



# User manual



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## 1 Customer Support

If the product fails to function properly or when assistance, service, or recalibration is needed, please contact:



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Phone: +31 (0) 885 – 585 266

Fax: +31 (0) 885 – 585 267

Internet: [www.enose.nl](http://www.enose.nl)

Email: [info@enose.nl](mailto:info@enose.nl)

The year of manufacture of the aeoNose™ is mentioned on the identification plate at the bottom side of the device. An example of a aeoNose™ label is shown below.



**Figure 1: Label of aeoNose™**

If accessories for aeoNose™ are needed, such as extra mouthpieces, carbon filters or nose clips please contact eNose B.V.

The aeoNose™ contains no parts that can be serviced by others than eNose B.V.

Unauthorized repairs and modifications will void the warranty and may violate the conformity of the aeoNose™ with the requirements of the IVD Directive IVDD 98/79/EC.

## 2 **Warranty**

The agreed warranty period is counted from the date of delivery. All damage to parts of the installation within this warranty are rectified by eNose B.V. as soon as possible. Consequential damages and damages caused by improper use are not covered by the warranty.

### 3 Disclaimer

eNose B.V. is not liable for unsafe situations, accidents and injury or damage which are caused by:

- Neglecting warnings or prescriptions as stated in this User Manual and/or additional hardware and software manuals.
- The use of the aeoNose™ for other applications or under other circumstances than stated in this User Manual.
- Modifying the aeoNose™ in any way (including application of other spare parts and changing the control program).
- Insufficient and improper maintenance.

eNose B.V. is not liable for resulting injury following aeoNose™ malfunctions.

## 4 Preface

This User Manual informs the user about the safe operation and everyday maintenance of the aeoNose™. Read this User Manual carefully before starting to use the aeoNose™. Only then optimal safety can be obtained. Operation (and everyday maintenance) of the aeoNose™ may only be done by qualified personnel.

The user must be acquainted with the entire contents of this User Manual before starting to use the aeoNose™.

Always keep this User Manual near the aeoNose™.



## 5 Introduction

### 5.1 aeoNose™

The aeoNose™ is an electronic nose dedicated for exhaled-breath analysis. It has been specifically developed for medical use.

The aeoNose™ is used in combination with an Apple iPhone or iPad to screen individuals on specific diseases. A dedicated Application has been developed for this purpose. Data obtained are transmitted from the aeoNose™ to the iPhone or iPad using Bluetooth, and then sent to eNose B.V. datacenter for analysis. The result is sent back within minutes.

### 5.2 Intended use and environment

aeoNose™ test is an automated, semi-quantitative test intended for measuring volatile organic compounds (VOCs) profiles in exhaled breath of patients suspected of Lung Cancer, Colorectal Cancer or Barrett's Esophagus. For physicians, the test result is useful as an aid to diagnose Lung Cancer, Colorectal Cancer or Barrett's Esophagus.

The aeoNose™ is used in a professional medical environment (i.e. hospitals, clinics and research institutions etc.).

### 5.3 Intended user

The user of the aeoNose™ should be a qualified operator. The operator should have knowledge of the system and data interpretation, obtained via medical education, system manuals and/or specific courses. He/she is the person operating the aeoNose™.

### 5.4 Intended patient population

#### 5.4.1 Age

Children from age 4 to adults

#### 5.4.2 Weight

No restrictions

#### 5.4.3 Health

The measurement consists of the collection of exhaled breath through a non-harmful device

#### 5.4.4 Condition

Patients are asked to inhale and exhale through the (disposable) mouthpiece of the aeoNose™ for 5 minutes. The circulation of air should only go through the aeoNose™. Therefore, nose breathing will be interfered by using a nose clip and

patients are instructed to enclose the lips over the mouthpiece at all times. Mostly patients require some test in- and exhales to get acquainted with the aeoNose™.

## 5.5 Side Effects, warnings & contra indications

### 5.5.1 Side Effects

Possible side effects during measurements are dizziness and nausea, probably due to hyperventilation. Other possible side effects are hypo- or hyper salivation during measurements.

### 5.5.2 Warnings



***No single diagnostic test has 100% accuracy, the performance of aeoNose™ in the above mentioned indications is published on [www.enose.nl](http://www.enose.nl), and should always be combined with the clinical opinion of the medical professional***

### 5.5.3 Contra indications

Patients with an inability to breathe through mouthpiece for 5 minutes

## 5.6 Device Classification

The aeoNose™ is classified as a CLASS II ME EQUIPMENT according to IEC 60601-1.

The applied part is classified as TYPE B APPLIED PART

For immunity, the aeoNose™ is classified as Not Life-supporting equipment.

The aeoNose™ has a protection degree against harmful ingress of water or particulate matter of IP30. This means that the aeoNose™ is protected against ingress of solid foreign objects having a diameter of  $\geq 2,5$  mm and not protected from liquids per IEC 60529.

