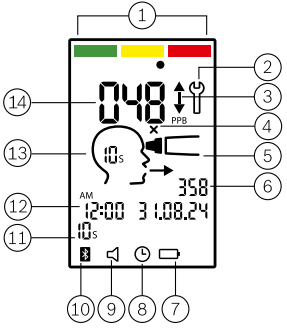
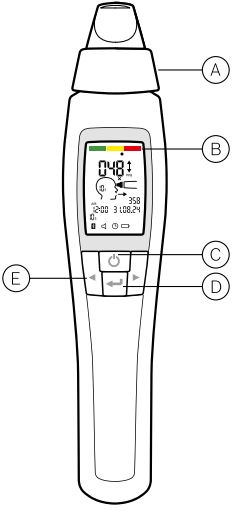
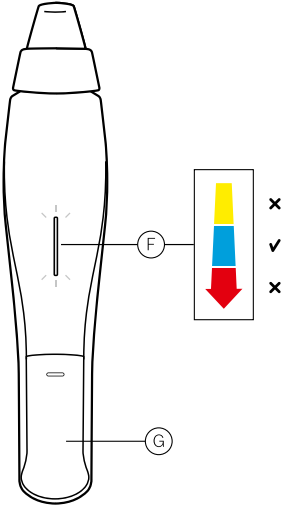
BOSCH

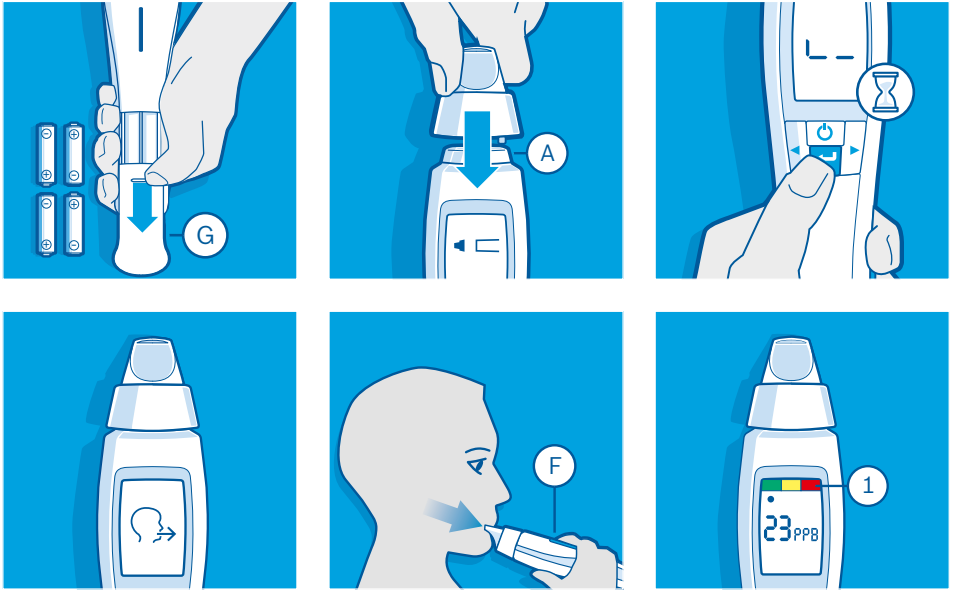
Vivatmo me

Instructions for use


1
2
3
4
5
6
14
13
12
11
10
9
8
7
048
PPB
10
S
AM
12:00
31.08.24
358


A
B
C
D
E


F
G
×
✓
×


G
A
F
1
23 PPB

en

Content

 © Bosch Healthcare Solutions GmbH

© Bosch Healthcare Solutions GmbH

en

1 Your Vivatmo *me*

1.1 Welcome to Vivatmo *me*, the monitoring system for your respiratory disease

Please consider before using Vivatmo *me*:
Take the time to read these instructions for use carefully before using the monitoring system.
You need to understand the functions, warnings, displays and operations for a safe and reliable use.
- Set the time and date on your Vivatmo *me* before you begin a measurement.
- Select the appropriate measurement mode (6 or 10 seconds) before measurement.

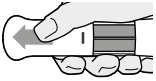
WARNING	Do not use any defective devices or accessories to avoid malfunction or hazardous situations.

If you need service, information, have a problem or want information about data privacy, please visit the Bosch Vivatmo website at www.vivatmo.com or contact your distributor or the Vivatmo *me* customer service center at service@vivatmo.com. Please have your serial number available when contacting the service center, see 12-digit code on your Vivatmo *me* next to the SN symbol at the bottom of the device.

