



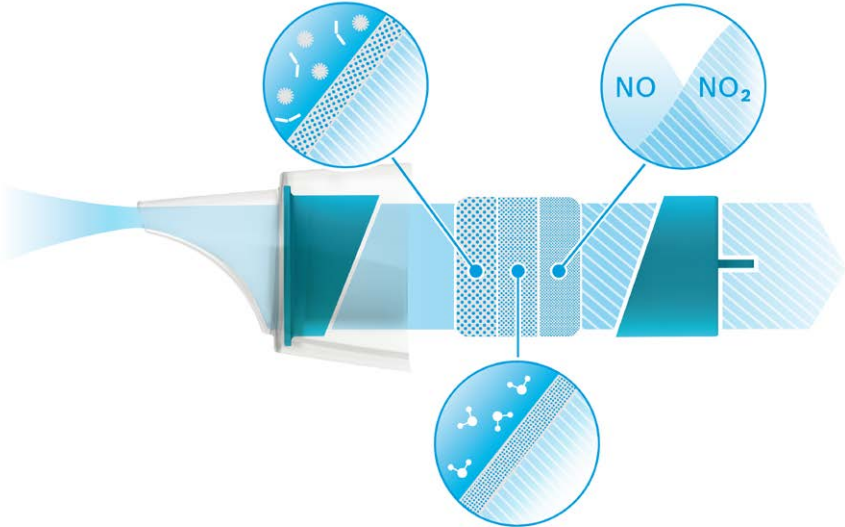
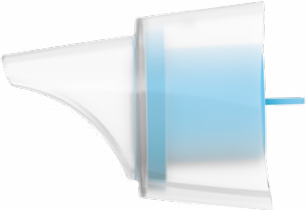
BOSCH



vivatmo
pro

Instructions for use

Vivatmo Oxycap



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1 Initial information

1.1 Package contents

- Vivatmo *pro* basestation (F09G100246)
- Breath analyzer (Vivatmo *pro* handheld device) (F09G100078)
- Instructions for use (F09G100176 Western Europe; F09G100548 Eastern Europe; F09G100552 Asia)
- Power supply unit with connectors
- Rechargeable lithium-ion battery (F09G100314)



INFORMATION

Keep these **Instructions for use** for future reference. For frequent used functions see chapter 3, 4, 5, 7 and 8. For Administration instructions see specific manual at www.vivatmo-hcp.com/en/service-and-support/downloads/. Hereafter, referenced "Vivatmo *pro*" covers all variants, including e. g. "Vivatmo *pro* Asia".

1.2 Before using Vivatmo pro

Welcome to Vivatmo pro, the measurement system to support a monitoring of respiratory diseases.

Please consider the following before using Vivatmo pro:

- Take enough time to carefully read the instructions for use before using the measurement system. You must understand the functions, warnings, displays, and operations for a safe and reliable use.
- Inspect the basestation, the handheld, the disposable mouthpiece and the mouthpiece pouch before use. If you notice any damage do not use the device or accessories.

WARNING	Do not use any defective devices or accessories to avoid malfunction or hazardous situations.
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If you need any support or have additional questions including information about data privacy, please contact your distribution partner or visit the Bosch Vivatmo website at www.vivatmo-hcp.com/en/.

INFORMATION	Have your serial number of your handheld or your basestation available when you contact the service center. You find the twelve digit code on your Vivatmo pro handheld, next to the symbol SN at the bottom of the device.
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Bosch privacy statement: This product stores the measurement data and personal information of patients.

1.3 Safety information

WARNING

The following conditions can cause malfunction or disturbance to the Vivatmo *pro* and the disposable mouthpiece:

- High humidity, extreme temperature (– “9.1 Device data”).
- Direct sun radiation or high exposure to dust or volatile substances, e.g. disinfectants or nail polish remover.
- Places that are subject to vibration or shock, or near hot surfaces.
- Rooms with open flames, gas range, smoke, or tobacco consumption.
- Adjacent or stacked use close to other systems. If adjacent or stacked use is necessary, observe normal operation of the Vivatmo *pro*.
- Use of mobile phones and other devices even if compliant with CISPR emission requirements.
- Ingress of moisture or liquid.
- Immerse the device or disposable mouthpiece into water or other liquids.
- More than 10 hours nonstop usage with a frequency above 10 measurement trials/hour.

Use the device for a maximum of 10 hours nonstop and allow a break of 10 hours before restarting to avoid system overload.

When you disconnect the device from the power line, first remove the plug from the wall outlet, then disconnect the cable from the device to avoid contact to line voltage.

WARNING

The assembly of Vivatmo *pro* and modifications during the actual service life require evaluation to the requirements of the applied standard. Only connect printers and computers that comply with EN 60950-1, EN 60601-1 or EN 61010-1 standards, or that bear the UL or CSA mark. Connect ethernet port only to networks with galvanic isolation certified to EN 60601-1 or use an external network isolator certified to EN 61010-1. Modifications of the system can lead to endangerments and result in the warranty becoming invalid.

Data security and protection

- Vivatmo *pro* shall not be used in unprotected networks or work environments. Data protection is under the responsibility of the organization using Vivatmo *pro* and can be supported by the use of credentials on your network. When printing to a network printer in the local area network, consider that data is transmitted unencrypted with the risk of unprotected access to patient data by somebody who managed it to intercept the network connection.
- Setup, changes and reconfigurations to the network or connected devices is under the responsibility of the organization using the system and might introduce new risks.
- Delete personal data on the basestation and handheld prior to disposal or service returns.

INFORMATION

Bluetooth is activated as long as the basestation is power supplied.

Notice to Users in EU: Any serious incident that has occurred in relation to the device, should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

1.4 Intended use/Indications for use

The Bosch Vivatmo *pro* system is intended for quantitative measurement of fractional nitric oxide (FeNO) in human breath.

Measurement of changes in the fractional nitric oxide concentration in expired breath aids in evaluating a patient's response to anti-inflammatory therapy, as an adjunct to establish clinical and laboratory assessments of inflammatory processes such as asthma.

The Bosch Vivatmo *pro* system is an automated non-invasive measuring device intended to be used in healthcare environment (*in vitro* diagnostic use) by healthcare professional users only.

The results of the Vivatmo *pro* should not be used as a sole parameter for the diagnosis or screening of airway diseases. The Vivatmo *pro* measurement procedure requires patients' cooperation by breathing into the device via a disposable mouthpiece (Vivatmo Oxycap). Patients should be 7 years or older and capable to complete the breathing maneuver.

The measurement procedure of the Vivatmo *pro* generates the fraction of the exhaled breath (FeNO) based on the recommendations for the measurement of exhaled respiratory nitric oxide of the European Respiratory Society (ERS) and the American Thoracic Society (ATS).

FeNO is recommended by the ATS in the diagnosis of eosinophilic airway inflammation and in determining the likelihood of responsiveness to anti-inflammatory pharmacological therapy in individuals with chronic respiratory symptoms possibly due to airway inflammation [ATS, 2011].

The Vivatmo *pro* should only be used as directed in the Vivatmo *pro* Instruction for Use (IFU). Regardless of displayed measured results mind signs or symptoms of chest tightness, shortness of breath, coughing or wheezing for decision about treatment.

2 System elements

Basestation frontside



- ① Handheld
- ② Charging cradle
- ③ On/Off button
- ④ Touchscreen

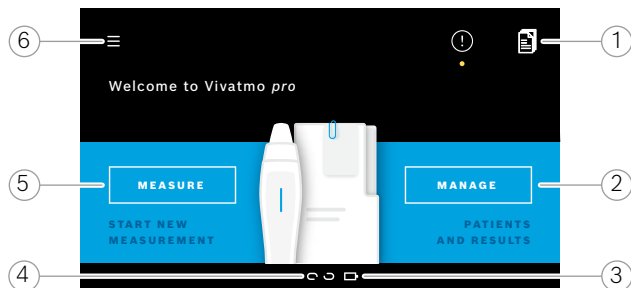
Basestation backside





- ① Ethernet port
- ② USB ports
- ③ Power adapter port

2.1 Screen elements


Elements of the basestation homescreen












- ① Measurement orders from electronic patient record system
- ② Manage patients, measurements and orders
- ③ Charging status handheld battery
- ④ Handheld
 -  connected
 -  disconnected
- ⑤ Start measurement
- ⑥ Settings menu/logout









You see the basestation homescreen when you finished the installation, see – “3 Installation”.

