BOSCH

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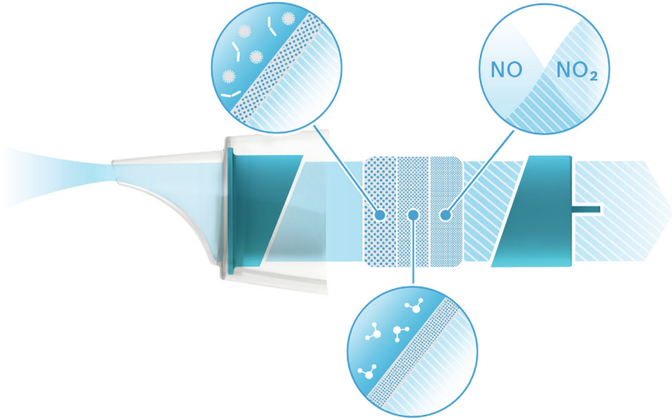
vivatmo *pro*

Instructions for use

Vivatmo Oxycap



Content

1 Initial information

1.1 Package contents

- Vivatmo *pro* basestation
- Handheld device
- Instructions for use

- Power supply unit with connectors
- 1 rechargeable lithium-ion battery

Keep these **Instructions for use.** For frequently used functions see chapter 3, 4, 5, 7 and 8.

1.2 Before using Vivatmo *pro*

Welcome to Vivatmo *pro*, the measurement system to support monitoring of asthma treatment.

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 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.

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.com.

	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.

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 (see “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. Changes or modifications made to this equipment not expressly approved by Bosch Healthcare Solutions may void the FCC authorization to operate this equipment. 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 60601-1. 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 connecting the basestation to the local area network consider that data is transmitted unencryptedly with the risk of unprotected access to patient data.
- 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.

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

1.4 Intended use/Indications for use

Vivatmo *pro* Nitric Oxide Test is a portable, non-invasive device to measure fractional exhaled nitric oxide (FeNO) in human breath.

FeNO is increased in some airway inflammatory processes, such as asthma, and often decreases in response to anti-inflammatory treatment. Measurement of FeNO by Vivatmo *pro* is a method to measure the decrease in FeNO concentration in asthma patients that often occurs after treatment with anti-inflammatory pharmacological therapy as an indication of therapeutic effect in patients with elevated FeNO levels. FeNO measurements are to be used as an adjunct to established clinical assessments.

Vivatmo *pro* is suitable for children, approximately 7–17 years, and adults 18 years and older.

Testing using the Vivatmo *pro* should only be done in a point- of-care healthcare setting under professional supervision. Vivatmo *pro* should not be used in critical care, emergency care or in anesthesiology.

Special Conditions for Use Statements

Regardless of displayed measured results, monitor signs or symptoms of chest tightness, shortness of breath, coughing or wheezing for decision about treatment. Do not use the device for subjects suffering from acute upper or lower respiratory infection disease or with current serious medical conditions (other than asthma).

Vivatmo *pro* should not be used in critical care, emergency care or in anesthesiology. The following conditions can influence correct measurement of results and shall be avoided: smoking or tobacco consumption for at least 1 hour before the measurement, eating or drinking at least 1 hour before the measurement, especially nitrate rich food (e. g., spinach), strenuous exercise, use of rescue inhaler or leukotriene modifier 1 h before measurement.

The device is not indicated for children under 7 years of age including infants, or by patients who are unable to understand and execute the instructions given by healthcare providers, as measurement requires patient cooperation.

For prescription use only.

2 System elements

Basestation frontside

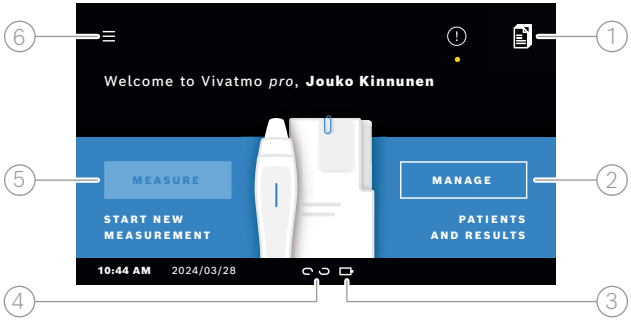
1. Handheld
2. Charging cradle
3. On/Off button
4. Touchscreen

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 the installation is complete, see “3 Installation”.

Screen elements

Element	Function
	**Help** Opens the Help screen.

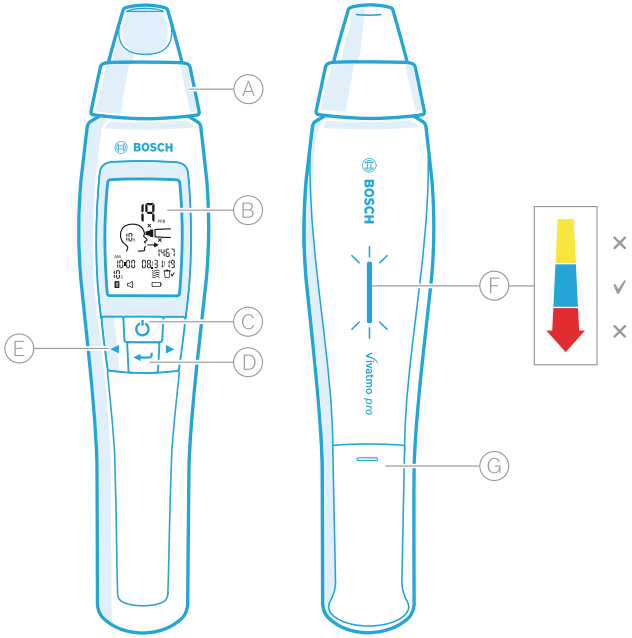
Element	Function
	**Close** Closes the current file.

Element	Function
	**Arrow left** Moves one screen backward.
	**Orientation beads** Shows the current step during the installation procedure.
	**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:



Ⓐ Disposable mouthpiece: Interface to breathe into the Vivatmo *pro* handheld.

Ⓑ Display: Shows current and stored measuring data and device messages.

Ⓒ **ON/OFF** button: Activate and deactivate the device.

Ⓓ **ENTER** button: Press this button to start the regeneration or to confirm selection.

Ⓔ **ARROW** buttons: Press these buttons to change the settings and to access stored measuring data.

Ⓕ 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.

When the handheld is placed on the basestation blue blinking light indicates that battery is charging.

Ⓖ Battery compartment

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.

2.3 Disposable mouthpiece

To perform a measurement with the Vivatmo *pro* system a disposable mouthpiece is needed.

Regular disposable mouthpiece (Vivatmo *pro* Oxycap)

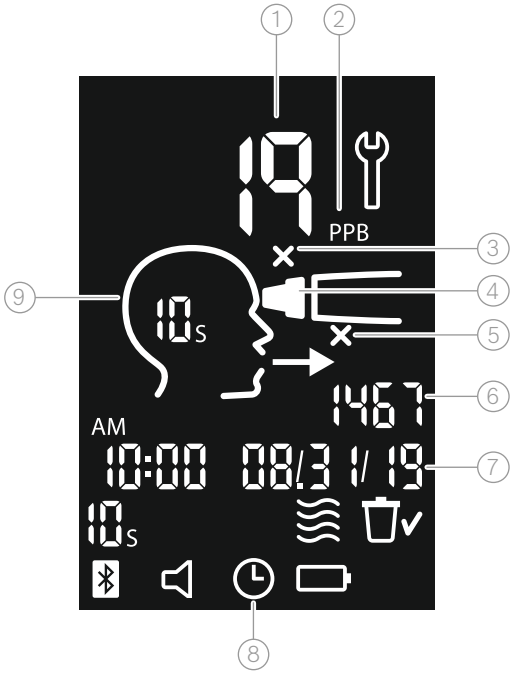
The regular Vivatmo *pro* disposable mouthpiece must be attached for performing all measurements (except of QC Level 0 measurements as described below). The outside of the regular disposable mouthpiece is transparent.

The disposable mouthpiece chemically prepares the test sample. Human breath is cleaned from contaminants and stabilized to guarantee reliable test results.

Vivatmo *pro* Level 0

Level 0 Quality Control (QC) measurement is performed with a specific Level 0 disposable mouthpiece, see “6.3.2 Performing QC”. A comparison measurement is performed for a concentration below 5 ppb. The outside of the Level 0 disposable mouthpiece is white.

2.4 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. Device ready for measurement

Handheld symbols

Icon	Function
	Reconditioning active.
	Regeneration in progress.
	Ambient NO measurement in progress.
	The memory is cleared.
	The Vivatmo *pro* handheld is connected to the Vivatmo *pro* basestation. The icon disappears when the Vivatmo *pro* handheld is used as a stand-alone device without the Vivatmo *pro* 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.

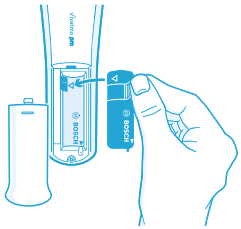
3 Installation

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. Hold 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 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 short. • Dispose of the used battery in compliance with the national or local regulations for battery disposal, see “8.1 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 “6.1 General settings”.
- Perform Ambient NO measurement, see “6.2 Ambient NO”.
- Perform QC-measurement, see “6.3.2 Performing QC”.
- Export and print.

