EXHALION

User Manual

Revision 1.0 -March 2021
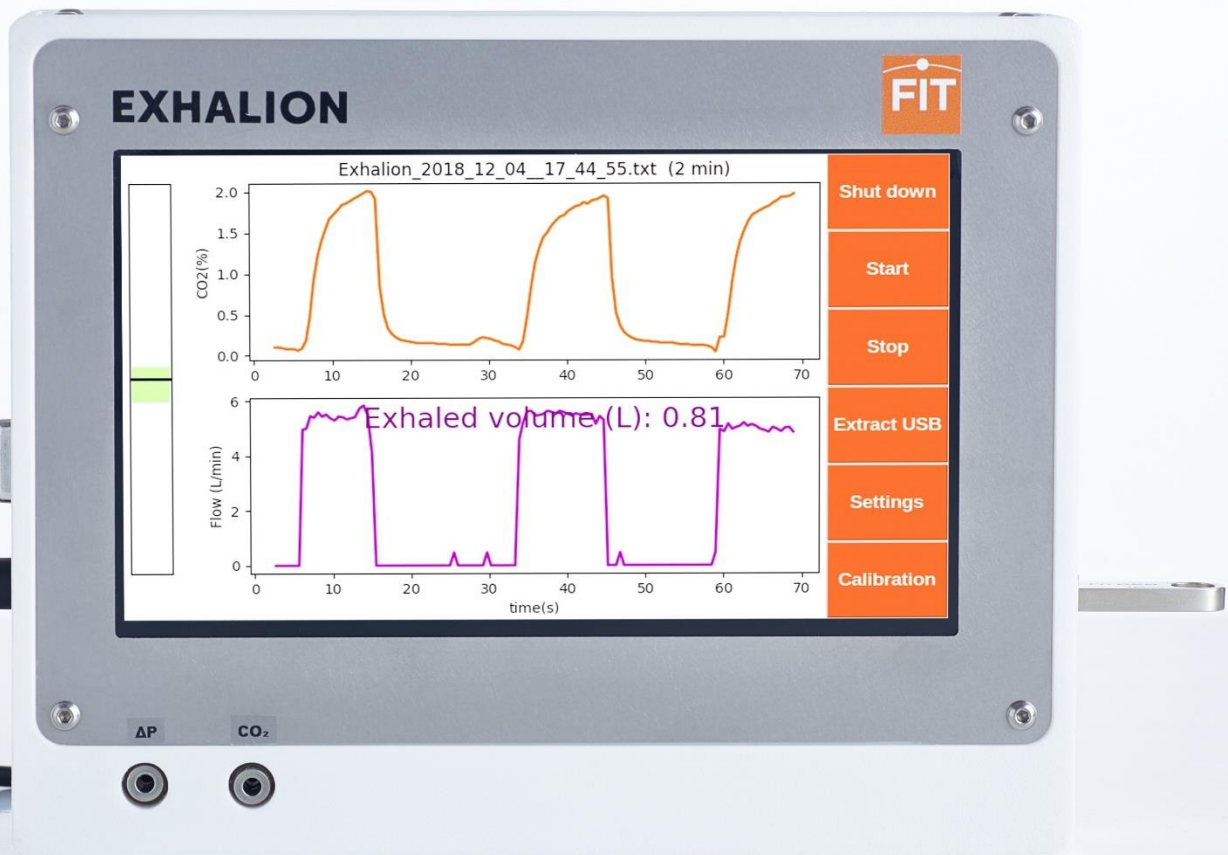
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Release history: Revision 1.0 (pre-certification release), march 2021

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Preface

This *User Manual* describes how to install, remove, use and maintain the EXHALION system developed and commercialized by Fossil Ion Technology.

If you would like to suggest a change in this document, or if you need further assistance, please email us at info@fossiliontech.com. You can also contact us through our online contact form: http://www.fossiliontech.com/contact-us/

WEEE compliance: Directive 2002/96/EC

This product complies with the European Union's Waste Electrical & Electronic Equipment (WEEE) Directive 2002/96/EC. It is marked with the following symbol:

If this product is located in Europe and you want to discard it, please send an email request to info@fossiliontech.com with the following information:

- Product specification
- Number of product pieces and estimated total weight and volume.
- Pick-up address and contact person (please include contact information)
- Declaration of decontamination, stating that all hazardous fluids or materials have been removed from the product.