Screen elements

Element	Function
	Help Opens the Help screen.

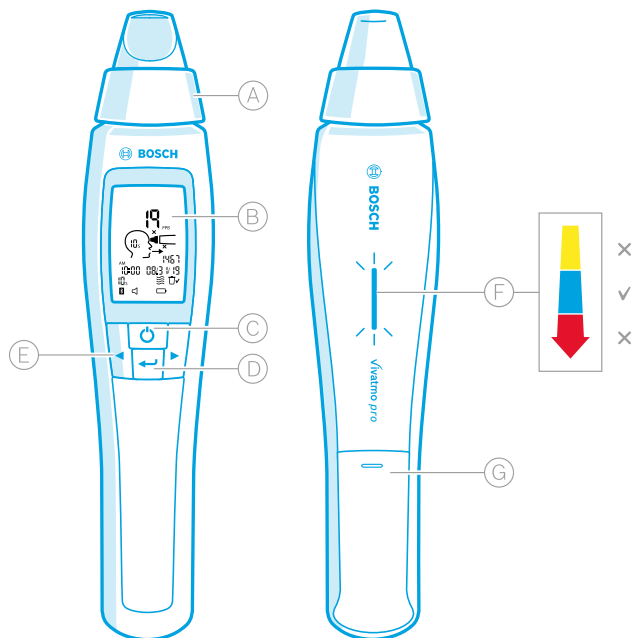
Element	Function
	Close Closes the current file.

Element	Function
	Arrow left Moves one screen backward.
	Orientation beads Show the current step during the installation procedure.
	Notification New/open notifications available.
	View trials / Reconditioning active Shows the number of measuring trials.
	Comment Adds a comment to the current patient data file.
	Search Opens a window for entering search criteria.
	Quality Control (QC) status Shows the QC status.
	Unassign measurement result Releases measurement result from set of patient data.

Element	Function
	Arrow right Moves one screen forward.
	User Administration Disable access control by user accounts.
	Enable/Disable user Enables or disables access for user in user management.
	Add new user/patient Opens the screen for the data input of a new user/patient.
	Pencil Opens the current data file for editing.
	Export Exports the current data file.
	Print Prints the current data file.
	Delete Deletes the current entry.

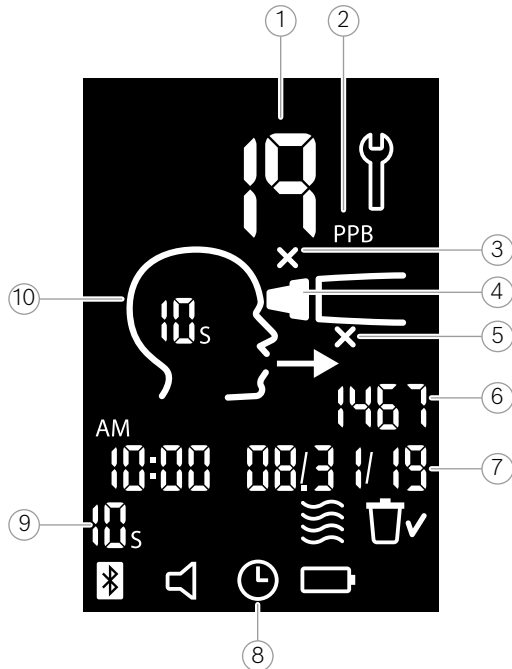
2.2 Handheld elements

On the handheld, you see the following operating elements:










- (A) Disposable mouthpiece: Interface to breath into the Vivatmo *pro* handheld.
 - (B) Display: Shows current and stored measuring data and device messages.
 - (C) **ON/OFF** button: Activate and deactivate the device.
 - (D) **ENTER** button: Press this button to start the regeneration or to confirm selection.
 - (E) **ARROW** buttons: Press these buttons to change the settings and to access stored measuring data.
 - (F) Breath intensity display:
Feedback during the measurement
Yellow: Caution, the breath intensity is too weak.
Blue: The breath intensity is right.
Red: Warning, the breath intensity is too strong.
Procedure correct: Blue blinking.
Procedure failed: Red blinking.
 - (G) Battery compartment.
- When the handheld is placed on the basestation blue blinking indicates the charging of the battery.

2.3 Handheld display



- ① Measured value
- ② Concentration of nitric oxide (NO) in exhaled breath in ppb (parts per billion)
- ③ Invalid disposable mouthpiece: Use a new disposable mouth piece
- ④ Attach disposable mouthpiece
- ⑤ Measurement procedure incorrect
- ⑥ Measuring ID
- ⑦ Time and date of the stored measurement result
- ⑧ Device busy
- ⑨ Measurement mode
- ⑩ Device ready for measurement

Handheld symbols

Icon	Function
	Reconditioning active.
	Regeneration in progress.
	Ambient NO measurement in progress.
	The memory is cleared.
	The Vivatmo <i>pro</i> handheld is connected to the Vivatmo <i>pro</i> basestation. The icon disappears when the Vivatmo <i>pro</i> handheld is used as a stand-alone device without the Vivatmo <i>pro</i> basestation.
	The audio sound is activated. The icon appears when audio sound is activated.
	Battery icon displayed: The battery charge is low. Recharge the handheld device as soon as possible. Battery icon blinking: The battery charge is too low to perform measurements. No battery icon displayed: The battery charge is sufficient.

2.4 Disposable mouthpiece

To perform a measurement with the Vivatmo *pro* system a disposable mouthpiece is needed (purchase separately).



Regular disposable mouthpiece (Vivatmo Oxycap) (F09G100152)

The regular Vivatmo *pro* disposable mouthpiece must be attached for performing all measurements (except of QC Level 0 measurements as described below). The outside of the regular disposable mouthpiece is transparent. The disposable mouthpiece chemically prepares the test sample. Human breath is cleaned from contaminants and stabilized to guarantee reliable test results.



QC Level 0 disposable mouthpiece (F09G100230)

Level 0 Quality Control (QC) measurement is performed with a specific Level 0 disposable mouthpiece, see – “6.2.2 Performing QC”. A comparison measurement is performed for a concentration below 5 ppb. The outside of the Level 0 disposable mouthpiece is white.

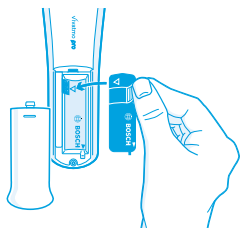
3 Installation

Before you start using your Vivatmo *pro* perform the following steps:

- Install the handheld.
- Install the basestation.

3.1 Installing the handheld

To install the handheld, insert the rechargeable battery.



1. Open the battery compartment on the back of the Vivatmo *pro* handheld.
2. Pick the handling tab with two fingers and insert the rechargeable battery into the battery compartment. Mind the triangle marks on the battery and inside the battery compartment.
3. Apply the battery cover.
4. Remove the protective cap and place the handheld on the basestation cradle for charging. Charge before first use. The recharging time for a completely exhausted battery is about 12 hours. As long as the LED is blinking blue, the handheld is charging.
5. Press the **ON/OFF** button to turn on the handheld. You see all screen icons and the system performs a brief self-test. Then the software version on the handheld is shown.
6. Turn off the device before you replace the battery.

WARNING

- After 5 minutes of inactivity, the handheld will turn off automatically.
- The stored measured values and the date, time setting will remain stored in the memory for 5 minutes when the rechargeable battery might need to be changed.
- Remove the battery if you are not using the device for a prolonged period of time.
- Do not touch the battery contacts to avoid electrical shortcut.
- Dispose of the used battery in compliance with the national or local regulations for battery disposal, see “8 Disposing the Vivatmo *pro* device and the battery”.

3.2 Installing the basestation

3.2.1 User concept

User accounts protect your patient data by access control to the system. When the user management is activated, the access is protected by the user name and a numeric passcode. You can use Vivatmo *pro* also when the user management is deactivated. Vivatmo *pro* supports 2 levels of user access:

Professionals can:

- Perform measurements, see – “4 Measure”.
- Manage patient data and measurement orders, see – “5 Manage”.
- Change display, see – “6 Settings”.
- Perform Ambient NO measurement, see – “6.1 Ambient NO”.
- Perform QC-measurement, see – “6.2.2 Performing QC”.
- Export and print.

