# BreathSpec®



# **Quickstart Manual**



G.A.S. Gesellschaft für analytische Sensorsysteme mbH

#### Version 1.01, February 2021

#### Valid from BreathSpec® Firmware Version 4.00

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BreathSpec® is a registered trademark. Any infringement may be subject to legal actions.

The BreathSpec® does not have a medical approval.

CE-Marking according to:

International Standard EN ISO 17050-1:2004
Directive 2014/35/EU (Low voltage directive);
Directive 2014/30/EU (Electromagnetic compatibility);
Directive 2011/65/EU (RoHS);
Directive 2012/19/EU on waste disposal (Waste Electrical and Electronic Equipment – WEEE)

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G.A.S. Gesellschaft für analytische Sensorsysteme mbH Otto-Hahn-Str. 15 D-44227 Dortmund

Germany

Phone: (+49) 231/9742-6550 Fax.: (+49) 231/9742-6555

E-Mail: support@gas-dortmund.de Internet: www.gas-dortmund.de

## **Table of Content**

1	Ger	neral Information	5				
	1.1	Information about the Manual	5				
	1.2	Explanation of Symbols	5				
	1.3	Notation for dialogs, elements and references	6				
	1.4	Scope of Supply BreathSpec® with Circular Gas Flow Unit (Version 4G1).	7				
	1.5 4G2)	Scope of Supply Special edition BreathSpec with Airsense $\mu TD$ Unit (Version 12					
	1.6	Liability and Guarantee	. 16				
	1.7	Copyright	. 17				
	1.8	Return and Disposal	. 17				
	1.9	Software Updates	. 17				
	1.10	Customer Service	. 17				
2	Saf	ety	18				
	2.1	Intended Use Only	18				
	2.2	Responsibility of Operator	. 18				
	2.3	Requirements of Personnel	. 19				
	2.4	Dangers	20				
3	Tra	nsport, Packing and Storage	21				
	3.1	Inspection after Transport	21				
4	Pac	king	21				
	4.1	Storage and Transport	21				
	4.2	Cleaning and Maintenance	22				
	4.3	Cleaning	22				
	4.4	Maintenance	22				
5 ((		allation BreathSpec® Device (Version 4G1) with Ciruclar Gas Flow Unit	. 24				
	5.1	Installation Requirements	24				
	5.2	Installing the device	25				
	5.3	Mounting the Mouthpiece holder	. 29				
	5.4	Connecting the Mouthpiece tube	30				
	5.5	Installation of Luer-Lock adapter [optional]	34				
	5.6	Prepare the device for operation	. 38				

6	Inst	tallat	tion BreathSpec® Device (Version 4G2) with Airsense µTD	42
	6.1	Inst	tallation Requirements	42
6.2		Inst	talling the device	43
	6.3	Pre	pare the device for operation	49
7	Sys	stem	Operation	53
	7.1	Me	asurement Reqiurements	53
	7.2	Me	asurement Program	53
	7.3	Wo	rkflow: Breath Sampling via Handheld Breath Sampler	54
	7.3	.1	Workflow: Installation of Disposable Reservoir Tube and Mouthpiece	54
	7.3	.2	Workflow: Execute a breath measurement using the Handheld	55
	7.4	Wo	rkflow: Breath Sampling via Disposable Breath Sampler	58
	7.4	.1	Start a breath measurement using disposable breath sampler	58
	7.5	Wo	rkflow: Exemplary Breath sampling with a sample bag	61
	7.6	Wo	rkflow: Measurement in ID Input Mode	63
8	App	pend	lix	65
	8.1	.1	IMS-Spectrum Examples	65
	8.2	Cor	responding G.A.S. Documents and Tutorials	67

#### 1 General Information

#### 1.1 Information about the Manual



#### **INFORMATION!**

This **Quickstart User Manual** is an excerpt of the most important information for installation and initial setup from the User Manual. It is an **addition to the User Manual** and does not replace the User Manual.

This manual describes a safe and adequate handling of the device. Following the instructions of the indicated safety aspects and instructions as well as the national and/or local rules and general safety regulations concerning the prevention of accidents are absolutely imperative.

Before starting the work with the device read the manual completely and thoroughly particularly the chapter security and respective safety references. Assure that you/the operator comprehend the terms described.

The manual is part of the device. It must be stored together with and next to the device at any time.



#### **INFORMATION!**

The graphics in this user manual are schematic and may differ from the actual conditions. The firmware and PC software screenshots in this user manual may differ from the actual conditions.

## 1.2 Explanation of Symbols

Important and safety-relevant references in this manual are characterized by symbols. These indications which are in-line with industrial safety must be respected and followed at any time.



#### INFORMATION

This symbol calls information, which are to be considered for efficient and perfect handling of the equipment.



#### WARNING

This symbol indicates references, which can lead to damages, malfunctioning and/or loss of the device.



#### DANGER

This symbol marks references, which can lead to health impairments, injuries, lasting body damages or to death due to electric current.



#### **DANGER**

This Symbol marks paragraphs, which describe potential dangers and damage due to exposure to radioactive radiation.



#### **DANGER**

This symbol marks references, which describe working procedures that demand special attention to avoid spreading of biohazard



#### WARNING

This symbol marks references, which can lead to health impairments, injuries due to pinching.

## 1.3 Notation for dialogs, elements and references

**Example Dialog:** 

System > Connections > LAN File Transfer > Settings... > Test Connection

**Example Elements:** 

Gas Out, Sample gas in

**Example: References** 

Advanced User Manual, Chapter 5.1 Installation Reguirements

**Example: Information** 

keep the transport box

# 1.4 Scope of Supply BreathSpec® with Circular Gas Flow Unit (Version 4G1)

Assure that you have received the full scope of supply. If there is any part missing, please contact the GAS-hotline immediately.

## Standard Scope of Supply



BreathSpec® Device (1 piece) including connected Circular Gas Flow Unit (CGFU) (1 piece)



Power supply with power plug (1 piece)



Mouthpiece Handheld holder arm with screws



Mouthpiece Handheld with heatable Transferline



## **BreathSpec® Gas tube Kit (installed)**

- Driftgas/Carriergas Adapter (1 piece)
- 0,6 m 3mm PFA Tubes with 3 mm Swagelok-Connector (2 pieces)



CGFU Connection cable (installed) (1 piece)



LAN Cable (1 piece)



## Luer-Lock Adapter-Kit

- Luer-Lock Adapter (1 piece)
- Luer-Lock Adapter Heater (1 piece)



## **Disposable Breath Reservoir Kit**

- Mouthpieces (100 pieces)
- Reservoir tube (100 pieces)



Inner Syringe Body (2ml syringe) (50 pieces)



Sampling Syringe (5ml syringe) (100 pieces)



BreathSpec® Blind plug Set (5 pieces)

(Swagelok 3mm Blind plug with red cap installed on device connectors)



#### **Torx Tool Kit**

- Torx Srewdriver 8 mm (1 piece)
- Torx Srewdriver 10 mm (1 piece)
- Torx Srewdriver 30 mm (1 piece)



Document Map with Documents and Device User Manuals



USB-Stick Box with Software und Documents (1 piece)



Transport box (1 piece)



Transport palett (60 x 80 cm)

## Optional Scope of Supply (only available if ordered)



Laptop Computer (different design) including software for control and evaluation



**CGFU-Filter Set** (2 x Moisture-Trap, 1 x Hydrocarbon-Trap)

# 1.5 Scope of Supply Special edition BreathSpec with Airsense μTD Unit (Version 4G2)

Assure that you have received the full scope of supply. If there is any part missing, please contact the GAS-hotline immediately.

