



It's simply breathtaking

INSTRUCTIONS FOR USE BREATH EXPLOR SAMPLING DEVICE

Content

- A** Product and Manufacturer **B** Symbols **C** Intended Use **D** Classification
- E** Important User Information **F** Package Content **G** Safety and Precautions
- H** Disposal **I** Instructions **J** Languages

A Product and Manufacturer

Breath Explor® Sampling Device
Ref: 07983



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Exhaled breath is always readily accessible and sampling is convenient for the donor and non-invasive in nature.

B Symbols

Conformité Européenne	Read the instructions for use	Manufacturer
Lot number / Batch number	Warning	Expiry date
Referencnumber / Article number	Temperature limit	Do not use if the package is broken
For single use only	In vitro diagnostic medical device	Recycling PP

C Intended Use

The intended use of Breath Explor® is the sampling of exhaled breath particles carrying non-volatiles from the distal parts of the lung, for medical investigation and monitoring purposes. The sample is intended to be analysed for occurrences of drug substances in individuals, for diagnostic purposes. Sampling is performed under supervision of health care professionals within health care facilities.

D Classification

Breath Explor® is CE-marked and classified as an IVDR Class A in vitro diagnostic medical device according to Regulation (EU) 2017/746 and the Swedish Medical Products Agency's Regulations (LVFS 2001:7).

E Important User Information

Breath Explor® is intended for professional use.
The medical laboratory providing analysis must be accredited.
If a serious incident were to occur in relation to the device, the incident must be reported to the manufacturer and the relevant national competent authority.

F Package Content

Breath Explor® Sampling Device. Ref: 07983.
Protective Bag.

G Safety and Precautions

- Sampling is to be done by a professional in a separate and controlled environment.
- Both patient and sampling professional shall wear gloves while handling the device.
- Use the Chain of Custody form and reference labels provided by an accredited medical analysis lab.
- After sampling, the sample must be sent directly to the lab. If not sent directly, the sample must be stored in a refrigerator.
- Samples can be sent by priority mail. Transport can be done without cold keep.
- The sampling device is for single use.
- Storage between -30°C (-22°F) and +40°C (+104°F).

H Disposal

Polypropylene copolymer (PPC) Recycling



I Instructions

- 1 Remove the plastic protective cover from the sampling device.
- 2 Remove the caps from the sampling device. **The large oval opening is the mouthpiece.**
- 3 Prepare for a sample: Patient breathes out to empty the lungs, holds breath for three seconds, and breathes in deeply to prepare for an exhalation through the Breath Explor device.

Leave the sample: Patient closes lips around the mouthpiece and breathes out through the device to empty lungs (5-8 s). **Remove the device from mouth before inhaling as normal.** Repeat the procedure (exhale, pause 3 seconds, inhale, exhale through device) 10-12 times. If patient feels dizzy, take a break to breathe normally for a few breaths. Once sampling is complete, put the caps back on the Breath Explor device.

For guided assistance through the breath-sampling procedure, please download our free app **Breath Explor Operator Guide** from the App Store or Google Play. The app will help with timing and recording the breaths.

- 4 Take the barcode from the Chain of Custody form and apply it to the sampling device.
- 5 Put the sampling device into the provided protective bag. Seal the bag shut using another barcode sticker from the Chain of Custody form. Make sure that the sticker both **closes the bag** and **covers the perforation**.
- 6 Apply the third and last barcode sticker to the Chain of Custody form. Put the filled-out Chain of Custody form and the sealed-shut bag in an envelope and send to the appointed laboratory. PLEASE NOTE: **store the sample in a fridge until it is time to send it off.**

