ReCIVA® Breath Sampler:

User Manual

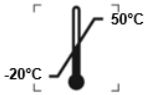
BREATH® BIOPSY

00-0142

00-0175

OWLSTONE MEDICAL

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	
Fragile, handle with care		Use-by date	
Storage Temperature Limit		Humidity Limit	
USB 3.0		DO NOT dispose of in household waste	
This mark indicates approval for use in the United Kingdom			

Contents

1 General Information

1.1 Introduction

It is essential that this user manual be read and understood before commencing any work with the ReCIVA Breath Sampler. Read and understand the various precautionary notes and symbols contained inside this manual pertaining to the safe use and operation of this product before using it. If the ReCIVA Breath Sampler is used in a way that is not specified in this manual, the protection provided by the equipment may be impaired.

The ReCIVA Breath Sampler is for professional research and development use only. The ReCIVA Breath Sampler is only to be used in the presence of a trained user who is capable of removing the ReCIVA Breath Sampler from the test subject. It is the responsibility of the user to monitor the test subject's wellbeing at all times while using the ReCIVA Breath Sampler. ReCIVA is only for use with the CASPER™ Portable Air Supply.

This symbol is used to highlight a section explaining particularly important safety considerations

1.2 Safety Instructions

ReCIVA should only be used with the CASPER Portable Air Supply.

Using ReCIVA in a way not specified in this manual may lead to harm.

The manufacturer is not responsible for harm caused by misuse.

It is recommended that use of the ReCIVA Breath Sampler should be supervised by a trained user who is capable of removing the ReCIVA Breath Sampler from the test subject. It is the responsibility of the operator to monitor the wellbeing of the test subject at all times while using ReCIVA. ReCIVA does not monitor the health of the test subject during sampling. If there is any doubt about the health or wellbeing of the test subject, then the breath collection should be stopped immediately.

We advise monitoring of the breathing frequency of the study subject throughout the breath collection.

We recommend that a low-level disinfection, according to the instructions provided in this manual, is carried out as soon as possible after each breath collection and before using ReCIVA on another study subject.

Always observe the following standard safety precautions:

- Please refer to expert medical opinion when assessing whether the ReCIVA Breath Sampler is suitable for your population of interest. Where the population of interest includes immunocompromised individuals or individuals with a contagious respiratory disease, a suitable risk assessment, according to local context, should be carried out to determine if any additional precautions are required in addition to the disinfection procedure and safe use instructions provided in the User Manual.
- 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 medical professional 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.
- The ReCIVA Breath Sampler is specifically not to be used on subjects who have undergone biopsy of lung parenchyma within the last 36 hours. Ensure that the system is correctly assembled before use.
- The ReCIVA Breath Sampler should be disinfected between subjects (ideally as soon as possible after each breath collection) according to the instructions provided in this manual.
- Do not disassemble any of the individual system components.
- Wear new nitrile examination gloves when handling the ReCIVA Breath Sampler and the parts contained in the Breath Biopsy Kits; 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.

- The ReCIVA Breath Sampler is only to be used with the CASPER Portable Air Supply.
- Do not use the Breath Biopsy Mask or Mouthpiece if the packaging is damaged or if the vacuum seal is broken.
- Check the Breath Biopsy Mask and Mouthpiece before use to make sure the filter is present.
- Use a new Breath Biopsy Kit with each study subject (this includes a single use mask or mouthpiece assembly, a sample cartridge assembly and a replacement non-return valve) and do not use the kit if the packaging is damaged.
- Do not use the Breath Biopsy Cartridge assembly if it is dropped or damaged prior to the breath collection commencing.
- It is recommended to only use ReCIVA with the Breath Biopsy Kits supplied by the manufacturer. If you wish to use an alternative, please ensure you carry out your own risk assessment to prevent potential harm to the test subject.
- Only use the ReCIVA Breath Sampler with the USB lead provided.
- Disconnect the USB cable from the ReCIVA Breath Sampler when not in use.
- Use only laptop computer power supplies complying with IEC 60950-1 or IEC 60601-1.
- The study subject must be monitored at all times when using the ReCIVA Breath Sampler.
- If the study subject shows any signs of distress remove the ReCIVA Breath Sampler and allow them to recover.
- Do not allow the study subject to breath into the ReCIVA Breath Sampler without the mask or mouthpiece assembly and sample cartridge assembly fitted.