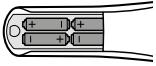
Please keep these instructions for future reference. Hereafter, referenced “Vivatmo *me*” covers all variants, including e. g. “Vivatmo *me* Asia”.

Bosch privacy statement:
This product stores measurement data, but no personal information about the user. Configuration, changes and occurring risks by connection to other devices via Bluetooth® are in the responsibility of the user of Vivatmo *me*.

1.2 Activate your Vivatmo *me*



1. Open the battery compartment on the back of the Vivatmo *me*.
2. Insert the 4 AAA primary batteries as shown on the inside of the battery compartment.



3. Remove the battery cover.
4. If the batteries are inserted correctly, the device will turn on automatically.
5. After turning on all display icons will be shown and the system displays the software version 1.4.3 and higher.

6. The symbol to attach the disposable mouthpiece is shown.

WARNING	For safe use: • Turn device off before battery replacement if batteries are inserted. • Use batteries from the same type as delivered with the device (lithium/iron disulfide or alkaline cells). • The date and time setting will remain stored in the memory for 5 minutes when the batteries are removed. However, check whether the time and date setting is still correct after the battery replacement. • Remove the batteries if you are not using the device for a long period of time. The stored measured values are retained.

© Bosch Healthcare Solutions GmbH

1.3 Intended use / Indications for use

Intended use: The Vivatmo *me* is intended for quantitative measurement of fractional nitric oxide in human breath.
Indication: Measurement of changes in the fractional nitric oxide concentration in expired breath aids in evaluating a patient's response to anti-inflammatory therapy, as an adjunct to established clinical and laboratory assessments of inflammatory processes such as asthma.

The Bosch Vivatmo *me* system is an automated, non-invasive self-testing device intended to be used at home (in-vitro diagnostic use) as an aid to monitor airway diseases whilst under the care of their physician or healthcare expert. Vivatmo *me* measurement procedure requires patient's cooperation by breathing into the device via a disposable mouthpiece. Patients should be 7 years or older and capable to complete the breathing maneuver.

The measurement procedure of the Vivatmo *me* system generates the fraction of the exhaled breath (FeNO) based on the recommendations for the measurement of exhaled respiratory nitric oxide of the European Respiratory Society (ERS) and the American Thoracic Society (ATS). FeNO is recommended by the ATS in the diagnosis of eosinophilic airway inflammation and in determining the likelihood of responsiveness to anti-inflammatory pharmacological therapy in individuals with chronic respiratory symptoms possibly due to airway inflammation [ATS, 2011]. Vivatmo *me* should only be used as directed in the Vivatmo *me* instructions for use and as recommended by healthcare professionals. Regardless of displayed test results, if signs or symptoms of chest tightness, shortness of breath, coughing or wheezing occur, the users should contact their healthcare professional immediately.

Contra-indications: Not known.

 © Bosch Healthcare Solutions GmbH

WARNING	For individual assignment mark device, if several devices are used in the same household. When the device shall be used by another patient, continuously stored data must be deleted to avoid misinterpretation. The following conditions can influence correct measurement results or cause malfunction or disturbance to the Vivatmo *me* and the disposable mouthpiece: • Smoking or tobacco consumption for at least 30 minutes before the measurement. • Eating or drinking shortly before the measurement. • Strenuous exercise. • Rooms with high air pollution or open flames, for example gas range or tobacco smoke. • Ingress of moisture or liquid. Device contains small parts which can lead to choking. Children shall use the device supervised by an adult only to ensure correct use of the device. Store the device outside the access of children when not in use.

When liquid ingresses into the device, remove batteries and prevent further usage of the device to avoid malfunction.

Literature

ATS / ERS, 2005: ATS / ERS recommendations for Measurement of Exhaled Respiratory Nitric Oxide.
ATS, 2011: An Official ATS Clinical Practice Guideline: Interpretation of Exhaled Nitric Oxide Levels (FeNO) for Clinical Application.

