Plasmion
simple smart sensitive

Installation and Operation Manual

SICRIT® Breath Analysis Module

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Plasmion GmbH – Am Mittleren Moos 48 – 86167 Augsburg – Germany

This manual must be stored carefully and must be at hand to any user of the described system. In addition to this manual, Plasmion GmbH provides further installation documentation e.g.:

- *Installation Manual for SICRIT® Interface MS TX 2/3*
- *Hardware and Operations Manual for SICRIT® SC-30X Ionization Set*

Please check for further and updated versions of this manual on www.plasmion.com.

	Attention! Please read and understand this manual before operating the described system. In case you discover obvious errors or contradictions for your product, contact the manufacturer before operating the system.

The content of this document has been checked thoroughly and is considered to be reliable. However, Plasmion GmbH does not take responsibility for damage of foreign or own products and instruments resulting from improper use. Plasmion GmbH is not liable for consecutive damage resulting from integration and/or operation of its products in/with other systems. If the system is used in any manner not specified by Plasmion GmbH, the protection of the system could be impaired. Plasmion GmbH is not responsible for ignoring the outlined safety guidelines or the misuse of this system.

The technology and application of the system described in this manual is covered by patents and patent applications and is used under license.
All trademarks are property of their respective owners.

Declaration of conformity

The products outlined in this manual are engineered and built according to the requirements of electrical safety and health protection as outlined in the EC low voltage directive and electromagnetic compliance (EMC) directive. Any change or modification of any of the referred products, not verified by Plasmion GmbH, voids this declaration.

Plasmion GmbH certifies that the

SICRIT® Breath Analysis Module

is designed and built to meet the EU Regulation No. 2014/35/EU (low voltage directive) and the Guideline 2014/30/EU (EMC Directive). The product fulfils the following safety requirements and safety standards for electrical measurement, control and laboratory use:

IEC 61010-1:2010
ICE 61010-1:2010/AMD1:2016
EN 61010-1:2010/A1:2019
IEC 61010-2-010:2019
EN IEC 61010-2-010:2020

The product fulfils the following directives for electromagnetic compliance of electrical measurement, control, and laboratory use:

IEC/EN 61326-1:2012, Class A

CISPR 11/EN 55011:2009

The product is compliant with RoHS-Guideline 2011/65/EU.

CE

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EG Konformitätserklärung
EC Declaration of conformity

Name des Herstellers: manufacturer's name	Plasmion GmbH
Adresse des Herstellers manufacturer's address	Am Mittleren Moos 48 86167 Augsburg Germany

Der Hersteller erklärt, dass das Produkt
The manufacturer declares that the following product

Name des Produkts: product name	***SICRIT* Breath Analysis Module**

mit den folgenden EG Richtlinien und harmonisierten Standards übereinstimmt:
is in conformity with the following EC Directives and harmonized standards

Niederspannungsrichtlinie Low Voltage Directive **2014/35/EU**	EN 61010-1:2010 EN 61010-2-010:2014
EMV-Richtlinie EMC Directive **2014/30/EU**	IEC/EN 61326-1:2012, Klasse /class A CISPR 11/EN 55011:2009
Ergänzende Informationen: Complementary information	Das Produkt hält die RoHS-Bestimmungen ein The product is in conformity with RoHS Directive 2011/65/EU

Augsburg, Germany, 15.01.2020

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Am Mittleren Moos 48
86167 Augsburg

Jan-Christoph Wolf
Geschäftsführer
Executive Director

Safety Instructions

The following safety labels on the product and within this manual indicate safety risks and necessary precautions that arise during installation or from operating the products.

	[Attention!], marks possible dangers to your safety and health.
	[Dangerous Voltage!], indicates parts and situations where there is the risk of exposure to dangerous electrical voltages.
	[Attention Hot Surface!], indicates potentially hot surfaces that might cause burning injuries if touched without protective gear.
	[Note], marks important information or advice, not related to safety issues.