## Standard Scope of Supply



BreathSpec® Device (1 piece)



μTD with accessories in transport case (1 piece)



Power supply with power plug (1 piece)



BreathSpec® Gas tube Kit
Driftgas/Carriergas/µTD Adapter (1 piece)

 2 m 3mm PFA Tubes with 3 mm Swagelok-Connector (4 pieces)



Molecular sieve trap (200 ml) (1 piece)



LAN Cable (1 piece)



BreathSpec® Blind plug Set (7 pieces)

(Swagelok 3mm Blind plug with red cap installed on device connectors)



## **Torx Tool Kit**

- Torx Srewdriver 8 mm (1 piece)
- Torx Srewdriver 10 mm (1 piece)



Document Map with Documents and Device User Manuals



USB-Stick Box with Software und Documents (1 piece)

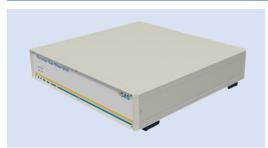


Transport box (1 piece)



Transport palett (60 x 80 cm)

# Optional Scope of Supply (only available if ordered)



Circular Gas Flow Unit with accessories



Nitrogen Generator with accessories (example picture)



Laptop Computer (different design) including software for control and evaluation



#### Luer-Lock Adapter-Kit

- Luer-Lock Adapter (1 piece)
- Luer-Lock Adapter Heater (1 piece)



Sampling Syringe 5ml syringe for Luer Adapter) (100 pieces)

## 1.6 Liability and Guarantee

This user manual describes the safe and proper handling of the device.

All data and reference within this manual are compiled under the valid regulations, the state-of-the-art as well as G.A.S. experiences of several years.

This user manual must be stored together with and close to the device at any time and accessible to all persons, who operate or handle the device at any time.

This user manual must be read carefully before starting to work with the device. G.A.S. does not assume any liability for damage and disturbances, resulting from disregard of the instructions contained in this user manual. All claims of any kind related to damage from a not intended use of the device will be rejected.

G.A.S. reserves the right to realize technical changes of the product due to improvements without explicitly mentioning them.

## 1.7 Copyright

The manual is confidential. It is beyond doubt exclusively made and also meant for the personnel directly dealing with the equipment. All data, texts, designs, pictures and other representations within this manual are protected in the sense of the copyright law and are subject to further commercial patent rights. Each abusive is punishable by law.

Passing it on to third persons as well as duplications in any kind and form - also in part - as well as the use and/or report of contents are not permitted without written agreement of the manufacturer. Offences lead to payment of damages. We reserve ourselves all rights of the practice of commercial patent rights.

#### 1.8 Return and Disposal

For an adequate disposal, the device or/and its equipment must be returned to the G.A.S. or to a third party authorized by the G.A.S.! For questions please contact G.A.S.

#### 1.9 Software Updates

If there are any software updates customers will be contacted by G.A.S. Gesellschaft für analytische Sensorsysteme mbH as soon as the updates are available. The updates are free of charge within the first 12 month after delivery. Users will be provided with information about the changes and instructions for executing the updates.

### 1.10 Customer Service

For questions concerning G.A.S. products a customer service is available:

G.A.S. Gesellschaft für analytische Sensorsysteme mbH

Otto-Hahn-Straße 15

44227 Dortmund

Germany

Phone: +49 (0) 231 / 97 42 - 65 50 Fax: +49 (0) 231 / 97 42 - 65 55

support@gas-dortmund.de

The telephone hotline is available from monday to friday from 9:00 to 16:00 hours. In urgent cases or if you use fax or email please provide a telephone number for callbacks.

## 2 Safety

## 2.1 Intended Use Only



#### **WARNING!**

Usage other than described in this manual may damage the device and/or harm persons involved.

Do not use the device for other purposes. Damages due to misuse are not covered by the guarantee. Such damage claims will be rejected.

The device and its equipment are not certified for the employment in areas with explosive gas air mixtures.

All claims or requirements of any kind against the manufacturer and/or its authorized persons that arise due to damages from a not intended use of the device will be rejected. All damages that arise from a not intended use are of the operator's responsibility.

The intended use of the equipment and its correct handling according are described in the operating instructions of this manual. Other parts than the parts belonging to the scope of supply, may only be used after G.A.S. approval.

## 2.2 Responsibility of Operator

The device may only be operated in a perfect technical condition. Before putting the device into operation, the condition of the device and its equipment must be checked. The information and instructions provided in this manual must be followed at any time.

Besides the instructions provided in this manual the local rules for the prevention of accidents, general safety regulations - valid for the area of application of the device - as well as the valid environmental-protection regulations must be considered and respected.

The responsible technicians and operators must make sure a failure-free use of the device. Responsibilities among the involved persons regarding installation, operation, maintenance, and cleaning must be made clear.

The device can be used to analyze human breath. A hygienic operation must be ensured at all times. Ensure that human breath analysis does not conflict with local

ethical compliance. The breath analysis data might imply private information covered by data privacy protection that has to be obeyed.

#### 2.3 Requirements of Personnel

Only authorized and trained technical personnel may work with the instruments. The operator must have received an instruction over existing and all possible dangers and should be regularly instructed in safety procedures and environmental protection and that the personnel is fully aware of the complete operating instructions and particularly the safety notes. Personnel that might be under the influence of drugs or alcohol are to be kept off the device at any time.

Technical personnel in this context are defined as skilled employees who are knowledgeable due to their educational background. In case the foreseen personnel do not have the necessary qualifications to operate the instrument, it must be trained. Further to that non-authorized personnel should not operate the device.

The competencies for the work on and with the device must be specified and kept undoubtedly at any time so that with respect to security issues no unclear situation might come up.

Any changes of the equipment, which impair security of the personnel, must immediately be reported to the operator and every person dealing with it.



#### **INFORMATION!**

- Operators must be aware of local hygienic standards.
- Operators must be aware of local ethical compliances regarding human breath analysis.
- Operators must be aware of local privacy protection compliances.

### 2.4 Dangers

The device and its equipment is subject to an endangerment analysis. The construction and execution of the device corresponds to the today's state-of-the-art. The device is reliable in service when operated according to its intended use.



