid until it clicks.

WARNING	• **Do not** attempt to **reopen the cartridge** lid.
	• Insufficient or incorrect sample volume or sample types other than those recommended can lead to incorrect results.
	• You will find a detailed description of the recommended **sample types and volume** in the corresponding **application-specific instructions for use**.
	• Be careful not to contaminate the cartridge.

Inserting the cartridge
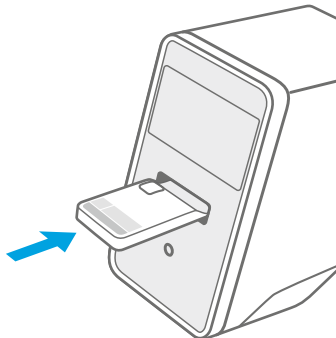
With the analyser slot open, **insert the closed cartridge** in the direction shown by the **arrow**.

The cartridge is drawn in and the **test starts automatically**.

i	Make sure to insert the same cartridge as scanned to avoid a mix-up.

WARNING	• **Do not** try to block the door of the analyser slot.
	• **Do not** reach into the analyser slot.

3.4 While running a test
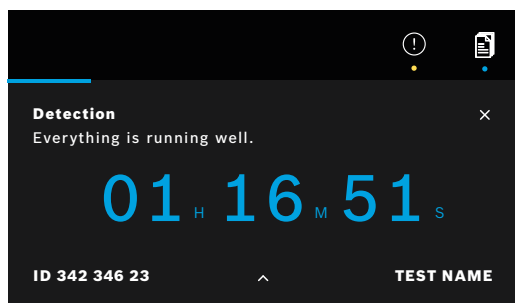
During a test the following information will be displayed:
• Current test status information
• Remaining test time
• Sample data
• Test description

⌃ Press to see further detailed information.

✕ Press to **cancel** the test run and confirm that you want to cancel.

i	• User can be switched during a test run.
	• Cancelled test runs also appear in the joblist.

3.5   Test result and test report

The results are displayed in three levels of detail: **overview, data list** and **illustrations**.

After execution of a test, the result **overview screen** appears. It shows if the **test is valid** or **invalid**.

Press **details** to view a **data list** which shows results for available targets:

- Positive: target(s) detected
- Negative: target(s) not detected

By pressing on the next tab, more information is visible. When a target is selected, the corresponding signal will be highlighted. The displayed images and curves are for illustration purpose only.

For further information about test results please refer to the application-specific instructions for use.

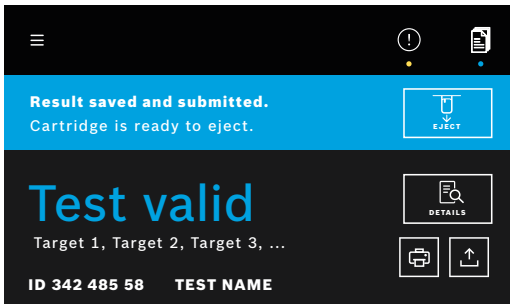↑ **Export** a **specific test** to save the test report in PDF format.

🖶 **Print** a test report of a **specific test** run.

The **test report** summarises the sample and test description, the results and illustrations of the test run, the user who started the test and information about the analyser and the cartridge.

ℹ		• The results should not be used as a sole parameter for a diagnosis or screening.
		• You can find **running, pending** and **done** test runs by pressing **joblist**. For further information, please see chapter 4.
		• If a test failed, check the notice and follow the given instructions.

3.6   Finishing a test
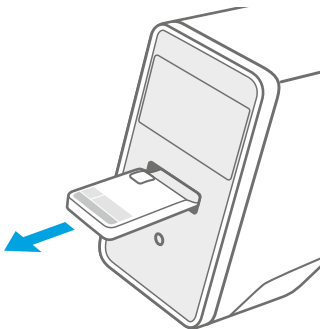
Close the **details** screen after checking the test results.

✕ Press **eject to eject the cartridge.**

The cartridge is ready to be **removed** and **disposed of**.

The **home** screen appears.

ℹ	Please be aware that potentially infectious material remains in the cartridge. It has to be disposed of according to regional and laboratory standards.

4 Data management and export

The **joblist** shows an overview of test runs stored on the analyser or in the queue.