Administrators can additionally:

- Change QC settings, see “6.5.2 Quality Control (QC) settings”.
- Change language, see “Setting the language” in 6.5.1.
- Change time and date, see “Setting date and time” in 6.5.1.
- Activate/de-activate auto-lock, see “Setting Auto-Lock” in 6.5.1.
- Install printers and export locations, see “6.5.3 Printer configuration” and “6.5.8 Export and Backup file configuration”.
- Change Vivatmo *pro* handheld used with the basestation, see “6.5.5 Release the handheld”.
- Configure network, see “6.5.6 Network configuration”.
- Configure HL7 or GDT interfaces, see “6.5.7 Order/result interface”.
- Manage user accounts, see “6.6 User administration”.

3.2.2 Onboarding

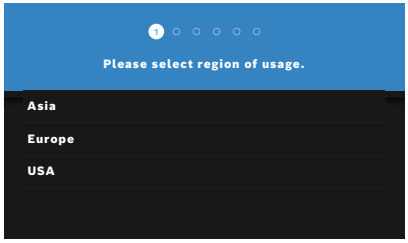
WARNING	
	Only use the Vivatmo *pro* basestation with the provided low voltage power supply unit. Attempted use with other power sources may cause irreparable damage and invalidate the warranty. Avoid connection of the Vivatmo *pro* basestation to a multiple socket-outlet to prevent interference by other 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 5 simple steps, which helps you to enter all the required settings.

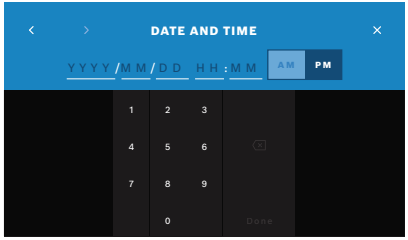
1. Switch on the basestation, by pressing the **ON/OFF** button.
   The **Region** screen is displayed.



Region and Language

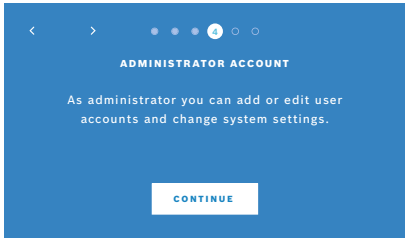
1. Select a region.
   The region selection defines the functionality approved for the region.
   The **Language** screen is displayed.

2. Select a language.
   The **Date and Time** screen opens.



Date and Time

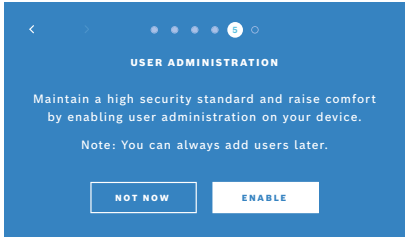
1. Set up date and time. For details, see “Setting date and time” in 6.5.1.
2. Confirm with **DONE** after successful setting.
   The **Administrator Account** screen opens.



Administrator account

1. Create an administrator account. For details, see “Add new user” in 6.6.
2. Select the **CONTINUE** button after the successful addition of an administrator.
   The **User administration** screen opens.

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.

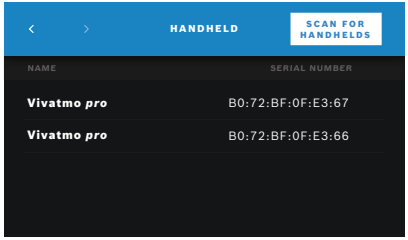


User administration

1. Select **ENABLE** to activate the user administration.
2. Create a new user by entering a user name and a passcode. For details, see “3.2.1 User concept” and “Add new user”.
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.

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.

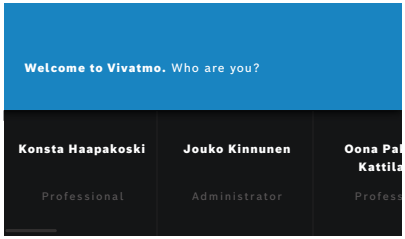


Assign handheld

1. Select the **CONTINUE** button to set up and install the handheld. To assign the handheld press **SCAN FOR HANDHELDS**. For details, see “6.5.4 Assigning the handheld”.
2. On the screen, select the **FINISH** button.The setup procedure is completed.

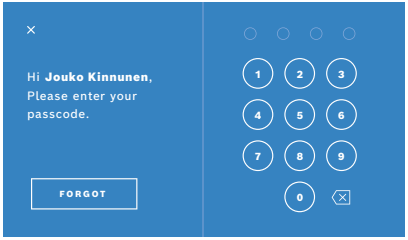
3.3 Login

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”.

The **Home** screen opens.

- Select the **MEASURE** button to start a measurement, see “4 Measure”.
- Select the **MANAGE** button to manage the data, see “5 Manage”.

4 Measure

WARNING

If the Vivatmo *pro* device has been stored in warm and humid environment or not been in use for a longer time, 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 1 hour before the measurement.
- Eating or drinking at least 1 hour before the measurement, especially nitrate rich food (e.g. spinach).
- Strenuous exercise.
- Use of rescue inhaler or leukotriene modifier 1 h before measurement.
- 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:

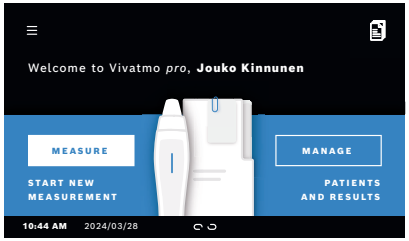
- Use only disposable mouthpieces approved for this device and from intact and unopened pouches that are not expired. See the expiration date on the pouch. Store in outer package.
- Do not clean the disposable mouthpiece.
- Take care to use regular disposable mouthpieces with transparent cover. The use 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.

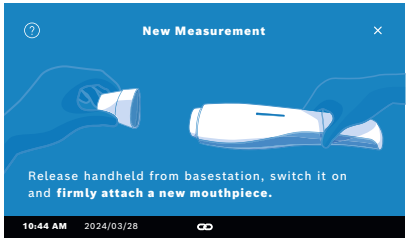
Leakage at the disposable fitting may lead to a lower measurement result.

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

4.1 Measurement using the 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.

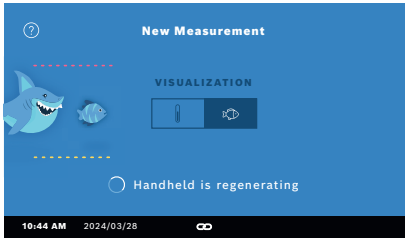


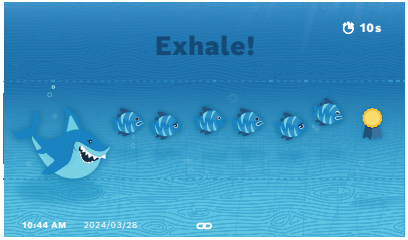
3. On the handheld display, the **Disposable mouthpiece** icon flickers. Open the pouch and attach the disposable mouthpiece firmly in a way that it fits securely on the device.

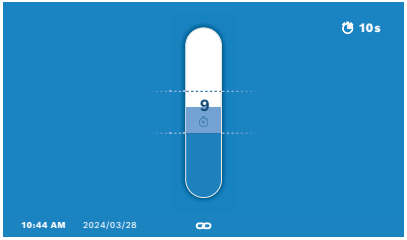
   On the handheld display, the **Disposable mouthpiece** icon stops blinking.

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.

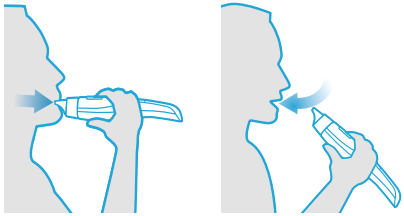
   On the lower part of the screen, you can observe the handheld regenerating and preparing the measurement.

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.

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.

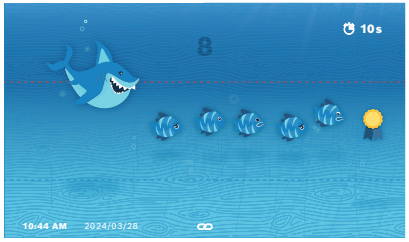
Measuring

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



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

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



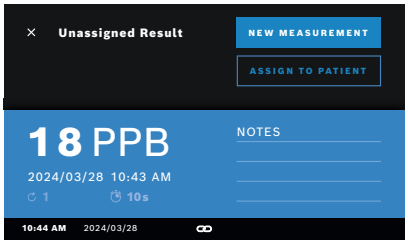
2. Exhalation should be performed through the disposable mouthpiece like blowing into a recorder or cooling a hot drink. The breath control visualization helps the patient to **stay within the dotted lines for the entire duration.**

   On the display, you see the remaining time to the end of the measurement.

   Having performed the measurement the **Result** screen opens.

	Inhalation through the disposable mouthpiece is without harm but not recommended. When the regeneration is done, start the measurement within 120 seconds. Before the next FeNO determination, you must remove and dispose the mouthpiece, see “8.2 Disposing the mouthpiece”.