#### **INFORMATION!**

If the housing of the device is damaged, the device must not be used anymore and must be returned to the G.A.S. by using the original transportation case.



#### **DANGER**

The BreathSpec® device contains a radioactive radiation Tritium source of 75 MBq which in all EURATOM countries is below the exemption limit. Do not open the device! Do not try to recover malfunctions of the device! Malfunction recovery, repairs and any maintenance work may only be performed by G.A.S. or by qualified personnel authorized by G.A.S.



#### **DANGER**

The BreathSpec® and its equipment is not certified for the employment in areas with explosive gas air mixtures (Zone 0).



### DANGER

Exercise great care in handling current-carrying parts like the power supply cord. Do not get directly in touch with current-carrying parts. Do not open the housing. Do not use damaged parts.



#### DANGER

All parts of the equipment that are in contact with human breath must either be disposed of or sanitized to prevent biohazard



#### DANGER

When Nitrogen is used as drift gas and helium as carrier gas, ignition of a helium plasma may occur due to the high voltage present in conjunction with a radiation source. This can damage the IMS.

## 3 Transport, Packing and Storage

### 3.1 Inspection after Transport

Check the supply immediately after delivery concerning its completeness and/or transport damages. If you detect externally visible transport damage, do not receive the supply, or only under reservation. State the extent of the damage on the provided delivery note and/or the transportation documents of the feeder. Generate a complaint. Lodge a complaint of covered defect immediately after recognizing, as claims due to transport damages can only be made valid within the complaint periods (usually 7 days).

## 4 Packing

If no return agreement regarding the packing was agreed upon dispose the packaging material always in an environmentally friendly way and according to valid local regulations. If necessary, ask a recycling company.



#### **INFORMATION!**

It is recommended to **keep the transport box** for a safety return transport.

## 4.1 Storage and Transport

Store the device only under the following conditions:

- When not in use store the equipment in the supplied casing
- Prevent unauthorized access
- Do not store outside
- Protect the equipment from moisture and dust
- Put protective caps on all gas sockets
- Avoid mechanical vibrations
- Do not expose the equipment to aggressive substances
- Protect the equipment from direct sun light
- Storage temperature: 5 to 40 °C

- Relative Air Humidity: 0- 90%Rh, prevent condensation
- Instrument's position: Horizontal

The equipment should be moved only within the provided carrying case. By this means, transport damages can be avoided. The above-mentioned values are considered for an instrument transported in its original new packing.



#### **WARNING!**

Protective caps should be put on gas sockets in case the device is stored or transported.

## 4.2 Cleaning and Maintenance

Natural aging and the wear of certain components of the equipment require a regular cleaning and maintenance.

### 4.3 Cleaning

Clean the device only with a dry or easily damp cloth.



#### **WARNING!**

Do not use cleaning agents, which contain solvents, acids or bases.

#### 4.4 Maintenance



#### **INFORMATION!**

Maintenance of the device should only be carried out at G.A.S. or through specially trained and by G.A.S. authorized personnel.

The recommended maintenance interval for BreathSpec® device is 12 months for Circular Gas Flow Unit (CGFU) is 6 months.



#### **INFORMATION!**

Maintenance of the equipment must be carried out by G.A.S. or personnel authorized by G.A.S.

Please contact G.A.S. 6-8 weeks in advance to optimize the turnaround time!

# 5 Installation BreathSpec® Device (Version 4G1) with Ciruclar Gas Flow Unit (CGFU)

## 5.1 Installation Requirements

The following requirements must be fulfilled by the customer:

#### **Location of Installation**

- Available space of 600 x 700 x 300 mm (W x D x H)
- Ambient temperature of 5 40 °C
- Humidity: 0-90 % RH, non-condensating

#### **Electricity**

- Electricity supply free of interferences
- Power Supply of 230 V ± 10%, 50- 60 Hz ± 1%

#### Safety

• Availability of exhaust system for device exhaust gas tube (Sample Gas out)

#### Computer

- Computer with current Microsoft Windows operating system
- Administrator right to install G.A.S. software



#### **INFORMATION!**

To ensure correct measurements it is necessary to **connect the** supplied exhaust tube (Sample gas out).

The exhaust system must not generate any negative pressure.

## 5.2 Installing the device

1



Unpack the device.

Remove the foam spacers.

Remove the accessories boxes.

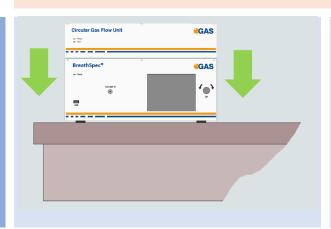
Lift the device from the transport box.



#### **WARNING!**

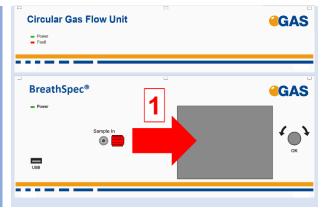
Do not deploy the device in areas exposed to explosive substances or mixtures!

2



Place it on a robust tabletop of minimum footprint size of 60 cm x 70 cm. Ensure that there is enough working space at the rear side of the device.

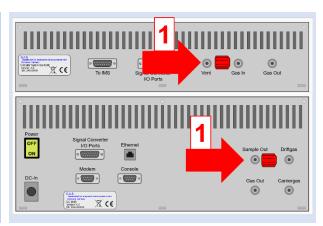
3



**Remove red protective cap** from gas sockets at front of housing.

Retain for future use.





**Remove red protective**caps from gas socket at rear of housing.
Retain for future use.



#### **INFORMATION!**

Protective caps should be put on gas sockets in case the device is stored or transported.



#### **WARNING!**

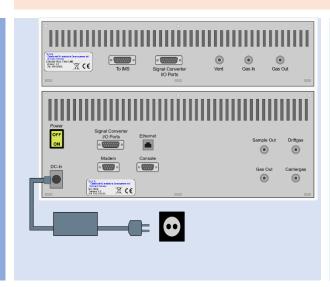
It is absolutely necessary to remove all protective caps before the system is switched on.



#### **INFORMATION!**

Gas tubes and GCFU Connection Cable are preinstalled.

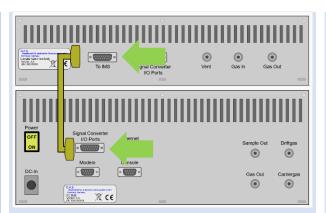
5



Connect device to power supply.

Connect power supply to power socket.

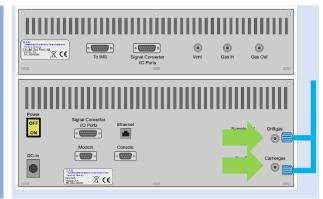
6



Connection-Cable.

(normally pre-installed!)