## 5.7 Accessories

The aeoNose™ has the following accessories for measuring exhaled breath:

- Disposable mouthpiece
- Carbon filters
- Nose clip
- Battery charging power adapter
- iPhone/iPad with AeoNose application




***The aeoNose™ may only be used in combination with accessories provided by the manufacturer!***



**Only use the adapter that is provided:**

**Manufacturer: Friwo**

**Type: GPP10**

**Reinforced insulation  (symbol IEC 60417-5172)**

**DC 5V  1.6A   (symbol IEC 60417-5031 and polarisation)**

## 6 Warnings and safety precautions

### 6.1 Safety and precautionary symbols



*Suggestion to carry out tasks easier.*



*Draws attention to potential problems.*



*Draws attention to the danger of serious injuries to the user or patient if the instructions are not carried out carefully.*

### 6.2 Warning pictorials



Consult instructions for use



General mandatory action sign



Dangerous voltage



Equipotential



USB connection



Type B applied part



Manufacturer



Year of manufacture



Dispose as hazardous waste

**IP30** Protection degree against harmful ingress of water or particulate matter

### 6.3 Warnings and cautions



Read this manual carefully and ensure that all instructions are understood. For your personal safety, it is important to understand the consequences of your actions. Do not perform any actions not described in this manual.



The aeoNose™ may not be used in an explosion risk area.



Ensure the power supply is disconnected before maintenance.



Never use strong chemical- or ammonia containing liquids to clean the aeoNose™. Clean, if needed, with a clean soft cloth moistened with some water or alcohol (70%), no disinfectant. Allow 1 hour before next measurement.



Contact eNose B.V. if the aeoNose™ is not functioning as intended if all instructions in this manual are observed.



Never place objects on top of or directly besides the aeoNose™. Keep a clearance of 10 cm around the aeoNose™. All inlets and exhausts need to remain clear at all times. Never put anything inside the enclosure or inlets or exhausts.



Ensure there are no objects placed on top of the cables and that the cables are not such as to endanger people



Do not use the aeoNose™:

- in a closed or badly ventilated room;
- directly under or above other equipment;
- on a surface that blocks the aeoNose™.



Do not expose the aeoNose™ to:

- direct sunlight or other heat sources;
- magnetic objects like electrical engines, transformers, loudspeakers, etc.;
- severe vibration.

**IP30** Do not expose the aeoNose™ to rain or fluids;

### 6.3.1 Electrical safety



When connecting or using electrical equipment, general safety must always be observed to reduce the risk of fire, electric shock and personal injury.



When connecting and disconnecting always beware of ESD (Electrostatic Discharge). Never touch connector pins with unprotected skin.



The unit uses a rechargeable battery to work without power supply. It can be operated for more than 12 hours on this battery.

Please leave the aeoNose™ charged overnights.

## 7 Installation

### 7.1 Unpacking the aeoNose™



Always check the package of aeoNose™ for damage before starting to unpack

In case of damage contact eNose B.V. before continuing.

#### 7.1.1 Package contents

Verify the contents of the package with the delivery note.

In case of an incomplete delivery contact eNose B.V.

### 7.2 Installation

1. **Place** the aeoNose™ on a flat surface.

2. **Switch the on/off [0 – I]** switch to “I” at the bottom of the aeoNose™

3. **Connect** the power cable to the socket at the bottom of the aeoNose™



Location of power socket



***During charging the aeoNose™ should be positioned such that the power socket at the back is easy accessible.***



***After switching on the device wait at least 4 hours for the sensors to function optimally***



***After installing, always check the functioning of the aeoNose™ before performing a measurement***



## 8 aeoNose™ description

### 8.1 Description of the aeoNose™



Figure 2 aeoNose™ device

### 8.2 Connection and controls

On the front, back and on the lower side of the aeoNose™ several connections and controls are positioned.

#### Controls on the front

On the front of the touch foil you will find the stand-by (Wake Up) button:



Figure 3: Stand-by button

On the front of the touch foil you will find the process indicator LED's and the battery indicator:



**Figure 4: process indicator LED's and battery indicator**

### Controls and connections on the lower side

On the lower side of the housing general connections and the mains switch of the aeoNose™ can be found (Figure 5).

1. Mains connection
2. Mains switch
3. USB connection (only for service by eNose B.V.)



**Figure 5: Connections on the lower side**

### 8.2.1 Accessories

The aeoNose™ is provided with the following accessories:

1. Power Adapter



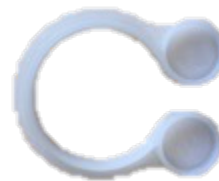
2. Mouthpiece



3. Carbon Filters



4. Nose Clip



4. iOS device (iPad or iPhone) with AeoNose application



### 8.3 User interface

The aeoNose™ is mainly controlled through its graphical user interface using the AeoSose application on the iPad and the touch foil on front of the aeoNose™. The AeoSose application allows the operator to set up the aeoNose™, to perform measurements and to review stored data. **Download the AeoSose app from the App store. Search criteria: aeoNose datacollector.**



*The user interface is explained in detail in Appendix 3*



**Figure 6: screenshot of AeoSose application**

## 9 Operation

### 9.1 Switching on (wake up)

#### Wake Up

By pressing stand-by button (1) the device will wake up after sleep mode or power Up

power led is green (steady)

Power led flashing > device still stabilizing (4 Hours)

