AENOSE

User manual

The eNose company

Address:
Industrieweg 85
7202 CA Zutphen
The Netherlands

Website:
www.enose.nl

Version 1.8
May 2021

Copyright

User manual

Contents

1 Customer Support

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

The eNose Company, Industrieweg 85, 7202 CA Zutphen
The Netherlands

Phone: +31 (0) 885 – 585 266

Fax: +31 (0) 885 – 585 267

Internet: www.enose.nl

Email: 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 The eNose Company.

The Aeonose™ contains no parts that can be serviced by others than The eNose Company. 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 The eNose Company as soon as possible. Consequential damages and damages caused by improper use are not covered by the warranty.

3 Disclaimer

The eNose Company 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.

The eNose Company is not liable for resulting injury following Aeonose™ malfunctions, such as operation breaks etcetera.

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 The eNose Company's datacenter for analysis. The result is sent back within minutes.

5.2 Intended use and environment

Aeonose™ is a handheld device intended to be used for the measurement of gasses in exhaled breath - for review by physicians to assist in forming a clinical judgment.

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™.

5.4.5 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.

Diagnosis

The Aeonose™ has shown to be a non-invasive safe device to collect breath samples for exhaled breath analysis. Electronic noses with similar characteristic properties have been used for multiple indications. In particular in Asthma, COPD, Lung Cancer and Tuberculosis the different electronic noses show consistent behaviour. In these indications, the electronic nose shows great potential. There are however only very few indications, where the electronic nose and the Aeonose™ are truly validated, so the actual performance of the electronic nose in the different indications remains unknown.

At www.enose.nl the latest clinical results are published

Contra indications

Patients with an inability to breathe through mouthpiece for 5 minutes

5.5 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 ≥2,5 mm and not protected from liquids per IEC 60529.

5.6 Accessories

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

☐ Disposable mouthpiece

☐ Carbon filters

☐ Nose clip

☐ Battery charging power adapter

☐ iPhone/iPad with hAermes application

☐ USB cable

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.

Transfer of data using USB should not be executed in an Intensive Care environment

Ensure the power supply is disconnected before maintenance. Never open the enclosure without removing the power supply.

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 The eNose Company 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 no 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 The eNose Company before continuing.

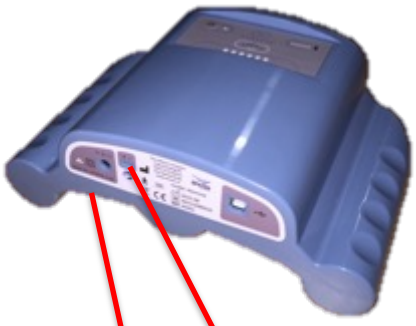
7.1.1 Package contents

Verify the contents of the package with the delivery note.

In case of an incomplete delivery contact The eNose Company

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 touch ON/OFF (Wake Up) touch button:

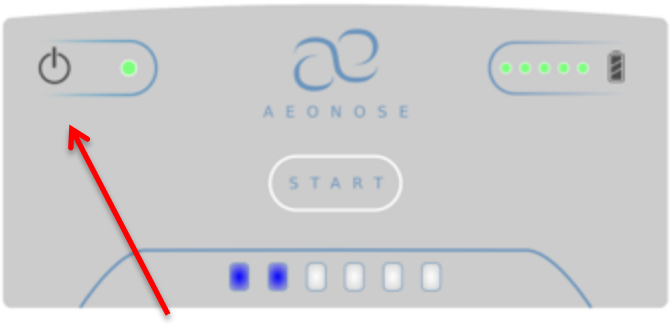


Figure 3: Wake Up button

On the front of the touch foil you will find the START touch button:

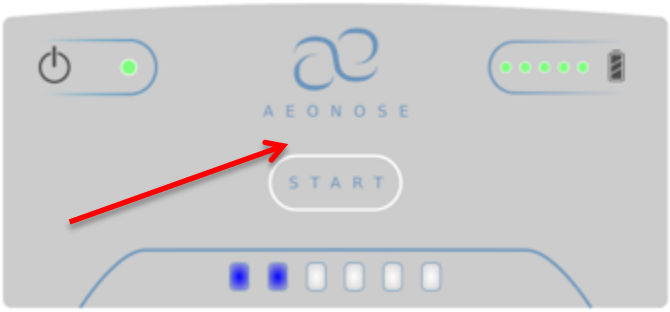


Figure 4: START button

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

Figure 5: Connections on the lower side

8.2.1 Accessories

The Aeonose is provided with the following accessories:

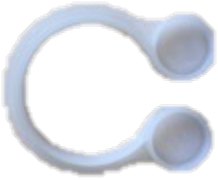
1. Power Adapter

2. USB cable

3. Mouthpiece

4. Carbon Filters

5. Nose Clip



6. iOS device (iPad or iPhone) with hAermes application

8.3 User interface

The Aeonose is mainly controlled through its graphical user interface using the eNose application on the iPad and the touch foil on front of the Aeonose. The eNose application allows the operator to set up the Aeonose, to perform measurements and to review stored data.

The user interface is explained in detail in Appendix 3– on page 32.

Figure 6: screenshot of hAermes eNose application

9 Operation

9.1 Switching on (wake up)

Wake Up By pressing power button (1) the device will wake up after sleep mode or power Up – *Time and battery level is checked*	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) Battery low > charge battery Self-test fails > Power led Red > return for maintenance

9.2 Switching off

Sleep By pressing power 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 eNose hAermes 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 hAermes 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 eNose hAermes app on the IOS device

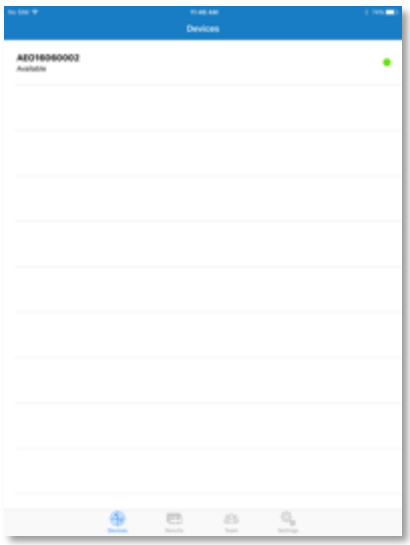
Not possible to login > ask administrator for credentials

Login in with username and password

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 > BT 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)

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

Start Measurement Press start on the IOS App to start measurement	Patient indicator led flash rapid Audio signal can be heard	Patient led indicator not flashing rapid > re-enter patient information and restart procedure 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	Patient led indicator not working 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 put in 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	Patient led indicator not working 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, hAermes 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 high voltage. The housing may only be opened by The eNose Company

The Aeonose contains no parts that can be replaced by others than The eNose Company

Maintenance should only be executed by qualified persons.

10.2 Service schedule

The eNose Company recommends that the device is checked yearly for a service and calibration check. This can occur at the health care facility.

Please contact The eNose Company for instructions.

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.

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

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 The eNose Company.

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	USB 1.1 for back-up data retrieval 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 hAermes 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