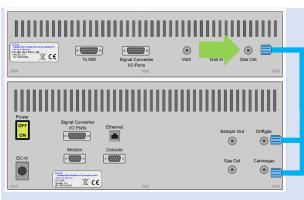
7



Connect the Diftgas-/
Carriergas-Adapter to the Driftgas- and the Carriergas-Connector.

(normally pre-installed!)

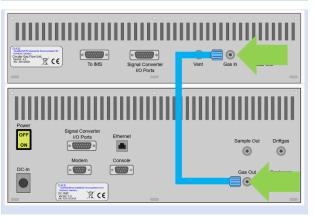
8



Connect CGFU Gas Out
outlet to Driftgas-/
Carriergas-Adapter
using a PFA tube.

(normally pre-installed!)

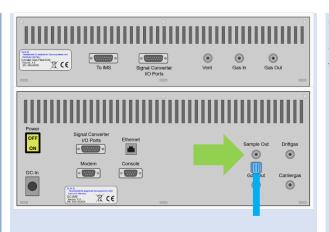
9



Connect CGFU Gas In inlet to GC-IMS Gas Out outlet using a PFA tube.

(normally pre-installed!)

10



Connect **Sample Out** to an appropriate waste gas ventilation system.



#### **INFORMATION!**

To ensure correct measurements it is absolutely necessary to **connect the supplied exhaust tube** (Sample out).

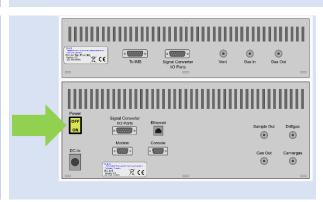
The exhaust system must not generate any negative pressure.

11

Connect the Sampling System:

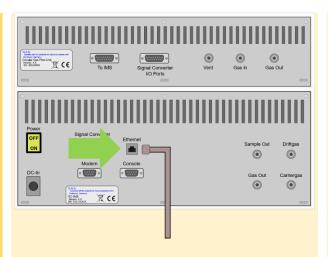
- Mouthpiece tube with heated transferline see chapter 5.4
- Heated Luer-Lock-Adapter see chapter 5.5

12



Switch on device.

13
Option



For file transfer via LAN: Connect the **Ethernet** socket with an appropriate Ethernet cable to a LAN.



#### **INFORMATION!**

When using a CGFU unit the total flow (EPC1 and EPC2) is limited to 400ml/min.

## **5.3 Mounting the Mouthpiece holder**

1



Mouthpiece-Handheld holder arm with screws

2



For mounting the arm use the marked holes.

3



Mount the arm with a Torx screwdriver T30.

# 5.4 Connecting the Mouthpiece tube

1



Mouthpiece Handheld with heatable Transfer-line

2



Pull the screw upwards.

3



Remove the handling screw.

4



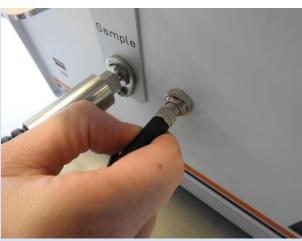
Connect the transferline to the sample-in connector.





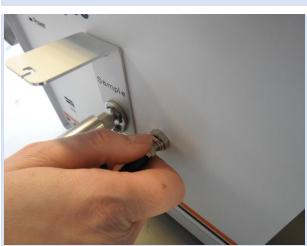
Tighten the screw with a spanner.

6



Connect the current supply cable.

7



Tighten the current supply cable.

8



Push the Transfer-line connector onto the Sample in connector.

9



Place the Mouthpiece handheld into the handheld holder.

10



Switch on the BreathSpec.

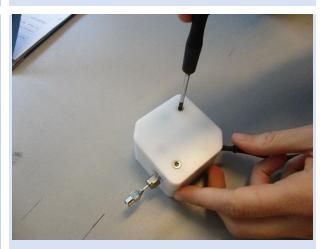
# 5.5 Installation of Luer-Lock adapter [optional]

1



Luer-Lock-Adapter with heater

2



Loosen both screws and remove the plastic cover.

3



Loosen all screws and remove the heating block.





View of Luer-Lock-Adapter with opened heating block.

5



Connect the Luer-Lock-Adapter to the Sample In connector and tighten the screw with a spanner.

6



Attach one side of the heating block.





Attach the other side of the heating block and tighten all screws.

8



Attach the plastic cover and tighten all screws.

9



Connect the current supply cable and tighten it.



Switch on the BreathSpec.

#### 5.6 Prepare the device for operation

Before using the device for the first time or after being disconnected from the nitrogen source for some time it must be cleaned to ensure proper operating conditions. In this case start the **cleaning mode**.

An appropriate cleaning period duration must be chosen depending on how long the device was switched off and on the extent of contamination. It is recommended to clean the device for at least 15 hours before operating it for the first time. If the Spectrum is not clean repeat the process. A reference spectrum for the evaluation can be found in the supplied Analytical Approval.

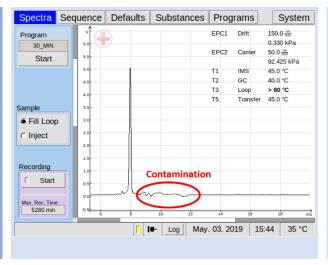


#### **INFORMATION!**

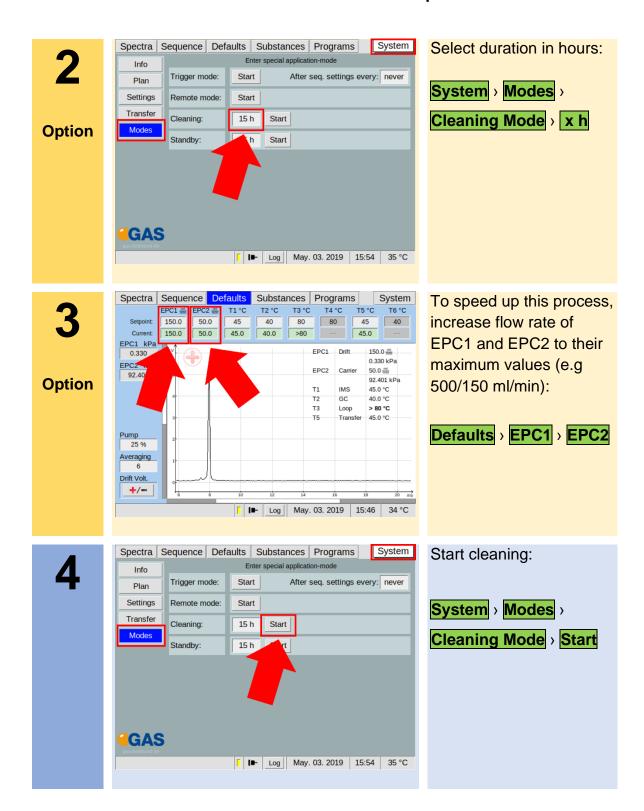
After the cleaning process the device needs at least **2 hours** to cool down the internal components to their required temperatures.