Table of Contents

1. Intended Use of the SICRIT® Breath Analysis Module

The system described is intended for use only in laboratory and/or R&D environment. If the system is used in a way not specified by the manufacturer, misused, or modified causing an infringement of the safety measures, Plasmion GmbH refuses any liability for consecutive damage in any form.

1.1 The SICRIT® Technology

Soft Ionization by Chemical Reaction In Transfer (SICRIT®) is a flow through ionization technique to be coupled with LC mass spectrometers featuring an API. Inside the ion source a cold plasma is used for ionization of the analytes passing through. This enables direct gas phase measurements as well as coupling with chromatographic systems as GC or HPLC. While approach employing any chromatography requires additional modules, direct breath analysis can be conducted using breath analysis module as explained in this manual.

1.2 The SICRIT® Breath Analysis Module

The SICRIT® Breath Analysis Module is designed to be used for direct exhaled breath measurements. Generally, the SICRIT® Breath Analysis Module can be used for both non-diluted breath measurements and diluted breath measurement, respectively. The SICRIT® Breath Analysis Module is always being directly connected to the SICRIT® Ion Source which is mounted onto the mass spectrometer (MS) inlet and controlled via the SICRIT® Control Unit.

In Figure 1 the main parts of the SICRIT® Breath Analysis Module are shown.

The SICRIT® Breath Analysis Module consists of a mouthpiece adapter (c, Art-Nr. 16-023) equipped with a one-way check valve. The inner chamber of the inlet part is continuously flushed by purge gas to prevent room air to enter the sampling region and thus hypothetically interfere with the sample. In both, diluted and non-diluted operation modes, analytes pass through the heated sampling line (a, Art.-Nr. 15-002) which is connected to the SICRIT® Ion source via the module connector. The purge and dilution gas, typically nitrogen (N_2), is supplied directly by the MS.

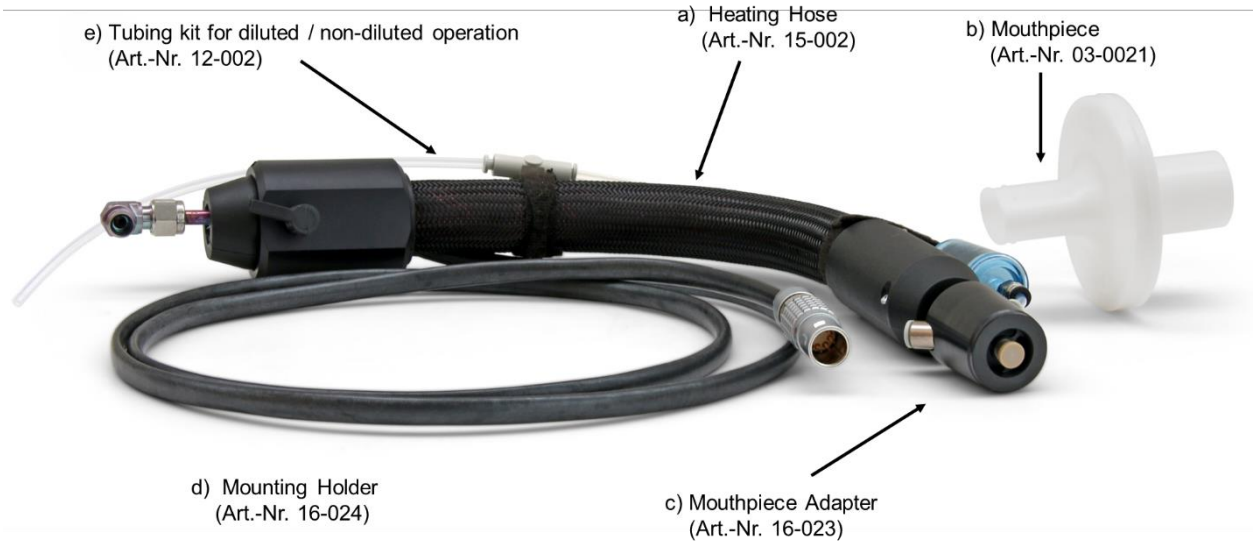


Figure 1: Components of the SICRIT® Breath Analysis Module.