 © Bosch Healthcare Solutions GmbH

en

1.4 User interface

① Traffic light scale – a bullet point displays the result on the scale
Ask your physician or healthcare professional for interpretation advise
② Reconditioning
③ Trend since last measurement:
↑ The measured value has increased by at least 10 ppb (parts per billion)
↓ The measured value has decreased by 10 ppb (parts per billion) or more
④ Invalid disposable mouthpiece: Use a new disposable mouthpiece
⑤ Attach disposable mouthpiece
⑥ Measuring ID
⑦ Battery status
⑧ Change date and time or device busy
⑨ Activate / deactivate audio sound
⑩ Activate / deactivate Bluetooth connection
⑪ Measurement mode
⑫ Time and date of the performed measurement
⑬ Device ready for measurement
⑭ Measured value in ppb

Ⓐ Mouthpiece: Place your lips tightly around the mouthpiece and exhale into the Vivatmo *me*
Ⓑ Display: Shows current and stored measuring data and device messages
Ⓒ **ON/OFF** button: Activate and deactivate the device
Ⓓ **ENTER** button: Press this button to confirm the selection in the display
Ⓔ **ARROW** buttons: Press these buttons to change the settings and to access stored measuring data
Ⓕ Breath intensity display LED: During the measurement, you get a feedback on your breath intensity
Blue: Your breath intensity is right
Yellow: Caution, your breath intensity is too weak
Red: Warning, your breath intensity is too strong
Ⓖ Battery compartment: Open the battery compartment to exchange the batteries if required

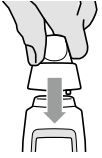
© Bosch Healthcare Solutions GmbH

en

2 Measurement of FeNO in exhaled breath

2.1 Attaching the disposable mouthpiece

The Vivatmo *me* disposable mouthpiece chemically prepares the breath test sample. Human breath is cleaned from contaminants and stabilized to guarantee reliable test results. Use the disposable mouthpiece directly after opening the pouch. The disposable mouthpiece must be attached firmly to perform a measurement.



1. Remove the protective cap from the device.
2. Open the pouch of the disposable mouthpiece.
3. Check the device and disposable mouthpiece and do not use when any damage is noted.

4. Attach the disposable mouthpiece firmly and make sure that it fits securely on the device.
   The **MOUTHPIECE** icon on the display stops moving.

5. “Invalid mouthpiece” is shown on the display if more than 5 attempts have been performed with the same mouthpiece or if the filter capability is used up by the reconditioning.
   Remove the mouthpiece and attach a new one.

WARNING	Disposable mouthpiece shall be handled with care for correct measurement results: • Only use disposable mouthpieces approved for this device. • Avoid leakage when fitting the disposable to the device. • Do not clean or dry the disposable mouthpiece. • Use each disposable mouthpiece for one person and one measurement only, 5 attempts are maximal possible with 1 mouthpiece. Use the mouthpiece within 15 minutes after opening its pouch. • Take care to use regular disposable mouthpieces with transparent cover. Level-0 disposable mouthpieces with white cover lead to 0 ppb measurements, see chapter “5.5 Quality Control”. • Use only disposable mouthpieces from unopened and undamaged pouches that have not expired. See the expiration date on the package.

© Bosch Healthcare Solutions GmbH

en

2.2 Performing the measurement

For measuring the FeNO value, you have to exhale through the device with a constant breathing rate:

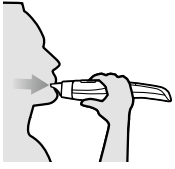
INFORMATION	Check the measurement mode before use (6 / 10 seconds). The 10 seconds test is the preferred measurement mode for all ages. The 6 seconds test is for children ages 7 - 11 years old who are not able to complete a 10 seconds measurement mode.

1. Turn **ON** the device, see “1.2 Activate your Vivatmo *me*”.
2. Attach a new disposable mouthpiece, see chapter “2.1 Attaching the disposable mouthpiece”.
3. Press the **ENTER** button to start the regeneration process and wait until the regeneration process is completed. This may take up to 100 seconds. During the regeneration process segments of the display will be animated to indicate the regeneration process is working and the remaining regeneration time is shown.

   If the Vivatmo *me* device has been stored in warm and humid environment or not been in use for a longer time, the wrench symbol may appear and a reconditioning will start automatically to provide consistent measurement performance, see chapter “5.4 Reconditioning”.

4. When the display shows the **EXHALING** icon, perform the measurement within 120 seconds (see next steps). The LED on the back of the device turns blue.