Press **joblist** to view list of jobs.

Pending jobs available from a network infrastructure are shown, if connected.

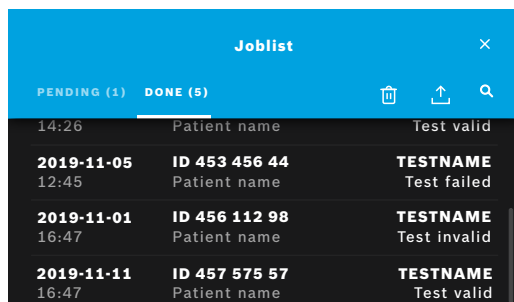**Done** tests can be viewed in the done tab. By selecting a test, detailed test information will be displayed. The results for the selected test run can be printed and exported (see also chapter 3.5).

Search for jobs.

Export all test data by pressing **export** on the joblist screen to save the test reports. To configure export location see chapter 5.5.

Delete data. Before deleting the data make sure that all test runs are exported.

WARNING	Deletion of data is permanent. Data cannot be recovered afterwards. Make sure that all test runs are exported.

i	• The results are automatically submitted to an HIS/LIS. See chapter 5.4 for how to connect the analyser. • On the home screen a blue dot underneath the joblist symbol indicates a new job entry. • Only done tests can be exported or deleted. • After 4 days a pending job will be deleted. • A notification is displayed if no more storage capacity is available.

5 Menu
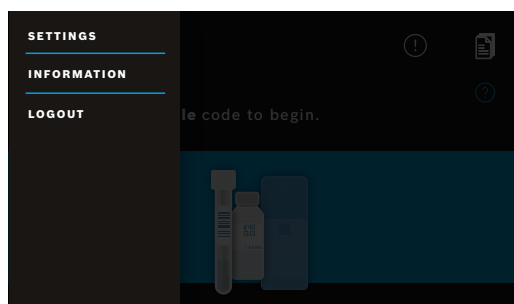
On the home screen, press **menu** to change settings, display information about the analyser or to log out.

5.1 Device settings

> ℹ The greyed-out items are only accessible when logged in as an administrator.

☰ In the **menu**, select **settings**, then select **device settings**.

Select **display** and set the desired brightness by moving the slider.

Select **language** and choose the desired language from the list.

Select **date and time** to change the date and time of the analyser. Select "**>>**" to continue.

5.2 User accounts and passcode

> ℹ The greyed-out items are only accessible when logged in as an administrator.

☰ In the **menu,** select **settings** then select **user accounts**.

A list of registered users appears.

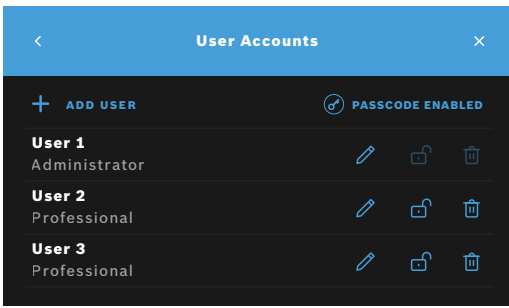| <	User Accounts	×
+ ADD USER	⊘ PASSCODE ENABLED	
User 1 Administrator	✎ 🔓 🗑
User 2 Professional	✎ 🔓 🗑
User 3 Professional	✎ 🔓 🗑

✎ Press **edit** to change name and/or passcode for the selected account.

🔓🔒 **Activate** or **deactivate** an account.

🗑 Press to **delete** an account.

+ Press **add user** to create a new account. Select the **type of account**:
  • Administrator
  • Professional

Afterwards type in a **username** and a **numeric passcode**.

⊘ **Enable** or **disable** passcode protection for professional accounts.

> ℹ
> • Only an administrator user can edit, activate/deactivate or delete the account of another user. Professional users can only edit their own account.
> • At least one administrator account must exist.
> • When passcode protection is enabled, access is protected by a username and a numeric passcode. A passcode is required to access an administrator account, even if passcode protection is disabled.
> • Deactivated accounts cannot be logged in until they have been activated again.
> • The passcode consists of 8 digits for an administrator account and 4 digits for a professional account.