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

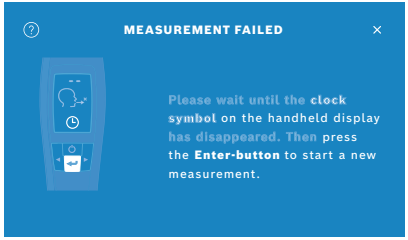


The result “5 ppb -LO-” or “<5 ppb” represents a result below the lower detection limit of the device. The result “300 ppb - HI- or “>300 ppb” represents a result above the upper detection limit of the device.

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.

Failed measurement



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.

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

4.2 Measurement stand-alone with the handheld

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. Attach a new disposable mouthpiece.

3. 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.

4. When the display shows the **Breathing** icon, start the measurement procedure within 120 seconds. The LED on the back of the device turns blue.

5. Turn the device display downwards, so that you can see the LED at the back of the device.

6. Sit in a relaxed position, inhale deeply through your mouth and lift the handheld to your mouth.
7. 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”.
8. Remove the mouthpiece.
9. Discard the mouthpiece, see “8.2 Disposing the mouthpiece”.

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 60 seconds after the regeneration:

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

Possible interpretation of results according ATS Guideline 2011 and ATS guideline 2021, see chapter “11.3 Literature”.

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.

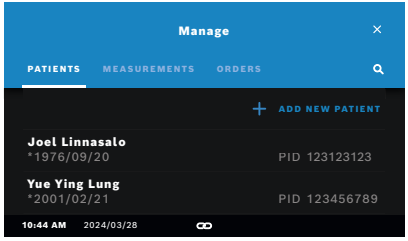
5 Manage

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.

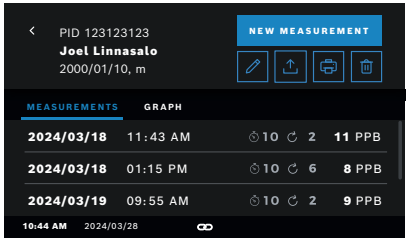
5.1 Patient records



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

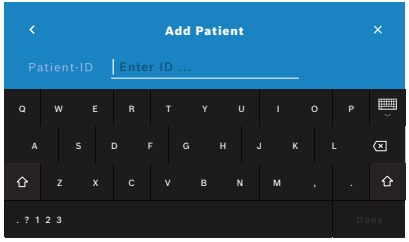
- View patient file and start new measurement, see “ Viewing patient file”.
- Add new patients, see “Adding patients”.
- Search patients, see “Searching patients”.
- Edit patient data, see “Editing patients”.
- Delete patient data, see “Deleting patients”.

Viewing patient file

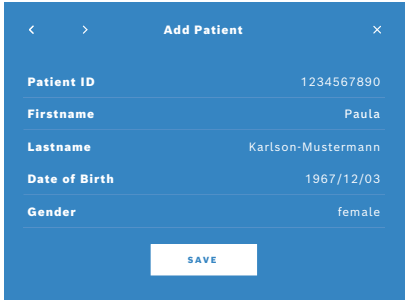


1. From the patient list, select a patient.
   The patient file is displayed and shows the last measurements.
2. Select **MEASUREMENTS** or **GRAPH** of the last measurements.
   The validity of the QC is displayed with the results. For further information on QC, see “6.3 Quality control (QC)”.
3. Select **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

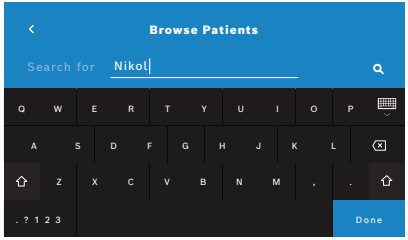


1. On the **PATIENTS** tab, select **+ ADD NEW PATIENT**.
   The **Add Patients** screen opens. Entering a alphanumeric **patient ID** is mandatory, all other entries are optional.
2. Select the patient ID (PID) from the list,
   change content on the **Patient ID** screen and confirm with **DONE**.
3. Select the Firstname, Lastname and Date of Birth if required, change content on the selected screen and confirm with **DONE**.
4. The gender of the patient can be changed in a drop-down menu.



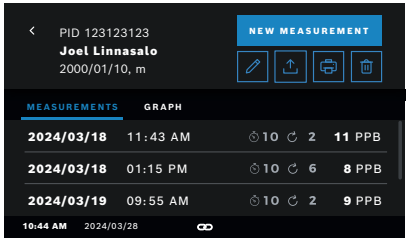
5. Confirm all entries with **SAVE**.

Searching patients



1. On the **PATIENTS** tab, select the **Search** button.
   The **Browse** 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

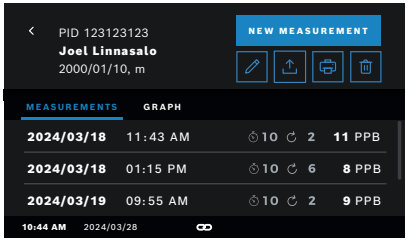


1. In the patient list, select the patient you want to edit.
   The **Patient File** screen opens.
2. Select the **Pencil** button to edit the patient data.
3. Follow the wizard step-by-step to edit the data.

Deleting patients

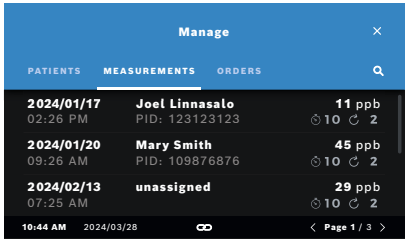
1. In the patient list, select the **Delete** button.
   You are asked to confirm before a patient file is deleted.

5.2 List of measurements



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, see page 29.

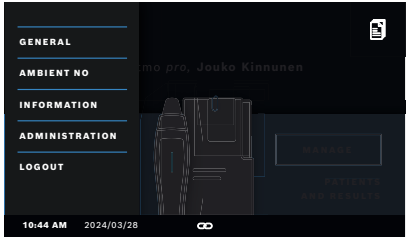
5.3 List of measurement orders



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 send back to the electronic patient record system.
   The patient is added to the list of patients on the Vivatmo *pro* basestation.

6 Settings

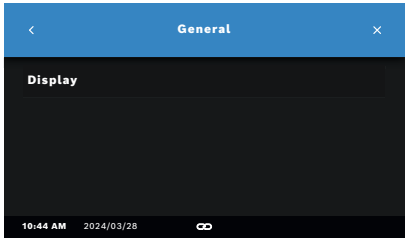
The access to settings depends on the login as professional or administrator, see “3.2.1 User concept”.



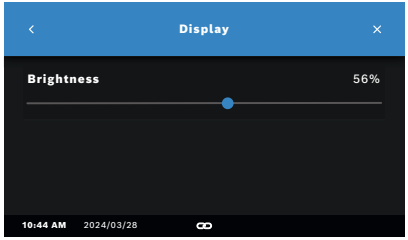
1. On the **Home** screen, select the **Settings** menu.

6.1 General settings

Setting the display

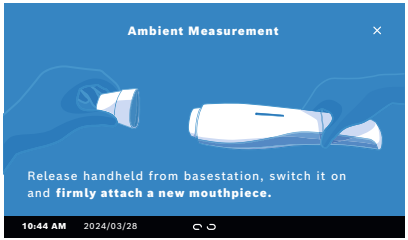


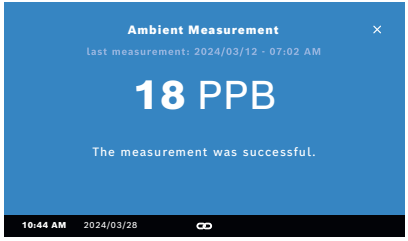
1. Select **General Settings** to change display settings.
   Select **Display**.



2. Select the point and move it to set the brightness.

6.2 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.
3. Attach a new mouthpiece, see “4.1 Measurement using the basestation”.
4. Lay down the handheld in a way that the device has good access to the ambient air.
5. Select the **RUN MEASUREMENT** button.
   On the screen, you see that the ambient NO measurement is running.

When the ambient NO measurement is done, you see the result on the screen.

6.3 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.

Quality Control should be conducted in accordance with federal, state, and local regulations. QC is recommenended 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, “6.5.2 Quality Control (QC) settings”.

Vivatmo *pro* supports QC for 2 reference concentrations:

- **Level 0**

  Level 0 is performed with a specific white Vivatmo *pro* Level 0 disposable mouthpiece, see “2.3 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.

6.3.1 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.

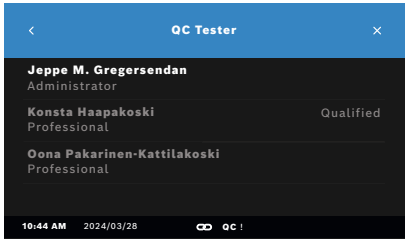
To qualify as tester, you must complete the following steps:

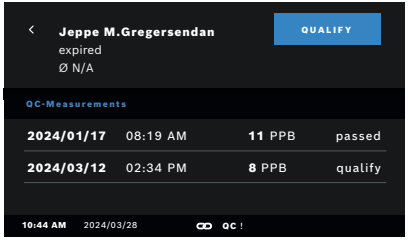
- Perform 4 measurements within 7 days, not more than one qualification measurement per day.
- The QC-measurement on the fourth day must be within accepted range of 5 ppb ± 3 x standarddeviation, at least ± 3 ppb from the mean value.