5. Turn the device display downwards and make sure you can see the LED at the back of the device. Sit in a relaxed but upright position, inhale deeply through the mouth, then lift the device to your mouth. Avoid inhalation through the nose to exclude influence of nasal NO concentrations.
6. Exhale through the disposable mouthpiece in a controlled manner like blowing into a flute or cooling a hot drink for 10 seconds. Feedback is given by the LED on the back of the device:



LED color	Breathing advise for your exhalation
blue	correct
yellow	too weak, caution
red	too strong, warning

© Bosch Healthcare Solutions GmbH

If the measurement is successful, the LED flashes blue and the result appears on the display.

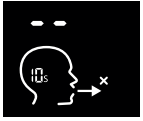
The result “5 ppb -LO-” represents a result below the lower detection limit of the device. The result “300 ppb -HI-” represents a result above the upper detection limit of the device.

7. All results are automatically stored on the device. If the measurement fails, the icon **“exhalation failed”** appears on the display.
8. Remove and discard the disposable mouthpiece, see chapter “6.4 Disposal of device, batteries and mouthpieces”.
9. Place the protective cap on the device.

To save battery power hold the **ON / OFF** button until the display turns off. The device might show being busy with the **CLOCK** icon blinking. If you press the **ON / OFF** button in this mode, the device will turn off afterwards. The device will turn off automatically after 5 minutes of inactivity.

2.3 Measurement failed

Measurement failed when
- the exhalation through the device was excessively weak or strong.
- the measurement was not performed within 120 seconds after completed regeneration process.



Display shows exhalation failed, the LED flashs red and an audio signal occurs.

The regeneration process must be repeated for a new measurement trial:

1. If the **CLOCK** icon is blinking, the device is busy. Wait until the blinking stops.
2. Press the **ENTER** button.
3. When the device is ready to measure, perform steps 3 to 7 of the procedure, see chapter “2.2 Performing the measurement”.

2.4 Interpretation of results

The measured value is shown on the display. The bullet point under the traffic light scale ranks the result relative to the patient's threshold references.

INFORMATION	**Interpretation of the results and setting of thresholds must be advised by your physician or healthcare professional.** Default values set for the traffic light scale for adults in accordance with the ATS Guideline 2011, see "Literature" in chapter 1.3: Green: < 25 ppb, Yellow: 25 ppb - 50 ppb, Red: > 50 ppb For children below 12 years ATS guideline defines: Green: < 20 ppb, Yellow: 20 ppb - 35 ppb, Red: > 35 ppb If you have further questions, contact your distributor or the Vivatmo *me* service center.

2.5 Displaying stored measured values

The Vivatmo *me* automatically stores up to 1,000 measured FeNO values identified by time, date, and ID number. The measured values are stored in descending order starting with the latest. You can retrieve the measured values anytime.

- Press one of the **ARROW** buttons to show older measured values.
- Press the **ENTER** button to exit the view.

3 Settings / Transmission of Measurement Data

3.1 Deactivate / activate Bluetooth

Measurement data can be transmitted encryptedly via Bluetooth to a remote device like a smartphone with the Vivatmo *app* (see www.vivatmo.com).

1. Change Bluetooth by holding the **ENTER** button for 2 seconds.
   The settings toolbar appears.

2. In the menu screen, use the **ARROW** buttons to select the **BLUETOOTH** icon.
   The icon starts flashing.
3. Press the **ENTER** button to activate / deactivate Bluetooth.
   Press one of the **ARROW** button to confirm selection.
4. To exit the basic settings toolbar press the left or right **ARROW** button repeatedly until icons stop flashing, then press the **ENTER** button.

© Bosch Healthcare Solutions GmbH

3.2 Activating / deactivating audio sound

1. Hold the **ENTER** button for 2 seconds. The settings toolbar appears.

2. In the menu screen, use the **ARROW** buttons to select the **AUDIO** icon. The selected icon flashes.
3. Press the **ENTER** button to activate / deactivate the sound. If the check mark is shown, the audio is on. Press one of the **ARROW** buttons to confirm selection.
4. To exit the basic settings toolbar press the left or right **ARROW** button repeatedly until no icons are flashing, then press the **ENTER** button.

3.3 Changing date and time

1. Hold the **ENTER** button for 2 seconds.
   The settings toolbar appears.

2. In the menu screen, use the **ARROW** buttons to select the **CLOCK** icon, the icon starts flashing, then press the **ENTER** button.