Power led fails to switch on > power switch or power led defect (return for maintenance)

*Time and battery level is checked*

Battery low > charge battery

Self-test fails > Power led Red > return for maintenance

### 9.2 Switching off

#### Sleep

By pressing stand-by button (1) the device will go to sleep mode

power led is turned off

Power led flashing > device still stabilizing (4 Hours)

Power led fails to switch off > power switch or power led defect (return for maintenance)

Battery low > charge battery

Self-test fails > Power led Red > return for maintenance

### 9.3 Measuring



***Power supply should not be connected during measurement***

#### 9.3.1 Cleaning measurement



***Perform cleaning measurement when last measurement was more than 24 hours ago***

### Start cleaning measurement

Start AeoNose app on the IOS device as described in section 9.3.3  
 Enter "Flush" in patient information text box to indicate the start of a cleaning measurement and select model Flush  
 Press start on the AeoNose App to start cleaning measurement



### 9.3.2 Connecting carbon filters and mouthpiece

Before the measurement with a patient is started, the carbon filters must be attached to the aeoNose™ and on the mouthpiece.

Let the patient breath slowly through mouthpiece before the measurement is started, to get acquainted with breathing through a mouthpiece.

If needed change of carbon filters and/or mouthpiece.

The mouthpiece needs to be connected to the aeoNose™.



***Place new carbon filters on device before every measurement***



***Ensure that the Mouthpiece is properly applied to the aeoNose™ prior to starting a measurement. Don't push the mouthpiece into the aeoNose™ with too much force, the aeoNose™ may be damaged.***

### 9.3.3 Starting a measurement

#### Connect IOS to Server

Start the Aeonose app on the IOS device

Login in with username and password

Not possible to login > ask administrator for credentials

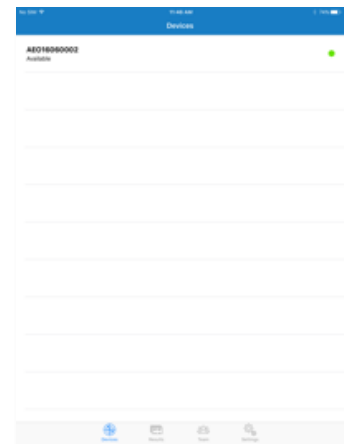
No network connection > check sim card and/or network



#### Connect IOS to aeoNose™

Select aeoNose™ in IOS app  
Enter patient information in IOS app  
Select model to be tested against and answer possible questions

No aeoNose™ available > Bluetooth is not working, no aeoNose™ assigned to you or out of range (5m); make sure Bluetooth is switched ON on the IOS device (Settings->Bluetooth -> ON)



*IOS app will sent current Date/Time (clock sync)*



***Ensure selecting the right indication (model) for classification***



***Place Nose Clip on patients nose. Nose breathing may affect the results***

**Start Measurement**

Press start in the IOS App to start measurement

“aeoNose™ started measurement” appears

“aeoNose™ started measurement” doesn’t appear > re-enter patient information and restart procedure

Audio signal can be heard

No Audio signal > Buzzer defect > return for maintenance after measurement



***In case of difficulty with breathing take away the device from the patients mouth***

**Measurement**

Let the patient breath gently through the aeoNose™ for 5 minutes

Progress indicator LED’s are incremented from left to right in steps of 150 seconds Audio signal can be heard after 5 minutes indicating end of breathing

Progress indicator LED’s not working> LED’s defect> return for maintenance after measurement

No Audio signal > Buzzer defect > return for maintenance after measurement



### 9.3.4 Stopping a measurement

**End of Measurement**

After breathing test take away device from the patient and place it straight up on the table

Progress indicator LED's are incremented from left to right in steps of 150 seconds; Audio signal can be heard after 15 minutes indicating end of measurement

Progress indicator LED's not working > LED's defect > return for maintenance after measurement  
No Audio signal > Buzzer defect > return for maintenance after measurement



***If the power led is blinking green/blue, data is transmitted from aeoNose™ to iOS device, do not switch off iOS device.***



***Do not switch off iOS device immediately after measurement, allow the iOS app some time to send data to server.***

### 9.3.5 Disconnecting the carbon filters and mouthpiece



***The mouthpiece, carbon filters and nose clip should be disposed after each use.***

### 9.3.6 Reviewing a measurement

**Review of Measurement**

After test, the result will appear on the iPad screen

Results can be validated by conventional methods



### 9.3.7 Logout

#### Logout on iPad

After testing is completed, AeoNose app needs to be closed. Press Settings on the lower right of the screen. Next select "Logout" on the upper right of the screen.



## 10 Maintenance and cleaning

### 10.1 Maintenance

The user is not allowed to perform technical maintenance on the aeoNose™.



***The housing contains components that are energized with voltage. The housing may only be opened by eNose B.V.***



***The aeoNose™ contains no parts that can be replaced by others than eNose B.V.***



***Maintenance should only be executed by qualified persons.***

### 10.2 Service schedule

eNose B.V. recommends an annual service measurement.

See Appendix 8: Service instructions.

If you have any problems or questions please contact eNose B.V. .