- When using ReCIVA with the Breath Biopsy Mask, do not commence the breath collection until the headset is attached to the subject using the supplied head strap. If the study subject wishes to hold ReCIVA as well, ensure that they hold it by the sides and not with their fingers or hand over the base of the unit as this could block the exhaust ports
- Do not use the supplied head strap when using ReCIVA with the Breath Biopsy Mouthpiece.
- Do not block the exhaust ports in the base of ReCIVA.
- Do not place the air supply tube or USB cable where they can cause a trip hazard.
- Connect the ReCIVA Breath Sampler to a USB3 port on the laptop/PC (see Symbol Key). ReCIVA may not operate correctly when connected to a USB1 or USB2 port as these do not provide sufficient electrical current.
- Do not assemble, operate or store the headset and headset components near sources of biological, chemical or particulate contamination.
- ReCIVA should not be used to deliver concentrated oxygen.
- Do not use in oxygen rich environments.
- If you encounter any problems with the equipment or this procedure, please contact Owlstone Medical Ltd immediately using the contact details provided.

1.3 Warranty Statement

Owlstone Medical is proud of our quality, reliability and our after-sales service. We continuously strive to improve our service to our customers.

Warranty provisions necessarily vary to comply with differences in national and regional legislation. Specific details can be found in the delivery documentation or from your dealer or representative.

Please note that your warranty may be invalidated if:

- this instrument is modified in any way, or not used as intended by Owlstone Medical
- accessories and reagents which have not been approved by Owlstone Medical are used.
- the instrument is not operated or maintained in accordance with instructions.

1.4 Recycling and Disposal

This Product has been designed and manufactured with high quality materials and components, which can be recycled and reused.

As a responsible manufacturer Owlstone Medical Ltd has chosen to voluntarily adhere to the European Union's Waste Electrical & Electronic Equipment (WEEE) Directive 2012/19/EU guidelines for this product so it should not be disposed of in normal waste.

Please consult Owlstone Medical Ltd for details of our recycling and disposal program for this product. For users outside the European Union consult local authorities for correct disposal or contact Owlstone Medical Ltd.

2 Introduction to the ReCIVA Breath Sampler

2.1 Intended Use

ReCIVA is used to collect samples of volatile organic compounds (VOCs) present in exhaled breath for subsequent laboratory analysis. The device is intended for professional use only with study subjects aged 5 years or older who can follow verbal instructions. It is supplied on a business-to-business basis for research and development only. ReCIVA is only for use with the CASPER Portable Air Supply.

2.2 Technical Specifications

Operating Condition	Value
Input Voltage	5V
Power consumption	4.5W
Storage Temperature range	15 - 30°C
Operating Temperature range	15 - 30°C
Weight	250g (approx.)
Size	120 x 100 x 140mm (approx.)

2.3 Identification of Parts

The ReCIVA Breath Sampler is supplied with the following parts:

Part No	Name/Title
00-0142 or 00-0175	ReCIVA RD Breath Sampler (CE) ReCIVA RD Breath Sampler (RUO)
50-1251	ReCIVA Head strap NOTE For use with the Breath Biopsy Mask. Not required for use with the Breath Biopsy Mouthpiece.
50-1229	Non-return Valve. NOTE A new non-return valve should be fitted for each test subject. A replacement non-return valve is included in each Breath Biopsy Kit.
50-1257	USB Cable
02-1898	Cartridge End Cap Jig
95-0034	ReCIVA Breath Sampler – User Manual

3 Setting up the ReCIVA Breath Sampler

Wear gloves when handling ReCIVA

The ReCIVA Breath Sampler requires a laptop computer for operation. A laptop computer is included as part of the Breath Biopsy Collection Station Support Pack.

Ensure that the laptop computer power supply complies with IEC 60950-1 or IEC 60601-1.

3.1 Breath Sampler Controller (BSC) Software

Breath Sampler Controller (BSC) software is required to use the ReCIVA Breath Sampler.

The ReCIVA Breath Sampler is usually supplied with a Breath Biopsy Support Pack, and a laptop is provided with the BSC software preloaded onto it, ready for use.

Please refer to the Software Guide or Study Reference Guide supplied with the ReCIVA Breath Sampler for instructions on how to use the BSC software.

3.2 Mask, Mouthpiece and Sample Cartridge Assembly

ReCIVA may be used with either a mask or a mouthpiece depending on the nature of the study.

The mask, mouthpiece and cartridge assemblies are provided as part of the Breath Biopsy Kits. Instructions on how to fit these to the ReCIVA Breath Sampler are provided in the corresponding Breath Biopsy Kit User Guides.

3.3 Non-return Valve

The non-return valve ensures that the study subject breathes air supplied by 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.

The non-return valves are single-subject use, and a new non-return valve should be fitted for each test subject. A replacement non-return valve is included in each Breath Biopsy Kit.

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 the clear film in the valve is on the outside so that it can open outwards.