3. Use the **ARROW** buttons to choose the date format dd.mm.yy or mm/dd/yy, then press the **ENTER** button.

4. Use the **ARROW** buttons to select the year, then press the **ENTER** button.
5. Use the **ARROW** buttons to select the month, then press the **ENTER** button.
6. Use the **ARROW** buttons to select the day, then press the **ENTER** button.

7. Use the **ARROW** buttons to switch between 0 - 24 h and 0 - 12 h, AM / PM time format, then press the **ENTER** button.

8. If you have chosen 0 - 12 h time format, you can select between AM and PM, then press the **ENTER** button.
9. Use the **ARROW** buttons to set the hours, then press the **ENTER** button. Then set the minutes and press the **ENTER** button.
10. To exit the basic settings toolbar, press the left or right **ARROW** button repeatedly until icons stop flashing, then press the **ENTER** button.

© Bosch Healthcare Solutions GmbH

en

4 Advanced Settings

WARNING	These settings shall be performed by healthcare professionals only. Incorrect operation may lead to misinterpretation of the measuring results or deletion of the stored data. If you have further questions, contact the Vivatmo *me* service center.

In order to access the advanced settings, press the **ENTER** button and the right **ARROW** button for 3 seconds.

4.1 Changing the measurement mode

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

1. Use the **ARROW** buttons to select the measurement mode. The icon starts flashing. Press the **ENTER** button to select the flashing icon.
2. Use the **ARROW** buttons to select the measurement mode.
3. Press the **ENTER** button to confirm 6 or 10 seconds measurement mode.
4. To exit the advanced settings toolbar, press the **ARROW** buttons until no icons are flashing, then press the **ENTER** button to return to the main screen.

4.2 Setting the upper and lower thresholds for the traffic light scale

The default values set for the traffic light scale are the reference values for adults in accordance with the ATS Guideline 2011, see chapter “2.4 Interpretation of results”.

Use the **ARROW** buttons to select the **THRESHOLD** icon. The icon starts flashing.
Press the **ENTER** button to select the flashing icon

Use the ARROW buttons to set the threshold value for the lower threshold. Confirm with **ENTER** button.

Use the **ARROW** buttons to set the threshold value for the upper threshold. Confirm with **ENTER** button.
To exit the advanced settings toolbar press the **ARROW** buttons until no icons are flashing, then press the **ENTER** button to return to the main screen.

© Bosch Healthcare Solutions GmbH

en

4.3 Clearing the memory / reset settings

1. Use the **ARROW** buttons to select the **CLEAR MEMORY** icon. The icon starts flashing. Press the **ENTER** button to select the flashing icon.

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

3. Press the **ENTER** button to confirm the clearing. The **CLEAR MEMORY** icon is shown and flashes.
4. To exit the advanced settings toolbar, press the **ARROW** buttons until no icons are flashing, then press the **ENTER** button to return to the main screen.

5 Maintenance and Troubleshooting

5.1 Battery indicator

no icon		The batteries charge is sufficient.
	shown	The charge is low and the batteries should be replaced soon.
	blinking	The batteries should be replaced before using the device again.

INFORMATION	When replacing the batteries, always replace the whole set of batteries, see chapter “1.2 Activate your Vivatmo *me*”.

5.2 Cleaning and disinfecting

Clean the device regularly or when used by another patient.

1. Turn off the device. Wash hands thoroughly with soap and water.
2. Wipe the entire Vivatmo *me* with disinfectant wipes with maximum 30 % alcohol e.g. Mikrobac Tissues (Bode Chemie GmbH) or Sagrotan Wet Wipes 2 in 1 (Reckitt Benckiser) or with a soft cloth, moistened with soap cleaning agents. Carefully wipe around openings.
3. For disinfecting repeat step 2 with disinfectant wipes with maximum 30 % alcohol following the wipe’s manufacturer’s instructions for disinfecting.

 © Bosch Healthcare Solutions GmbH

WARNING	The following conditions can cause malfunction to the Vivatmo *me* or the disposable mouthpiece: • Fractures in the housing. • Ingress of spray, moisture or liquid.

5.3 Storage

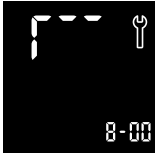
Protect your Vivatmo *me*:

- Always attach the protective cap when Vivatmo *me* is not in use.
- Keep the Vivatmo *me* and its components in a clean, cool and dry place.