Fossil Ion Technology shall contact you and arrange a pick-up service at the most convenient time to recycle your product at no cost for you. Please note that this recycling program is not for biological hazard products and contaminated products. You must treat these types of products as biohazard waste and dispose of them in accordance with your local regulations. SUPER SESI is specifically designed solely for the purposes of research and development.

EMC Compliance: Directive EMC 2014/30/EC

EXHALION meets the requirements of the directive EMC 2014/30/EC in accordance with the norm IEC 61326-1.

Low Voltage Safety Compliance: Directive LVD 2014/35/EC

EXHALION meets the requirements of the directive LVD 2014/35/EC in accordance with the norm IEC 61010-1.

Notices and symbols used in this manual

Please make sure that you understand the special notices, symbols, and caution labels in this guide. Most of the special notices and cautions appear in boxes; those pertaining to safety also have corresponding symbols. Some symbols are also marked on the SUPER SESI source itself and

can appear in color or in black and white. Some safety and notices used in this user manual include the following:

⚠️ **CAUTION NOTE** highlights hazards to humans, property, or the environment. Each CAUTION warning is accompanied with the corresponding CAUTION symbol.

IMPORTANT NOTE highlights information to prevent invalid test results, damage to software or loss of data.

INTERESTING NOTE highlights information of general interest

TIPS & TRICKS highlights key information that can be useful to complete of a task or to improve the quality of the results.

Contacting us

If you need further assistance, please contact us.

Address: *Fossil Ion Technology S.L.: Cipreses No. 18, 28036, Madrid, Spain.*

You can also contact us via email: info@fossiliontech.com, or through the contact form in our Technology web page: http://www.fossiliontech.com/contact-us/

General safety precautions and important notes

⚠️ **CAUTION** Do not perform any servicing that is not contained in this manual. In order to avoid injury or damage to the instrument, **do not perform any servicing that is not specified in this manual unless you are qualified to do so**.

⚠️ **CAUTION** The CO2 sensor is sensitive to water condensation. Avoid entrance of condensed liquids and condensed humidity trough the sampling tubes.

IMPORTANT NOTE The CO2 line used to dehumidify air prior to CO2 analysis is vulnerable to UV radiation. Avoid exposing it to sunlight

Description

Principle of operation

EXHALION guides the exhalation maneuver for online breath analysis. It provides a visual clue that helps everyone exhale at a consistent volume and flow rate. EXHALION measures and logs exhaled CO_2, pressure, flowrate, and volume. Data is automatically stored in an open format (*.txt) file, so that it can be processed and synchronized with other data. EXHALION comprises an autoclavable Breath Inlet, and a Sensors Module that houses the touchscreen and all electronics. The Breath Inlet is compatible with medical grade disposable spirometry mouth-piece filters, and SUPERSESI. The Sensor Module can be seamlessly attached to the MS. EXHALION incorporates sensors and routines to facilitate calibration. EXHALION integrates a relay that is activated when exhaled breath reaches a desired flow rate, CO2 concentration, and exhaled volume.
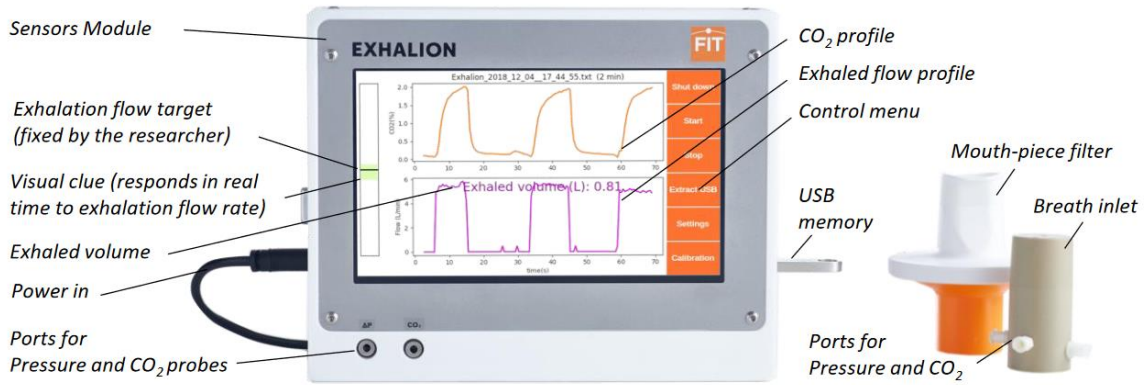
Intended use

EXHALION is designed to be used by trained personnel in a laboratory environment. The purpose of EXHALION is to enable collection of breath in real time and to differentiate different fractions of the exhalation.