3.4 Connection to CASPER Portable Air Supply

Connect the air supply tubing from the CASPER Portable Air Supply into the port on the side of the unit.

Switch on the CASPER. This gives the CO_2 sensor in ReCIVA time to equilibrate and flushes it with air ready to take a breath sample.

3.5 Connection to Computer

Connect the ReCIVA Breath Sampler to a USB3 port on the laptop/PC using the supplied USB cable. The USB connector can be found on the base of ReCIVA.

Lipstick, lip balm, make up and aftershave should be removed prior to sampling as they can contaminate the sample.

They should be removed using unscented soap and water or a tissue. Do not use make up wipes as these will leave residual VOCs.

4 Taking a Breath Sample

Please refer to expert medical opinion when assessing whether the ReCIVA Breath Sampler is suitable for your population of interest.

The ReCIVA Breath Sampler is specifically not to be used on subjects who have undergone biopsy of lung parenchyma within the last 36 hours.

Please refer to the Software Guide or Study Reference Guide supplied with the ReCIVA Breath Sampler for instructions on how to use the BSC software to run a breath collection.

ReCIVA may be used with either a mask or a mouthpiece depending on the nature of the study. Please refer to the User Guide supplied with the corresponding Breath Biopsy Kit for instructions on how to load the sample cartridge and how to attach the mask or mouthpiece to ReCIVA.

4.1 Using a Breath Biopsy Mask

A head strap is supplied for use when using ReCIVA with a Breath Biopsy Mask.

Do not use the head strap when using the ReCIVA with a Breath Biopsy Mouthpiece.

Pass the ReCIVA Breath Sampler to the study subject and allow them to breathe through it, giving them time to get used to the unit and get comfortable with it. Ask them to breathe normally and check that they are comfortable doing this.

Check that the non-return valve on the rear of ReCIVA is opening as the study subject breathes, to vent any excess air. The valve should be replaced if it is not opening freely.

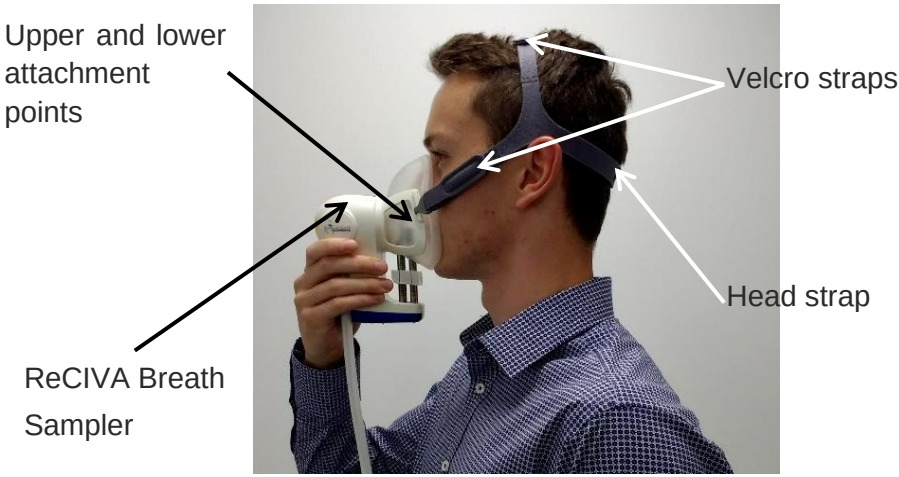
Once the study subject is comfortable, fit the head strap as described below. In addition to the head strap, the study subject may also hold the ReCIVA during the breath collection if they wish.

With the secondary Velcro strap adjusters on top of the subject's head, attach the hook on one side of the head strap to the attachment point on ReCIVA. For most people, the hook needs to be in the uppermost position.

Take the strap around the study subject's head and hook it to the corresponding attachment point on the other side of ReCIVA. Using the primary and secondary Velcro adjustment straps, fit ReCIVA so that the mask forms a comfortable seal against the subject's face with no gaps. To ensure a good fit, it may be necessary to change the hook position on ReCIVA as follows:

- Move the straps up if the mask is falling away from the bridge of the study subject's nose.
- Move the straps down if the mask is coming away at the bottom of the mask.
- The straps should be tightened until the mask is a tight fit so that if the head it tilted up and down as if nodding, or from side to side, that the mask stays in good contact with the face all around the mask.

Once the head strap is in place and the study subject is comfortable and breathing normally, the breath collection may be started using the software on the laptop. Please refer to your Software Guide or Study Reference Guide for details as to the operation of the software.



During the breath collection, remind the study subject to breathe normally; slower, comfortable breaths are more effective than rapid breathing patterns. Continue to monitor the subject to ensure that they are not distressed. If the study subject appears distressed remove the ReCIVA Breath Sampler immediately.