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 “6.5 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.

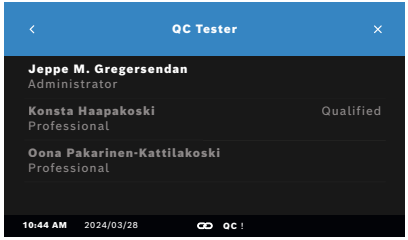
6.3.2 Performing QC

QC provides 2 reference measurement tests:

1. Level 0
2. Defined NO with QC tester

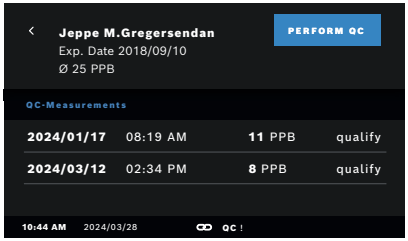
In the “6.5.2 Quality Control (QC) settings”, QC can be restricted to 1 QC reference measurement only. Dependant on the QC settings, QC is performed first with Level 0 and then with defined NO with QC tester, or with the selected reference QC-measurement only.

Start QC-measurement



1. 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

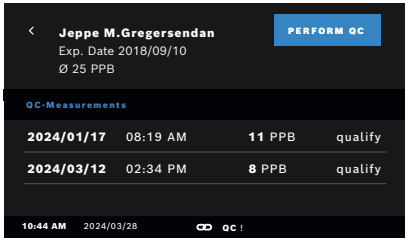


If Level 0 QC is configured perform the following steps:

1. Select your user name and select the **PERFORM QC** button (only if QC tester is activated).
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.

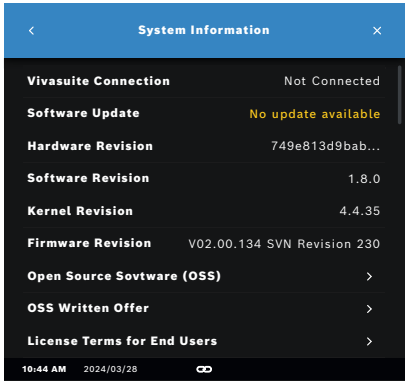
QC-measurement QC tester

The second reference QC-measurement is performed by a qualified QC tester. For the QC tester qualification procedure, see “6.3.1 QC Tester qualification”.



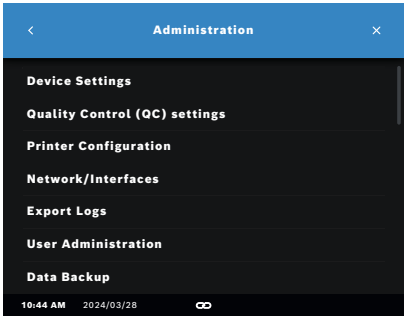
1. Select your user name.
   You can see your datasheet with the list of your last QC-Measurements.
2. Select the **PERFORM QC** button.
3. Attach a regular transparent disposable mouthpiece.
4. Perform the measurement, see “4.1 Measurement using the basestation”.
   When the result is in the acceptance 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 peformed.

6.4 System information



1. In the **Settings** menu, select **INFORMATION**.
   The **System information** screen opens. Find the versions of the used software components might 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.

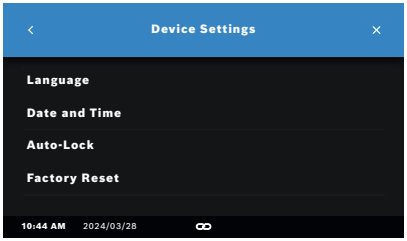
6.5 Administrator settings



Administration settings are activated only if you are logged in as administrator.

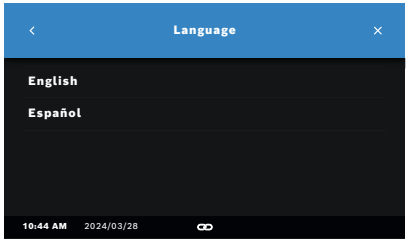
1. Log in as administrator.
2. In the **Settings** menu, select **ADMINISTRATION**.

6.5.1 Device settings



1. On the **Administration** screen, select **Device Settings**.
   The **Device Settings** screen opens for changing Language, Date and Time, Auto-Lock or Factory Reset. Factory Reset resets all stored data and settings.

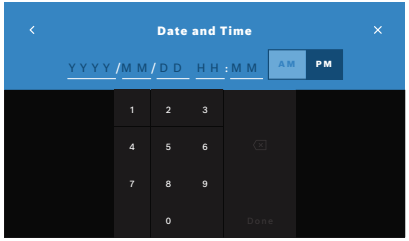
Setting the language



1. On the **Device Settings** screen, select **Language**.
2. Select the desired language.

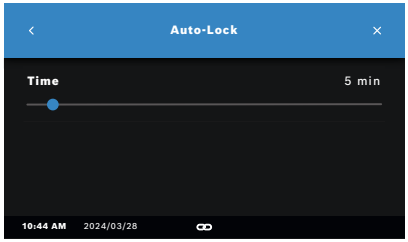
Setting date and time

The time format is <yyyy/mm/dd>, <hh:mm> 0–12 AM/PM.



1. On the **Device Settings** screen, select **Date and Time**.
2. Enter year, month and day. Enter the time and select AM or PM.
3. Confirm with **DONE**.
4. Select the **CONTINUE** button to confirm your settings.

Setting Auto-Lock



When Auto-Lock is activated, the system shuts down to save energy and protect patient data. The user needs to log in again after an automatic lockoff.

You can set the interval according to the needs in the clinical environment.

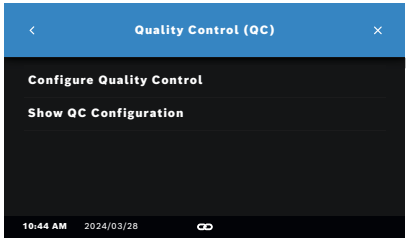
5. On the **Device Settings** screen, select **Auto-Lock**.
5. Select and hold the blue point and move it to the desired Auto-Lock time.

Factory reset

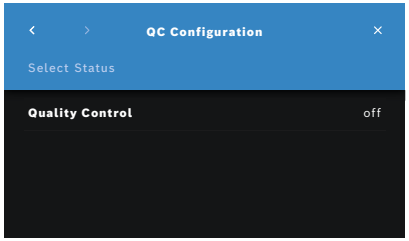
Factory reset removes all stored measurements from the basestation and all data of patients and users. Date and time are reset and no handheld will be connected afterwards.

Use factory reset prior to disposal or service returns only.

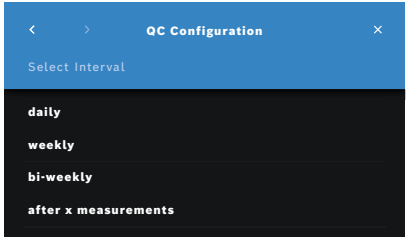
6.5.2 Quality Control (QC) settings



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.

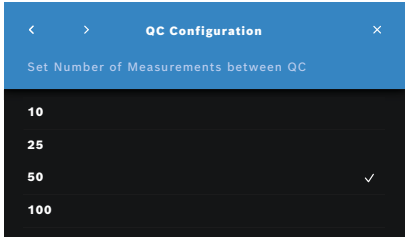


2. Select **Configure Quality Control**.
3. Select **ON/OFF** to activate or deactivate the QC mode.
   For further information see “6.3 Quality control (QC)”.
4. Select the **Arrow Right** button to move to the next screen.

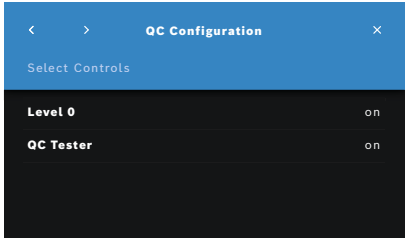


5. Select the interval to perform the quality control
   - by time: select daily, weekly, bi-weekly or
   - by number of performed measurements: select **After x measurements**.

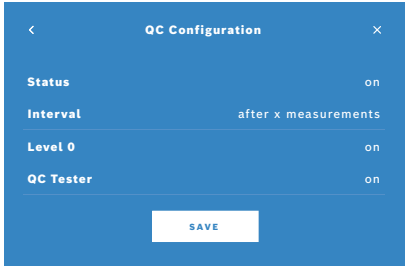
   Select the **Arrow Right** button.



6. Enter the number of measurements to be performed before next quality control.

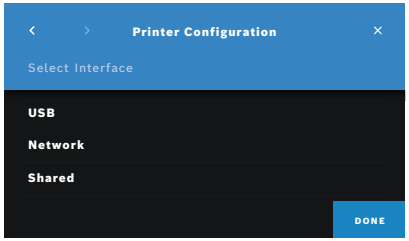


7. After selecting the interval, select the **Arrow Right** button.
   Quality control is recommended with both Level 0 and QC Tester reference controls.
8. Select activation or deactivation of this control methods.