5.3 Network configuration

A local area network can be configured to establish a connection to a HIS/LIS-System or Vivasuite. The analyser supports two types of network connection:

• Ethernet
  Make sure the **Ethernet cable** is connected to an **Ethernet port** at the back of the analyser.
• Wireless LAN (WLAN)

> ℹ Log in as an **administrator** for access.

☰ In the **menu**, select **settings**, select **network/interfaces**, then select **network configuration**.

To configure or set up a new Ethernet connection:

Select **configure network**:

As network type select **Ethernet 1**.

Select **DHCP enabled** to support dynamic host configuration protocol from the network.

Select **DHCP disabled** to set the following components manually:
- Internet protocol address (IP address)
- Subnet mask
- Gateway

Please follow the instructions displayed on the screen.

To configure or set up a new WLAN connection:

Select **configure network**:

As network type select **WLAN**.

Select **DHCP enabled** to support dynamic host configuration protocol of your network.

Select **DHCP disabled** to set the following components manually:
- Internet protocol address (IP address)
- Subnet mask
- Gateway

Please follow the instructions displayed on the screen.

If necessary a **proxy** can be configured.

To view the current configuration, select show network configuration.

5.4 Configuration of order/result interface (HIS/LIS)

The analyser exchanges information with hospital and laboratory information systems (HIS/LIS), if connected. It receives orders from the system and uploads results.

i	Log in as an **administrator** for access.

☰ In the **menu**, select **settings**, select **network/interfaces**, then select **order/result interface**.

To configure or set up a new order/result interface to HIS/LIS:

Select **configure interface**:

The following components have to be set manually:
- Inbox Location
- Outbox Location
- Username
- Password

Follow the instructions displayed on the screen.

To view the current configuration, select show interface configuration.

i	The network must be connected to set up an HIS/LIS configuration.

English

5.5 Configuration of data export to USB or network drive

$\boxed{\mathbf{i}}$	Log in as an **administrator** for access.

In the **menu**, select **settings**, select **network/interfaces**, then select **export configuration**.

To configure or set up a new USB location:

Select **configure export**:

As export location select **USB** and make sure a USB drive is inserted.

Follow the instructions displayed on the screen.

To configure or set up a new network location:

Select **configure export**:

As export location select **network**. The following components have to be set manually:
- Location
- Username
- Password

Follow the instructions displayed on the screen.

To view the current configuration, select show export configuration.

5.6 Printer configuration

$\boxed{\mathbf{i}}$	Log in as an **administrator** for access.

In the **menu**, select **settings** then select **printer configuration**.

To configure an existing printer as standard printer:

Select **configure printer**:

A list of configured printers will be displayed.

To set a **standard** printer, mark it in the list

To remove a printer from the list, press **delete**

To configure a new printer:

Press **add printer** and select the desired **printer interface**:
- USB
- Network
- Shared

A list of available printers for the selected interface will be displayed. Select the desired printer or URL.

Follow the instructions displayed on the screen.

To view the current configuration, select show printer configuration.

$\boxed{\mathbf{i}}$	Printer must be selected and switched on.

5.7 Software update

i	• You will receive a notification about available software updates on the analyser and also through Vivasuite, provided the analyser is connected. Otherwise contact your sales partner if you want to conduct a software update. • Check which tests are supported by the installed software revision in the system information.

5.8 Factory reset

i	Log in as an **administrator** for access.

☰ In the **menu,** select **settings** then select **factory reset**.

Follow the instructions displayed on the screen.

i	The factory reset will delete all user and patient data and clear the settings.

5.9 System information

☰ In the **menu** select **information**.

The following information will be displayed:
• Select **customer service** to find more information about customer service.
• **Hardware revision**
• **Software revision**
• **Kernel revision**
• **Firmware revision**
• **IP address**
• Select **Open Source Software (OSS)** to find information about the Open Source components used in this product.
• Select **OSS Written Offer** to find how you can obtain the Open Source components you are entitled to.
• Select **License Terms for End Users** to find information about license terms and included Java Programs.
• Select **Software Update** to see new available software updates.