The duration of the cool down process is depending on the temperature default settings.

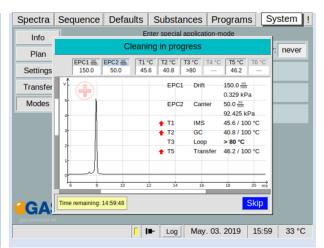
1



Inspect spectrum for contamination. Control the baseline. Start cleaning when contaminated. Contamination is indicated by peaks or the disappearing of the RIP.

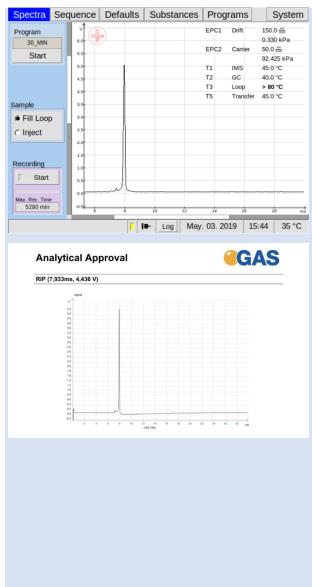






Wait until cleaning process is completed. The process can be stopped with **Skip**.

6



After all temperatures reached the default values inspect visually the current spectrum and compare it with the reference spectrum of the analytical approval. The RIP should reach ~80% of the RIP height displayed in the delivered Analytical

Approval of the device under same measurement conditions of G.A.S.

The assessment of the readiness to measure is additionally supported

If not check the gas quality and/or install additional purification cartridges and start the cleaning procedure again.

by the system.



#### **INFORMATION!**

The device is delivered with an acceptance snapshot. This snapshot defines the system performance during device acceptance and is used to assess the readiness for measurement. Any deviations from this are displayed in the Error Information Window. The default values can be adjusted by the customer.

# 6 Installation BreathSpec® Device (Version 4G2) with Airsense μTD

### **6.1 Installation Requirements**

The following requirements must be fulfilled by the customer:

#### **Location of Installation**

- Available space of 600 x 700 x 300 mm (W x D x H)
- Ambient temperature of 5 40 °C
- Humidity: 0-90 % RH, non-condensating

#### **Electricity**

- Electricity supply free of interferences
- Power Supply of 230 V ± 10%, 50- 60 Hz ± 1%

#### Gas supply

- Nitrogen (Quality 5.0 (99,999%) or Synthetic Air (Quality 5.0 (99,999%)
- Stainless steel pressure reducer adjustable adjustable pressure range of 3
   6 bar and 3 mm Swagelok connector

#### Safety

 Availability of exhaust system for device exhaust gas tubes (Gas out and Sample Gas out)

#### Computer

- Computer with current Microsoft Windows operating system
- Administrator right to install G.A.S. software



#### **INFORMATION!**

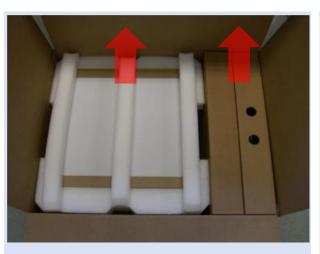
To ensure correct measurements it is absolutely necessary to connect the supplied exhaust tubes (Gas out and Sample gas out).

The exhaust tubes (Gas out and Sample gas out) must be led separately into the exhaust system and must not be connected.

The exhaust system must not generate any negative pressure.

# 6.2 Installing the device

1



Unpack the device.

Remove the foam spacers.

Remove the accessories boxes.

Lift the device from the transport box.



#### **WARNING!**

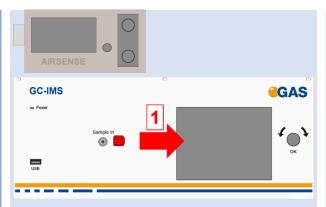
Do not deploy the device in areas exposed to explosive substances or mixtures!

2



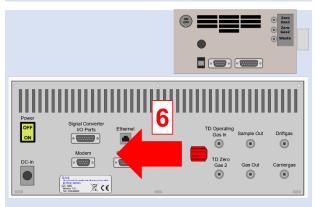
Place it on a robust table top of minimum footprint size of 60 cm x 70 cm. Ensure that there is enough working space at the rear side of the device.





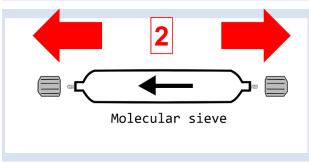
Remove red protective caps from gas sockets at front of housing.
Retain for future use.





Remove red protective caps from gas socket at rear of housing.
Retain for future use.





Remove protective caps from molecular sieve.
Retain for future use.



#### **INFORMATION!**

Protective caps should be put on gas sockets in case the device is stored or transported.



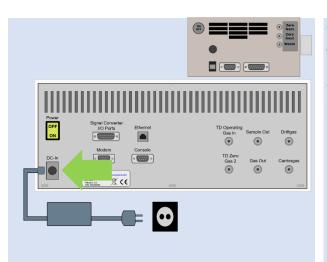
#### **WARNING!**

It is absolutely necessary to remove all protective caps before the system is switched on.



#### **INFORMATION!**

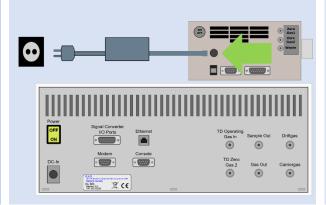
Make sure that the power switch is set to OFF before connecting the power supply.



Connect BreathSpec device to power supply.

Connect power supply to power socket.

7



Connect µTD device to power supply.

Connect power supply to power socket.



#### **INFORMATION!**

Only use stainless steel pressure reducers, PFA tubes with 3 mm outer diameter and 3 mm Swagelok connectors.

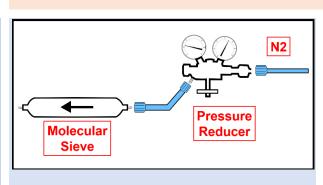
Screw on the Swagelok caps manually and fix them by screwing a further half-turn using a 12 mm open-end wrench.



#### **WARNING!**

Do not introduce aggressive gases or liquids into the device.

8



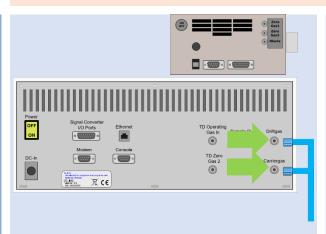
Connect nitrogen gas (Purity 5.0 or better) source to input of supplied molecular sieve using a PFA tube.