⚠️ **CAUTION** Exhalation is intended for research purposes only, and with healthy non-infectious volunteers.
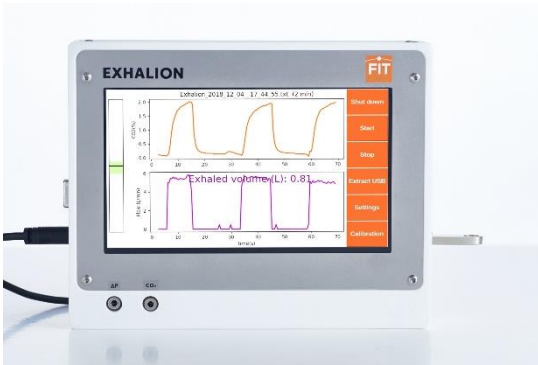
Complete system: EXHALION

Sensors Module

Exhalation flow target
(fixed by the researcher)

Visual clue (responds in real
time to exhalation flow rate)

Exhaled volume

Power in

Ports for
Pressure and CO_2 probes

CO_2 profile

Exhaled flow profile

Control menu

USB
memory

Mouth-piece filter

Breath inlet

Ports for
Pressure and CO_2

Components:

- Sensors Module

- Stand

- Power supply

- Mouthpiece

- Pressure line

- CO2 line

- USB memory

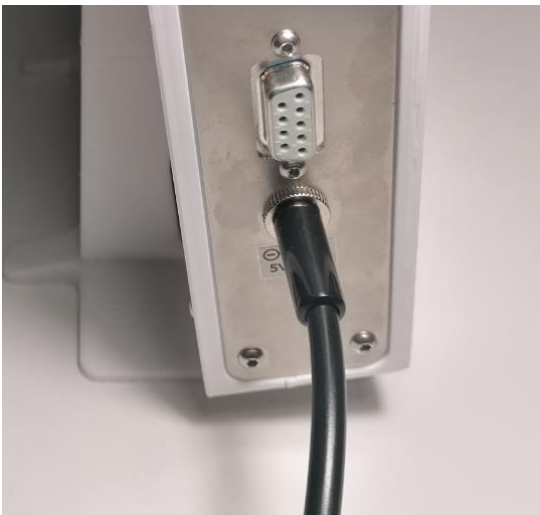- Line filters (3x)

Installation

Assembly

Mouthpiece

Connecting mouthpiece and sensors module

Powering sensors module:

Operation

Turning on

Connect Power supply and turn on. Press On button

Once on, wait tree minutes for temperatures and voltages to equilibrate so as to obtain best precision and repeatability.

Soft shut down

In the touchscreen, press shut down, and follow pop-up instructions, or Press the on button on the side of Exhalion and follow pop-up instructions. Do not interrupt power until system is completely off.

Hard shut down

Press the on button on the side of Exhalion for several seconds until the system shuts down

Start an acquisition

Press Start. Data will be stored in a txt file in the USB memory. Make sure the USB memory is inserted.

Stop acquisition

Press stop and follow pop-up instructions.

Retrieve data

Data is stored in txt files in the USB memory. For safety, only the USB memory provided with EXHALION is compatible with it.

To extract USB. press Extract USB and follow pop-up instructions.

