



ReCIVA Breath Sampling Software v3.4

User Guide



95-0023



OW-023295-QM

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2 Introduction

Breath Sample Collect (BSC) v3.4 is a software package designed for use with the ReCIVA Breath Sampler. It is essential that this user manual and the user manual for the ReCIVA be read and understood before commencing any work with the ReCIVA.

The BSC software used with the ReCIVA Breath Sampler is for professional research and development use only.

This manual is written for use with BSC software version 3.4



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

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.

3 Safety Instructions

Refer to the ReCIVA Breath Sampler User Manual (PN 90-0796) for safety instructions when using the BSC software with the ReCIVA Breath Sampler. It is essential that these safety instructions are read and understood before commencing any work.

4 Technical Specifications

The minimum laptop specification for this software is:

- Windows 10
- 8GB RAM
- CORE i3 Processor
- One free USB 3.0 port

5 Installation

The BSC software will normally be preinstalled on the laptop which is supplied with the Breath Biopsy Support Pack. Installation will add a desktop shortcut and start menu entry for the BSC software.

To uninstall the software, navigate to:

Start – Owlstone Breath Sampler Collection – Uninstall Breath Sample Collect.

If this software is required to be re-installed for any reason, please contact Owlstone Medical Ltd for support.

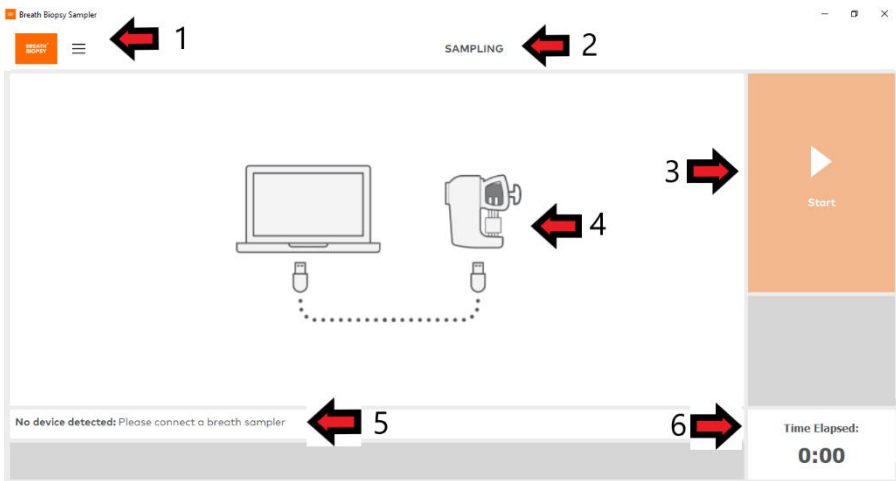
The installer will default to use of the mouthpiece with ReCIVA. This only affects images and text shown and does not affect the collection functionality This can be changed to mask in the settings page of the software (see section 8).

6 Instructions – Standard Collect

To launch the breath collection software, either double-click the desktop shortcut for **Breath Sample Collect**, or navigate to:

Start - Owlstone Breath Sampler Collection - Breath Sample Collect.

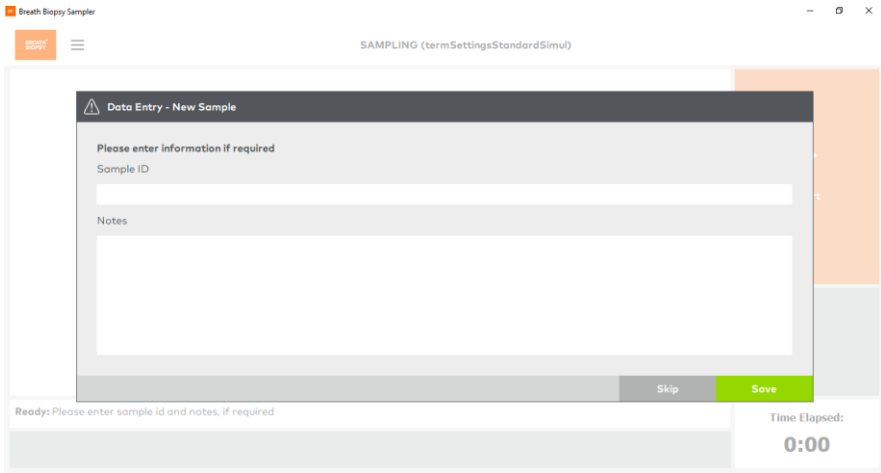
The initial screen presented will be as follows:



- 1 = change view (home/advanced/settings/about);
- 2 = settings currently applied (see section 8)
- 3 = start button (initially disabled);
- 4 = infographic;
- 5 = message box (advice and status);
- 6 = time elapsed (m:ss)

The infographic shown will display either ReCIVA with mouthpiece, or ReCIVA with mask depending on the software settings. A mix of images representing both are shown throughout this user manual.