The study subject may talk during the breath collection. However, talking will slow the collection down so it is preferable to request that study subjects remain silent during the breath collection.

When the collection is complete, remove the ReCIVA Breath Sampler from the study subject.

4.2 Using a Breath Biopsy Mouthpiece

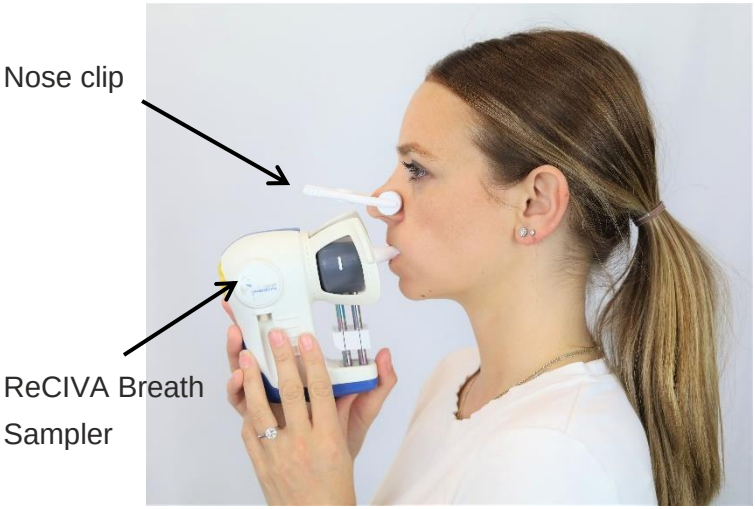
A nose clip is supplied in each Breath Biopsy Kit for use when using ReCIVA with a mouthpiece. Fit the nose clip as shown below.

If using ReCIVA with a mouthpiece, the study subject will need to hold ReCIVA during the breath collection

Pass the ReCIVA Breath Sampler to the study subject and allow them to breathe through it, giving them time to get used to the unit and get comfortable with it. Ask them to breathe normally and check that they are comfortable doing this.

Check that the non-return valve on the rear of ReCIVA is opening as the study subject breathes, to vent any excess air. The valve should be replaced if it is not opening freely.

Once the study subject is comfortable and breathing normally through the mouthpiece, the breath collection may be started using the software on the laptop. Please refer to your Software Guide or Study Reference Guide for details as to the operation of the software.



During the breath collection, remind the study subject to breathe normally; slower, comfortable breaths are more effective than rapid breathing patterns. Continue to monitor the subject to ensure that they are not distressed. If the study subject appears distressed remove the ReCIVA Breath Sampler immediately.

The study subject must not talk when using a mouthpiece. Please request that study subjects remain silent during the breath collection.

When the collection is complete, remove the ReCIVA Breath Sampler from the study subject.

Make sure the study subject does not block the two exhaust ports on the base of the ReCIVA Breath Sampler during the breath collection

If at any time the study subject shows any signs of distress remove the ReCIVA Breath Sampler and allow them to recover

5 After the Breath Sample Collection

Having removed the ReCIVA Breath Sampler from the subject follow the Breath Biopsy Kit User Guide for instructions on how to remove and disassemble the mask or mouthpiece and Breath Biopsy Cartridge assembly and to prepare the cartridge for shipping to Owlstone Medical (if required).

Remove the USB cable from ReCIVA.

If the ReCIVA Breath Sampler is not to be used again that day, disconnect the CASPER air supply tube and attach the stopper on the air supply hose to prevent any contamination of the hose.

Disinfect ReCIVA according to the instructions provided.

For storage return the ReCIVA Breath Sampler (and the USB lead) to its shipping case, making sure to put the ReCIVA Breath Sampler back in its storage bag.

Store the ReCIVA Breath Sampler and all parts away from chemical and biological contamination and away from particulates.

6 Disinfection

This section provides instructions on how to disinfect the ReCIVA Breath Sampler.

Owlstone Medical Ltd recommend that a low-level disinfection, is carried out as soon as possible after each breath collection and before using ReCIVA on another study subject.

The disinfection protocol described in this document has been developed specifically for ReCIVA and has been validated by an independent, specialist test laboratory as effective in exceeding the 6-log (i.e. greater than 99.9999%) reduction required for low-level disinfection in accordance with international guidelines concerning the use of non-critical equipment in healthcare facilities.

The disinfection process takes approximately 15 minutes to complete. After disinfection, ReCIVA should be left to air dry in a clean environment for at least 30 minutes before re-use.

New nitrile gloves must always be worn when handling ReCIVA, including during the disinfection process described below.

Before using ReCIVA again, remember to fit a new non-return valve, following the instructions provided in this User Manual.