2. Technical Data

Dimensions	0.45 x 0.3 x 0.3 m (without disposable mouthpiece on)
Weight	0.7 kg
Supply Voltage	Supply by SICRIT® Control Unit SC-30 24 VDC, 100 W
Electrical Connectors	1.4 m cable with plug for SC-30 Control unit
IP-Code	IP40
Protective Class	I
Operation Conditions	5°C to 25°C surface temperature 0 to 80 % humidity (non-condensing)
Maximum and Recommended Operation Temperature	200 °C (Recommended 150 °C)
Storage Conditions	-5°C to 50°C surface temperature 0 to 80 % humidity (non-condensing)
Possible Purge / Dilution Gases	Air, N_2, CO_2 Flow (Purge Gas) ≈ 2 L/min Flow (Dilution Gas) ≤ 1 L/min* *optional
Note	For mounting, the mounting system (**Art-Nr. 26-011**) is required The Breath Analysis Module kit includes a tubing kit for diluted and non-diluted operation (Art.-Nr. 12-002)

3. Setup and Operation Modes of the SICRIT® Breath Analysis Module

The SICRIT® Breath Analysis Module is installed by mounting it on the respective SICRIT® MS-Interface, using the universal mounting system (Art. 26-011).

The following installation procedure is described exemplarily for a Thermo Fisher system and the corresponding SICRIT® Interface TX2. However, it applies similarly for other systems and interfaces.

3.1 Installation Prerequisites

Before mounting the SICRIT® Breath Analysis Module to the MS, install the specific SICRIT® MS-Interface and the SICRIT® Ion source following the steps in the provided manuals:

- *Installation Manual for SICRIT® Interface*
- *Hardware and Operations Manual for SICRIT® SC-30X Ionization Set*

3.2 Operation Modes of the SICRIT® Breath Analysis Module

The SICRIT® Breath Analysis Module can be generally operated in two individual modes depending on user's requirements. It should be mentioned that switching in between does not require module uninstallation or reconfiguration.

3.2.1 Non-diluted Breath Mode

By using the SICRIT® Breath Analysis Module in non-diluted breath mode, the sample is directly transferred from the breath inlet into the SICRIT® Ion Source. In that case purge gas provided directly by MS is the only gas being used with the flow rate slightly above the MS intake. The setup is depicted in Figure 2.

Figure 2: The SICRIT® Breath Analysis setup installed in non-diluted breath mode.

3.2.2 Diluted Breath Mode

The diluted breath mode ensures sampled breath to be diluted in a certain ratio before it enters the SICRIT® Ion Source and thus prevent the MS detector from oversaturating. Operating the SICRIT® Breath Analysis Module in diluted breath mode requires the dilution gas to be employed in addition to the purge gas. If only 1 gas line is available, an adjustable split flow valve can be installed to ensure respective gas flow is delivered into the sample dilution region (T-piece). The recommended dilution value should not exceed 80 % (usually 0.7 L/min of dilution gas) and should be measured during the installation. The setup is depicted in Figure 3.