### 10.3 Cleaning

The aeoNose™ can be cleaned after each day of use. The aeoNose™ may be cleaned by whipping its surface using a soft, slightly moistened (with tap water or alcohol 70%, Sodium Hypochlorite <0,6%, no disinfectant) cloth. Cleaning fluid or any liquid should not be sprayed directly onto the device or its units. Detergents or strong chemical agents such as refined petrol, thinner or alcohol >70% should never be used as they can damage the aeoNose™.

1. Remove the power supply.
2. Wait at least 10 seconds to avoid possible electrostatic damage.
3. Only use a soft, lint free cloth to clean the aeoNose™.
4. The cloth may be moistened with a little tap water, sodium hypochlorite or clear (70%) alcohol
5. Do not use other cleaning agents as they might disturb the sensors.
6. Clean as often as needed.
7. After cleaning with alcohol allow at least 1 hour before starting the next measurement.
8. Perform Flush measurement (section 9.3.1) after cleaning with alcohol

The aeoNose™ can also be cleaned with Sodium Hypochlorite <0,6%. Sodium Hypochlorite is NOT affecting the sensors and can be used safely after each measurement.



***Never clean the aeoNose™ with strong chemical agents or alcohol >70% as they can damage the Aeonose***



***After cleaning the aeoNose™ with alcohol make sure to allow at least 1 hour before starting the next measurement as the sensors may still be unstable; Do not use alcohol in the same room of the aeoNose™ tests. Perform Flush measurement prior to further testing.***



***Do not allow any water to enter the device or connectors at any time.***

## 10.4 Inspection

Outer surface needs to be checked weekly.

1. Check the aeoNose™ for damaged or missing parts.
2. If any damage is observed please contact eNose B.V.

## 11 Transport and storage



**See Appendix 4 – “Environmental conditions” for the environmental storage and transport conditions.**

### 11.1 Transport

When shipping back the aeoNose™, please return the complete device and all its accessories. Use, if possible, the original suitcase and protection buffers to avoid damage during transport. If this is not available make sure that the used box is compatible with the aeoNose™ and packed securely to help assure safe transportation, keeping in mind ordinary care in handling by couriers.



**Figure 7: aeoNose™ kit transport box label**



**Figure 8: aeoNose™ mouth piece/ carbon filter/ nose clip transport box label**

Prepare a Pro forma invoice to accompany the shipment mentioning “for customs use only”, or “non-commercial invoice” and make sure to mention “repair return”.

The aeoNose™ can be returned by a courier service, for instance FedEx or DHL, please do not use UPS for the return shipment. UPS doesn't work with the term "repair return" and it is not possible to perform a temporary clearance for a repair return shipment.



***Always follow the instructions on the transport labeling while transporting the aeoNose™ in its transport box.***

## 12 Disassembly and disposal of the device

The aeoNose™ contains materials suitable for recycling.

Special companies can recycle the equipment, so that more material can be used again and less material waste must be processed.

Enquire about the local regulations for disposal of the equipment.



Environmental note!

Dispose of packaging in an environmentally responsible manner. Try to separate the packing material as much as possible for re-use.



Environmental note!

Remove dead batteries in an environmentally responsible manner. Find out about the local regulations.

## Appendix 1 Technical specifications

### aeoNose™

Dimensions	245 x 180 x 90 mm (L x B x H)
Weight	726g
Power supply	Rechargeable battery 5,2 Ah
Operational temperature	5° C - 40° C ± 0,2° C
Relative Humidity	Max 90% ± 3%
Communication interface	Bluetooth 4.0 online communication
Data buffer	On-board Data Flash™, stores up to 15 hours of measurements
User Interfaces	On/OFF button: blue/red LED Battery status indicator: green/red LEDs Patient indicator: blue/white LED Start button AeoNose App for iOS device (iPhone / iPad)
Bacterial filter (present in mouthpiece)	Application in aeoNose™: Prevention of device contamination by potential pathogen transmission via the patients exhaled air, and prevention of cross contamination. Contact time (indirect) ≈ 5 min Bacterial filtration efficiency >99% Viral filtration efficiency >99%