Administrators can additionally:

- Change QC settings, see – “6.2 Quality control (QC)”.
- Change language, see “2.1 Setting the language” in Administration instructions.
- Change time and date, see “2.2 Setting date and time” in Administration instructions.
- Activate/de-activate auto-lock, see “2.3 Setting Auto-Lock” in Administration instructions.
- Install printers and export locations, see “4 Printer configuration” and “5.4 Export and Backup file configuration” in Administration instructions.
- Change Vivatmo *pro* handheld used with the basestation, see “5.1.2 Release the handheld” in Administration instructions.
- Configure network, see “5.2 Network configuration” in Administration instructions.
- Configure HL7 or GDT interfaces, see “5.3 Order/result interface” in Administration instructions.
- Manage user accounts, see “6 User administration” in Administration instructions.

3.2.2 Onboarding

WARNING

Only use the Vivatmo *pro* basestation with the provided low voltage power supply unit. Attempted use with other power sources may cause irreparable damage and invalidate the warranty.

Avoid to connect the Vivatmo *pro* basestation to a multiple socket-outlet to prevent interferences by other devices.

1. Connect the jackplug from the power supply unit into the power adapter port on the rear of the Vivatmo *pro* basestation.
2. Plug the suitable adapter for your country firmly on the power supply unit.
3. Plug the main plug into a suitable socket. The Vivatmo *pro* basestation starts automatically.

Software setup

When you start your Vivatmo *pro* basestation for the first time, you will be guided through a setup procedure of 6 simple steps, which helps you to enter all the required settings.

Region and Language (Basestation-Software V1.6.0 and higher)

1. Switch on the basestation, by pressing the **ON/OFF** button.
2. Select a region
The region selection defines the functionality approved for the region.
The **Language** screen is displayed.
3. Select a language.

Date and Time

1. Set up date and time. For details, see “2.2 Setting date and time” in Administration instructions.
2. Confirm with **DONE** after successful setting. The **Administrator account** screen opens.

Administrator account

1. Create an administrator account. For details, see “6.1 Add new user” in Administration instructions.
2. Select the **CONTINUE** button after the successful addition of an administrator. The **User accounts** screen opens.

INFORMATION

You need at least one administrator account to use Vivatmo *pro*.

Remember this access code carefully. The reset of the administrator account can only be done by service personnel.

User accounts

1. Select **ENABLE** to activate the user accounts.
2. Create a new user by entering a user name and a passcode. For details, see “3.2.1 User concept” and “6.1 Add new user” in Administration instructions.
3. Select **CONTINUE** after successful addition of a user and see the list of user accounts.
4. Select the **Arrow** to leave the list.
5. On the next screen, select the **CONTINUE** button. The **Handheld** screen opens.

INFORMATION

When you select the **NOT NOW** button, the user identification will be deactivated. You can activate or deactivate user accounts within the settings as well.

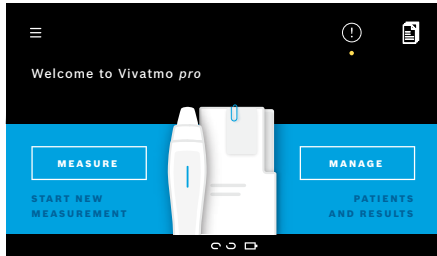
Using the Vivatmo *pro* without the user management is only recommended when you do not use patient records. When you select the **NOT NOW** button, the user identification will be deactivated.

Assign handheld

1. Select the **CONTINUE** button to set up and install the handheld.
To assign the handheld press **SCAN FOR HANDHELDS**. For details, see “5.1.1 Assigning the handheld” in Administration instructions.
2. On the screen, select the **FINISH** button. The setup procedure is completed.

3.3 Login

When user accounts are enabled, Vivatmo *pro* demands authentication on the system. You have to login before you can start using the system.



The **Welcome** screen opens automatically, when you turn on the basestation. You see the list of all users.

1. Select your account from the user list.
2. Enter your passcode.
Professionals use a 4-digit passcode, administrators an 8-digit passcode. If you forgot your passcode, see – “7.5.1 Wrong or forgotten passcode”.
3. The **Home** screen opens.

4 Measure

If the Vivatmo *pro* device has been stored in warm and humid environment or not been in use for a longer time, a reconditioning may be required and starts automatically during first measurement. Therefore perform a test measurement every day before using the device with the patient, see “7.3 Reconditioning”.

Following conditions can influence correct measurement results and shall be avoided:

- Smoking or tobacco consumption for at least 30 minutes before the measurement.
- Eating or drinking shortly before the measurement.
- Strenuous exercise.
- Rooms with high air pollution, high ambient NO or open flames, for example gas range, smoke, or from tobacco consumption.

Disposable mouthpiece shall be handled with care for correct measurement results:

- Use only disposable mouthpieces approved for this device and from intact and unopened pouches that are not expired. See the expiration date on the pouch.
- Do not clean the disposable mouthpiece.
- Take care to use regular disposable mouthpieces with transparent cover. The use of Level 0 disposable mouthpieces with white cover and a “0” on the disposable pouch leads to 0 ppb measurements.

Always check your Vivatmo *pro* basestation, handheld, and the disposable mouthpiece for damages before using to avoid injury or malfunction.

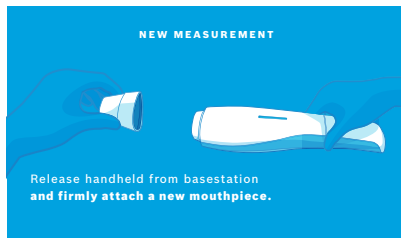
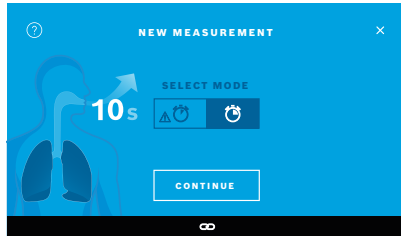
Leakage at the disposable fitting may lead to a lower measurement result.

A mouthpiece can be used for one patient measurement only. In case of an unsuccessful measurement note that 5 attempts are maximal possible with 1 mouthpiece. Use the mouthpiece within 15 minutes after opening its pouch.

WARNING

4.1 Measurement using the basestation

The measurement procedure is guided by an animation on the display of the basestation or the LED on the back of the handheld. Synchronize measurement results of stand-alone measurements with the Vivatmo *pro* handheld by placing the switched on Vivatmo *pro* handheld in the cradle of the Vivatmo *pro* basestation.



1. Ensure that your handheld is switched on and connected to the basestation (the bluetooth symbol on the handheld finished blinking, the **handheld connected** icon is shown).
2. On the **Home** screen, select the **MEASURE** button. On the basestation, **SELECT MODE** screen opens. The regular measurement mode with a duration of 10 seconds is pre-selected. Select 6 seconds test if required. Press **CONTINUE**.
3. On the handheld display, the **Disposable mouthpiece** icon flickers. Open the pouch and attach the disposable mouthpiece firmly in a way that it fits securely on the device. On the handheld display, the **Disposable mouthpiece** icon stops blinking.

INFORMATION

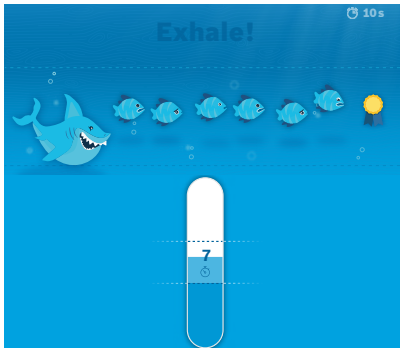
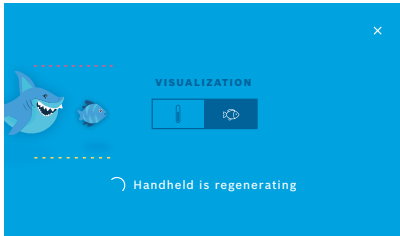
The 10 seconds test is the preferred measurement mode for all ages. The 6 seconds test is for children ages 7 - 11 years old who are not able to complete a 10 seconds measurement mode.

INFORMATION

Attaching the mouthpiece

The Vivatmo *pro* disposable mouthpiece cleans and stabilizes the breath sample from contaminants to guarantee reliable test results. Use the disposable mouthpiece directly after opening the pouch.

Visualization and regeneration



4. On the **VISUALIZATION** screen, select the button for the visualization you want to use, either the fish or the scale. The visualization helps the patient to control the strength of the breath during the measurement.