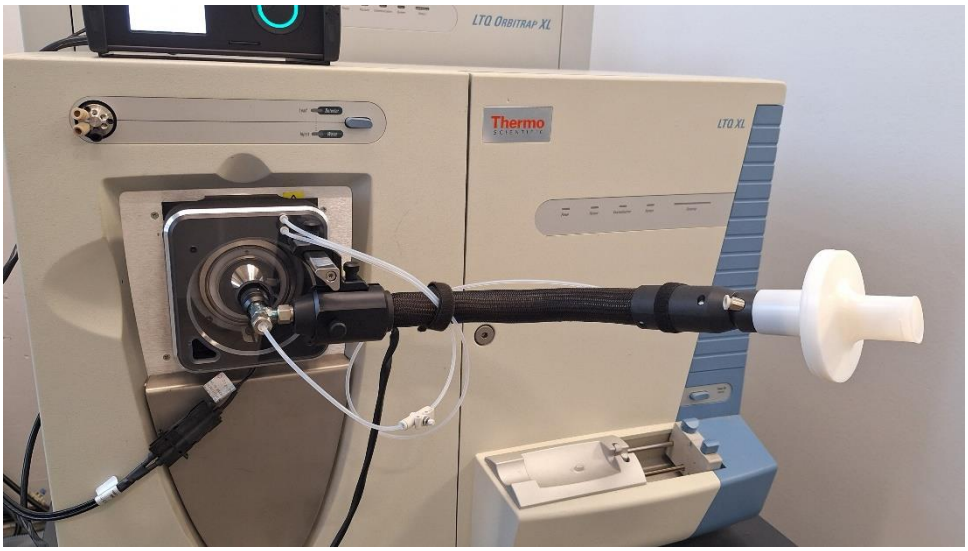


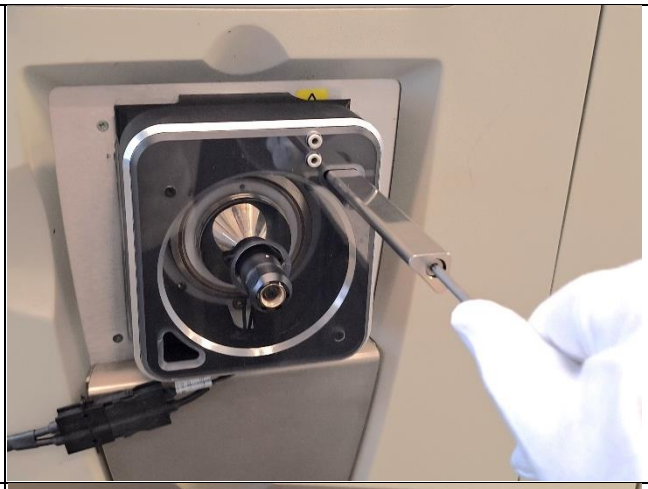
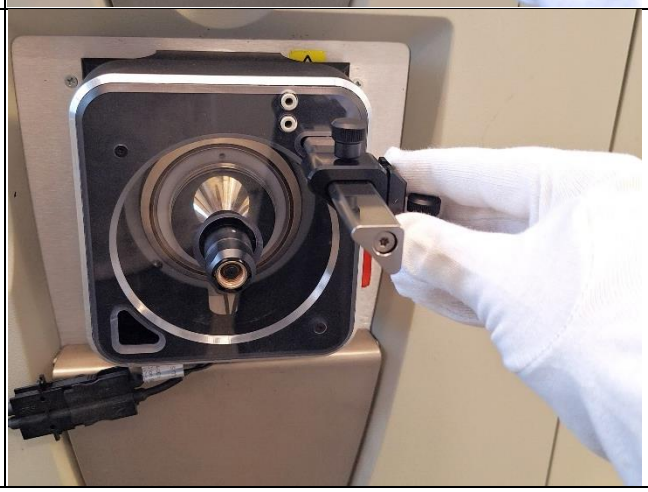
Figure 3: The SICRIT® Breath Analysis setup installed in diluted breath mode.

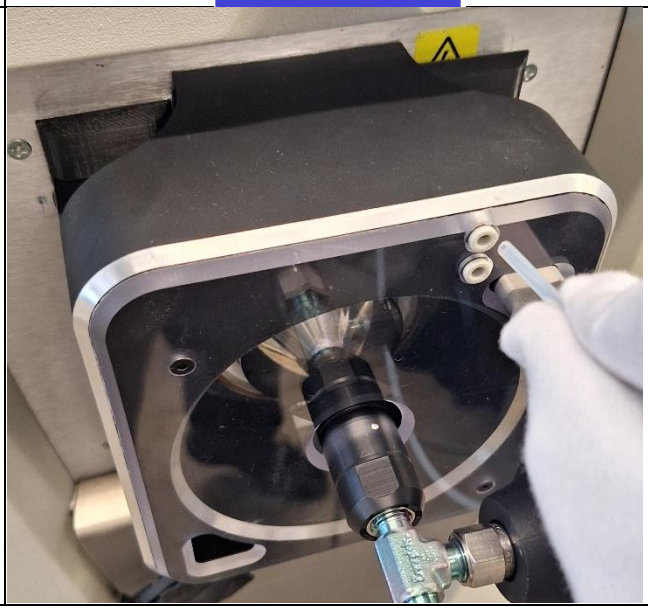
3.3 Installation of the SICRIT® Breath Analysis Module for non-diluted breath mode