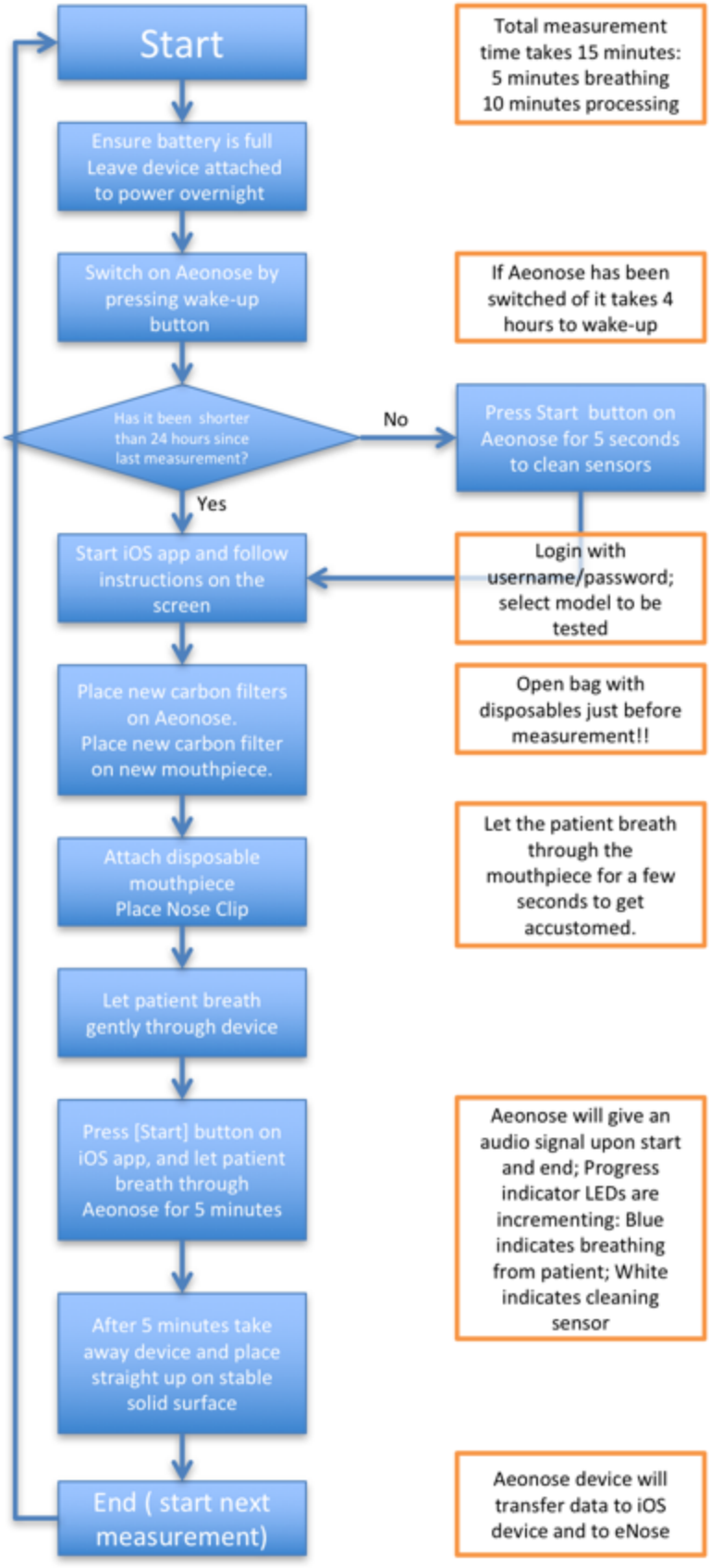
For the data transfer by Bluetooth:

- Apple iPhone or iPad with DATA SIM card or WIFI

For the Aescape back-up data retrieval software

- Windows (version 7 or higher)
- Internet connection
- the PC should be compliant to IEC 60601-1 or IEC 60950-1.

Appendix 2 User Interface flowchart



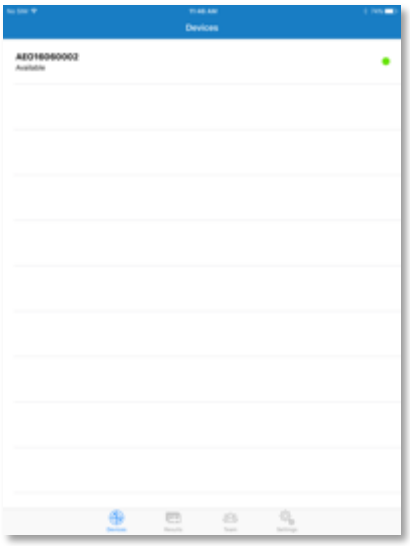
Appendix 3 Detailed user interface description

Connect IOS to Server

Start IOS hAermes 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 The eNose Company. Depending on authority of the user, he/she may view the success/failure of test, the outcome and other tests performed.