On the lower part of the screen, you can observe the handheld regenerating and preparing the measurement.

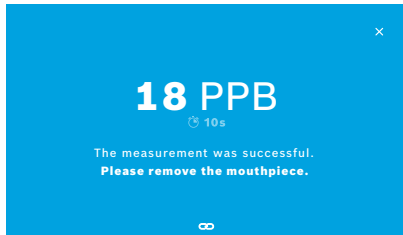
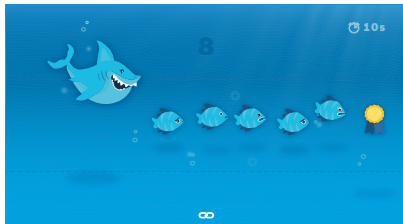
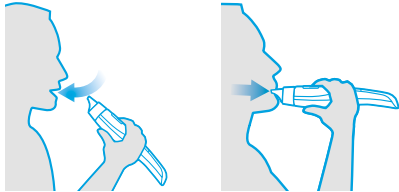
5. When the preparation process is finished, you have to start the measurement within 120 seconds. According to your selection, the respective visualization is shown.

INFORMATION

The regeneration may last up to 100 seconds and is needed to guarantee reliable results. To stop the regeneration, remove the mouthpiece from the handheld.

Measuring

When you assist a person with the measurement, pay attention to the following steps:



1. The patient should sit in a relaxed but upright position, inhale deeply through the mouth and then lift the handheld to the mouth.

WARNING

The patient should avoid inhalation through the nose to exclude influence of nasal NO-concentrations.

2. Exhalation should be performed through the disposable mouthpiece like blowing into a recorder or cooling a hot drink. The breath control visualization helps the patient to **stay within the dotted lines for the entire duration**.

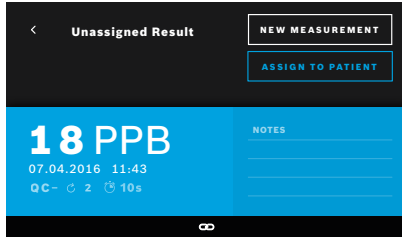
On the display, you see the remaining time to the end of the measurement. Having performed the measurement the **Result** screen opens.

INFORMATION

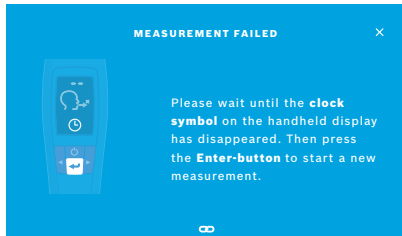
Inhalation through the disposable mouthpiece is without harm but not recommended. When the regeneration is done, start the measurement.

Before the next FeNO determination, you must remove and dispose the mouthpiece, – “8 Disposal” .

3. Select the **x** to leave the **Result** screen. The **Patient File** screen opens.



Failed measurement



The result “5 ppb -LO-” or “< 5 ppb” represents a result below the lower detection limit of the device. The result “300 ppb -HI-” or “> 300 ppb” represents a result above the upper detection limit of the device.

When performing a measurement without selecting a patient before, the result is shown as unassigned. You can assign the measurement to a patient immediately or later from the list of measurements:

1. Select the **ASSIGN TO PATIENT** button.
The patient list is opened.
2. Select the dedicated patient from the list.
3. Measurements assigned to a patient can be unassigned by the **UNASSIGN** button.

In case your measurement failed, the **MEASUREMENT FAILED** screen opens.

1. The screen might show being busy to prepare the next measurement. Wait until the clock icon on the handheld stops blinking. Press the **ENTER** button on the handheld and the measurement procedure starts again with the **VISUALIZATION** screen and the animation on the screen indicates that the regeneration process is ongoing.

INFORMATION

The display depends on the selected visualization, see – “Visualization and regeneration” in 4.1.

4.2 Measurement stand-alone with the handheld

INFORMATION

The 10 seconds test is the preferred measurement mode for all ages. The 6 seconds test is for children ages 7 - 11 years old who are not able to complete a 10 seconds measurement mode.

Stand-alone measurements can be used when the handheld has no connection to the basestation. The handheld must be out of range of the basestation or the basestation must be switched off.

The measurement procedure is guided by the handheld display and the LED on the upper side. Synchronize measurement results of stand-alone measurements with the Vivatmo *pro* handheld by placing the switched on Vivatmo *pro* handheld in the cradle of the Vivatmo *pro* basestation.



1. Use the **ON/OFF** button to activate your Vivatmo *pro* handheld. You see all screen icons and the system performs a brief self-test. Then the software version installed on the handheld is shown shortly. After the self-test, the handheld shows:
 - the **audio** icon on the handheld is activated,
 - the bluetooth connection is not activated. The **Bluetooth** icon is blinking, as the handheld is not connected to the basestation.
2. The measurement mode is displayed in the settings bar. For changing press **ENTER** for 3 seconds to reach the measurement mode selection, select with the **ARROW** buttons and confirm with **ENTER**.
3. Attach a new disposable mouthpiece.



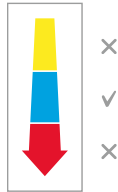


4. The handheld device might be busy. Wait until the **clock** icon stops blinking. Press the **ENTER** button to start the regeneration cycle.

While the handheld is regenerating, segments of the display will be animated to indicate the handheld is preparing the measurement.



5. When the display shows the **Breathing icon**, start the measurement procedure within 120 seconds. The LED on the back of the device turns blue.
6. Turn the device display downwards, so that you can see the LED at the back of the device.
7. Sit in a relaxed position, inhale deeply through your mouth and lift the handheld to your mouth.
8. Exhale softly through the disposable mouthpiece like cooling a hot drink, while observing the LED side of the handheld.



The color of the LED provides feedback on the correct breathing strength:

yellow: caution, too weak

blue: correct

red: warning, too strong

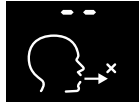
Successful measurement: The LED flashes blue and the result appears on the display. All results are automatically stored on the device.

Failed measurement: The LED flashes red and the **Exhalation failed** icon appears on the display, see – “Failed measurement”.

9. Remove the mouthpiece.
10. Discard the mouthpiece, – “8 Disposal”.

Failed measurement

A) The measurement failed because the exhalation through the device was excessively weak or strong:



- The LED flashes red, you hear an audio signal, and the screen shows that the exhalation failed.
- Repeat the measurement, see – “4.2 Measurement stand-alone with the handheld”, start at point 3.

B) The measurement failed because the start was not performed within 120 seconds after the regeneration:

- Repeat the measurement, see – “4.2 Measurement stand-alone with the handheld”, start at point 4.

Displaying stored measured values

Your Vivatmo *pro* handheld automatically stores up to 1,000 measured FeNO values, identified by time, date and measuring ID. The measured values are stored in descending order starting with the latest.

To retrieve the measured values:

- Press the **ARROW left** button to show older measured values.
- Press the **ARROW right** button to scroll to the more recent values.
- Press the **ENTER** button to exit the view.

Possible interpretation of results according ATS Guideline 2011, see chapter “11.3 Literature”:

- < 25 ppb (children below 12 years < 20 ppb): eosinophilic inflammation and responsiveness to corticosteroids less likely
- 25 ppb - 50 ppb, (children below 12 years 20 ppb - 35 ppb): interpret cautiously and with reference to the clinical context
- > 50 ppb (children below 12 years > 35 ppb): eosinophilic inflammation and, in symptomatic patients, responsiveness to corticosteroids are likely

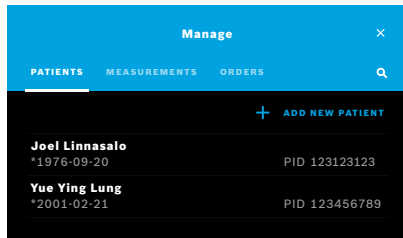
5 Manage

In the **Manage** menu, you can manage the following data records:

- 5.1 Patient records
- 5.2 Measurements
- 5.3 Measurement orders

Data records can be managed without a handheld connected to the basestation.