Controlling external units

(This option is available only for models including an I/O relay for offline operation). You can define a set of thresholds to control a relay, based on CO2 levels, flow rate, and exhaled volume. This relay is linked to pins 8 and 9 of the D Sub connector. This relay is only for signaling purposes. It cannot be used to directly control power (i.e. valves with solenoids, pumps, or similar)
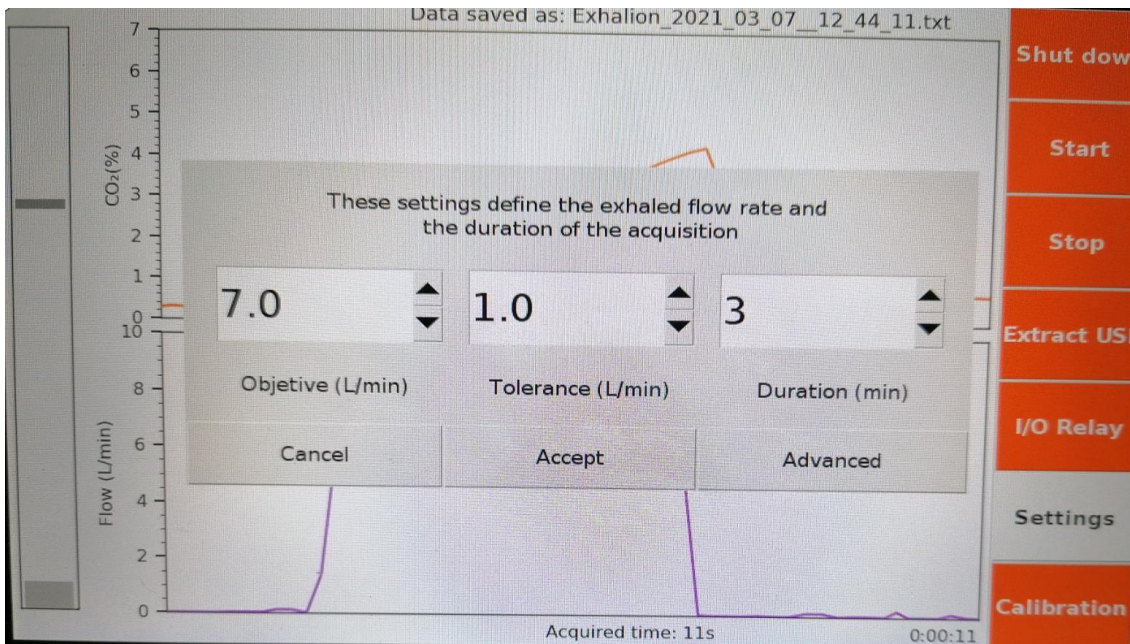

To define the conditions at which the relay is triggered, press I/O relay button, and follow pop-up instructions.
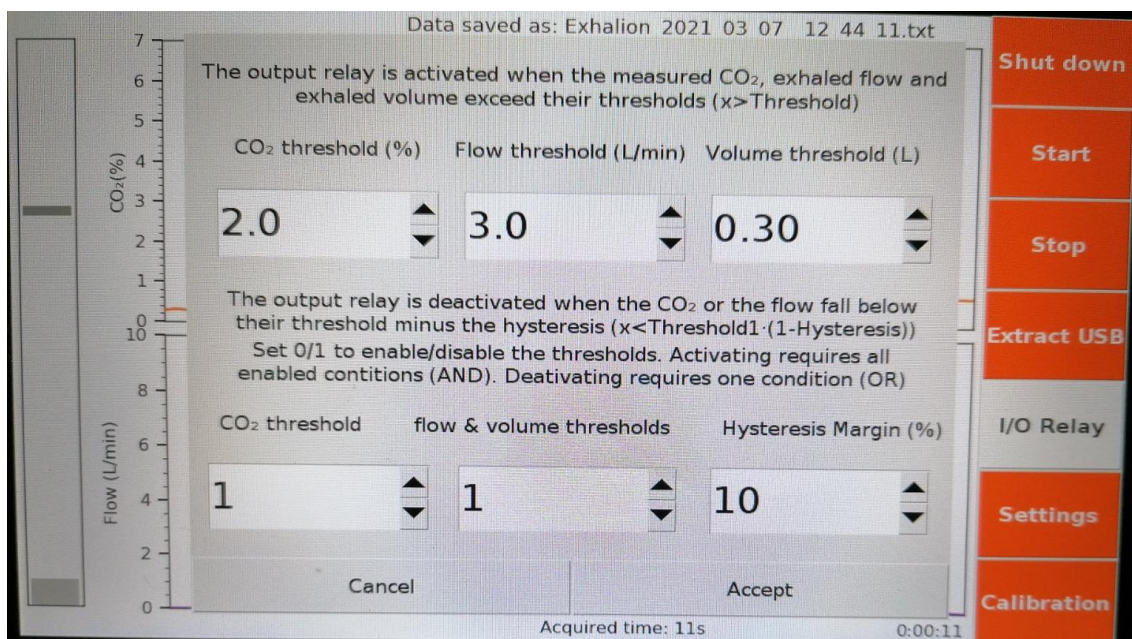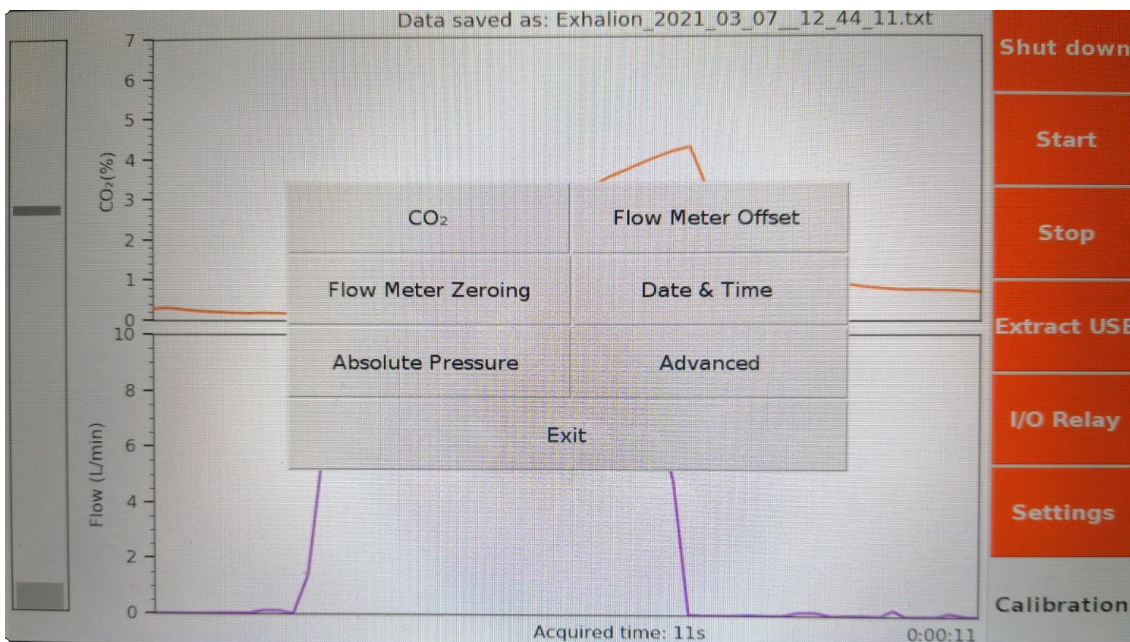
Setting exhalation and data acquisition conditions