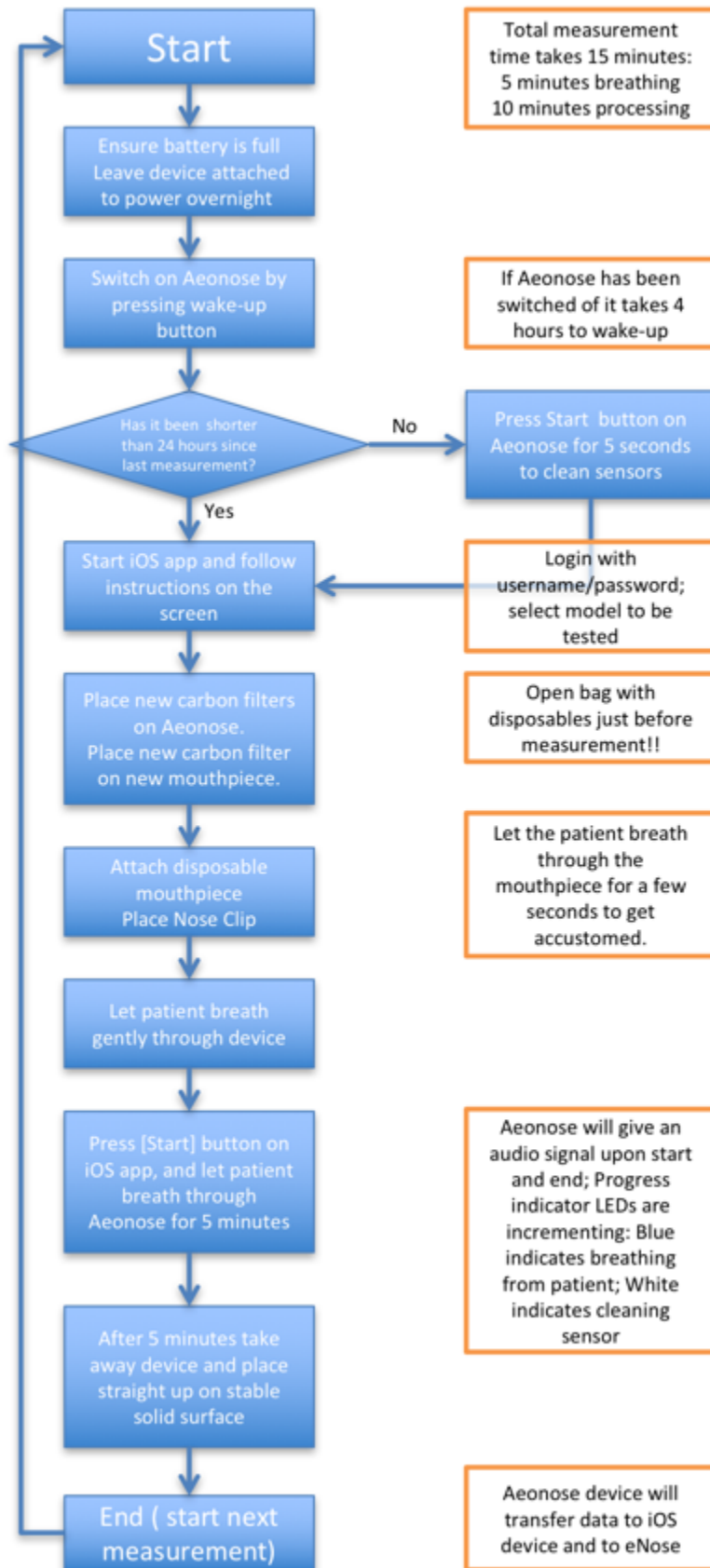
### System requirements

For the data transfer by Bluetooth:

- Apple iPhone or iPad with DATA SIM card or WIFI



## Appendix 2 User Interface flowchart



## Appendix 3 Detailed user interface description

### Connect IOS to Server

Start IOS AeoNose app, log in with username/password that was previously given and follow the instructions on the screen.



### Connect IOS to aeoNose™.

Please select the correct aeoNose™ by means selecting "devices" in the bottom menu. All available aeoNose™ devices are listed with a green dot, and the available aeoNose™ serial number. After the aeoNose™ is selected, the aeoNose™ power led will switch to steady green. The aeoNose™ is now connected to the IOS device by means of Bluetooth.



Please enter patient information in IOS app (patient ID, Disease model to be tested, patient specific questions), and arm the aeoNose™ with IOS app.

### Disposable mouthpiece, nose clip, test breath.

Place new carbon filters on aeoNose™. (Open bag with disposables just before measurement!!). Place new carbon filter on new mouthpiece. Attach disposable mouthpiece. Place nose clip and let patient breath gently through device.



### Start Measurement.

Press the start button on the iOS app and have the patient slowly breathe through the mouthpiece. An audio signal will be heard, indicating start of measurement. In case of difficulty with breathing, take away device from mouth.

**Collect Breath data**

*During the measurement cycle breath data is collected automatically while the patient is breathing in and out through the mouthpiece, and this is indicated by means of the blue LEDs on the user interface. At the end of the measurements (after 5 minutes) a new audio signal will be given indicating end of measurement.*

**Post measurement**

*Once the measurement is complete, please put the aeoNose™ on the table for Post Measurement and Cleaning. White LEDs will indicate the progress of the recovery phase.*

**Transport data.**

*The IOS app will automatically transfer data to eNose B.V. Depending on authority of the user, he/she may view the success/failure of test, the outcome and other tests performed.*

## Appendix 4 Environmental conditions

Operation temperature: 10 °C to 40 °C

Storage temperature: -40 °C to 70 °C

Humidity: 10 to 85 % non-condensing

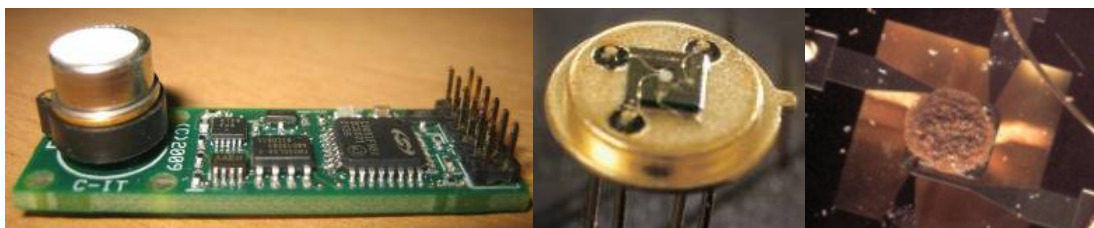
Operational Atmospheric pressure: 700 to 1060 hPa

Storage Atmospheric pressure: 500 to 1060 hPa

Note: The device may not meet its performance specifications if stored or used outside the ranges specified above.