Generally, the mounting system allows for easy and flexible alignment of add-on modules for use with the SICRIT® ionization technology. A lock lever sysem enables fine adjustment of the modules in x, y, and z-direction.

During the first installation of the system, some adjustments must be performed to meet the individual space and orientation requirements. These pre-settings can then be used for future installations.

Please follow the step-by-step instructions below:

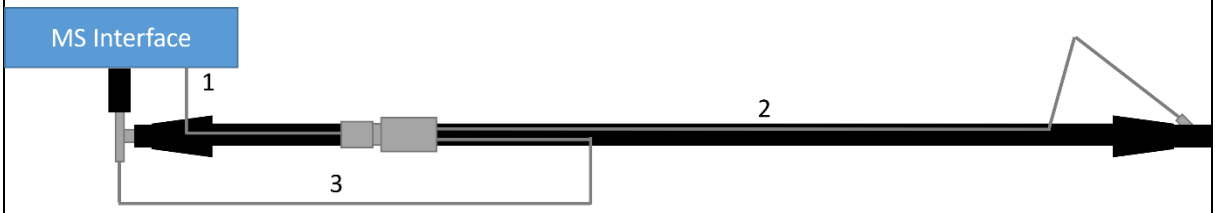
1		Insert the rail of the mounting system in the designated rail mount at the top right of the interface and secure it with the provided Torx tool.
2		Place the slider with fixing screw on the rail.

		Slide the Breath Analysis Module into the slider and make an initial rough position adjustment. **Do not lock the fixing screws yet! During first installation you might have to adjust the z-position.**
4		Connect the provided T-piece with the inlet of the SICRIT® Ion Source and use the blind plug for non-diluted measurements **Lock the fixing screws to secure the position!**
		Only tighten the Swagelok connection hand tight to avoid mechanical stress.
5		Connect 3.2 mm tubing of the breath module to the MS gas outlet. As purge gas any gas provided by the MS can be used. Flow of the purge gas should be generally slightly higher than the flow which is drawn in by the vacuum of the MS inlet. Recommended value is 2 L/min

6		Put the disposable mouthpiece on.
7		Connect the Breath Analysis Module cable with the SICRIT® Control unit.
Your setup is complete!		

3.4 Installation of the SICRIT® Breath Analysis Module for diluted breath mode

Please follow the step-by-step instructions below:

1-3	Follow the steps as described in section 3.3	
4		Connect the provided T-piece with the inlet of the SICRIT® Ion Source and use the additional tubing of the tubing kit for diluted measurements. **Lock the fixing screws to secure the position!**
4		Connect dilution and purge gas lines according to scheme 1.
	 *Scheme 1: Gas connection for diluted breath measurements* 1 – MS gas outlet to the split valve. 2 – Purge gas outlet of split valve to the purge gas inlet. 3 – Dilution gas outlet of split valve to the T-piece.	
		Only tighten the Swagelok connection hand tight to avoid mechanical stress.