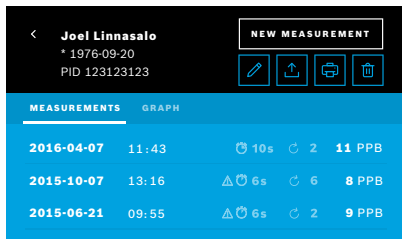
5.1 Patient records



On the **Manage** screen, select the **PATIENTS** tab. In the **PATIENTS** tab you can perform the following:

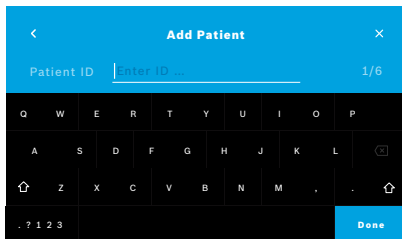
- View patient file and start new measurement, see – “Viewing patient file”.
- Add new patients, see – “Adding patients”.
- Search patients, see – “Searching patients”.
- Edit patient data, see – “Editing patients”.
- Delete patient data, see – “Deleting patients”.

Viewing patient file



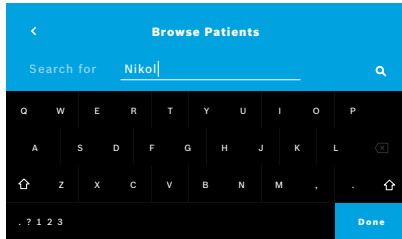
1. From the patient list, select a patient.
The patient file is displayed and shows the last measurements.
2. Select **MEASUREMENTS** or **GRAPH** of the last measurements.
The validity of the QC is displayed with the results. For further information on QC, see – “6.2 Quality control (QC)”.
3. Select **NEW MEASUREMENT** to perform a measurement with the patient, see – “4.1 Measurement using the basestation”.
4. Select the **Arrow** to leave the patient file.

Adding patients



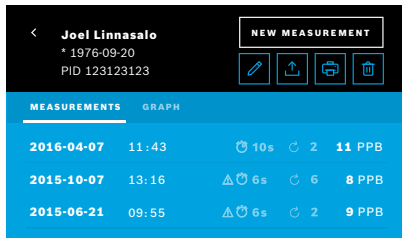
1. On the **PATIENT** tab, select **+ ADD NEW PATIENT**.
The **Add Patient** screen opens. Entering an alphanumeric **Patient ID** is mandatory, all other entries are optional.
2. Select the list item “Patient ID (PID)” and enter the **Patient ID**. Confirm with **DONE**.
3. Select the the firstname, lastname and date of birth if required, enter content on the selected screen and confirm with **DONE**.
4. The gender of the patient can be changed in a drop-down menu.
5. Confirm all entries with **SAVE**.

Searching patients



1. On the **PATIENTS** tab, select the **Search** button.
The **Browse patients** screen opens.
2. Enter name or patient-ID.
3. Confirm with **DONE**.
A list opens that shows all patients that correspond to your search criteria.

Editing patients



1. In the patient list, select the patient you want to edit.
The **Patient File** screen opens.
2. Select the **Pencil** button to edit the patient data.
3. Select the respective **Pencil** button to edit the patient-ID, first name, last name, the date of birth or the gender.
4. Enter content on the selected screen and confirm with **DONE**.
5. Confirm all entries with **SAVE**.

Deleting patients

1. In the patient list, select the **Delete** button.
You are asked to confirm before a patient file is deleted.

5.2 List of measurements

DATE	PATIENT	PID	MEASUREMENT	STATUS	RESULTS
17.01.2018	Joel Linnasalo	PID JL78910	11 ppb	10	2
17.01.2018	Mary Smith	PID MS78911	45 ppb	6s	2
17.01.2018	unassigned		29 ppb	6s	2

1. On the **Manage** screen, select the **MEASUREMENTS** tab. Here you can view all measurements in chronological order.
2. The measurements are displayed in pages of 10 measurement results. Change the pages using the arrow buttons bottom right.
3. If you perform a measurement without having selected a patient, you can select a measurement result and assign the result to a patient, – “4.2 Measurement stand-alone with the handheld” – “Displaying stored measured values”.

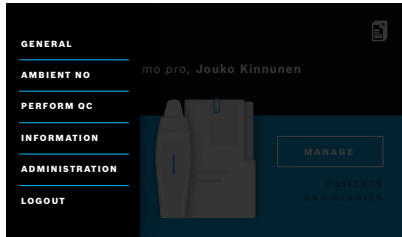
5.3 List of measurement orders

PATIENT	DATE OF BIRTH	PID
Joel Linnasalo	*1976-09-20	PID 123123123
Yue Ying Lung	*2001-02-21	PID 123456789
Nikola Matějková	*1987-11-07	PID 123456788

1. On the **Manage** screen, select the **ORDERS** list. The list of measurement orders opens.
2. Select a patient to perform a measurement, see – “4.1 Measurement using the basestation”.
When the measurement is done, the result is sent back to the electronic patient record system.
The patient is added to the list of patients on the Vivatmo *pro* basestation.

6 Settings

The access to settings depends on the login as professional or administrator, see – “3.2.1 User concept”.



1. On the **Home** screen, select the **Settings** menu.
Following options are available:
 - **General Settings** to change the brightness of the display.
 - **Ambient NO** to perform an Ambient NO measurement, see “6.1 Ambient NO”.
 - **Perform QC**, see “6.2.2 Performing QC”.
 - **Information**, see “6.3 System information”.
 - **Administration**, see Administration instructions.
 - **Logout** to leave settings menu

6.1 Ambient NO

Ambient NO measurement may help to interpret FeNO measurement results. To perform an ambient NO measurement:

1. In the **Settings** menu, select **AMBIENT NO**. The **AMBIENT MEASUREMENT** screen opens.
2. Turn on the handheld and attach a new mouthpiece, see – “4.1 Measurement using the basestation”.
3. Lay down the handheld in a way that the device has good access to the ambient air.
4. Select the **RUN MEASUREMENT** button.
On the screen, you see that the ambient NO measurement is running.
5. When the ambient NO measurement is done, you see the result on the screen. Remove the mouthpiece.

6.2 Quality control (QC)

External QC tests are used to control the measurements of the Vivatmo *pro* handheld in comparison to reference concentrations of nitric oxide (NO). The system documents the tester who performs the QC tests by the user login.

QC is recommended weekly or after 50 measurements if Vivatmo *pro* is used in a clinical environment. Commitment, frequency and reference measurements to be performed are dependent on the local quality control standards of the operating organization. The settings for the QC are done only by administrators, – “6.4.1 Quality Control (QC) setting”.

Vivatmo *pro* supports QC for 2 reference concentrations:

- **Level 0**

Level 0 is performed with a specific white Level 0 disposable mouthpiece, see – “2.4 Disposable mouthpiece”. A comparative test is performed for a concentration below 5 ppb which is below the detection limit.

- **Defined NO with QC tester**

The comparative test is performed by a qualified QC tester with a FeNO concentration below 50 ppb. For this test a regular transparent disposable mouthpiece is used.

QC with defined NO is performed by users who have the QC tester qualification. A minimum of 1 individual needs to qualify, 2 are recommended, see below.

When QC for the Vivatmo *pro* is invalid or failed, the measurements are stored with the QC status **QC !** in the patient data.

6.2.1 QC Tester qualification

For the tester qualification, you have to meet the following criteria:

- Over 18 years of age.
- No ongoing cold or known airway disease.
- Non-smoker.
- Expected stable FeNO values below 50 ppb.

To qualify as tester, you must complete the following steps:

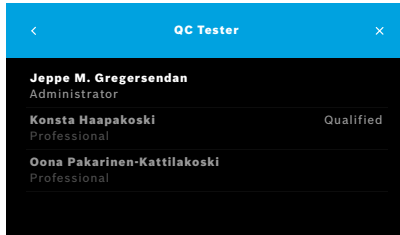
- Perform 4 measurements within 7 days, not more than one qualification measurement per day.
- The QC-measurement on the fourth day must be within accepted range of $5 \text{ ppb} \pm 3 \times \text{standard deviation}$, at least $\pm 3 \text{ ppb}$ from the mean value.

INFORMATION

The moving mean value is recalculated when the QC tester performs a new QC-measurement within 7 days.

The qualification of a QC tester expires after 60 days. Then the qualification is suspended and the QC tester needs to qualify again, according to the qualification procedure.

Qualification procedure



Note: In the QC settings, the QC Tester control must be activated, see – “6.4 Administrator settings”. Perform the following steps:

1. In the **Settings** menu, select **PERFORM QC**.
The **QC Tester** screen opens and the actual user is highlighted and can be selected.
2. Select the **QUALIFY** button.