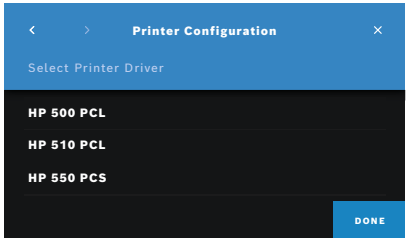
9. Select the **Arrow Right** button to move to the next screen.
   The **QC Configuration** screen opens with an overview of the current QC settings.
10. Check your QC configuration.
11. Confirm with **SAVE** to save the QC configuration.

6.5.3 Printer configuration



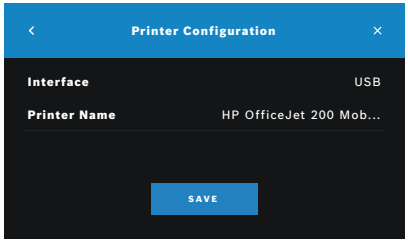
1. On the **Administration** screen, select **Printer Configuration**.
   The **List of Printers** screen opens. The standard printer is highlighted.
2. Select **Add new printer**.
3. Select the desired printer interface:
   - USB
   - Network
   - Shared

   Select the **Right Arrow** to move to the **Select Printer** screen.



Printing data is transmitted unencrypted.

4. On the **Select Printer** screen, select the desired printer.
5. Select the **Right Arrow** to move to the **Select Printer Driver** screen.
6. Select the **printer driver**.



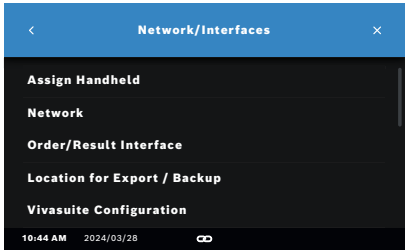
The **Printer Configuration** screen is displayed.

7. Confirm with **SAVE** to save the printer configuration.
   The list of printers is shown.

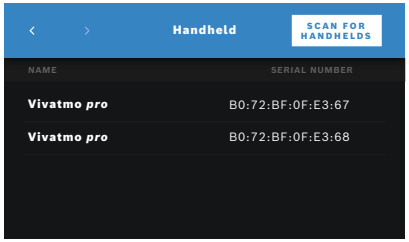
Elements in the list of printers:

1. Mark a printer to select your standard printer.
2. Select the **Delete** button to delete a printer from the list.
3. Select the **x** button to close the list.

6.5.4 Assigning the handheld



1. On the **Administration** screen, select **Network/Interfaces.**



2. On the **Network** screen, select **Assign Handheld**.
3. Turn on your handheld.
4. Select **SCAN FOR HANDHELDS**.
5. Wait until the scan procedure is completed.

   You see the list of active handhelds.

   If no handheld is active, you see the message: “No handhelds available”.
6. Compare the number of the Vivatmo *pro* handheld in the list with the serial number beneath the symbol SN on the handle of the handheld.
7. From the list, select the Vivatmo *pro* handheld which shall be installed with your Vivatmo *pro* basestation.
8. The Configuring device screen opens.The handheld and the basestation connect automatically.

The Vivatmo *pro* handheld and the Vivatmo *pro* basestation show the same date and time now.

If QC is activated, perform a QC-measurement after assigning a new handheld. The basestation software stores the QC status of the handheld with each measurement.

6.5.5 Release the handheld

In case another handheld was installed before, it is disconnected by tapping the **Release Handheld** button. If you want dispose of the old handheld, clear the memory and take out the battery.

1. Keep the **ENTER** button and the **Arrow right** button pressed for 3 seconds.

The **Clear memory** icon is selected.

2. Use the **Arrow** buttons to select the check mark.

3. Press the **ENTER** button to confirm the clear memory.

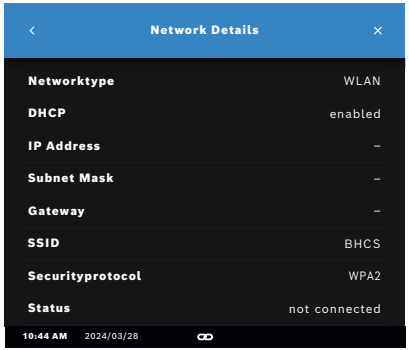
An animation is shown while the **Clear memory** icon flashes.

4. Press the **ENTER** button to return to the main screen.
5. Switch off the handheld.

6.5.6 Network configuration

Vivatmo *pro* can be connected to a local area network to receive measurement orders, send back measurement results, export patient related measurement data, or use a network printer. Vivatmo *pro* supports Ethernet and Wireless via WLAN connection.

Vivatmo *pro* shall not be used in unprotected networks. Data security using user credentials shall be used in accordance with the local data security policies. Data is transmitted unencrypted.

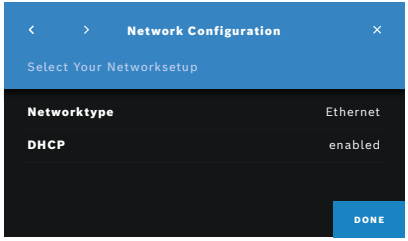


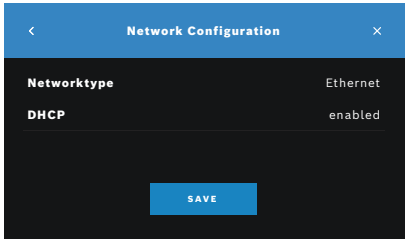
1. On the **Network/Interfaces** screen, select **Network**.
2. If a network access is configured already, select **Show Network Configuration**.

   The **Network Details** are:

   - **Networktype:** WLAN or Ethernet
   - **DHCP**: **D**ynamic **H**ost **C**onfiguration **P**rotocol
     When DHCP is enabled, the device supports the configuration of the network.
   - **SSID**: **S**ervice **S**et **Id**entifier
     Shows the name of the WLAN network.
   - **Securityprotocol**: Shows the security protocol used for your system.
   - **Password**: Shows the network password.

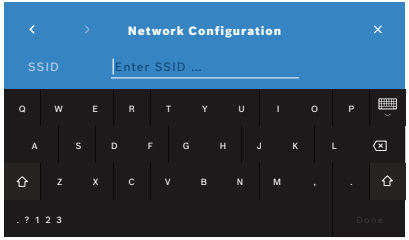
Supported configuration of an ethernet connection

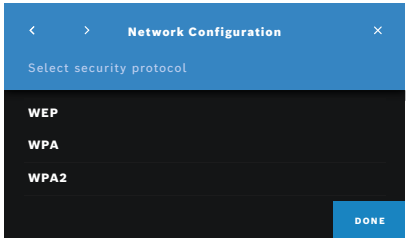




1. Plug in the ethernet cable in the ethernet port on the rear of the Vivatmo *pro* basestation.
2. On the **Network** screen, select **Configure Network**.
3. Select the Networktype **Ethernet** in the drop down menu.
4. Enable **DHCP**.
5. Confirm with **SAVE**.

Supported installation of a WLAN connection

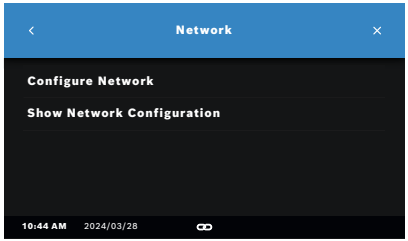




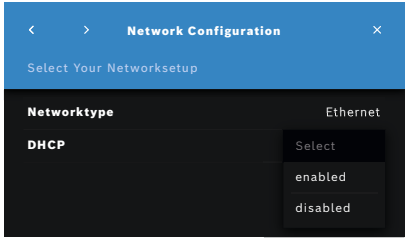
1. On the **Network** screen, select **Configure Network**.
2. Select the Networktype **WLAN**.
3. Enable **DHCP**.
4. On the **Set network SSID** screen, enter the name of the WLAN.
5. Select the **Right Arrow** or the **DONE** button to leave the screen.

6. Select the security protocol activated in your WLAN.
7. Select the **Right Arrow** button to leave the screen.
8. On the next screen, enter the WLAN Password of your WLAN.
9. Select the **Right Arrow** or confirm with **DONE** to leave the screen.
10. Confirm with **SAVE**.

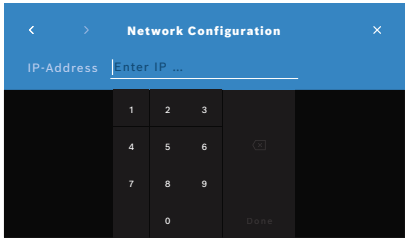
Manual ethernet configuration



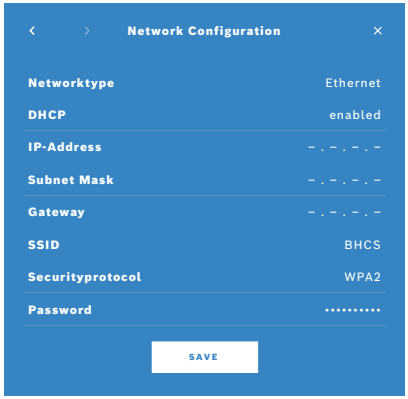
1. Plug in the ethernet cable in the ethernet port of the basestation.
2. On the **Network** screen, select **Configure Network**.