WARNING	The following conditions can cause damage and may cause malfunction to the Vivatmo *me* and the disposable mouthpiece: • Storage in high humidity, high temperature, direct sun radiation or high exposure to dust or volatile substances (e. g. disinfectants or nail polish remover). • Places that are subject to vibration, shock, or near hot surfaces. • Rooms with open flames (e. g. gas range) or smoke (e. g. from tobacco consumption).

5.4 Reconditioning

If the Vivatmo *me* device has been stored in warm and humid environment or not been in use for a longer time, the wrench symbol may appear and a reconditioning is required to provide consistent measurement performance. In this case the wrench symbol appears during the regeneration process on the pacifier screen and the device automatically starts the reconditioning.



1. The **wrench** symbol indicates that the reconditioning process is working. Segments of the display will be animated and the remaining reconditioning time is shown in minutes.

2. The system beeps and blinks 3 times blue when reconditioning is finished and the device shows the **EXHALING** icon when it is ready to measure. Perform steps 3 to 7 of the procedure, see chapter “2.2 Performing the measurement”.
3. Use the **ARROW** buttons to view the stored data during the reconditioning and return with **ENTER** to the animated screen.

© Bosch Healthcare Solutions GmbH

en

INFORMATION	The reconditioning takes between 7 and 90 minutes and cannot be interrupted. The wrench symbol is shown during all activities: • Change the batteries if E-6 and the blinking battery symbol appears during reconditioning, see chapter “1.2 Activate your Vivatmo *me*”. • Change the disposable mouthpiece if the “Invalid mouthpiece” screen appears during reconditioning, see chapter “2.1 Attaching the disposable mouthpiece”. • If you push the **ON / OFF** button, **OFF** appears as long as the reconditioning is active.

5.5 Quality Control

Quality Control lets you know that your device gives reliable results.
Perform quality control when:

You dropped the device.
You want to make sure you are testing correctly.

Confirm a measurement below the detection limit of 5 ppb by using a white Level-0 disposable mouthpiece. Above the detection limit compare with results achieved with another certified FeNO measurement system under consideration of the measurement performances. When used in clinical settings perform quality control regularly. If one of the confirmations failed, prevent further usage of the device to avoid misinterpretation.

5.6 Troubleshooting

When using the Vivatmo *me*, an error message may indicate a problem.
The following table gives explanations of the error messages as well as recommendations for solving the problem.

Display	Description	Solution
	Regeneration or reconditioning process is ongoing.	Wait for the process to be completed. Do not remove the mouthpiece.
E-1	Permissible number of measurements < 20, measurements still possible.	See display for number of remaining measurements.
E-2	Maximum number of permissible measurements reached. Device does not perform any more measurements.	Dispose Vivatmo *me*, see chapter “6.4 Disposal of device, batteries and mouthpieces”.
E-4	Humidity too high.	Check ambient conditions and take a new mouthpiece, see chapter “2.1 Attaching the disposable mouthpiece”.

© Bosch Healthcare Solutions GmbH

Display	Description	Solution
E-5	Ambient temperature or air pressure (altitude) is outside the specified range.	Use the Vivatmo *me* in location with permissible ambient conditions. When transporting the device from one place to another, a stabilization period of at least 20 minutes should be allowed before use.
E-6	Batteries are too weak for measurement.	Replace batteries with new ones, see chapter “1.2 Activate your Vivatmo *me*”.
E-7	System self-test failed.	Replace batteries with new ones, see chapter “1.2 Activate your Vivatmo *me*” and start again. If the error persists, read out E7 error code and contact the service center.
E-8	Regeneration failed.	Press the ENTER button to repeat the regeneration. If the error persists, contact the service center.
None – The device will not turn on.	Batteries are empty.	Replace batteries with new ones, see chapter “1.2 Activate your Vivatmo *me*”.
	Batteries are inserted the wrong way.	Ensure the batteries are inserted with correct polarity.

If you have any problems which you cannot solve with these Instructions for use or the device shows unexpected operations, contact your distributor or the Vivatmo *me* customer service center at service@vivatmo.com. For the contact data see chapter “7 Manufacturer”.