6 Maintenance and troubleshooting

6.1 Shutting down the analyser

If you need to disconnect the analyser from the power source for maintenance or transport, you will need to shut down and turn off the analyser.
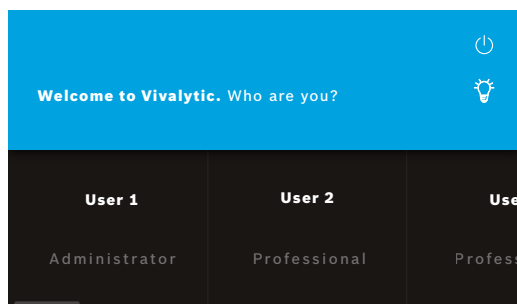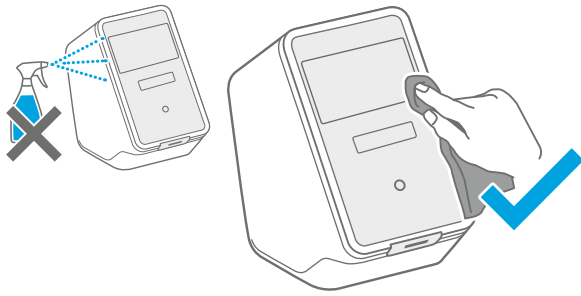

For shutdown you need to **log out**.

Press **shutdown** and confirm that you want to shut down.

⏻ Wait for the system to shut down. When the screen turns black, use the **power switch** on the back to turn the analyser off.

6.2 Cleaning and disinfecting the analyser

Shut down and **disconnect** the analyser from the power supply.

To **clean** wipe the surface of the analyser with a **cleaning tissue**.

For surface disinfection use a tissue soaked in **70% ethanol/propanol-based** cleaning agent. If necessary, **use DNAExitus**.

Only clean and disinfect the analyser on its exterior surfaces and carefully wipe around openings.

|	
i	• Clean the analyser including the scanner regularly. • Disconnect the analyser from the power supply for cleaning.

6.3 Changing the air filter of the analyser

In order to ensure proper performance please make sure to replace the air filter of the analyser **every 6 months.** The flap is part of the analyser. Make sure to close it after changing the air filter. Dispose of used air filters according to regional and laboratory standards.
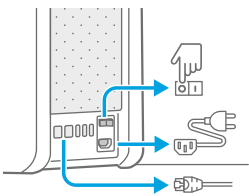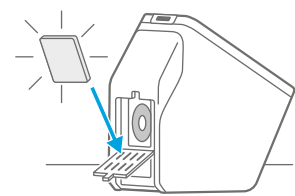
Shut down and turn the analyser **off** and **unplug** all connections on the **back**.
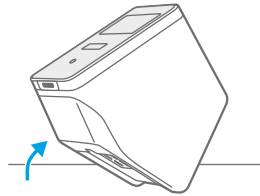
Grasp the analyser with both hands and **turn** it **over** its rearmost corner until it is resting on its back.
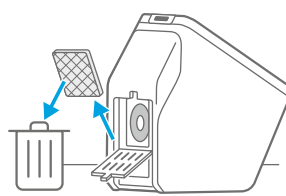
**Open** the flap on the analyser **bottom** and **remove** the used air filter.

Insert a new air filter into the flap with the soft surface side facing towards the interior of the analyser. Afterwards **close** the flap.

6.4 Quality control testing

It is strongly recommended to perform quality control testing regularly. For information about recommended procedures please refer to the application-specific instructions for use.

6.5 Notice and error
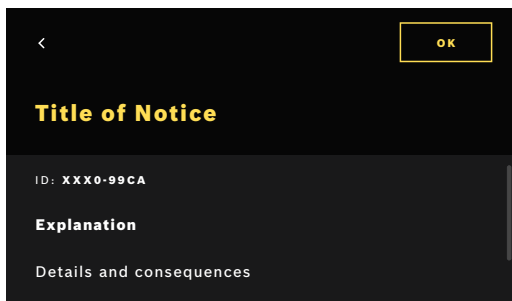
A **yellow dot** underneath the notice symbol indicates a new entry. **Press** to open the list.

By selecting a notice further information will be displayed. Read the explanation carefully.

Press to go **back**. The notice **remains** in the list.