3. Perform a regular measurement.

After the measurement the result can be:

- **Qualify:** Status during first 3 measurements of **QC tester** qualification.
- **Passed:** Result is within acceptance range of the mean of the last 3 measurements.
- **Failed:** Result is outside acceptance range of the mean of the last 3 measurements.

When the qualification procedure is passed, the qualification status of the QC tester is changed to **Qualified**.

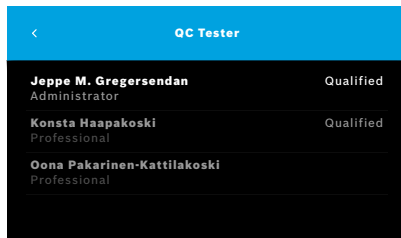
The qualified QC tester can perform the defined NO reference measurement test.

6.2.2 Performing QC

QC provides 2 reference measurement tests **Level 0** and defined NO with **QC tester**.

In the – “6.4.1 Quality Control (QC) setting”, QC can be restricted to 1 QC reference measurement only. Dependent on the QC settings, QC is performed first with Level 0 and then with defined NO with QC tester, or with the selected reference QC-measurement only.

Start QC-measurement



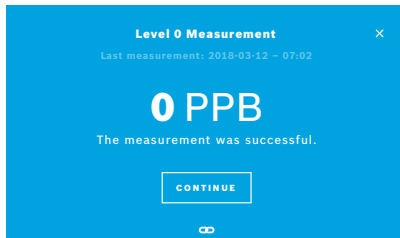
4. In the **Settings** menu, select **PERFORM QC**.

The **QC Tester** screen opens (only if QC tester is activated).

In the list, you see all users with their QC status. Your account is highlighted and can be selected.

If no user management is enabled only the administrator is shown in the list.

QC test Level 0

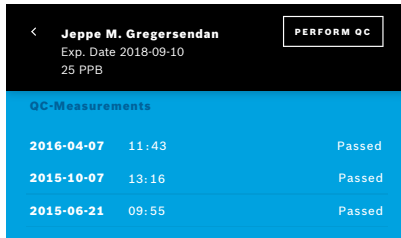


If Level 0 QC is configured perform the following steps:

- 1.1 If QC tester is not activated:
Go to the settings and select **PERFORM QC**. Level 0 measurement will start automatically.
- 1.2 If QC tester is activated and qualified:
Select **PERFORM QC** in settings. Then select your username and tap on **PERFORM QC**.
2. Release the handheld device from the basestation and attach a Level 0 mouthpiece.
3. Perform the measurement, see – “4.1 Measurement using the basestation”.
When the result is 0 ppb, the Level 0 QC test was successful.
If the result is 5 ppb or higher the Level 0 QC test failed.
Repeat the measurement and take care to use a new Level 0 mouthpiece.
When the Level 0 QC test still fails, contact the service.

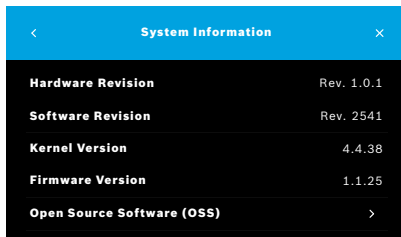
QC-measurement QC tester

This reference QC-measurement is performed by a qualified QC tester. When both Level 0 and QC tester are activated, then this measurement is the second one. For the QC tester qualification procedure, see – “6.2.1 QC Tester qualification”.



1. Select your user name.
You can see your datasheet with the list of your last QC-measurements.
2. Select the **PERFORM QC** button.
3. Attach a regular transparent disposable mouthpiece.
4. Perform the measurement, see – “4.1 Measurement using the basestation”.
5. When the result is in the acceptance range of the QC testers mean, the QC test is passed.
The QC test is passed, when all reference measurements defined in the QC settings are successfully performed.

6.3 System information



1. In the Settings menu, select **INFORMATION**.
The System information screen opens. Find the versions of the used software components. Might be needed in case of service.
2. Select **Open Source Software** to find information and a written offer concerning open source software components used in the product.

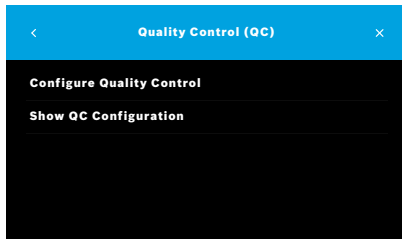
6.4 Administrator settings

Administrator settings can only be accessed by administrators. The Administrator settings contain:

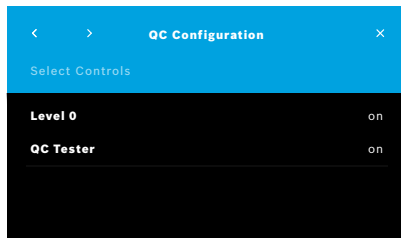
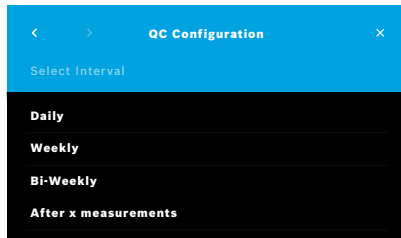
- Device settings e.g. language, date and time and Auto-lock
- Quality Control (QC) settings, see – “6.4.1 Quality Control (QC) setting”
- Printer configuration
- Vivatmo *pro* handheld settings
- Network configuration
- Order/result interface (HL7 or GDT)
- Export and backup file configuration
- User administration

For further information see “1 Administrator settings” in Administration instructions.

6.4.1 Quality Control (QC) setting



1. On the **Administration** screen, select **Quality Control (QC) Settings**. You can select:
 - **Configure Quality Control** to change the settings.
 - **Show QC Configuration** to display the current settings.
2. Select **Configure Quality Control**.
3. Select **ON/OFF** to activate or deactivate the QC mode. For further information see – “6.2 Quality control (QC)”.
4. Select the **Arrow Right** button to move to the next screen.



5. Select the interval to perform the quality control
 - by time: select daily, weekly, bi-weekly or
 - by number of performed measurements: select **After x measurements**. Select the **Arrow Right** button.
6. Enter the number of measurements to be performed before next quality control.
7. After selecting the interval, select the **Arrow Right** button. Quality control is recommended with both Level 0 and QC Tester reference controls.
8. Select activation or deactivation of these control methods.
9. Select the **Arrow Right** button to move to the next screen. The **QC Configuration** screen opens with an overview of the current QC settings.
10. Check your **QC Configuration**.
11. Confirm with **SAVE** to save the **QC Configuration**.

INFORMATION

Find the Administration instructions here:
www.vivatmo-hcp.com/en/service-and-support/downloads/



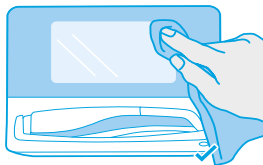
7 Maintenance and troubleshooting

7.1 Maintenance

WARNING

Fractures in the housing and ingress of spray, moisture or liquid may cause malfunction to the Vivatmo *pro* and disposable mouthpiece.

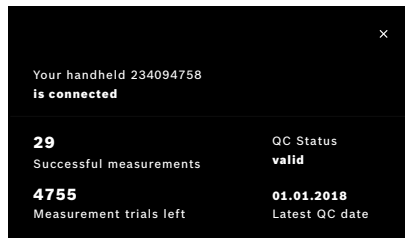
The Vivatmo *pro* is easy to maintain. Clean the device in accordance with the hygienic standards of your organization.




Cleaning and Disinfecting

1. Turn off the device. Wash your hands thoroughly with soap and water.
2. Wipe the entire Vivatmo *pro* with alcohol disinfectant wipes with maximum 30% alcohol e.g. Mikrobac Tissues (Bode Chemie GmbH) or mikrozyd universal wipes (Schülke & Mayr GmbH) or with a soft cloth, moistened with soap cleaning agents. Carefully wipe around openings.
3. For disinfecting repeat step 2 with alcohol disinfectant wipes with maximum 30% alcohol following the wipe's manufacturer's instructions for disinfecting.

7.2 Status information handheld



The number of measurement trials you can perform with one Vivatmo *pro* handheld is limited.

4. Slide up the handheld connected icon  to view the number of trials left.
5. If required, change the handheld, see “5.1.1 Assigning the handheld” in Administration instructions.