Please indicate the following information:

- Your name, address and phone number
- Serial number of the device (12-digit code on your Vivatmo *me* next to the SN symbol at the bottom of the device)
- Error message
- A detailed description of the problem

6 Technical information

6.1 Device data

Product description	FeNO monitoring system
Model	Vivatmo *me* (catalogue number F09G100149 Western Europe; F09G100525 Eastern Europe; F09G100526 Asia)
Measuring range	5 ppb to 300 ppb
Linearity	$r^2 \geq 0.99$, slope 1.00 ± 0.051 , intercept +/- 5 ppb

© Bosch Healthcare Solutions GmbH

Accuracy	± 5 ppb below 50 ppb, ±10 % for ≥50 ppb, ± 15 % for ≥ 160 ppb expressed as the upper/lower confidence limit of 95 %
Precision	± 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
Lifetime, device service life, memory capacity	1,000 measurements
Power source	4 AAA batteries 1.5 V, useful life of primary batteries: Lithium/iron disulfide up to 60 attempts, alkaline up to 25 attempts, (Battery and compartment lid are detachable parts)
Applied part	Type BF as per EN 60601-1 for handheld and disposable mouthpiece when attached
Electrical safety	ME device with internal supply, tested as per EN 60601-1-11 IP22 (protection against solid particles ≥ 12,5 mm and ingress of dripping water when tilted up to 15°) for basic safety but not for function

Maximum surface temperature	58 °C, touch time < 60 seconds
Electromagnetic emissions	CISPR 11 Group 1 (battery operated)
Electromagnetic immunity	EN 61000-4-2, EN 61000-4-3 (battery operated), EN 61000-4-8
Sensor	Chemical field-effect transistor
Sensing technology	Chemical field-effect transistor (Chem-FET) to measure nitrogen dioxide that is converted from nitric oxide by disposable mouthpiece
Data transfer	Bluetooth® Smart (low energy), 2.4 GHz frequency band, max. radiated power: ≤ 2.5 mW
Operating temperature / humidity / air pressure	+15 °C to +27 °C / 15 % to 60 % relative humidity (non-condensing) / 780 hPa to 1100 hPa, corresponds to 0 to 2,000 m above sea level
Storage and transport temperature / humidity	+5 °C to +27 °C / 10 % to 60 % relative humidity between uses

© Bosch Healthcare Solutions GmbH

Weight / Dimensions	170 g / 4.0 cm x 5.4 cm x 22.4 cm
Package contents	Vivatmo *me* device, 5 disposable mouthpieces (Vivatmo *me* Oxycap), 4 batteries, protective cap (detachable part), Instructions for use (catalogue number F09G100425 Western Europe; F09G100515 Eastern Europe; F09G100516 Asia)
Disposable mouthpiece single use (accessory)	Measurement within 15 minutes after opening the pouch. Lifetime is limited to use of 5 attempts. Shelf-life is limited to 2 years from date of manufacturing. Further purchase: Vivatmo *me* Oxycap (catalogue number F09G100124), Vivatmo *me* Level 0 (catalogue number F09G100174).

Limitations of the System: Exchange your Vivatmo *me* at the latest 3 years after manufacturing date.
Information concerning candidates of the REACH regulation can be found at www.vivatmo.com.

6.2 EMC information

Important information regarding electromagnetic compatibility (EMC)
Hereby, Bosch Healthcare Solutions GmbH, declares that the radio equipment type Vivatmo *me* is in compliance with Directive 2014/53/EU. The full text of the EU declaration of conformity is available at the following internet address:

www.vivatmo.com/en/service-support/additional-information.html

This device complies with EN60601-1-2:2015 for EMC with the objective to avoid insecure product situations. This standard regulates the levels of immunity against electromagnetic interferences and the maximum electromagnetic emission values for medical equipment. This medical device manufactured by the company complies with the standard 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. For manufacturers declaration regarding EMC see www.vivatmo.com.

Please note that portable and mobile HF communication systems may interfere with this device even if compliant with CISPR emission requirements. Do not staple the device or use any mobile phones or other devices generating strong electrical or electromagnetic fields. This could result in malfunction of the medical device and may create a potentially insecure situation. Portable RF communication devices are not to be used closer than 30 cm next to the device.

© Bosch Healthcare Solutions GmbH

en

6.3 Symbols

	Temperature range
	Application range humidity
	Manufacturer address
CE 0123	The IVD product meets the requirements of applicable European directives.
	Consult instructions for use
WARNING	Important information to avoid a hazardous situations
INFORMATION	Important advise

	Application range air pressure
SN	Serial number
REF	Reference number / type part number
	Applied part type BF as per EN 60601-1
IVD	In vitro diagnostic medical device 98 / 79 / EEC IVD Directive
	Keep dry
IPN_1N_2	IP Protection class

	Use-by date		Bluetooth compatible
	For single-use only		Manufacturing date
	Batch number		Regulatory compliance mark Australia

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

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

© Bosch Healthcare Solutions GmbH

en

6.4 Disposal of device, batteries and mouthpieces

INFORMATION	Delete the data on the device prior to disposal (see chapter 4.2).