6.1 Materials Required

Use only products approved by Owlstone Medical Ltd to disinfect ReCIVA. Please consult with Owlstone Medical Ltd before using any other products on the device.

The following items will be required to complete the disinfection process described in this document.

The quantities provided are the minimum recommended. Use additional fresh wipes and swabs as necessary to ensure that all treated surfaces remain wet for at least 5 minutes.

Item	Description	Quantity
Wipe	Veriguard 1 100% Polypropylene Wipes Impregnated with 70% IPA / 30% DI Product code WSVG05020	8
Swab	6” lint-free standard cotton swab	4

Disinfection materials are supplied with ReCIVA. Additional supplies are available on request.

6.2 Instructions

1. If still fitted, remove and discard the face mask and the yellow non-return valve (shown in Figure 1), in accordance with local guidelines for the disposal of infectious waste.

Figure 1

2. Take a fresh wipe and rub all of the outer surfaces thoroughly with the wipe as shown in Figure 2, paying particular attention to the joints and seams in the plastic casing. Use additional fresh wipes as necessary to ensure that all treated surfaces remain wet for at least 5 minutes.

Figure 2

3. Take a lint-free swab and wrap a fresh disinfectant wipe over it as shown in Figure 3.

Figure 3

4. Use the wrapped swab to thoroughly clean the numbered areas shown in Figure 4, making sure that the inner air hole (1) is cleaned first. The use of the swab will enable the disinfectant wipe to reach hard-to-reach areas. The cartridge recesses (2, 3, 4, 5) may turn the end of the swab black. This is normal. Use additional wipes and swabs as necessary to ensure that all treated surfaces remain wet for at least 5 minutes.

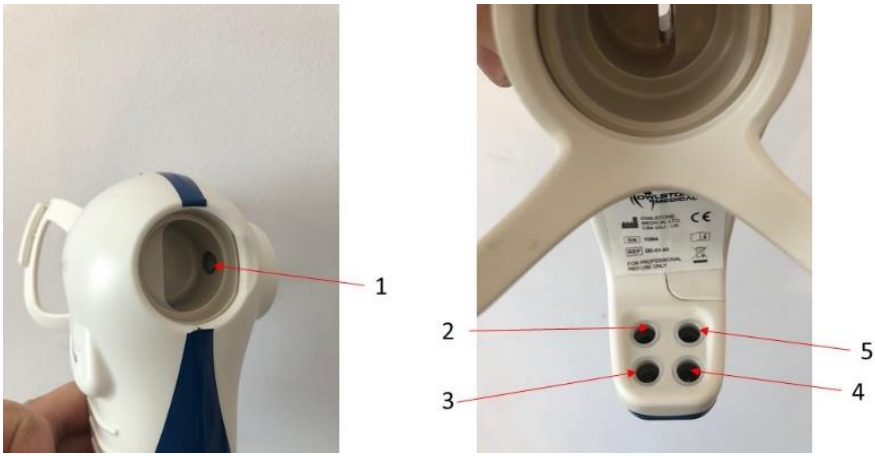


Figure 4

5. Take a new swab and wrap a fresh disinfectant wipe over it as shown in step 3.
6. Push the wrapped swab through the narrow slot located in the middle of the breathing gas pathway in the direction indicated and out the other end as shown in Figure 5. Do not push it all the way through yet.

Figure 5

7. When the wipe covers the circular beige part as shown in Figure 6, stop pushing it through the device and rub all the surfaces of the beige part thoroughly.

Figure 6

8. Grip both ends of the wipe and draw it back and forth through the ReCIVA at least twenty times, in a sawing motion as illustrated in Figure 7.

Figure 7

9. Pull the wipe through the ReCIVA and discard the wipe and the swab.
10. Take a fresh wipe and swab and repeat steps 6 through 9 as necessary to ensure that all treated surfaces remain wet for at least 5 minutes.
11. Take a fresh wipe and clean the outlet chamber by rubbing the surfaces thoroughly as shown in Figure 8. Use additional wipes as necessary to ensure that all treated surfaces remain wet for at least 5 minutes.