3. Select the **Networktype Ethernet**.
4. Disable **DHCP**.



5. Enter the **IP-Address** of your network and the Subnet Mask of your network.
6. Enter the **Gateway ID**.
7. Select the **Right arrow** or confirm with **DONE** to leave the screen.



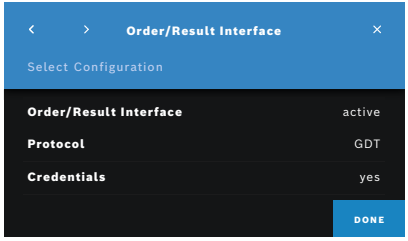
8. Confirm with **SAVE**.

Manual WLAN configuration

1. On the **Network** screen, select **Configure Network**. The **Network Configuration** screen opens.
2. Select the Networktype **WLAN**.
3. Disable **DHCP**.
4. Follow steps 4 to 8 of “Supported installation of a WLAN connection”.
5. Follow step 5 to 8 of “Manual ethernet configuration”.
   After a successful configuration, the **Network Configuration** screen is displayed.
6. Confirm with **SAVE**.

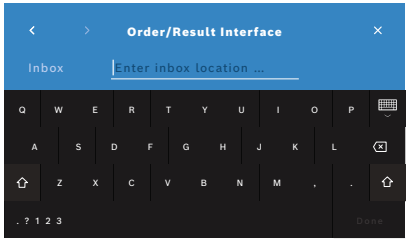
6.5.7 Order/result interface

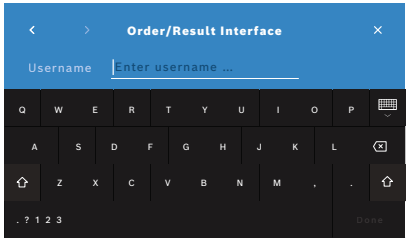
Vivatmo *pro* can receive measurement orders from and send results to an electronic patient record system (EPR), if the network is configured. The interface standards GDT (German Data Transfer) and HL7 (Health Level 7) are supported.
To configure the interface to your patient management system follow the installation wizard:

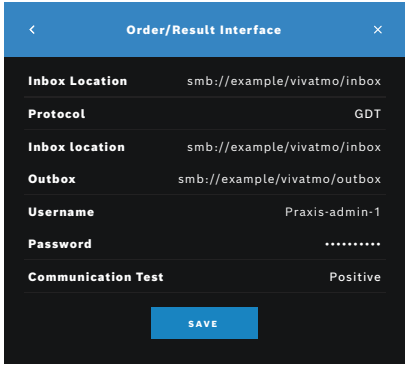


1. On the **Administration** screen, select **Network/Interface**.
2. On the **Network and Interface** screen, select **Order/Result Interface**.
   You can select:
   - **Configure Interface** to change the settings.
   - **Show Interface Configuration** to display the current settings.

   Select **Configure Interface** to change settings.
3. Activate the **Order/Result Interface**. The system keeps the interface settings when de-activated.
4. Select the **Arrow Right** button to move to the next screen.
   Select the desired protocol standard: **HL7** or **GDT**.
5. Select **Yes** for Credentials when the **Order/Result Interface** is access controlled by user name and password.







6. In accordance to IT definitions in your organization, define the location for the inbox for incoming measurement orders.
7. Repeat the procedure for the location of the outbox.
8. Confirm with **DONE**.

When credentials are required, follow steps 9 to 13.

9. Enter the user name required to access the data from the EPR system.
10. Confirm with **DONE** to move to the next screen.
11. Enter the password required to access the data from the EPR system.
12. Confirm with **DONE**.

    The settings for the **ORDER/RESULT INTERFACE** are displayed including the result of a Communication Test.
13. Check the data and confirm with **SAVE** when the data are correct.

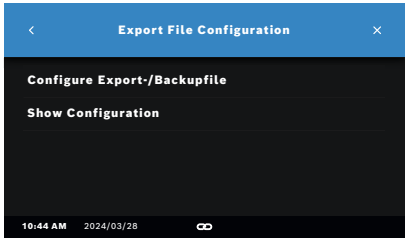
    On your home screen, you see the order button, see “2.1 Screen elements”.

    If you delete the inbox and the outbox, the order button disappears from the home screen.

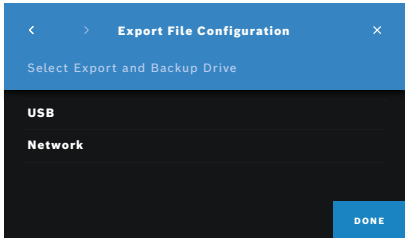
6.5.8 Export and Backup file configuration

You can export data from patient records (see “5.1 Patient records”) or backup the entire measurement and patient data (see “6.7 Data backup”) to a defined storage location. The storage location can rather be a USB drive or a network drive. Export files of a patient can be identified by the time stamp and the patient name. Export data are transmitted unencrpyted. The backup file is stored encrypted and can be imported to the same basestation only.

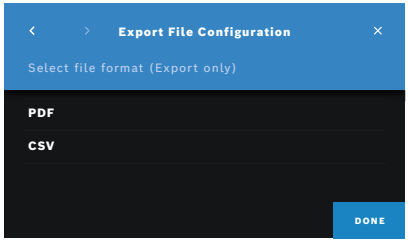
For configuration follow the configuration wizard:



1. On the **Administration** screen, select **Network and Interfaces**.
2. On the **Network and Interfaces** screen, select **Location for Export/Backup**.



3. Select **Configure Export/Backup File** to change the settings.
4. In accordance to IT definitions in your organization, define the location for the storage of the export and backup files on USB or network drive. End the location path always with “/”-symbol.



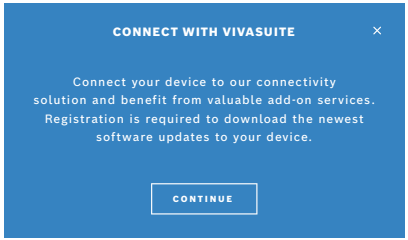
5. Select **CSV** or **PDF** as export format.
   The settings for the **Location for Export/Backup** are displayed.
6. Check the data and confirm with **SAVE** button when the data are correct.

6.5.9 Vivasuite configuration

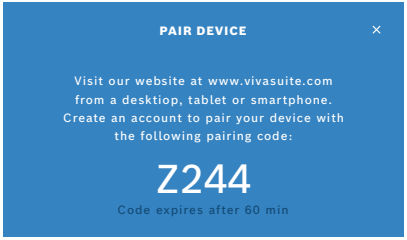
Vivasuite is the digital Vivatmo ecosystem allowing use of services such as device management and remote software update. Vivasuite runs in the Bosch managed Cloud and applies highest standards regarding IT security and data privacy. The Vivasuite service is not available in all countries. Ask your local distributor.

A registration to Vivasuite and pairing of your device is required. Your device must be connected to an internet- enabled network.

To connect Vivatmo *pro* to Vivasuite perform the following steps:

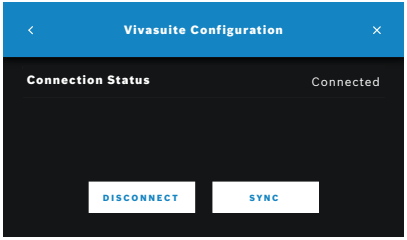


1. Vivasuite: Register an account on www.vivasuite.com and log into your account.
2. Vivatmo *pro*: On the Administration Screen select **Network/Interfaces**. On the **Network/Interfaces** screen, select **Vivasuite configuration**.
3. Vivatmo *pro*: Click through introduction and configure your network connection (for details see “6.5.6 Network configuration”) until devices show screen with the pairing code.



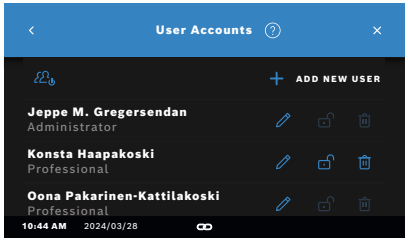
4. Vivasuite: Click **Add device**.
5. Vivasuite: Enter the pairing code shown on the Vivatmo *pro*.
6. Vivatmo *pro*: Confirmation screen is shown.

To disconnect Vivatmo *pro* from Vivasuite perform the following steps:



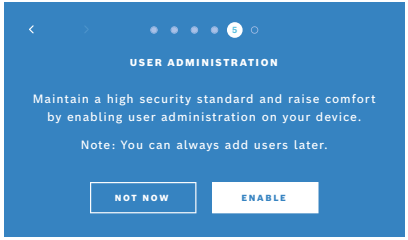
1. Vivatmo *pro*: On the **Network/Interfaces** screen, select **Vivasuite Configuration**.
2. Vivatmo *pro*: Select **Disconnect**. You are asked to confirm before device gets disconnected.

6.6 User administration



1. On the **Administration** screen, select **User Administration**.

   Access control by user accounts can be disabled by the button  .



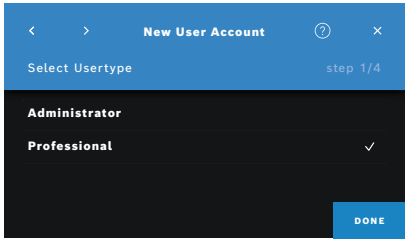
When **USER ADMINISTRATION** is not enabled in the setup procedure, the **User Accounts** screen opens to **ENABLE** individual user accounts.