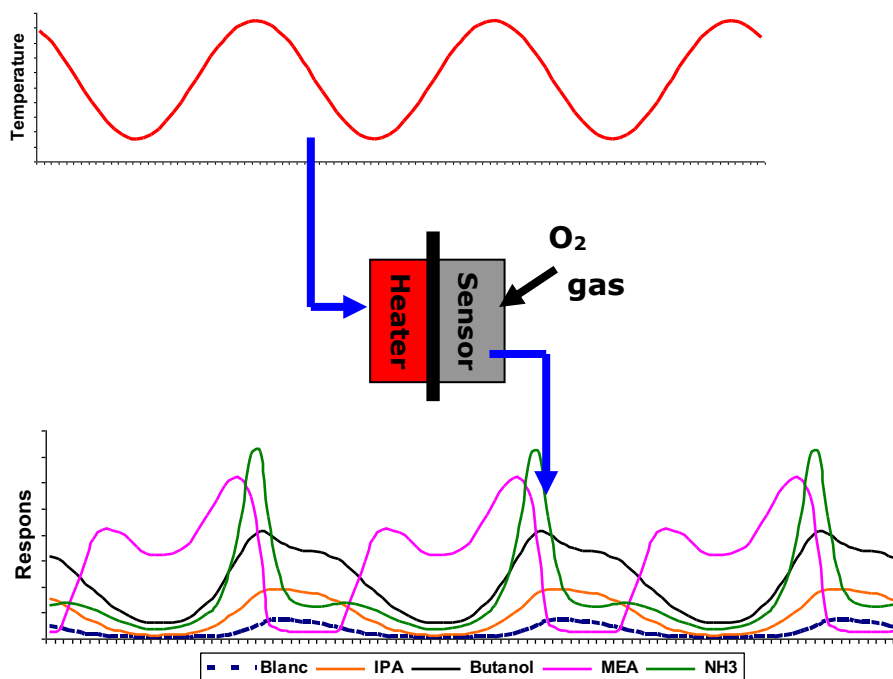
## Appendix 5 Chemical detection principle

The aeoNose™ employs an array of up to three 'intelligent' sensor modules. Each sensor module contains driving electronics, a microprocessor and a unique silicon serial number. The sensors are fitted on a connector. The sensors are micro-hotplate types as illustrated in the figure below. Due to the low thermal mass, temperature regulation is in the millisecond regime.



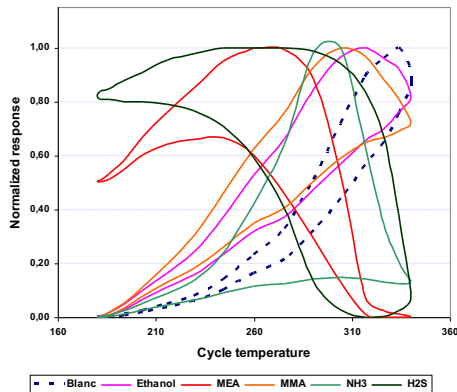
From left to right: The intelligent sensor module, the sensor with cap removed (the white dot is the actual sensor material), close-up of the micro-hotplate.

The metal-oxide sensors are temperature modulated under software control in a working range of typically 180-340 °C. In this range the metal-oxide sensors behave as semiconductors. When oxygen adsorbs and/or ionizes at the sensor surface the conductivity is low. Removal of oxygen due to reaction with other substances (redox reaction) results in a measurable change of conductivity. The change in conductivity is governed by the sensor material (metal-oxide type and catalyst), sensor temperature dynamics and the chemical reaction rates. The latter is determined in turn by the chemical concentrations (related to the adsorption/desorption rates) and the surface temperature (reaction rate). Features for pattern recognition are generated by recording the conductivity as function of the temperature dynamics. This is illustrated in the figure below.



Principle of thermal modulation. The isolated heater is modulated and the response of the sensor to ambient volatiles is recorded as function of this temperature. The time scales of lower and upper graphs are the same.

In further use, the data is normally visualized as series of one full period in a so-called 'thermal loop'. Examples of these thermal loops (taken from the same data as in the previous figure) are given in the figure below.



*Response plotted as function of the heater temperature during a full period.*

The electronics and system firmware allow for dynamic precise temperature control with a standard deviation of approximately 1 °C. The combination of the low thermal mass of the micro-hotplates and the dynamic temperature control allows for very fast modulation of the sensor temperatures.