Press **ok** to close the notice and it will be **deleted** from the list.

i	If an **error** is detected an error screen appears and the analyser is blocked. In case of error, please **contact customer service** (for contact information see chapter 1.2).

6.6 Troubleshooting

ℹ	For troubleshooting also see the information displayed on the screen.

Description	Solution
The analyser does not turn on.	Check the connection to the power source. Check if the cable is correctly plugged into the analyser and the plug socket. Try turning the power switch off and on again. Check if the power switch is turned on ⊡.
The screen does not turn on.	Check if the analyser is in standby (front button illuminated). Press the front button to wake up. Check the connection to the power source. Check if the cable is correctly plugged into the analyser and the plug socket. Try turning the power switch off and on again. Check if the power switch is turned on ⊡.
The analyser turned off during a test.	Check if the analyser is in standby (front button illuminated). Press the front button to wake up. Check if the power is in on mode. If not, try turning the power switch off and on again. Make sure the cable is not damaged and is plugged into both the analyser and the plug socket. If you cannot see any visible damage or a wrongly plugged-in cable, do not change anything on the analyser and contact customer service (see chapter 1.2).
Scanning the sample code is unsuccessful.	Make sure that the scanner is working and consider information displayed on the screen. Make sure the scanner of the analyser is capturing the sample code and check the distance between the scanner and the sample code. Vary the distance between code and scanner, hold the code closer and further away. Check if the scanner is blocked or dirty. If necessary clean it as described in chapter 6.2. The red light has to shine on the code. Make sure the code is not damaged. Make sure to use a sample with a code. If it cannot be read, type in the sample information manually.
Scanning the cartridge is unsuccessful.	Make sure that the scanner is working and consider information displayed on the screen. Make sure the scanner of the analyser is capturing the cartridge code and check the distance between the scanner and the cartridge code. Vary the distance between code and scanner, hold the code closer and further away. Check if the scanner is blocked or dirty. If necessary clean it as described in chapter 6.2. The red light has to shine on the cartridge code. Make sure the catridge code is not damaged or covered. If the cartridge code cannot be read, the user has the possibility to continue without scanning. Make sure the right cartridge for the test is used and that the cartridge is not expired.
The sample tube has no code.	Type in sample information manually, see chapter 3.3.
Network connection failure (Ethernet)	Check if the Ethernet cable is connected to the designated Ethernet port as the same for the configuration. Make sure if this Ethernet port is selected in the network configurations as described in chapter 5.3. Check the cable connection and LAN configuration. Check if the network is available and accessible.

English

Description	Solution
Network connection failure (WLAN)	Check the configured settings of the analyser and WLAN-Access point that you want to connect with. Check if the network is available and accessible. Check if reception is sufficient.
HIS or LIS (order/result interface) connection fail	Check if network connection is established and configured. Check if inbox and outbox locations are existing and available.
Export failed to network location	Check if network location is established and available. Check username and password. Try to use the prefix smb:// for the location path. Try to end the location path with slash /.
Export failed to USB location	Check if USB drive is connected correctly. Check if USB drive is compatible with USB 2.0 and file system FAT32. Check that USB drive has sufficient memory. Check that USB drive is not write protected.
Printing failure	Check if a printer is configured. Check if the printer is switched on and available. Check the USB connection in case of an USB printer. Check if the printer and its connection is established and available in case of network or shared printer.
Communication test is negative for order/result or export configuration	Check the settings of the export or order/result interface configuration and go to the troubleshooting points network connection failure, HIS or LIS (order/result interface) connection failure or export failure.
Memory full	Export all data on an external backup device. Make sure that the data was exported correctly and afterwards delete all data. Please refer to chapter 4 on how to export and delete all data.
Forgotten passcode	In case of a forgotten passcode press forgot. Professional users need to ask an administrator user to set a new passcode. Administrator users need to ask another administrator user to set a new passcode. If no other administrator user exists, please contact your sales partner or customer service. Press continue to return to the welcome screen showing the user list.
No access/ deactivated professional account	Contact an administrator user. An administrator can activate accounts as described in chapter 2.3.