#### **INFORMATION!**

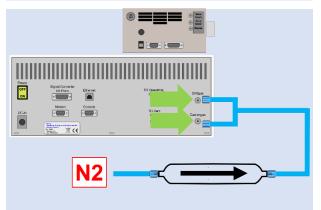
Recommended pressure of Operation Gas (Driftgas / Carriergas) is 3 bar (300 kPa). 6 bar (600 kPa) must not be exceeded.

8



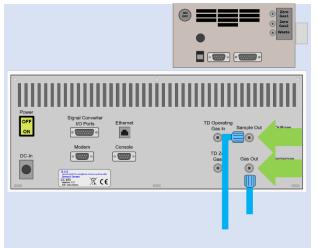
Connect the Driftgas-/
Carriergas-Adapter to the
Driftgas- and the
Carriergas-Connector.

9



Connect molecular sieve outlet to Diftgas-/
Carriergas-Adapter using a PFA tube.

10



Separately connect sockets Sample Out and Gas Out to appropriate waste gas ventilation system.



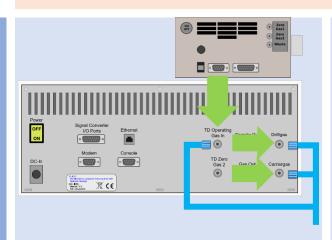
#### **INFORMATION!**

To ensure correct measurements it is necessary to **connect the supplied exhaust tubes** (Gas out and Sample gas out).

The exhaust tubes (Gas out and Sample gas out) must be led separately into the exhaust system and must not be connected.

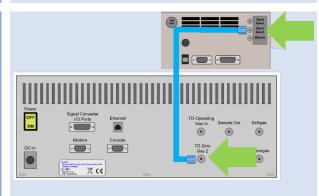
The exhaust system must not generate any negative pressure.

11



Connect TD operating gas in socket to **Driftgas-**/ Carriergas-Adapter
using a 3 mm Swagelok
PFA tube.

12



Also connect Outlet

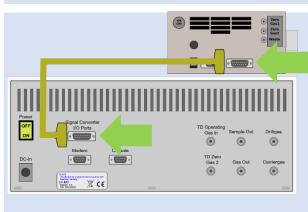
ZeroGas 2 and TDZero

Gas 2 using a 3 mm

Swagelok PFA tube.

For further Information see: Airsense µTD manual

13

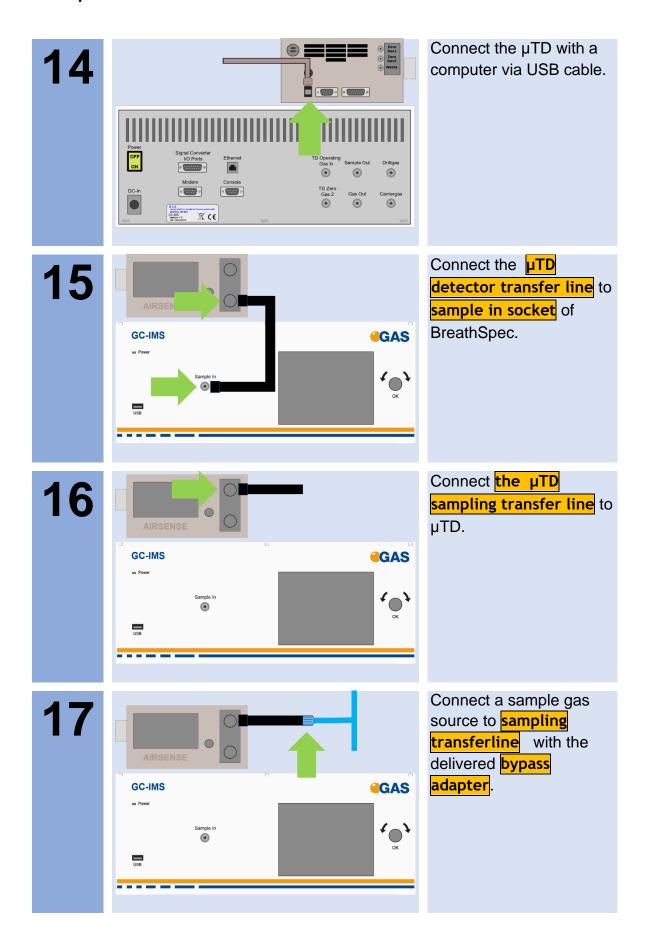


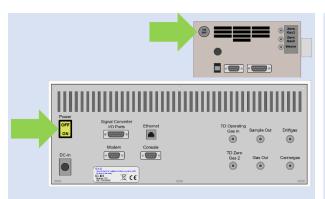
Connect BreathSpec

Signal Converter I/O
Port to µTD Digital Port

with appropriate

Connection-Cable.

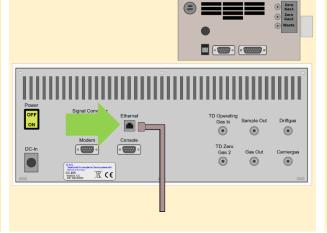




Switch on both devices.

19





For file transfer via LAN: Connect the Ethernet socket with an appropriate Ethernet cable to a LAN.



#### **INFORMATION!**

For detailed information about the installation and operation of the µTD please refer the µTD-GC-IMS Additional Information Quickstart and the Airsense µTD Manual.



#### INFORMATION!

When the  $\mu TD$  unit is connected to BreathSpec®, the current loop data output cannot be used.

# 6.3 Prepare the device for operation

Before using the device for the first time or after being disconnected from the nitrogen source for some time it must be cleaned to ensure proper operating conditions. In this case start the **cleaning mode**.

An appropriate cleaning period duration must be chosen depending on how long the device was switched off and on the extent of contamination. It is recommended to clean the device for at least 15 hours before operating it for the first time. If the Spectrum is not clean repeat the process. A reference spectrum for the evaluation can be found in the supplied Analytical Approval.

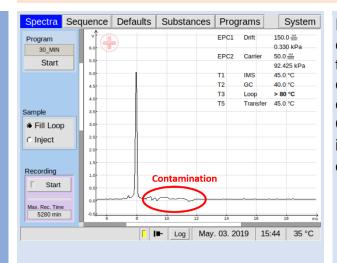


#### **INFORMATION!**

After the cleaning process the device needs at least **2 hours** to cool down the internal components to their required temperatures.

The duration of the cool down process is depending on the temperature default settings.

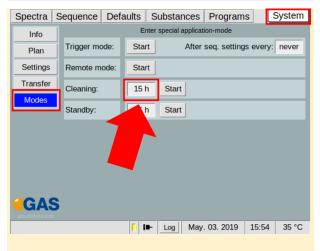
1



Inspect spectrum for contamination. Control the baseline. Start cleaning when contaminated. Contamination is indicated by peaks or the disappearing of the RIP.