Press settings and follow pop-up instructions

Calibration

press Calibration, select parameter to calibrate, and follow pop-up instructions.

EXHALION integrates an absolute pressure sensor. The absolute pressure measurement is used internally to correct for variations caused by climate related absolute pressure oscillations. To calibrate it, use data from the nearest meteorology station.

To Zero the CO_2 sensor, you will need a source of pure nitrogen.

To calibrate the gain of the CO_2 sensor, you will need a CO2-N2 calibration mixture. Mixtures

used to calibrate capnography systems are recommended.

To introduce the different gasses in the CO2 line, disconnect the CO2 line from the mouthpiece assembly, place the tube carrying the gas in front of the CO2 line leaving a gap to ensure the Exhalion sensor module and the pump is not exposed to high pressure, and provide sufficient flow of gas to make sure the sensor module is fed only with calibration gas and no room air is making its way into the CO2 sensor.

The advanced calibration is pin-protected because it provides direct access to parameters used for internal corrections. It also provides access to a routine that calibrates the flow sensor. To calibrate the gain of the flow sensor, you will need to provide a fixed flow of 6 slpm.

Connecting Exhalion with other collection devices
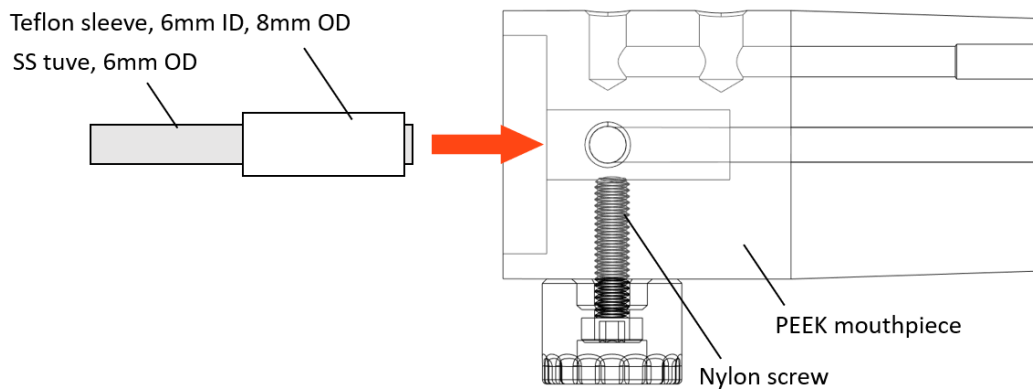
Exhaled pressure is not higher than 10 mBar. At this pressure, connections can be hand tightened. Recommended connection with EXHALION:

Use a 6mmOD Stainless Steel tube inserted in a 6mm ID -8mmOD teflon sleeve. Introduce the 8mm OD tube into the 8mm ID port of the mouthpiece, and tighten it with the nylon screw of the mouthpiece
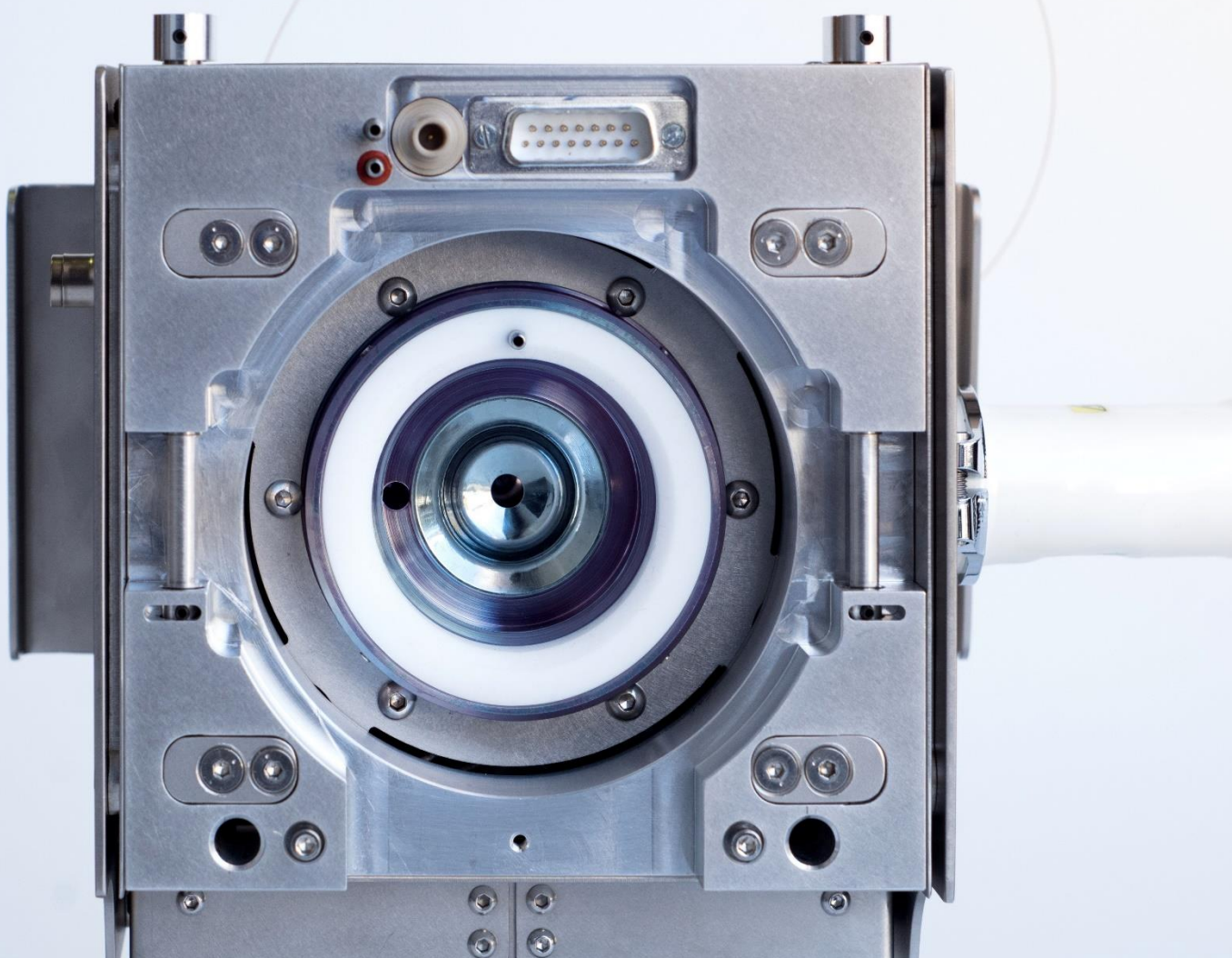
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