7.3 Reconditioning

Vivatmo *pro* performs an automatic stability check with the first measurement of the day: If the Vivatmo *pro* device has been stored in warm and humid environment or not been in use for a longer time, the **wrench** symbol may appear on the basestation and the handheld. Then a reconditioning is required to provide consistent measurement performance. In this case the wrench symbol appears during the regeneration process on the screen and the device automatically starts the reconditioning.



1. The **wrench** symbol on the handheld and the basestation indicates that the reconditioning process is ongoing. The remaining reconditioning time is shown in minutes.
2. The handheld beeps and blinks 3 times blue when reconditioning is finished.
3. Dispose the mouthpiece after reconditioning.

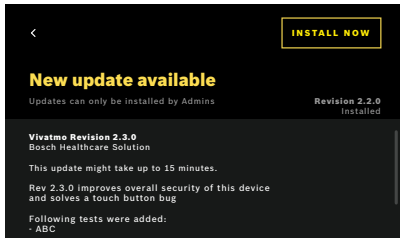
INFORMATION

The reconditioning takes between 7 and 90 minutes and cannot be interrupted. The **wrench** symbol is shown during all activities:

- If **E-6** and the **blinking battery symbol** appear during reconditioning, remove the mouthpiece and place the handheld on the basestation for 2–3 h for charging. Re-attach the mouthpiece afterwards to continue reconditioning.
- Change the disposable mouthpiece if the **invalid mouthpiece** screen appears during reconditioning.
- If you push the **ON/OFF** button, **OFF** appears as long as the reconditioning is active.

7.4 Remote Software Update

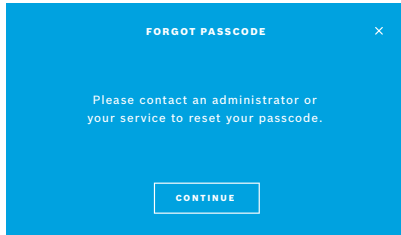
When the Vivatmo *pro* is connected to *Vivasuite* (see “5.5 *Vivasuite* configuration” in Administration instructions) new software updates will automatically be available on the device. The device administrator always has full control over new software updates. A notification informs about the availability of a new software update and the administrator can perform the software update whenever it fits the schedule.



1. A notification is shown when a new software update is available.
2. Select the notification icon on the dashboard and select the **New Software Update** notification.
3. Carefully read the Release Notes on the **Details** Screen. Press **Install Now** to start the software update.
4. When the software update is completed the basestation will restart automatically.

7.5 Troubleshooting

7.5.1 Wrong or forgotten passcode






If you forgot your passcode:


1. Select the **FORGOT** button.
A screen opens and tells you to ask your administrator to reset your passcode.
2. Select the **CONTINUE** button to return to the user list.

INFORMATION

The system needs at least 1 administrator login. If the administrator passcode is forgotten, Vivatmo *pro* needs to be reset by a service technician.

7.5.2 Troubleshooting handheld

Display	Description	Solution
	Regeneration is ongoing.	Wait for the purging to be completed. Do not remove the mouthpiece.
	Battery is almost empty.	Charge the handheld on the basestation cradle, see “3.1 Installing the handheld”.
	Disposable mouthpiece is not valid.	Exchange the mouthpiece and take a new one from the package, see – “4.1 Measurement using the basestation”.

	<p>Measurement procedure is incorrect, breathing was too strong, too weak or time-limit after regeneration was exceeded.</p>	<p>Repeat the measurement, see – “4.2 Measurement stand-alone with the handheld”.</p>
<p>E-1</p>	<p>Permissible number of measurement trials reached soon, measurements still possible.</p>	<p>See display for number of remaining measurement trials. Order new Vivatmo <i>pro</i> handheld, see – “7.2 Status information handheld”.</p>
<p>E-2</p>	<p>Number of permissible measurement trials reached. Device does not perform any measurements after maximum number of permissible tests is reached.</p>	<p>Connect a new Vivatmo <i>pro</i> handheld and dispose the old one, see chapter “Disposal”.</p>
<p>E-4</p>	<p>Humidity in device too high.</p>	<p>Check ambient conditions and take a new mouthpiece.</p>
<p>E-5</p>	<p>Ambient temperature and air pressure (altitude) is outside the specified range.</p>	<p>Use the Vivatmo <i>pro</i> in location with permissible ambient conditions.</p> <p>When transporting the device from one place to another, a stabilization period of at least 20 minutes should be observed before use.</p>
<p>E-6</p>	<p>Battery is too weak for measurement.</p>	<p>Place the device on the basestation for charging.</p>
<p>E-7</p>	<p>System self-test failed</p>	<p>Make sure the battery is sufficiently charged by positioning the handheld on the basestation for at least 2 hours.</p> <p>Take out and re-insert the battery of the handheld if the error persists and/or change the battery.</p> <p>If the error persists, read out E7 error code and contact your distribution partner.</p>
<p>E-8</p>	<p>Regeneration failed.</p>	<p>Press the ENTER button to repeat the regeneration.</p> <p>If the errors persists, contact your distribution partner.</p>

8 Disposal

Disposing the Vivatmo *pro* device and the battery

INFORMATION

Delete the data on your device prior to disposal or service returns ,see “Factory Reset” in “2.3 Setting Auto-Lock” and “5.1.2 Release the handheld” in Administration instructions.



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

Dispose of used batteries in compliance with the national/local regulations for the disposal of batteries separated from the device (in compliance with the European directive 2006/66/EC).

Disposing the mouthpiece



The mouthpiece is a single-use product. It contains small quantities of potassium permanganate KMnO_4 . Use a new mouthpiece for each measurement and dispose the used one in contaminated patient waste.

9 Technical data

9.1 Device data

Model	Vivatmo pro
Package contents	Vivatmo <i>pro</i> basestation; Handheld device; Instructions for use; Power supply unit with connectors; 1 rechargeable lithium-ion battery
Operating conditions temperature / humidity / air pressure	+15°C to +27°C / 15% to 60% relative humidity (non-condensing) / 780 hPa to 1,100 hPa
Applied part	Type B as per EN 60601-1 for handheld and disposable mouthpiece when attached
Air pressure range	780 hPa to 1,100 hPa, corresponds to 0–2,000 m above sea level
Storage and transport temperature / humidity	+5°C to +27°C / 10% to 60% relative humidity between uses
Data transfer	Ethernet 10/100 MB, WLAN 2.4 GHz b/g/n; internal: Bluetooth Smart (low energy); Max. radiated power: 2.4 GHz BT ≤ 2,5 mW; 2.4 GHz (WLAN) <100 mW
Basestation	Catalogue number F09G100246
Display basestation	7 inch 16:10, 1024 × 600 pixel touchscreen
Weight	1350 g
Dimensions	265 × 213 × 160 mm
Electrical safety	ME device with external supply, tested according to EN 60601-1, IP20 for basic safety








Wireless charging	Charging with constant current up to 220 mA followed by constant voltage up to 4.2 V stopping when fully charged. Radiated field strength 100–300 kHz \leq -10 dB μ A/m at 10 m
Power supply (accessory)	
Model type	UE electronic UE36LCP-240150SPA or DONGGUAN UES36LCP-240150SPA
Input voltage	100–240 V AC, 50–60 Hz
Output power range	< 25 W
Output voltage	24 V
Handheld	Catalogue number F09G100078
Measuring range	5 ppb to 300 ppb
Linearity	$r^2 \geq 0.99$, slope 1.00 ± 0.05 , intercept ± 5 ppb
Accuracy	± 5 ppb below 50 ppb, $\pm 10\%$ for ≥ 50 ppb, $\pm 15\%$ for ≥ 160 ppb expressed as the upper/lower confidence limit of 95%
Precision	± 5 ppb below 50 ppb, $\pm 10\%$ for ≥ 50 ppb, $\pm 15\%$ for ≥ 160 ppb expressed as one standard deviation for replicate measurements with the same instrument
Memory capacity	1,000 measurements
Maximum ambient NO-concentration	100 ppb
Power source handheld	Customized rechargeable Li-ion battery F09G100314, 3.6 V, battery: accessory; compartment lid: detachable part
Electrical safety	ME device with internal supply, tested according to EN 60601-1, IP20 for basic safety









Maximum surface temperature	58°C, touch time < 60 seconds
Electromagnetic emissions	CISPR 11 Group 1 (battery operated)
Electromagnetic immunity	IEC 61000-4-2, IEC 61000-4-3 (battery operated), IEC 61000-4-8
Sensing technology	Chemical field-effect transistor (Chem-FET) to measure nitrogen dioxide that is converted from nitric oxide by disposable mouthpiece.
Data transfer	Bluetooth® Smart (low energy), 2.4 GHz frequency band
Weight	170 g
Dimensions	4.0 cm × 5.4 cm × 22.4 cm
Lifetime	At least 5,000 measurement trials
Useful life of rechargeable battery	At least 40 measurement trials when fully charged
Disposable Mouthpiece	
Disposable mouthpiece single-time use	Measurement limited to 5 measurement trials within 15 minutes
Useful life of disposable mouthpiece	Limited by expiration date
	Purchase separately: Vivatmo <i>pro</i> Oxycap (catalogue number F09G100152), Vivatmo <i>pro</i> Level 0 (catalogue number F09G100230)








Vivatmo *pro* can contain following substances of the actual candidate list of the EU REACH regulation 1907/2006 in a concentration above 0.1%: Lead-monoxide.