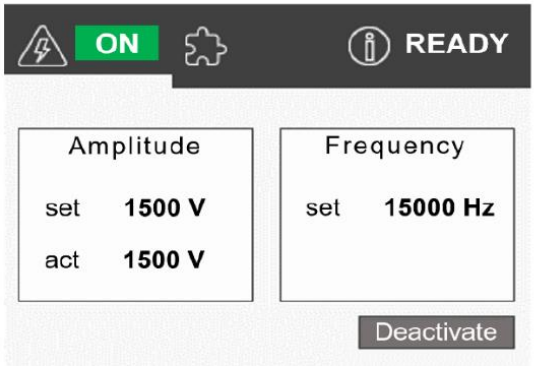
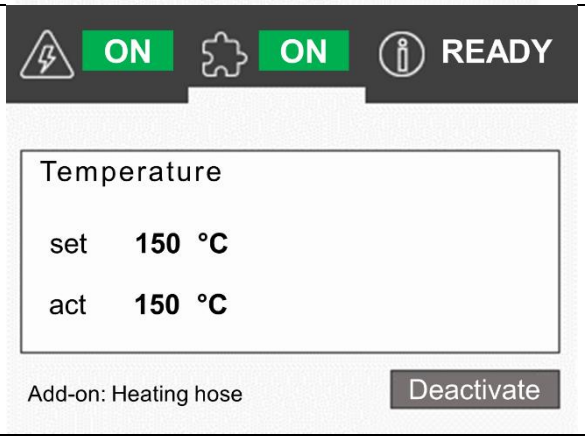
6		Put the disposable mouthpiece on.
7		Connect the Breath Analysis Module cable with the SICRIT® Control unit.
Your setup is complete!		

4. Performing Real-time Breath Measurements

Before conducting the measurement, please ensure the MS to be set up appropriately and according to your experiment expectations as well as that the SICRIT® Breath Analysis Module is configured in the desired mode and SICRIT® Control Unit SC-30 is turned on.

Follow the mentioned steps below to ignite the plasma and set the desired temperature.

During the measurement always use a disposable mouthpiece to avoid cross contamination.

1		Set the voltage and frequency to the recommended values of 1500 V and 15000 Hz respectively to ignite the plasma inside the SICRIT® Ion Source. Click Activate.
2		Set the desired temperature of the SICRIT® Breath Analysis Module in the module tab. Click Activate.
You are ready to measure!		

If you need further assistance or support, please contact Plasmion via support@plasmion.com.

5. Service and Maintenance

The SICRIT® Breath Analysis Module does not require any service or maintenance in routine operation.

5.1 Cleaning and Decontamination

In an unplugged state, the surface of the SICRIT® Breath Analysis module may be cleaned with a humid cloth. To remove contaminations a 50:50 methanol : water mixture can be used. If you use other solvents check the persistence of the surfaces against these cleaning agents.

Any contact of the inner cables and components with liquids must be avoided! Before next operation, the module must be completely dry.

5.2 Maintenance and Service of the SICRIT® Breath Analysis Module

The operational status of the module can be checked using the display of the control unit. After plugging in the cable of the module and turning on the control unit, the actual temperature of the module should be displayed, and the temperature should be adjustable by the rotary encoder. If there is no or a lost connection the display will show [--] for set and actual value.

If there is an overheating of the system, the control unit will stop operation and display a warning.

Correct heating of the module should show a response of the actual temperature value within 20 seconds in the display of the control unit.

Do not operate the system if the housing shows obvious damage.

In case of unrealistic actual temperature values or fluctuations in the displayed values without heating of the module, there is a defect of the module or the control unit. Please contact Plasmion or its respective sales agent for further advice.

6. Risk Avoidance or Residual Safety Risk

Regularly check the casing and cables for damage.

Ensure that access to the system is restricted for any unauthorized or untrained personnel.

Visually check the contact pins of the connectors for changes and damage.

Check if all connections are engaged before operating the system.

Never use the system without the connected ion source.

7. Operation with Potentially Harmful Substances

The risks of operation and handling of harmful or toxic substances that can be analyzed with the SICRIT® Ion Source fall to the operator. Stick to all safety guidelines and take all necessary precautions. Ensure that the substances introduced do not damage the system. The materials used in the SICRIT® Ion Source are PEEK, stainless steel, gold-plated copper alloys, and ceramics. Also consider the durability at higher temperatures.

The device itself does not contain harmful substances.

For recycling of the system, please contact the manufacturer.

8. Parts List

Description	Part No.
Heating Hose	15-002
Mouthpiece Adapter	16-023
Mounting Holder	16-024
Mouthpiece	03-0021
Mounting System for SICRIT® Modules (must be ordered separately!)	26-011