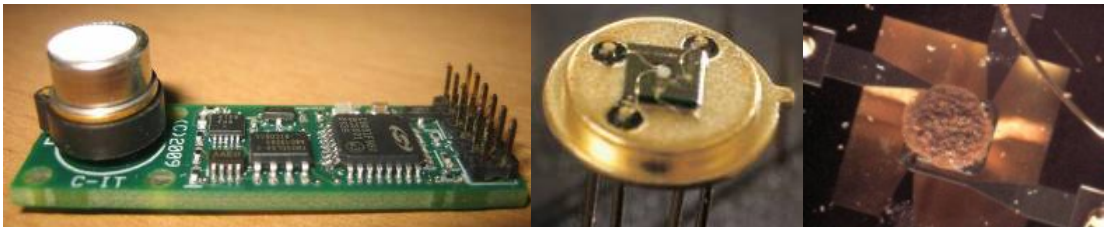
Appendix 4 Environmental conditions

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.

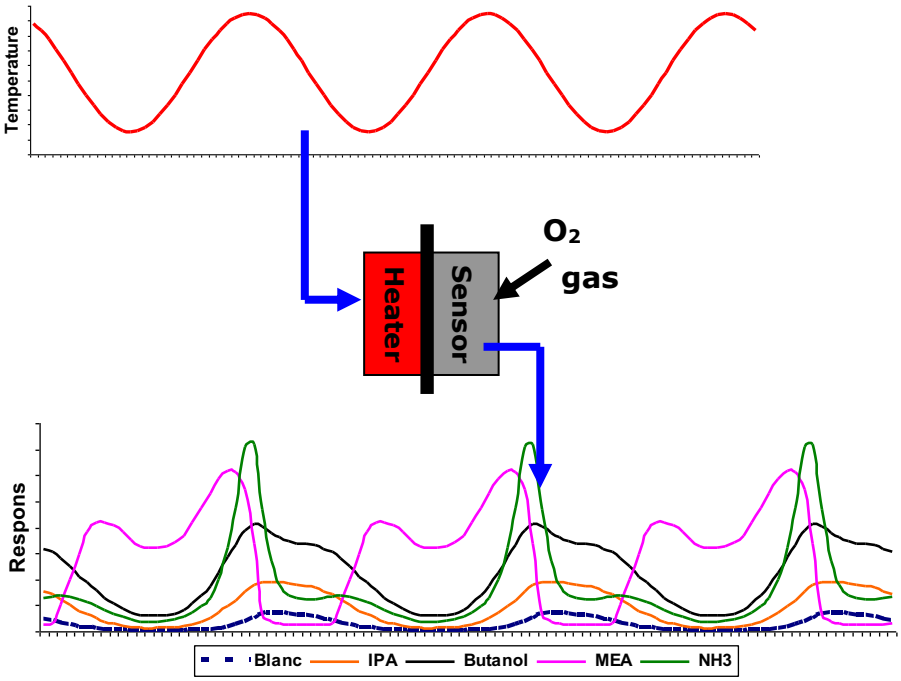
Appendix 5 Chemical detection principle

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.



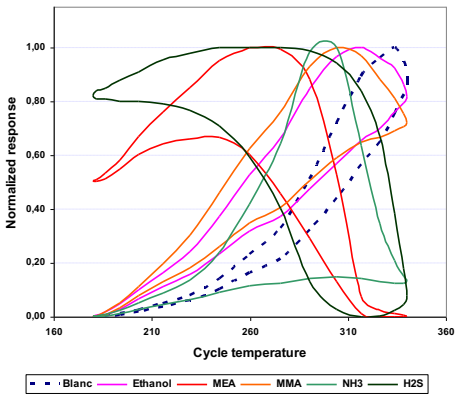
From left to right: The intelligent sensor module, the sensor with cap removed (the white dot is the actual sensor material), close-up of the micro-hotplate.