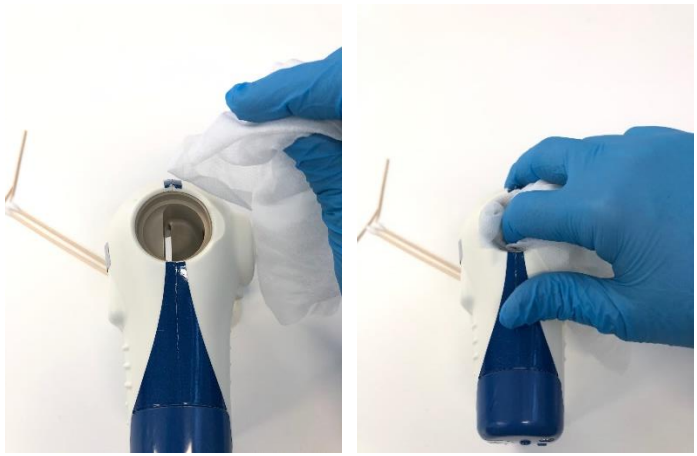


Figure 8

12. Leave ReCIVA to air dry in a clean environment for at least 30 minutes before re-use.

7 Other Use Cases

If ReCIVA is being used in a non-standard way, or you have questions about your configuration, we always recommend that you discuss this with Owlstone Medical before proceeding.

7.1 Using fewer than four sorbent tubes

In some cases, users may wish to use fewer than four sorbent tubes per sample, for example, if tube supply is limited. Particular care must be taken in this instance:

1. Ensure the **hardware** is configured appropriately. This generally means blocking any un-used ports with solid rods.
2. Ensure the **software** is configured to reflect the physical configuration (eg, specifying that a single sorbent tube is being used). This ensures that the software is still able to calculate flowrates and volumes correctly.
3. Ensure that an appropriate **risk assessment** is conducted on your new configuration. Solid rods can present a route for cross-contamination between subjects, so it is essential that measures are in place to prevent this (eg, disinfect solid rods).

7.1.1 Hardware configuration

ReCIVA contains four sorbent tube positions (ports), configured in pairs and controlled by two independent sampling pumps, as show in Figure 9:

- The left side (as viewed by the subject), positions 1 and 2, are controlled by a single sampling pump
- The right side, positions 3 and 4, are controlled by the second sampling pump

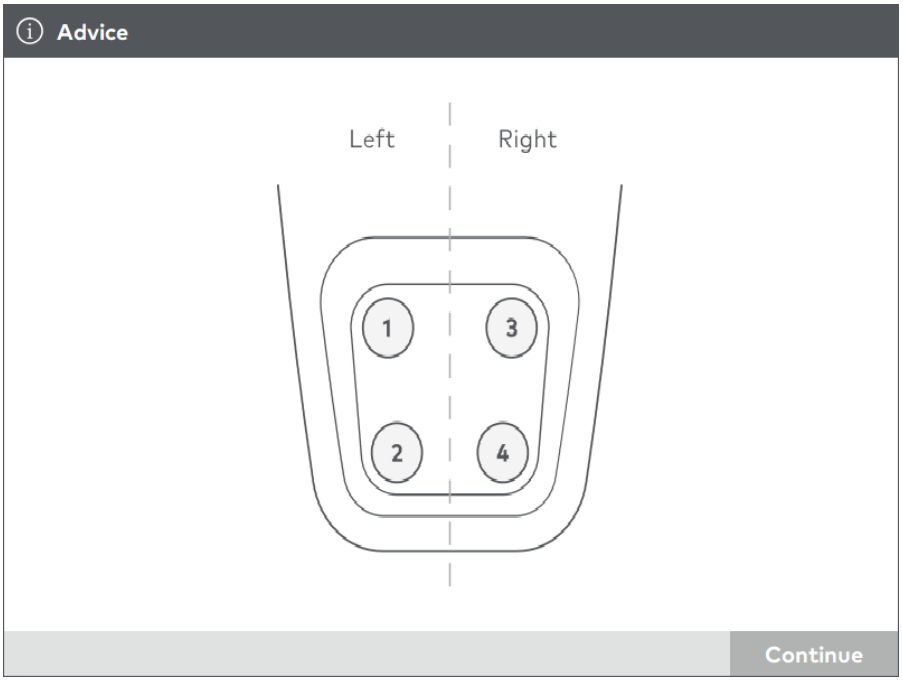


Figure 9

Each pair can operate entirely independently, but within a pair the device cannot differentiate between the two positions. Consequently, **any unused ports must be blocked during sampling** (with a solid rod of equivalent dimensions; 89mm length, 6.35mm diameter). This serves the dual function of blocking the sampling port and the hole in the mask/mouthpiece.

Do not leave any active sampling ports open, or use hollow tubes, as this will cause all of the sampling flow to be diverted from the target sorbent tube.

Furthermore, if both ports within a pair are to be blocked, the solid rods should only be inserted after the software has initialised and any device self-tests are complete. Blocking the entire flowpath while the device is initialising can cause a vacuum to form and an error message to be displayed (“Pressure sensor self-test failed”).

Unused ports should be blocked after the device has initialised, to prevent failure of the pressure sensor self-tests.

