



Breath Biopsy[®] Kit (Mouthpiece) User Guide















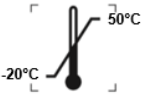



For use with Breath Biopsy
Kit part numbers:

00-0188
00-0214



OW-023379-TM V4

Symbol Key

Description	Symbol	Description	Symbol
Caution, Consult Accompanying Documents		Manufacturer	
Catalogue or Reference Number		Date of Manufacture	
Serial Number		Do Not Reuse	
Lot Number		Do not use if packaging is damaged	
Consult instructions for use		This mark indicates approval for use in the European Union countries	
Fragile, handle with care		Use-by date	
Storage Temperature Limit		Humidity Limit	
This mark indicates approval for use in the United Kingdom		DO NOT dispose of in household waste (WEEE Directive)	

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1 General Information

1.1 Introduction

The Breath Biopsy® Kit contains the consumable items required for the ReCIVA® Breath Sampler to collect samples of volatile organic compounds (VOCs) that are present in breath for subsequent laboratory analysis. It is supplied only on a professional business-to-business basis for the purpose of research and development.

The Breath Biopsy Kit should only be used with ReCIVA. If you wish to use an alternative, please ensure you carry out your own risk assessment to prevent potential harm to the study subject.



It is essential that this instruction manual be read and understood before commencing any work with the Breath Biopsy Kit.

Please read and understand the various precautionary notes and symbols contained inside of this manual pertaining to the safe use and operation of this product before using it.

1.2 Safety

Safety instructions for the use of ReCIVA and the Breath Biopsy Kit are provided in the ReCIVA User Manual. It is essential that these safety instructions are read and understood before commencing any work with the Breath Biopsy Kit.

Always observe the following standard safety precautions:

- Wear a new pair of nitrile examination gloves when handling the Breath Biopsy Cartridge as chemicals from your hands can affect the results and may lead to cross contamination.
- Wash your hands with soap and water – do not use alcohol-based gels (e.g. Cutan foam) as these leave volatile chemicals behind which may affect the breath collection.
- Use a new Breath Biopsy Kit with each study subject.
- Do not use the Breath Biopsy Cartridge if it is dropped or damaged prior to the breath collection commencing.
- If you encounter any problems with the equipment or this procedure, please contact Owlstone Medical Ltd immediately using the contact details in this guide.

1.3 Recycling and Disposal

The Breath Biopsy Mouthpiece, Noseclip and Non-return Valve are single-use only items and should be disposed of in clinical waste. For disposal of packaging, please follow local recycling rules.

2 Introduction to the Breath Biopsy Kit

2.1 Intended Use

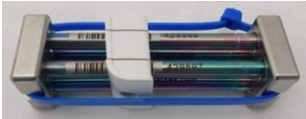




The Breath Biopsy Kit is intended for use with the ReCIVA Breath Sampler to collect samples of VOCs present in exhaled breath for subsequent laboratory analysis.

The ReCIVA Breath Sampler is not to be used on children who are too young to understand and act on instruction from the operator or on children too young to clearly inform the operator that the breath collection is causing them discomfort. For the avoidance of doubt, it is not to be used on children under 5 years old.

ReCIVA is supplied on a business-to-business basis for professional research and development only.

2.2 Identification of Parts

The Breath Biopsy Kit contains the following parts:

Description	Part No(s)	Qty	Picture
Breath Biopsy Cartridge	01-0867	1	
Breath Biopsy Mouthpiece	01-1016	1	
Noseclip	50-1990	1	
Blanking sticker	02-3135	1	
Non-return valve	50-1229	1	

Cable Tie, Green Nylon, Non-Releasable 300mm x 4.8 mm	50-1357		
Bubble wrap bag 130mm x 185mm	50-1358		
Clear Grip Seal Bag 5.5" x 5.5"	50-1541		

Depending on the intended application, some Breath Biopsy Kits may contain additional items not listed above. Please refer to your Study Reference Guide for instructions on how to use any items not covered in this User Guide and for instructions on how to package and return samples to Owlstone Medical for analysis (if required).

3 Setup of the Breath Biopsy Kit



Always wear clean nitrile examination gloves when assembling, operating and disassembling the ReCIVA Breath Sampler and ALL associated components. These gloves must be disposed of between study subjects.

3.1 Fitting the Non-return Valve, Breath Biopsy Mouthpiece and Breath Biopsy Cartridge



Ensure that work surfaces are clean, free from particulates and free from chemical contamination.