By disabling the User Administation the user settings are kept for later use. See also “3.2.1 User concept”.

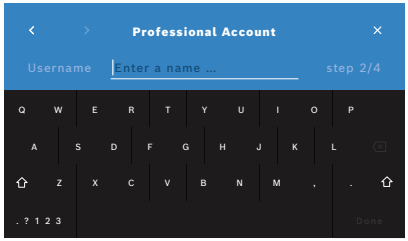
Add new user

For adding a new user, follow the configuration wizard:

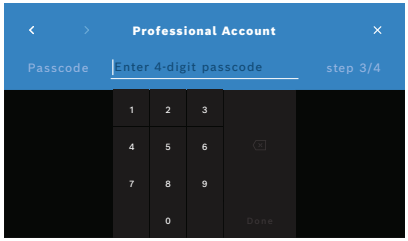
1. On the **User Accounts** screen, select the **+ ADD NEW USER** button.



2. Select the desired **user type**, see “3.2.1 User concept”:
   - Administrator
   - Professional



3. Enter the **name** of the user.



4. Enter the respective **passcode**:
   - a 4 digit passcode for a professional user.
   - an 8 digit passcode for an administrator account.
5. Repeat the passcode.
6. Confirm with **DONE**.
   The user is successfully added.

Editing and reset user accounts

1. On the **User Accounts** screen, select the user you want to edit.
2. Select the **Pencil** button.
3. Enter your changes to user name and passcode.
4. Confirm with **DONE**.

Enable/Disable user account

1. On the **User Accounts** screen, select the user you want to enable/disable.

2. Select the **Enable/Disable user** button.
   When lock is open, the user access is enabled.

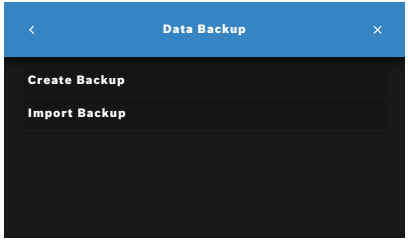
Deleting user accounts

1. On the **User Accounts** screen, select the user you want to delete.

2. Select the **Delete** button.
   The account is deleted.

6.7 Data backup

Data backup stores the entire measurement and patient data encrypted at the defined storage location, see “6.5.8 Export and Backup file configuration”. Due to the encryption mechanism the backup data can be imported to the same basestation only. The import of the backup overwrites the data stored on the basestation.



1. On the **Administration** screen, select **Data Backup**.
2. Select between:
   - **Create Backup**
   - **Import Backup**

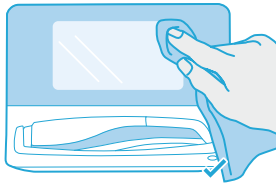
   The backup procedures might take up to 5 minutes.

7 Maintenance and trouble shooting

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.

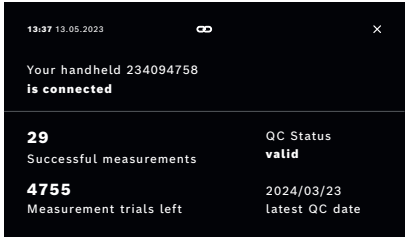
The Vivatmo *pro* is easy to maintain. Clean the device in accordance with the hygienic standards of your organization.



Cleaning and Disinfecting

1. Turn off the device. Wash hands thoroughly with soap and water.
2. Wipe the entire Vivatmo *pro* with alcohol disinfectant wipes with maximum 30 % alcohol, e.g., Caviwipes1 (Metrex), Mikrobac Tissues (Bode Chemie GmbH) or mikrozid 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 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.

1. Slide up the handheld connected icon to view the number of trials left.
2. If required, change the handheld, see "6.5.4 Assigning the handheld".

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 a warm and humid environment or has not been in use for a longer time, the **wrench** symbol may appear on the basestation and the handheld. 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.

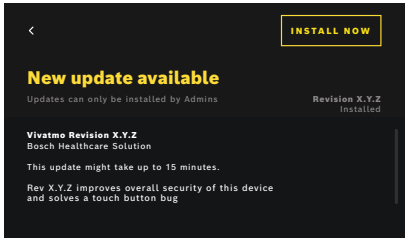
1. The **wrench** symbol on the handheld and the basestation indicates that the reconditioning process is on going. The remaining reconditioning time is shown in minutes.
2. The handheld beeps and blinks 3 times blue when reconditioning is finished.
3. Dispose mouthpiece after reconditioning.

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 2–3h 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

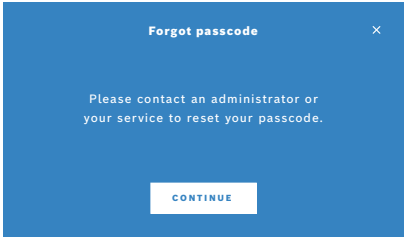
When the Vivatmo *pro* is connected to Vivasuite (see “6.5.9 Vivasuite configuration”) new software updates will automatically be available on the device. The device administrator always has full control over new software updates. A notification informs about the availablitiy of a new software update 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 Trouble shooting

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.

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 Trouble shooting 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”.
	Measurement procedure is incorrect, breathing was too strong, too weak or time-limit after regeneration was exceeded.	Repeat the measurement, see “4.2 Measurement stand-alone with the handheld”.
	Permissible number of measurement trials reached soon, measurements still possible.	See display for number of remaining measurement trials. Order new Vivatmo *pro* handheld, see “7.2 Status information handheld”.
	Number of permissible measurement trials reached. Device does not perform any measurements after maximum number of permissible tests is reached.	Connect a new Vivatmo *pro* handheld and dispose of the old one, see chapter “8.1 Disposing the Vivatmo *pro* device and the battery”.

Display	Description	Solution
	Humidity in device too high.	Check ambient conditions and take a new mouthpiece.
	Ambient temperature and air pressure (altitude) is outside the specified range.	Use the Vivatmo *pro* in a location with permissible ambient conditions. When transporting the device from one place to another, a stabilization period of at least 20 minutes should be observed before use.
	Battery is too weak for measurement.	Place the device on the basestation for charging.
	System self-test failed.	Make sure the battery is sufficiently charged by positioning the handheld on the basestation for at least 2 hours. Take out and re-insert the battery of the handheld if the error persits and/or change the battery. If the error persists, contact your distribution partner.
	Regeneration failed.	Press the **ENTER** button to repeat the regeneration. If the errors persists, contact your distribution partner.

8 Disposal

8.1 Disposing the Vivatmo *pro* device and the battery

Delete data on your device prior to disposal or service returns ,see “6.5.1 Factory Reset” and “6.5.5 Release the handheld”.

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.

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.

8.2 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 of the used one in contaminated patient waste.

9 Technical data

9.1 Device data

Model	**Vivatmo *pro***
Operating conditons temperature / humidity	+15 °C to +27 °C / 15 % to 60 % relative humidity (non-condensing)
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 / air pressure	+5 °C to +27 °C / 10 % to 60 % relative humidity between uses / 780 hPa to 1,100 hPA
Data transfer	Ethernet 10/100MB, WLAN 2.4 GHz b/g/n; internal: Bluetooth Smart (low energy), 2.4 GHz

Basestation	Catalogue number F09G100168
Display basestation	7 inch 16:10, 1024 x 600 pixel touchscreen
Weight	1350 g
Dimensions	265 x 213 x 160 mm
Electrical safety	ME device with external supply, tested according to EN 60601-1, IP20 for basic safety
Wireless charging	Charging w/ constant current up to 220 mA followed by constant voltage up to 4.2 V stopping when fully charged

Power supply (accessory)	
Model type	UE electronic UE36LCP-240150SPA or DONGGUAN UES36LCP-240150SPA
Input voltage	100 – 240 VAC,≤ 1.0 A, 50 – 60 Hz
Output power range	< 25 W
Output voltage	24 V

Handheld	Catalogue number F09G100078
Measuring range	5 ppb to 300 ppb
Linearity	r2 ≥ 0.998, slope 1.00 ± 0.05 , intercept +/– 5 ppb
Accuracy for 10 second measurement mode	± 5 ppb below 50 ppb, ± 10 % for ≥ 50 ppb, ±15 % for ≥ 160 ppb expressed as the upper/lower confidence limit of 95%
Precision for 10 second measurement mode	± 5 ppb below 50 ppb, ± 10 % for ≥50 ppb, ±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
Sensor	Chemical field-effect transistor
Data transfer	Bluetooth® Smart (low energy), 2.4 GHz frequency band
Weight	170 g
Dimensions	4.0 cm x 5.4 cm x 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 (accessory)	
Disposable mouthpiece single-time use	Measurement limited to 5 measurement trials within 15 minutes
Useful life of disposable mouthpiece	Limited by expiration date

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.