2

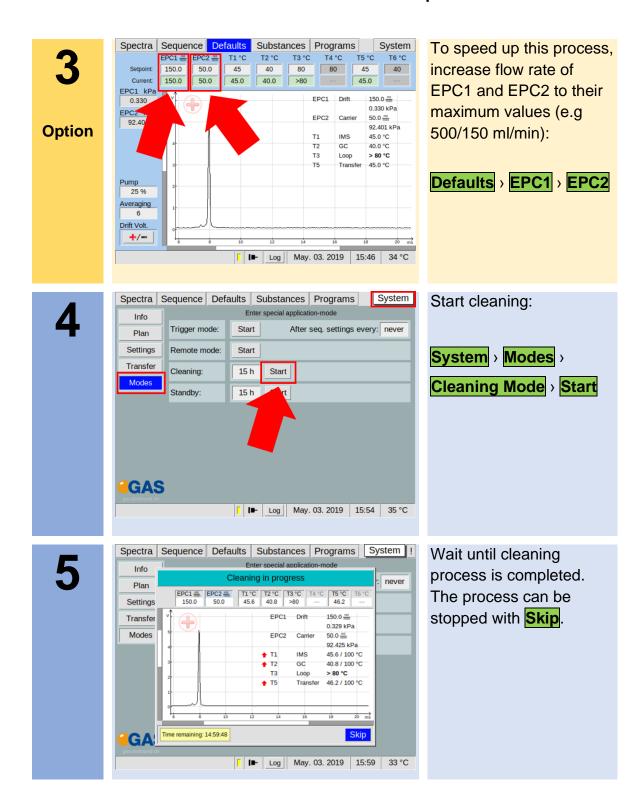
Option



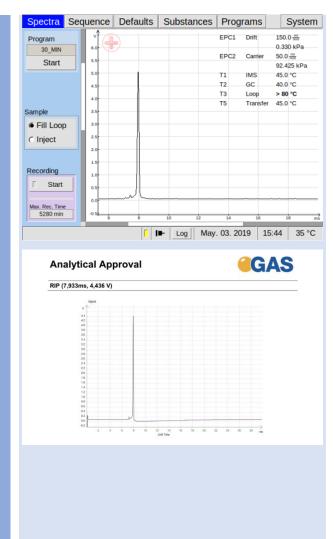
Select duration in hours:

System > Modes >

Cleaning Mode > x h







After all temperatures reached the default values inspect visually the current spectrum and compare it with the reference spectrum of the analytical approval. The RIP should reach ~80% of the RIP height displayed in the delivered Analytical Approval of the device under same measurement conditions of G.A.S. The assessment of the readiness to measure is additionally supported by the system. If not check the gas quality and/or install additional purification cartridges and start the cleaning procedure again.



#### **INFORMATION!**

The device is delivered with an acceptance snapshot. This snapshot defines the system performance during device acceptance and is used to assess the readiness for measurement. Any deviations from this are displayed in the Error Information Window. The default values can be adjusted by the customer.

# 7 System Operation

## 7.1 Measurement Regiurements



#### **INFORMATION!**

Only use the original accessories supplied with the device.



#### **INFORMATION!**

Make sure that the gas quality is 5.0 (99,999%) or better.



#### **INFORMATION!**

Only use stainless steel pressure reducer.



#### **INFORMATION!**

Make sure that the spectrum is clean a without contamination.



#### **WARNING!**

Do not introduce any liquids. This can destroy the device.



#### **INFORMATION!**

Make sure that that all temperature-, flow- and pressure values have reached their default value and are stabilized.

# 7.2 Measurement Program

The BreathSpec will **by default** be equipped with a general measurement program called **BREATH**. This program may need to be subject for method optimization **see BreathSpec User Manual**. Please be aware that editing the program may require changes in the timeline of sampling in order to sample the exhaled breath.

The following workflows describe the analysis of human breath exemplarily using the 'BREATH' program.

# 7.3 Workflow: Breath Sampling via Handheld Breath Sampler

#### 7.3.1 Workflow: Installation of Disposable Reservoir Tube and Mouthpiece



#### **INFORMATION!**

In order to sample via the handheld breath sampler, the respective tube port has to be installed see chapter 5.4.



#### **DANGER**

- Biohazard: wear appropriate gloves at all handling steps
- Take measures to prevent contamination from one subject/patient to other



#### **WARNING**

• Pinching possible

1



The image shows the parts necessary to set up the device for a breath analysis.

2



Insert new reservoir tube.

Check matching of Luer tip and reservoir's drilled hole.



Plug in the mouthpiece into narrow end of the reservoir tube. Screwing the mouthpiece may ease plugging in.

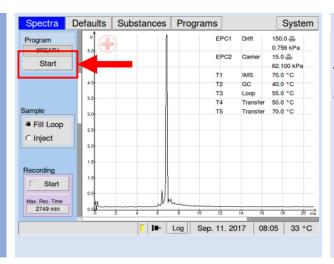
4



The image shows installed reservoir tube kit.

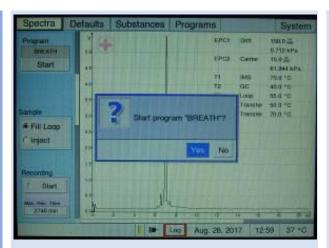
### 7.3.2 Workflow: Execute a breath measurement using the Handheld

1



Select the Start button.

The **dialog** 'Start program' appears.



Select the **Yes**>button with the pushable rotary knob (focus - background is blue), but do not start.

3

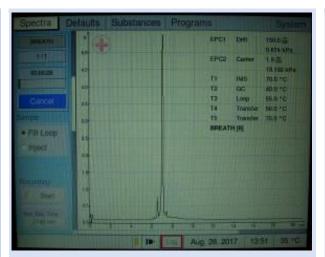




Ask the subject/patient to exhale smoothly into the mouthpiece mounted on the handheld.

[in case of a mistrial (cough etc.) the subject/patient can repeat exhalation]

{best practice is letting the subject/patient exhale into the handheld still attached to the device without touching it. If touched, the handheld can be wiped clean with an alcohol free tissue}



Upon ending of exhalation, the operator presses the pushable rotary knob to start the selected program.

[Arranging a sign with the patient to indicate ending of exhalation may be of benefit to match the right starting point]

- > subject/patient can stop exhaling
- analysis is initiated (progress bar indicates runtime)

5



Pull out the used disposable reservoir tube.

The analysis will continue as defined in the program (approx. 10min for the 'BREATH' program)



#### **INFORMATION!**

Dispose the syringe, reservoir tube and mouthpiece.

# 7.4 Workflow: Breath Sampling via Disposable Breath Sampler

#### 7.4.1 Start a breath measurement using disposable breath sampler



#### **INFORMATION!**

To sample via the Luer-Lock-Adapter the respective tube port has to be installed see chapter 5.5.