Software configuration

ReCIVA measures the sampling flowrate at each pump, so it is essential that the software understands how many sorbent tubes are being used with each sampling pump:

- Open the BSC software and navigate to the “Settings” page (Figure 10). Note that it is important not to press the “start” button until the settings have been configured correctly.
- Set the “Number of tubes” to the number of sorbent tubes being used on that side of ReCIVA. For example, Figure 11 shows the configuration if only the rear ports are being used, and the front ports are blocked (“1” and “1” respectively).
- If desired, the settings can be saved/loaded for quick access in future.
- Return to the homescreen and proceed with the collection as normal.

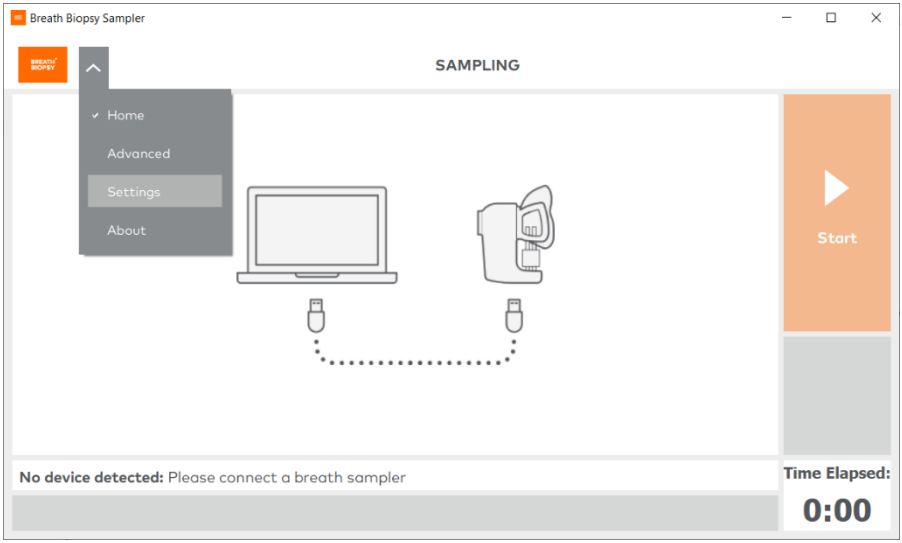


Figure 10

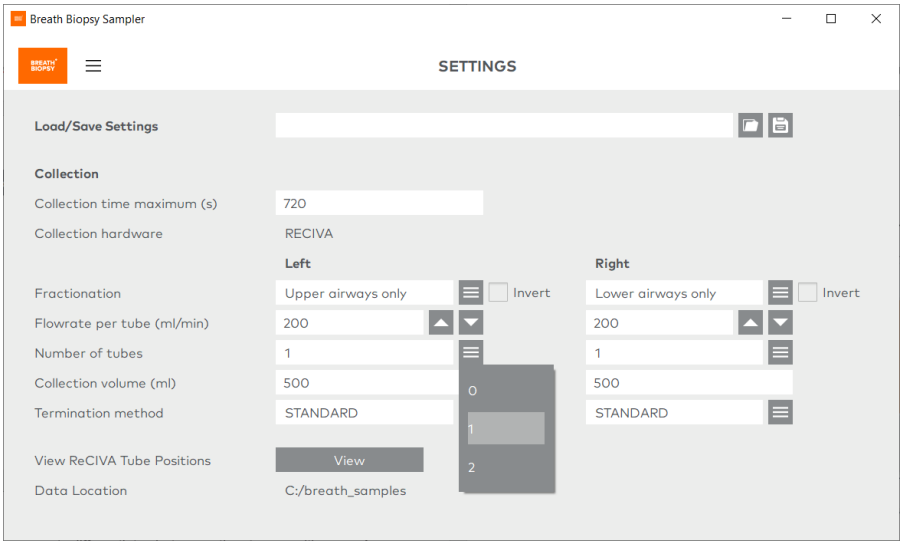


Figure 11

If the software settings do not match the physical configuration, ReCIVA may attempt to sample at an incorrect flowrate or volume.

7.1.2 Risk assessment

Since any solid rods will not typically experience the thermal cycles of a sorbent tube, it is essential that other measures are identified to prevent cross-contamination between users. Owlstone recommend that a risk assessment is conducted for your specific application, but these measures could include chemical disinfection, thermal disinfection or using new rods for each subject.

8 COVID-19 Additional Precautions

The following precautionary measures are also recommended where there is particular concern over the spread of COVID-19.