Vivatmo *pro* was tested for crossreaction and interference. Concentrations tested were equal to or higher than the concentration that might be expected for each substance in exhaled breath. For all relevant substances (e.g. Ethanol, H₂S, Acetone, Acetaldehyde, Ammonia, H₂O₂, Isoprene, Acetonitrile) in breath that could interfere with FeNO measurement, no interferences observed.

9.2 Symbols

	Temperature range
	Application range humidity
	Manufacturer address
	The IVD product meets the requirements of applicable European directives.
	Read instructions for use carefully
	Caution, read IFU regarding warnings
WARNING	Warning to avoid a hazard
IP20	IP Protection class
 YYYY-MM-DD	Date of expiration

	Application range air pressure
	Serial number
	Catalogue number
	Applied part type B as per EN 60601-1
	<i>In vitro</i> diagnostic medical device 98/79/EEC IVD Directive
	Keep dry
INFORMATION	Information and advises
	Bluetooth compatible
 YYYY-MM-DD	Date of manufacture

LOT	Batch number		For single use only
	Electrical safety class II		Direct current
	Regulatory compliance mark Australia		Prescription symbol
	Device for near-patient testing		Medical - General medical equipment as to electrical shock, fire and mechanical hazards only in accordance with ANSI/AAMI EN 60601-1:2005 + C1:2009 + A2:2010 + A1:2012, IEC 60601-1-6:2010 + A1:2013, CAN/CSA-C22.2 No. 60601-1:2014 & 60601-1-6:2011 + A1:2015

Further country-specific symbols (e.g. radio certification) are found at the end of this instruction for use or on the handheld device in the area below the buttons.

The Bluetooth® word mark and logos are registered trademarks owned by Bluetooth SIG, Inc. and any use of such marks by Bosch Healthcare Solutions GmbH is under license.

9.3 Warranty

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

10 Manufacturer

Bosch Healthcare Solutions GmbH

Stuttgarter Str. 130

71332 Waiblingen, Germany

E-Mail: info@vivatmo.com

Internet: www.vivatmo-hcp.com/en/

11 Appendix

11.1 Electromagnetic compatibility

Important information regarding electromagnetic compatibility (EMC)

Hereby, Bosch Healthcare Solutions GmbH, declares that the radio equipment type Vivatmo *pro* 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.vivatmo.com/en/service-support/additional-information.html

Vivatmo *pro* complies with EN 60601-1-2:2015 with the objective to avoid insecure product situations. This standards regulate the levels of immunity against electromagnetic interferences and the maximum electromagnetic emission values for medical equipment. Vivatmo *pro* manufactured by the company complies with the standard guidance and manufacturer's declaration – electromagnetic emissions EN 60601-1-2:2015 both in terms of immunity and of emissions and does therefore not need any service and maintenance regarding EMC and ESD over lifetime. Vivatmo *pro* basestations with a date of manufacture before 1st November 2018 comply with EN 61326-1:2013 for EMC. For manufacturers declaration regarding EMC see www.vivatmo.com.

WARNING

Note that portable and mobile HF communication systems may interfere with this device. Do not staple or use the device close to mobile phones or other devices generating electrical or electromagnetic fields. This could result in malfunction of the medical device and may create a potentially insecure situation. Portable RF communication devices (including peripherals such as antenna cables and external antennas) are not to be used closer than 30 cm next to any part of the Vivatmo *pro* system.

The Vivatmo *pro* is intended for use in professional healthcare facility environment. The customer or the user of Vivatmo *pro* should assure that it is used in such an environment.

Medical devices may be affected by cellular telephones and other personal or household devices not intended for medical facilities. It is recommended that all equipment used near the Vivatmo *pro* device comply with the medical electromagnetic compatibility standard and to check before use that no interference is evident or possible. If interference is suspected or possible, switching off the offending device is the normal solution, as is required in aircraft and medical facilities. Medical electrical equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided.

11.2 Compliant cables

WARNING

The use of accessories, transducers and cables other than those specified may result in increased emissions or decreased immunity performance of the equipment or system.

The following list shows cables, transducers, and other applicable accessories with which Bosch Healthcare Solutions claims EMC compliance.

- Ethernet cable, 3 m, shielded
- USB cable, 3 m, shielded

INFORMATION

Supplied accessories do not affect EMC compliance.

11.3 Literature

- [1] ATS & ERS: ATS/ERS recommendations for standardized procedures for the online and offline measurement of exhaled lower respiratory nitric oxide and nasal nitric oxide.
Am J Respir Crit Care Med 2005;171:912-30.
- [2] Dweik RA, Boggs PB, Erzurum SC et al.: Official ATS clinical practice guideline: interpretation of exhaled nitric oxide levels (FENO) for clinical applications.
Am J Respir Crit Care Med 2011;184:602-15.

11.4 License Terms for End Users






The following License Terms apply to your use of a BOSCH Vivatmo *pro* device (the “Bosch Product”) wherein Java Runtime Environment are embedded, see “6.3 System information”.



UK CA	UKCA mark refers to compliance with UK regulation "Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment Regulations 2012 (as amended)."
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CH REP	Decomplex AG Freiburgstrasse 3 3010 Bern Switzerland
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 MCMC HIDF24000106	Certification for telecommunications or multimedia products that meet the standards set by the Malaysian Communications and Multimedia Commission (MCMC) for use in Malaysia.
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 ift IFT TEBOV124-01350	La operación de este equipo está sujeta a las siguientes dos condiciones: (1) es posible que este equipo o dispositivo no cause interferencia perjudicial y (2) este equipo o dispositivo debe aceptar cualquier interferencia, incluyendo la que pueda causar su operación no deseada.
 NOM 	

Approved by Ministry of Communications of Israel התאמת מספר אישור מטעם הישראלי משרד התקשורת: 51-89211	חל איסור לבצע פעולות במכשיר שעלולים לשנות את התכונות האלחוטיות של המכשיר כולל שינויים בתוכנה, החלפת אבטכה מקורית או הוספת אפשרות חיבור לאבטכה חיצונית, ללא קבלת אישור ממשרד התקשורת, מחשש ל התערבות עובדים.
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 CCAF24LP145AT5	Without permission granted by the NCC, any company, enterprise, or user is not allowed to change frequency, enhance transmitting power or alter original characteristic as well as performance to a approved low power radio-frequency devices. The low power radio-frequency devices shall not influence aircraft security and interfere legal communications; If found, the user shall cease operating immediately until no interference is achieved. The said legal communications means radio communications is operated in compliance with the Telecommunications Management Act. The low power radio-frequency devices must be susceptible with the interference from legal communications or ISM radio wave radiated devices.
 CCAF24LP1330T6	



เครื่องวิทยุคมนาคมนี้ ได้รับยกเว้น ไม่ต้องได้รับใบอนุญาตให้มี ใช้ซึ่งเครื่องวิทยุคมนาคมหรือตั้งสถานีวิทยุคมนาคมตามประกาศ กสทช. เรื่อง เครื่องวิทยุคมนาคม และสถานีวิทยุคมนาคมที่ได้รับยกเว้นไม่ต้องได้รับใบอนุญาตวิทยุคมนาคม ตามพระราชบัญญัติวิทยุคมนาคม พ.ศ. 2498




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Complies with IDMA standards DA105282

72413/ SPDDI/2021 10325

72412/ SPDDI/2021 10325

BOSCH

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Germany



F09G100238 Version 11
Instructions for use
Latest change: 2024-10-16



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