9.2 Device Performance

Linearity

Three Vivatmo *pro* devices were tested on linearity as part of a study on accuracy. A range of contrived FeNO concentrations (in total, nine NO concentrations and a negative control) from 3 ppb to 330 ppb were tested to determine linearity. The data showed that the test is linear within the claimed range of 5–300 ppb NO, with a slope of 1.0 ± 0.05 and an r^2 coefficient ≥ 0.999. The results are listed in the table below.

	Slope	**Intercept**	**R^2**
Combined devices	0.97	2.23	0.999

Analytical Precision

A nested components-of-variance design with 20 testing days, two runs per day, three Vivatmo *pro* devices and two replicate measurements per run ("20 x 2 x 2" design) for each concentration was used for the determination of analytical precision. Five NO concentration levels (15 ppb, 25 ppb, 50 ppb, 200 ppb, 275 ppb) were tested with the Vivatmo *pro* devices at a gas flow of 50 ml/s. Analysis for measurements captured at each concentration used a two-way nested ANOVA to calculate the following variance components:

- Repeatability = estimate of variation within one test run in one day
- Within-device precision = estimate of variation between test runs and days

The precision and repeatability for Vivatmo *pro* is claimed to be a standard deviation of ≤ 5 ppb for readings ≤ 50ppb, and a CV of ≤ 10 % for readings > 50 ppb and ≤ 160ppb, and a CV of ≤ 15 % for readings > 160 ppb. The precision/repeatability testing performed confirmed that the precision/repeatability performance of Vivatmo *pro* fell within these specifications.

The results are listed in the tables below.

Within-device precision for 3 Vivatmo *pro* handheld devices

NO concentration	**15 ppb**	**25 ppb**	**50 ppb**	**200 ppb**	**275 ppb**
	SD	SD	SD	CV	CV
D01769D3B2CF	3 ppb	4 ppb	5 ppb	4 %	5 %
D01769D0FB36	3 ppb	4 ppb	5 ppb	3 %	5 %
D01769CC8580	3 ppb	3 ppb	5 ppb	4 %	4 %
Acceptance criteria	≤ 5 ppb	≤ 5 ppb	≤ 5 ppb	≤15 %	≤15 %

SD: standard deviation, CV: coefficient of variation

Repeatability for 3 Vivatmo *pro* handheld devices

NO concentration	**15 ppb**	**25 ppb**	**50 ppb**	**200 ppb**	**275 ppb**
	SD	SD	SD	CV	CV
D01769D3B2CF	2 ppb	2 ppb	2 ppb	3 %	4 %
D01769D0FB36	1 ppb	1 ppb	2 ppb	2 %	2 %
D01769CC8580	2 ppb	1 ppb	2 ppb	3 %	2 %
Acceptance criteria	≤ 5 ppb	≤ 5 ppb	≤ 5 ppb	≤15 %	≤15 %

SD: standard deviation, CV: coefficient of variation

Analytical Accuracy

Three Vivatmo *pro* devices were tested at nine NO concentrations between 3 and 330 ppb NO with two test runs and two replicates per device per run. The data showed that mean Vivatmo *pro* results were within 5 ppb for NO concentrations ≤ 50 ppb, and percent errors were less than 10 % for NO concentrations of 50 ppb and greater. The results are listed in the table below. The accuracy for all test cases is within the technical specification.

	D01769CC8580		**D01769D3B2CF**		**D01769D0FB36**		**Acceptance criteria**
NO Concentration	Lower 95 % CI	Upper 95 % CI	Lower 95 % CI	Upper 95 % CI	Lower 95 % CI	Upper 95 % CI	
≤ 50 ppb	1.6 ppb	3.1 ppb	0.8 ppb	2.0 ppb	0.6 ppb	1.9 ppb	± 5 ppb
> 50 ppb	1.9 %	5.0 %	−0.3 %	4.6 %	0.3 %	5.8 %	± 10 %

Limit of detection

The limit of detection was determined based on CLSI EP17-A2. Two Vivatmo *pro* devices were tested over 5 days with two Oxycap lots at 5 NO concentrations with a total of 40 replicates per NO concentration per Oxycap lot. The following NO concentrations above and below the claimed cutoff at 5 ppb were used: 3, 5, 7, 9, 11 ppb.

The following table shows all relevant data and the calculated LoD that supports the claimed LoD of 5 ppb:

Mean Blank (µB)	1.5 ppb
Standard deviation Blank (SD_B)	0.65 ppb
Limit of Blank (LoB)	2.6 ppb
Standard deviation LoD measurement (SD_D)	0.71ppb
Limit of Detection (LoD)	3.8 ppb

Summary of the clinical data

Clinical precision

Two clinical precision studies were performed with a total of 143 subjects (65 children and 78 adults). In the first study Participants were asked to obtain two Vivatmo *pro* measurements in two visits each for a total of N = 88 Vivatmo *pro* evaluations with 2 measurements. In the second study Participants [N = 95] were asked to obtain 3 repeated measurement pairs in one visit. Results are summarized in the table below.

N = analysis subjects

Median Concentrations [ppb]	N	Within subject mean SD [ppb]	95 % CI for SD	Within Subject Mean CV [%]	95 % CI for CV [%]
0 to < 10	28	1.09	0.93; 1.31	15.64 %	13.37 %; 18.85 %
10 to < 20	56	2.19	1.95; 2.51	15.47 %	13.74 %; 17.70 %
20 to < 30	28	2.45	2.12; 2.89	10.07 %	8.73 %; 11.91 %
30 to < 40	18	3.30	2.64; 4.41	9.62 %	7.69 %; 12.86 %
40 to < 50	8	4.46	3.43; 6.37	9.80 %	7.54 %; 14.00 %
>= 50 ppb	45	6.54	5.81; 7.47	7.75 %	6.88 %; 8.86 %

Clinical accuracy

A study was also performed to assess the clinical accuracy of the device. A total of 161 patients (n = 106 adults and n = 55 children) participated in a longitudinal study where measurements for FeNO, spirometry, and asthma control questionnaires were completed at baseline (Visit 1) and two weeks later (Visit 2) after therapeutic agents were administered.

For those with elevated initial FeNO levels > 30 ppb for adults and > 25 ppb for children (total n = 95),there was a fall in mean FeNO measured by Vivatmo *pro* in patients with elevated FeNO levels for combined adult and pediatric treatment populations. Results showed a mean change of – 39.1 ppb (– 41.6 %) with a mean SD of 43.9.

The decline in FeNO after 2 weeks of corticosteroid therapy resulted in the following changes in subjective and objective asthma measures.

- ACQ: Mean ACQ score fell by – 51.1 % after corticosteroids
- FEV1: There was a mean FEV1 change of 6.9 % after corticosteroids

9.3 Symbols

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

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

LOT	Batch number
	Electrical safety class II
	Regulatory compliance mark Australia
	For single use only
⎓	Direct current

Rx	For Prescription Use
CLASSIFIED c UL us E514097	Medical - General medical equipment as to electrical shock, fire and mechanical hazards only in accordance with ANSI/AAMI EN60601-1:2005 + C1:2009 + A2:2010 + A1:2012, IEC60601-1-6:2010 + A1:2013 CAN/CSA-C22.2 No. 60601-1:2014 & 60601-1-6:2011 + A1:2015

9.4 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: https://www.vivatmo-hcp.com/en/

11 Appendix

11.1 Electromagnetic compatibility

Important information regarding electromagnetic compatibility (EMC)

This device complies with Part 15 of the FCC Rules and contains license-exempt transmitter(s)/receiver(s) that comply with Innovation, Science and Economic Development Canada's licence-exempt RSS standard(s). Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

L'émetteur/récepteur exempt de licence contenu dans le présent appareil est conforme aux CNR d'Innovation, Sciences et Développement économique Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes: (1) l'appareil ne doit pas produire de brouillage, et (2) l'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

This radio transmitter (ISED certification number: 25982-VMPHH1 and 25928-VMPBS1) has been approved by Industry Canada to operate with the antenna types listed with the maximum permissible gain indicated. Antenna types not included in this list, having a gain greater than the maximum gain indicated for that type, are strictly prohibited for use with this device.

Le présent émetteur radio (ISED certification number: 25982-VMPHH1 and 25928-VMPBS1) a été approuvé par Industrie Canada pour fonctionner avec les types d'antenne énumérés ci-dessous et ayant un gain admissible maximal. Les types d'antenne non inclus dans cette liste, et dont le gain est supérieur au gain maximal indiqué, sont strictement interdits pour l'exploitation de l'émetteur.

RF Exposure Information: The device has been evaluated to meet general RF exposure requirement. The device can be used in portable exposure condition without restriction.

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with

the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures: Reorient or relocate the receiving antenna. Increase the separation between the equipment and receiver.Connect the equipment into an outlet on a circuit different from that to which the receiver is connected. Consult the dealer or an experienced radio/TV technician for help. Caution: Any changes or modications to this device not explicitly approved by manufacturer could void your authority to operate this equipment.

Vivatmo *pro* complies with EN60601-1-2:2015 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 EN60601-1-2:2015 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

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.

[3] Khatri SB, Iaccarino JM, Barochia A et al.: Use of Fractional Exhaled Nitric Oxide to Guide the Treatment of Asthma: An Official American Thoracic Society Clinical Practice Guideline. Am J Respir Crit Care Med 2021; 204(10): e97–e109.

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 “6.4 System information”.