The measurement interval (the time it takes to complete a full thermal cycle) is determined by the chosen modulation scheme. The limiting steps are the physical and chemical reaction rates at the sensor surfaces as the temperature modulation itself is extremely fast. A step from ambient to 350 °C can be achieved in several milliseconds. Modulation schemes are normally in the order of 5 to 30 seconds per full thermal cycle resulting in the same measurement intervals. As standard modulation scheme a sinusoidal period of 20 seconds is used.

### *Measurable substances*

The sensor array of the aeoNose™ is capable of detecting a very large group of volatile hydrocarbons and a range of inorganic substances.

Due to the detection mechanism the basic requirement is that the substance under investigation will react with oxygen at the sensor surface under the chosen temperature modulation scheme. This rules out substances such as the noble gases Argon, Radon and Neon. Also fully halogenated substances are difficult, but not impossible, to detect.

Note also that detection is governed by the gaseous concentration of the substance in air. Substances with very low volatility will not generate a concentration high enough to meet the lower detection limit of approximately 1 ppm (H<sub>2</sub>S and sulphur containing organic substances have a lower detection limit).

Examples of the inorganic substances are H<sub>2</sub>S, NO<sub>x</sub>, SO<sub>x</sub>, NH<sub>3</sub>, Cl<sub>2</sub> en O<sub>3</sub>. The group of organic substances is extremely large. An example shortlist (by no means exhaustive) is:

- Light alkanes, alkenes and alkynes
- Light alcohols and aldehydes
- Light amines and mercaptans
- Partly halogenated hydrocarbons
- Volatile acids
- Volatile aromatics

## Appendix 6 Trouble shooting

Problem	Possible causes and solutions	page
<b>Failure to switch device on</b>	Switch at bottom of device is off: turn switch on with small pen. Connect aeoNose™ to power, wait at least 4 hours to fully charge aeoNose™; perform test measurement and contact eNose B.V. to check signals.	14
	Battery not charged. Charge battery with power-adapter.	14
<b>Power led flashing</b>	Device is still stabilizing (4 hours).	14
<b>Power led red</b>	Self-test failed, please contact eNose B.V. for maintenance.	20
<b>Unable to login</b>	AeoNose app cannot start if iPad is not connected to internet: check Wifi or 4G connection.	22
<b>No devices available</b>	Bluetooth is not working or out of range (5m). make sure Bluetooth is switched ON on iOS device (settings->Bluetooth->ON).	22
	No device assigned to you, contact eNose B.V. to assign device to you.	22
<b>Aeonose is not responding (no leds)</b>	aeoNose™ is not charged, battery depleted. Connect aeoNose™ to power, wait at least 4 hours to fully charge aeoNose™ and perform test measurement. Contact eNose B.V. to check signals.	14
	Switch at bottom of device is off: turn switch on with small pen. Connect aeoNose™ to power, wait at least 4 hours to fully charge aeoNose™ and perform test measurement. Contact eNose B.V. to check signals.	14
	Power switch or power led defect, return to eNose B.V. for maintenance	20
<b>Measurement cannot start</b>	aeoNose™ is still connected to power, measurement cannot start with power connected: remove power from aeoNose™.	20
	Bluetooth connection was lost during data entry: return to 'Devices' on the top left, re-enter all data and restart measurement.	20
<b>Error: Login failed. 3 attempt(s) remaining.</b>	Login code wrong; try again, or ask eNose B.V. for correct /new username and password.	22
<b>Measurement indicator stays grey</b>	Data from aeoNose™ is not fully transferred to iPad; leave iPad ON and close to aeoNose™ to complete data transfer; In menu 'Devices' the progress of data-transfer can be monitored. If the measurement indicator remains grey, please contact eNose B.V.	24

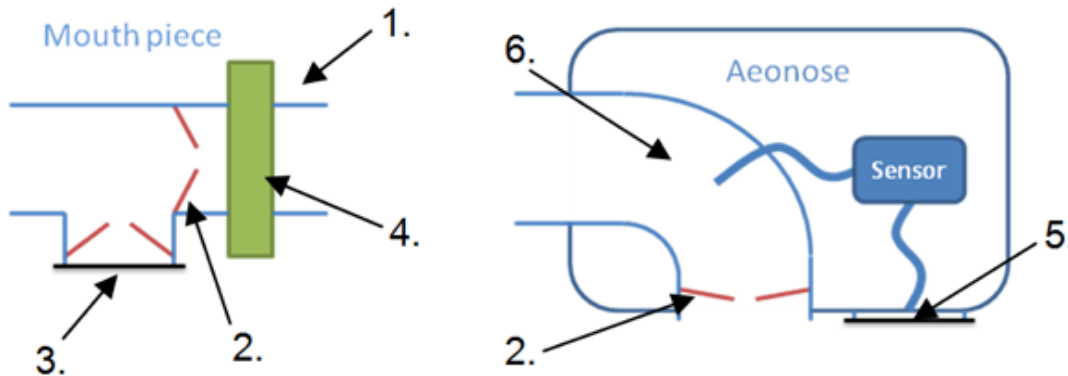


## Appendix 7 Disinfection

During the development of the aeoNose™, a number of important 'risk mitigations' have been included to ensure that the risk of cross infection is as small as possible.