- If not already required to do so, operators should consider wearing additional PPE when interacting with study subjects in accordance with a suitable risk assessment and local context.
- Provide new nitrile gloves for the study subjects to wear, so that they can hold or touch ReCIVA without additional risk of introducing contamination.
- Ensure that the Breath Biopsy Cartridge assembly containing the breath sample is removed from ReCIVA and bagged as soon as possible after completing the breath collection. The cartridge assembly is exposed to the subject's breath so it is imperative to follow our existing advice to always handle it with gloves. Take precautions when handling potentially contaminated materials in accordance with local guidelines. **DO NOT attempt to clean the sorbent tubes as this will affect the quality of the breath sample.** The outer zip lock bag used to contain the tubes can be cleaned with a disinfectant wipe once the bag has been properly sealed.
- Ensure that the disposable mask/mouthpiece (including integral biological filter) and the yellow non-return valve are disposed of as soon as possible after completing the breath collection in accordance with local guidelines for disposing of infectious waste. A replacement valve is now included in each Breath Biopsy Kit. Please contact us if you require additional valves.

- When using ReCIVA with the Breath Biopsy Mask, consider using a clean head strap for each study subject. Head straps can be bagged and washed in warm soapy water before re-use. Please contact us if you require additional head straps.
- Clean the outer surface of the air supply tubing connecting ReCIVA to the CASPER Portable Air Supply between breath collections using the supplied disinfection wipes. Use additional wipes as necessary to ensure that surface remains wet for at least 5 minutes and allow at least 30 minutes for the tubing to air dry after cleaning before collecting further study samples.
- All other breath collection equipment (CASPER Portable Air Supply, trolley, laptop etc.) should be periodically cleaned with disinfection wipes according to their Instruction for Use documents, and local requirements. Allow at least 30 minutes for the equipment to air dry after disinfection cleaning before collecting further study samples.
- Please refer to expert medical opinion and the latest official advice on COVID-19 in your location when assessing whether ReCIVA is suitable for your population of interest.

9 Troubleshooting

Problem Indication	Possible Cause	Action
Non-return valve damaged e.g. plastic flap is not flat.	Poor handling and touching or wiping of the plastic flap.	Replace the valve with one of the spares.
The non-return valve falls out when connected to CASPER or the subject breathes out.	The non-return valve is fitted back to front.	See section 3.2. Fit the valve so the plastic flap opens outwards and is securely seated (no wobbling).
The non-return valve falls out when fitted the right way around (see above)	The non-return valve outer diameter is too small.	Replace the non-return valve with a spare and check this one is sufficiently tight that it will stay in place.
Mask falls away from bridge of study subject's nose or ReCIVA Breath Sampler feels heavy against their chin	The head strap hooks are connected to the lower attachment point.	Move the head strap hooks to the upper attachment point. The subject may hold the ReCIVA on the sides, if they do not cover the exhaust ports on the bottom of the ReCIVA.
Mask falls away from the study subject's chin or cuts into their nose	The head strap hooks are connected to the upper attachment point.	Move the head strap hooks to the lower attachment point. The subject may hold the ReCIVA on the sides, ensuring they do not cover the exhaust ports on the bottom of the ReCIVA.

Problem Indication	Possible Cause	Action
Study subject's face, lips or nose are in contact with the sample tubes.	Head strap hooks are connected to the wrong attachment point.	Adjust the mask attachment point (upper or lower) until comfortable for the study subject. Direct contact should be minimised where possible.
	Breath Biopsy Cartridge is not fully inserted into the ReCIVA.	Push the Breath Biopsy Cartridge is fully into the ReCIVA. If left only 1-2mm from full insertion the tubes can move towards the subject face.
Subject wants to take a break during sampling	N/A	This is not recommended if the collection is to be successful. If the break is too long, the full sample volume may not be collected in the allotted time.
BSC software reports error that the target flow cannot be reached	The exhaust ports on the base of ReCIVA are blocked	Ensure that the subject is not holding ReCIVA in a way that blocks the exhaust ports.

10 Servicing

The ReCIVA breath sampler creates log files which allow Owlstone to monitor the equipment's performance over time. If the unit requires servicing Owlstone will get in touch with you to arrange this.

If you believe your ReCIVA has a fault or requires servicing, please contact Owlstone Medical using the details in Section 11.

The ReCIVA Breath Sampler does not contain any user serviceable parts. All servicing must be carried out by Owlstone Medical Ltd. Do not disassemble any of the individual system components.

If you encounter any problems with the equipment or this procedure, please contact Owlstone Medical Ltd immediately using the contact details below.

11 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:

Owlstone Medical Ltd.
183 Cambridge Science Park
Milton Road
Cambridge CB4 0GJ
United Kingdom

Tel: +44 (0) 1223 428200

Or email support@owlstone.com

12 Regulatory Information

12.1 United Kingdom

12.2 Europe