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_2S and sulphur containing organic substances have a lower detection limit).

Examples of the inorganic substances are H_2S, NO_x, SO_x, NH_3, Cl_2 en O_3. The group of organic substances is extremely large. An example shortlist (by no means exhaustive) is:

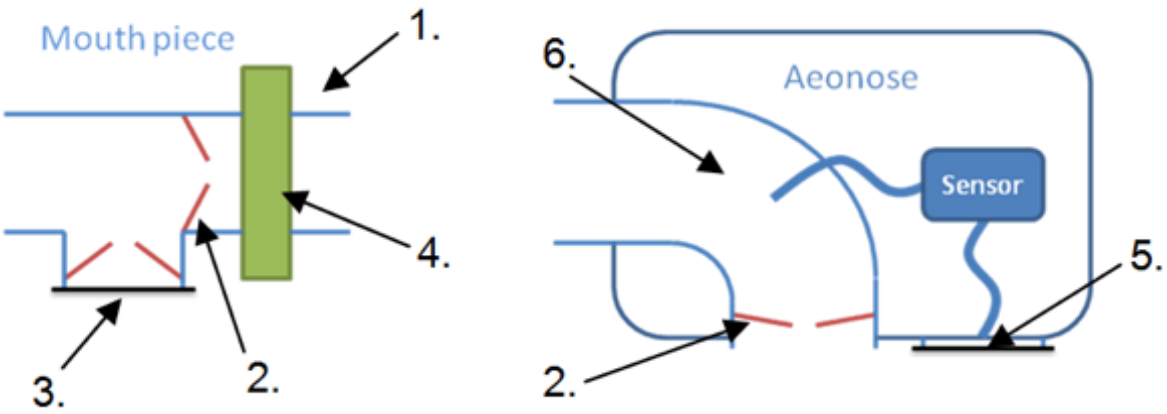
- Light alkanes, alkenes and alkynes
- Light alcohols and aldehydes
- Light amines and mercaptans
- Partly halogenated hydrocarbons
- Volatile acids
- Volatile aromatics

Appendix 6 Trouble shooting

Problem	Possible causes and solutions	page
Failure to switch device on	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 The eNose Company to check signals.	14
	Battery not charged. Charge battery with power-adapter.	14
Power led flashing	Device is still stabilizing (4 hours).	14
Power led red	Self test failed, please contact The eNose Company for maintenance.	20
Unable to login	Haermes app cannot start if iPad is not connected to internet: check Wifi or 4G connection.	22
No devices available	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 The eNose Company to assign device to you.	22
Aeonose is not responding (no leds)	Aeonose is not charged, battery depleted. Connect Aeonose to power, wait at least 4 hours to fully charge Aeonose and perform test measurement. Contact The eNose Company 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 The eNose Company to check signals.	14
	Power switch or power led defect, return to The eNose Company for maintenance	20
Measurement cannot start	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
Error: Login failed. 3 attempt(s) remaining.	Login code wrong; try again, or ask The eNose Company for correct username and password.	22
Measurement indicator stays grey	Data from Aeonose is not fully transferred to iPad; leave iPad ON and close to Aeonose to allow data transfer; In menu Devices the progress of data-transfer can be monitored. If the measurement indicator remains grey, please contact The eNose Company.	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).



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[1] 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.

[1] https://ntrs.nasa.gov/archive/nasa/casi.ntrs.nasa.gov/20170005166.pdf

Appendix 8 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[tm]
Model AE001
Is in conformity with the applicable requirements of the following documents:

IVDD 98/79/EC	In vitro diagnostic medical devices directive
MDD 93/42/EEC	Medical devices directive
EN ISO 13485:2016	Medical devices- Quality Management systems- Requirements for regulatory processes
ISO 14971:2012	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 *André Elands*
Position *CEO*
On *Nov 18 2020*