The non-return valve ensures that the study subject breathes air supplied by the CASPER™ Portable Air Supply and excess exhaled air not collected onto the Breath Biopsy Cartridges is exhausted into the room. This minimizes contamination of breath samples from VOCs present in ambient room air.

To reduce the risk of cross-contamination, a new non-return valve should be fitted for each test subject.

The valves are shipped in cardboard tube packaging, which must be disposed of before the valve is fitted.



When inserting the valve into ReCIVA, ensure that the clear film in the valve is on the outside so that it can open outwards.



Remove the Breath Biopsy Mouthpiece from its sealed packaging. Inspect the packaging to ensure that it is not damaged



Inspect the packaging of the Breath Biopsy Mouthpiece to ensure that it is not damaged prior to use.

DO NOT USE if the packaging is damaged. Quarantine the Breath Biopsy Mouthpiece and contact Owlstone Medical.

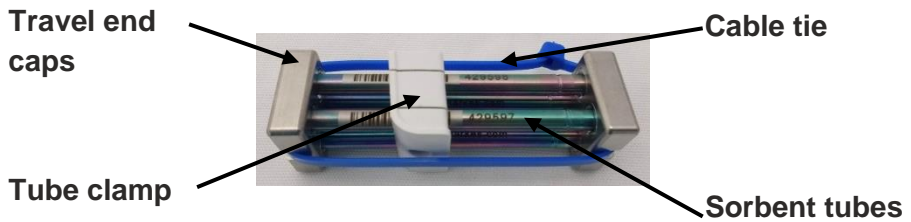
Ensure that the filter in the Breath Biopsy Mouthpiece is present prior to proceeding.



Inspect the packaging of the Breath Biopsy Cartridge to ensure that it is not damaged. Check the travel end caps to ensure that they have not become dislodged before use.

When you are ready for the breath collection cut the cable tie (if applied) holding the travel end caps on the Breath Biopsy Cartridge and then remove the travel end caps.

Place the end caps on a clean surface with the holes facing up to avoid any contamination and/or particulates from coming into contact with the end caps.





DO NOT USE if the packaging is damaged or the end caps are dislodged. Quarantine the Breath Biopsy Cartridge and contact Owlstone Medical.

Do not leave the sorbent tubes uncapped for more than two minutes before or after the test as they will absorb chemicals from the air in the room.

Handle the Breath Biopsy Cartridge with care; the inside is fragile and test performance can be affected if dropped or handled roughly.

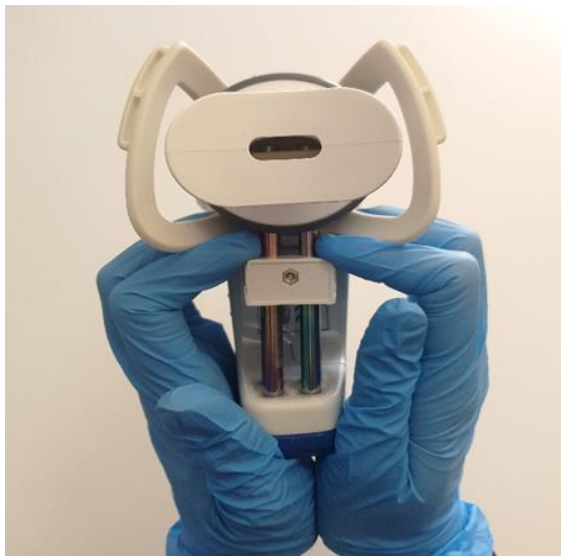
Push the Breath Biopsy Cartridge into the Breath Biopsy Mouthpiece (do not stop at the ridges in the tubes), ensuring the barcode (if used) is facing forward and upright.



Insert the Breath Biopsy Mouthpiece and Breath Biopsy Cartridge loosely into the into the ReCIVA Breath Sampler.



Push the Breath Biopsy Mouthpiece into the ReCIVA housing. Then, using fingers placed on either side of the white clamp, push the Breath Biopsy Cartridge firmly into the ReCIVA. Check to ensure both are fully seated into the ReCIVA.



4 Instructions for Breath Collection

Follow the ReCIVA Breath Sampler User Manual or Study Reference Guide (if supplied) to collect the breath sample, and for instructions on using the noseclip and blanking sticker.



NOTE: When using ReCIVA with the Breath Biopsy Mouthpiece, the study subject will need to be capable of supporting ReCIVA for the duration of the test.

5 After a Breath Collection



Always wear a new pair of nitrile examination gloves when assembling, operating and disassembling the ReCIVA and all associated components. These gloves must be disposed of between study subjects.