In brief:

Each patient receives a new mouthpiece (disposable, individually packed with nose clip and 2 carbon filters). This mouthpiece contains a carbon filter through which the patient breathes outside air. The system includes one-way valves through which the patient exhales through the device, but the one-way valves never allow air to return from the device to the patient (see illustration below).



**MOUTH PIECE AND AEONOSE SYSTEM**

1. Separate disposable mouth piece (clean mouth piece for each patient)
2. Valves (to prevent air from the aeoNose™ system to get into the patient)
3. Disposable carbon filter with check valve (clean inhaled air)
4. Bacterial and viral filter (remove bacteria and viruses from exhaled air)
5. Disposable carbon filter (clean air that is passed over the sensors)
6. Sample chamber (exhaled air is sampled by pumping it over the sensors)

The filter mentioned above is a HEPA filter. The HEPA filter is an electrostatic filter that is intended to stop bacteria, but because of the electrostatic also smaller particles, such as viruses, will be stopped.

After production, the nozzles are tested with a particle counter (0.3 -5) micrometer, with a limit of > 99% efficiency. Publications<sup>1</sup> show that electrostatic filters can filter a filter in two different ways. First, that is the traditional method, similar to a kitchen strainer. But there also appears to be a second filtering effect called diffusion. Very small particles, smaller than the holes in the filter, hereby "stick" to the filter.

The sensors are "heated" after each measurement so that no residual molecules remain.

As for holding the device:

Since it is not recommended to clean the device with alcohol after each use (the sensors get saturated and they have to stabilize again for some time), there are the following options:

- Clean the device with Sodium Hypochlorite <0,6%
- Use of disposable gloves.
- Wash hands well before and / or after the measurement.
- Alcohol wipe for the hands, after the measurement, outside the measuring space.
- The aeoNose™ can be cleaned after each measurement OUTSIDE the measuring space with a slightly damp cloth alcohol 70%. After 1 hour of waiting time, a FLUSH measurement must first be carried out before the next measurement can be taken (take waiting time into account).

At the end of the day, clean the aeoNose™ 1x with a slightly damp cloth with 70% alcohol.

<sup>1</sup> <https://ntrs.nasa.gov/archive/nasa/casi.ntrs.nasa.gov/20170005166.pdf>

## Appendix 8 Service measurement

Please perform the service measurement at the end of the day when no immediate patient measurements have been planned (because of ethanol use)

1. Place the Aeonose *flat* on the table



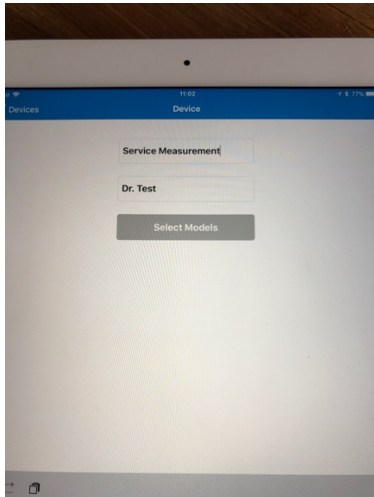
2. Dip some absorbing tissue in *Ethanol 70%*, make the paper *drip-free* (Please, do not use Propanol).



3. Place the 'ethanol' tissue in the tube (normally used for mouthpiece)



4. Use **service measurement** as PatientID



5. Select any model. **Start** the measurement.
6. Remove the ethanol-tissue directly after the service measurement is finished. Please throw away in another room, not used for measurements.

***Please inform eNose B.V. when the service measurement has been performed.***

## Appendix 9 CE Approval



### EC Declaration of Conformity

We The eNose Company  
 Of Industrieweg 85, - 7202 CA – Zutphen - The Netherlands  
 In accordance with the following Directive:  
 Annex III of 98/79/EC on in vitro diagnostic medical devices, hereby declare that:

Equipment Aeonose™  
 Model AEO01  
 Software version 1.4.x

Is in conformity with the applicable requirements of the following documents:

IVDD 98/79/EC	In vitro diagnostic medical devices directive
EN ISO 13485:2016	Medical devices- Quality Management systems- Requirements for regulatory processes
ISO 14971:2019	Medical Devices- Application of risk management to medical devices
EN 62366:2008	Application of usability engineering to medical devices
EN 62304:2006 /AC:2008	Medical device software – Software life-cycle processes
EN 1041:2008+A1:2013	Information supplied by the manufacturer of medical devices
EN ISO 10993-1:2009	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2009)
EN 13612:2002 /AC:2002	Performance evaluation of in vitro diagnostic medical devices
EN 60601-1:2006 + A1:2013	Medical electrical equipment- Part 1: General requirements for basic safety and essential performance
EN 61326-2-6:2013	Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment
EN 15223-1:2012 ISO 15223:2016	Medical Devices - Symbols to be used with medical device labels-labelling and information to be supplied-Part I General requirements

*I hereby declare that equipment above has been designed to comply with the relevant sections of the above referenced specification. The unit complies with all applicable essential requirements of the directives.*

Signature

Name Andre Elands  
 Position CEO  
 On 26 Apr 2022