7   Disposing of the analyser

For disposal, please separate this analyser from other waste to prevent possible harm to the environment or human health due to uncontrolled waste disposal. Submit the analyser for recycling in order to promote the sustainable reuse of material resources (in compliance with EU directive 2012/19/EU). The used or expired measuring unit should be recycled in compliance with the local recycling program for electronic equipment.

i	• Delete all the data on the analyser prior to disposal and disconnect the analyser from any other devices or networks. Make sure that there are no cartridges inside the analyser. Afterwards contact customer service. • Please follow regional and laboratory standards when disposing of an analyser or its packaging.

8   Technical data

Description	Value	Description	Value
Model	Vivalytic *one*	Dimensions	400 mm x 204 mm x 388 mm
Catalogue number	F 09G 300 115	Weight	15 kg
Display	7 inch 16:10, 1024 x 600 pixel touchscreen	Storage humidity	20–95% (not condensing)
Operating air pressure range	850–1,100 hPa, corresponds to 0–1,400 m above sea level	Operating humidity	30–80% (not condensing)
Operating temperature	15–30 °C	Electrical data	100–240 V~, 50/60 Hz, 160 VA
Storage temperature	-20–60 °C	Instrumental safety	IEC/EN 61010-1 IEC/EN 61010-2-010 IEC/EN 61010-2-101 Directive 98/79/EC
Data transfer	Ethernet 10/100MB, WiFi 2.4 GHz (802.11b/g/n); internal: Bluetooth v4.1, 2.4 GHz (low energy), USB 2.0	Memory capacity	16 GB
Electromagnetic compatibility	IEC/EN 61326-2-6 RED 2014/53/EC FCC47 CFR 15	Mean Loudness	≤ 55 dB(A) in operating mode. Short term loudness can exceed mean loudness.

This analyser is classified as laser class 1.

8.1   Compliant cables and accessories

i	Only use the cables and accessories provided by the manufacturer.

To reorder cartridges or accessories like power supply cable, Ethernet cable, air filter or instruction for use please contact your local sales partner.

8.2   Warranty

The statutory provisions on warranty rights in consumer goods sales in the country of purchase shall apply.

English

9   Symbols and abbreviations

Symbol	Description	Symbol	Description
	Temperature limit		NRTL certification
	Do not stack	SN	Serial number
	Manufacturer	REF	Reference number
CE	The IVD product meets the requirements of applicable European directives.	LOT	Batch code
	Consult instructions for use	IVD	In vitro diagnostic medical device
	Caution		Keep dry
	Warning to avoid a hazard	i	Information
	Do not use if package is damaged		WEEE - separate collection for EEE
	Use-by date (YYYY-MM-DD)		Date of manufacture (YYYY-MM-DD)
	This way up		Do no re-use
	Contains sufficient for <n> tests		Fragile, handle with care
	Fuse		Ethernet
	Liquid sample		USB
	On		Off
	Der Grüne Punkt		Bluetooth® compatible

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	FSC® Certification. Packaging board from responsible sources.		
	Simply.Connected		
	Supply voltage		iF DESIGN AWARD 2018
	Red Dot Award 2018		

 Instructions for use

Value/ abbreviations	Description	Value/ abbreviations	Description
DHCP	Dynamic host configuration protocol	LAN	Local area network
DMC	Data matrix code	LIS	Laboratory information system
EEE	Electric and electronic equipment	NRTL	Nationally Recognized Test Laboratory
EU	European Union	PCR	Polymerase chain reaction
FAT	File allocation table	PDF	Portable document format
FCC ID	Federal Communications Commissions ID	SSID	Service Set ID
FSC	Forest Stewardship Council	µl	Microlitre
ID	Identity/ Identifier	URL	Uniform resource locator
HIS	Hospital information system	USB	Universal serial bus
IP	Internet protocol	WEEE	Waste of electric and electronic equipment
IVD	In vitro diagnostic	WLAN	Wireless local area network

10 Appendix

10.1 Electromagnetic compatibility

Hereby, Bosch Healthcare Solutions GmbH declares that the radio equipment type Vivalytic one is in compliance with Directive 2014/53/EU. The full text of the EU declaration of conformity is available at the following Internet address: www.bosch-vivalytic.com

10.2 Licence terms of end users

 Please refer to www.bosch-vivalytic.com for more information about the Licence terms of end users.

11 Manufacturer

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