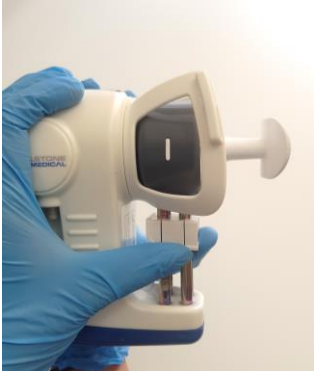
Ensure that work surfaces are clean, free from particulates and free from chemical contamination.



The following components are single use and must not be re-used between collections:

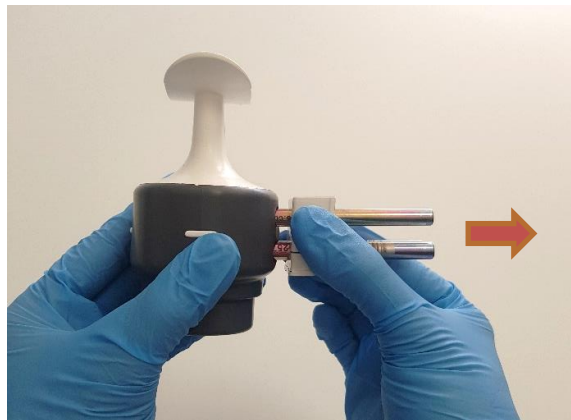
- Breath Biopsy Mouthpiece
- Breath Biopsy Cartridge
- Breath Biopsy Non-Return Valve
- Noseclip
- Blanking sticker

Remove the Breath Biopsy Mouthpiece together with the Breath Biopsy Cartridge by gripping ReCIVA with your fingers along the top edge, whilst using your thumbs to apply upwards pressure to pull up on the white Breath Biopsy Cartridge clamp. This can be quite stiff. Make sure not to use the wings of the ReCIVA as leverage when removing the Breath Biopsy Cartridge, as this is a weak point on ReCIVA.



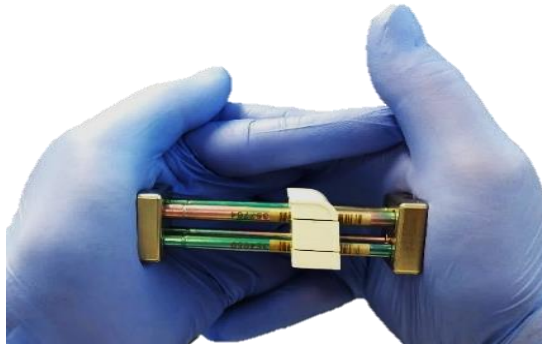
Now pull the Breath Biopsy Cartridge and Breath Biopsy Mouthpiece (with cartridge still inserted) forwards out of ReCIVA. They should come out easily.

Remove the Breath Biopsy Cartridge from the Breath Biopsy Mouthpiece by pulling it out from the holes.



Fit the end caps to the Breath Biopsy Cartridge. Note that they only fit on in one orientation. **DO NOT** leave the Breath Biopsy Cartridge uncapped for more than two minutes prior to or after the test as they will absorb chemicals from the air in the room.

When BOTH end caps have been pushed on, at least partially, push them between your palms with fingers interlocked for more force if needed. This will ensure that they are fully home.



Check that the end caps are on correctly by placing the Breath Biopsy Cartridge flat on the desk and making sure that the jig (supplied with ReCIVA) goes over it. If the end caps are not on correctly, then reseal the end caps and try again.



Fit the cable tie to avoid the end caps being removed by accident or during transportation.



Place the Breath Biopsy Cartridge into the supplied bubble wrap bag to protect it.



Place the bubble wrap bag containing the Breath Biopsy Cartridge into the supplied zip lock bag.



Handle the Breath Biopsy Cartridge with care; the sorbent material inside the tubes is fragile and test performance can be affected if dropped or handled roughly

If the sample is not being analysed on the same day, place the Breath Biopsy Cartridge in a refrigerator at a temperature between +4 and +8°C.



Owlstone does not recommend storing breath samples in a freezer.

Remove and dispose of the mouthpiece and the yellow non-return valve as soon as possible after completing the breath collection in accordance with local guidelines for disposing of clinical waste.

Please refer to your Study Reference Guide for instructions on how to use any items not covered in this User Guide and for instructions on how to package and return samples to Owlstone Medical for analysis (if required).



6 Troubleshooting

Please follow the troubleshooting guides in the ReCIVA and the CASPER User Manuals.

7 Contacts and Support

The Owlstone Medical Ltd team is dedicated to providing excellent support. For all technical and safe use questions relating to this manual, contact us at:

Or email support@owlstone.com



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