#### **DANGER**

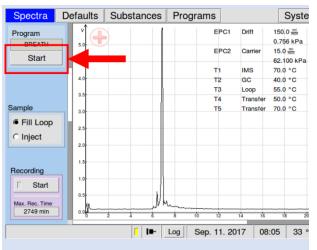
- Biohazard: wear appropriate gloves at all handling steps
- Take measures to prevent contamination from one subject/patient to other



#### **WARNING**

Pinching possible

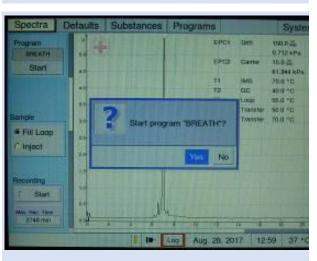
1



Select the Start button.

The **dialog** 'Start progam' appears.

2



Select the **Yes**>button with the pushable rotary knob (focus - background is blue), but do not start.



Plug in the mouthpiece into the narrow end of the reservoir tube. Screwing the mouthpiece may ease plugging in.

4



Connect the 5ml Syringe with the reservoir tube. Screwing the mouthpiece may ease plugging in.

5



Ask the subject/patient to exhale smoothly into the mouthpiece mounted on the handheld.

During the exhalation sample breathing air into the syringe.

[in case of a mistrial (cough etc.) the subject/patient can repeat exhalation]

[Note that the breath sample may alter with time in the syringe]





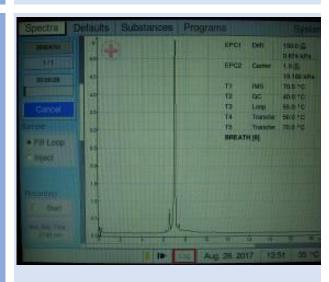
Disconnect the syringe from the reservoir tube.

Insert the syringe into the Luer lock adapter.

Smoothly inject the breathing air into the sampling Luer port.

Towards the ending of injection press the pushable rotary knob to start the selected program.

7



> analysis is initiated (progress bar indicates runtime)

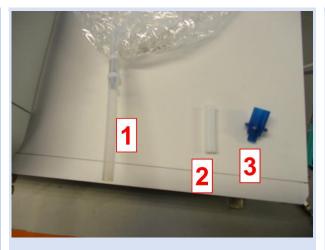


#### **INFORMATION!**

Dispose the syringe, reservoir tube and mouthpiece.

# 7.5 Workflow: Exemplary Breath sampling with a sample bag

1



The components for breathing air sampling with the gas bag:

- 1: Sampling bag
- 2: Sampling bag adapter
- 3: Mouthpiece

2



Put all components together

3



Fill the sample bag with breathing air.





Connect the sampling bag to µTD sampling transferline.

5



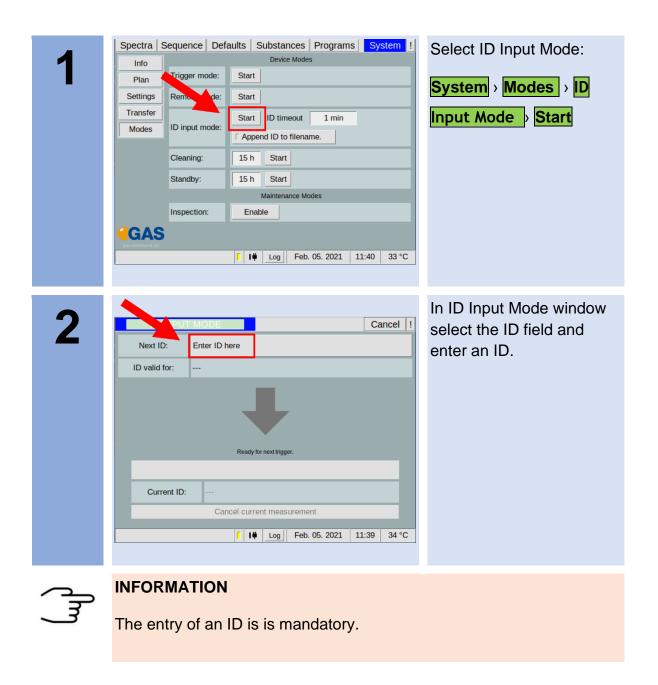
Set BreathSpec to  $\begin{tabular}{ll} Triggermode and start the $\mu TD. \end{tabular}$ 



## **INFORMATION!**

 For detailed Information refer to the Airsense uTD Handbook and the μTD GC-IMS Additional Information Quickstart

# 7.6 Workflow: Measurement in ID Input Mode



3

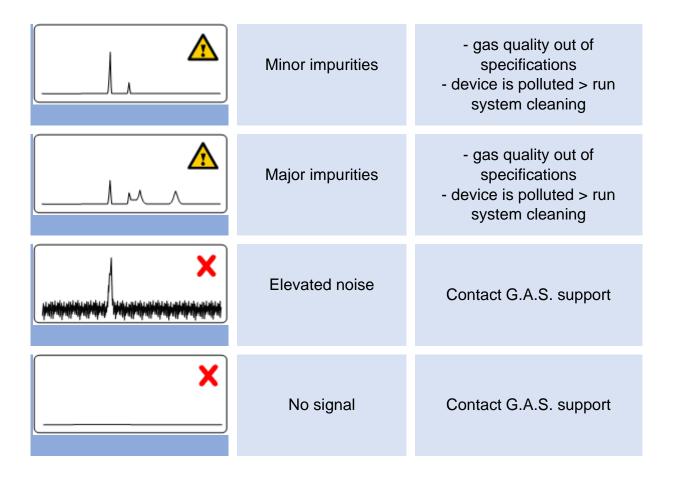


Start measurement with µTD-start button.

# 8 Appendix

# 8.1.1 IMS-Spectrum Examples

Schematic of IMS spectrum	Spectrum description	reasons / suggestions
	Clean spectrum	Perfect
	Clean spectrum, up to two extra signals left hand side of the RIP	Perfect
	RIP shifted to lower drift times	<ul><li>elevated temperature</li><li>reduced pressure</li></ul>
	RIP shifted to higher drift times	- low temperatures - elevated pressure
	RIP deformed	<ul> <li>gas quality out of specifications</li> <li>device needs to be flushed for some time</li> <li>flows not in range</li> </ul>
	RIP base deformed yet visible	<ul> <li>gas quality out of specifications</li> <li>device needs to be flushed for some time</li> <li>flows not in range</li> </ul>
	RIP deformed towards tailing	<ul> <li>gas quality out of specifications</li> <li>device needs to be flushed for some time</li> <li>flows not in range</li> </ul>



# 8.2 Corresponding G.A.S. Documents and Tutorials



#### **INFORMATION!**

- BreathSpec User Manual
- CGFU User Manual (optional)
- Airsense uTD Handbook (optional)
- µTD GC-IMS Additional Information Quickstart (optional)
- Sequence Designer Manual
- IMS Control TFTP-Server Manual
- Tutorials Sequence Designer
- Tutorials VOCal
- Manuals VOCal