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
or recycle in order to promote the sustainable reuse of material resources (in compliance with
EU directive 2012/19/EU). The used or expired device and batteries should be recycled in
compliance with the local recycling program for electronic equipment.
Dispose used batteries in compliance with the national/local regulations for the disposal of batteries separated from the measuring unit (in compliance with the European Guideline 2006/66/EC).

The mouthpiece is a single-use product. It contains small quantities of potassium permanganate ($KnMnO_4$). Use a new mouthpiece for each measurement and dispose the used one in residual waste.

6.5 Warranty

The statutory provisions on warranty rights in consumer goods sales in the country of purchase shall apply. Batteries are not covered by warranty.

WARNING	Do not disassemble Vivatmo *me* or its components, and do not try to repair it by yourself. Any changes or modifications to Vivatmo *me* that are not approved by the manufacturer may cause malfunction and result in the warranty becoming invalid.

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

7 Manufacturer

Bosch Healthcare Solutions GmbH
Stuttgarter Str. 130
71332 Waiblingen, Germany

E-Mail: service@vivatmo.com
Internet: www.vivatmo.com

 © Bosch Healthcare Solutions GmbH

UK CA	UKCA mark refers to compliance with UK regulation “Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment Regulations 2012 (as amended).”

CH REP	Decomplix AG Freiburgstrasse 3 3010 Bern Switzerland

MCMC HIDF24000106	Certification for telecommunications or multimedia products that meet the standards set by the Malaysian Communications and Multimedia Commission (MCMC) for use in Malaysia.

CCAF24LP1450T3	Without permission granted by the NCC, any company, enterprise, or user is not allowed to change frequency, enhance transmitting power or alter original characteristic as well as performance to a approved low power radio-frequency devices. The low power radio-frequency devices shall not influence aircraft security and interfere legal communications; If found, the user shall cease operating immediately until no interference is achieved. The said legal communications means radio communications is operated in compliance with the Telecommunications Management Act. The low power radio-frequency devices must be susceptible with the interference from legal communications or ISM radio wave radiated devices.

ift IFT TEBOVI24-01349 NOM NYCE	La operación de este equipo está sujeta a las siguientes dos condiciones: (1) es posible que este equipo o dispositivo no cause interferencia perjudicial y (2) este equipo o dispositivo debe aceptar cualquier interferencia, incluyendo la que pueda causar su operación no deseada.

กสทช.

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

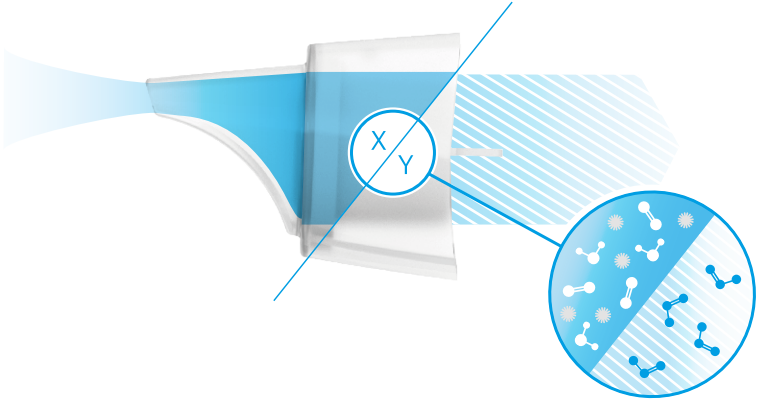
กสทช. โทรคมนาคม
กำกับดูแลเพื่อประชาชน
Call Center 1200 (โทรฟรี)

TRA
REGISTERED No.
ER92286/20
DEALER No.
DA97534/20

Complies with
IDMA standards
DA105282

72412/SPDDI/2021
10325

Vivatmo Oxycap



BOSCH

Bosch Healthcare Solutions GmbH
Stuttgarter Straße 130
71332 Waiblingen
Germany

CE 0123

IVD

F09G100186 Version 12
Instructions for use Latest change: 2024-11-13

Bosch Healthcare Solutions GmbH
Stuttgarter Straße 130
71332 Waiblingen, Germany