Upon connecting a ReCIVA, the Data Entry pop-up appears, allowing the user to enter a Sample ID and Notes for this collect.



Once sample information has been entered and the **Save** button clicked (or **Skip** if you don't need to associate data with this collect), the **Start** collection button on the standard view will be enabled.

To show the Data Entry form again (e.g., if it has previously been skipped or you would like to edit the information entered) then the **Sample Data Entry** button can be clicked.



Before starting a breath collect please refer to the ReCIVA User Manual for setup of the ReCIVA and subject guidance.

Once the subject is comfortable and breathing normally press the **Start** button. At this point ReCIVA Breath Sampler will automatically do the following:

- Wait for a few seconds (default 3 seconds) - 'starting' is shown in the message box
- Learn the subject's breathing pattern (default 30 seconds) – 'learning' is shown in the message box
- Start collecting the subject's breath – 'collecting' is shown in the message box

During breath collection, remind the subject to breathe normally; slower, comfortable breaths are more effective than rapid breathing patterns. Continue to monitor the subject to ensure they are not distressed. If the subject appears distressed remove the ReCIVA Breath Sampler immediately. The subject may subsequently continue by starting a new breath collection if they wish.

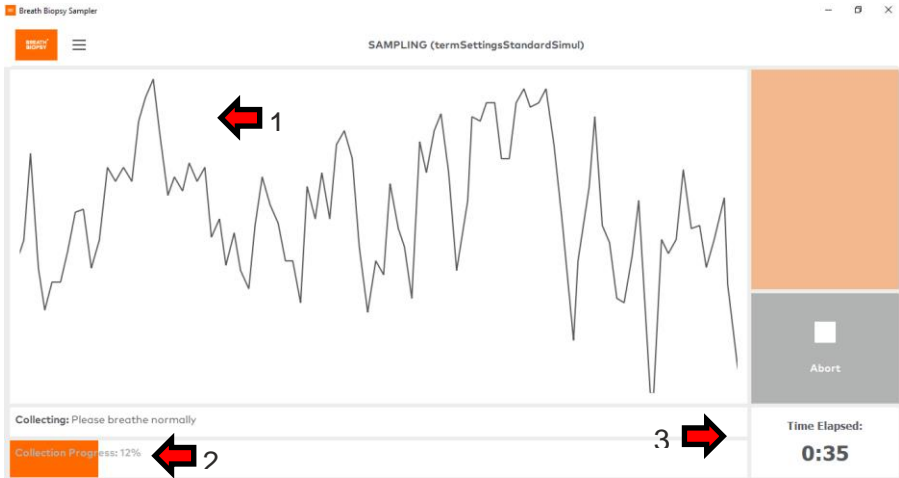


Make sure the subject does not block the two exhaust ports on the base of the ReCIVA Breath Sampler during the breath collection.

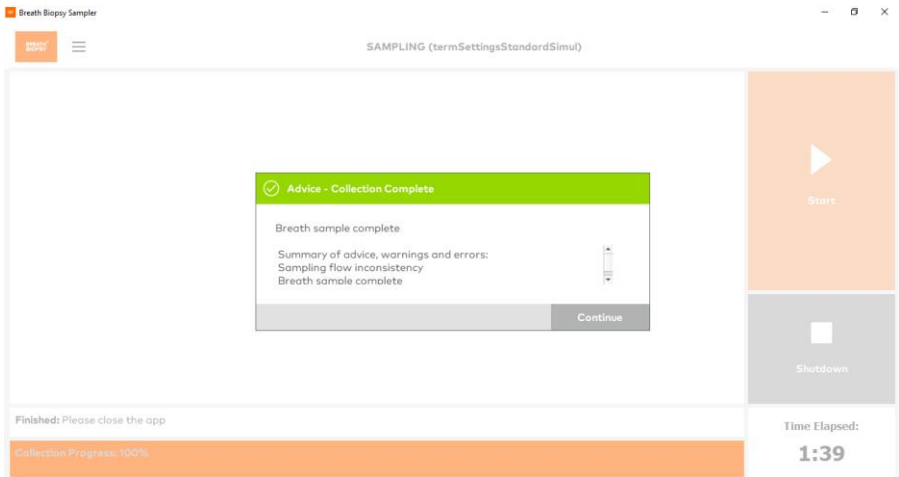


If the ReCIVA Breath Sampler is cold (lower than 15°C), allow it to run for at least 5 minutes before putting it on the subject. This allows the CO₂ sensor to warm up, preventing condensation which causes it to read full scale (20%).

The software shows progress of the collect via a breathing rate / pressure trace graph (1), percentage complete progress bar (2) and total time elapsed (3):



When the collection is complete, the message box will state **Finished** and a pop-up window will show **Collection Complete** along with a summary of any advice/warning/error messages that occurred during the collect (see section 10 for troubleshooting):

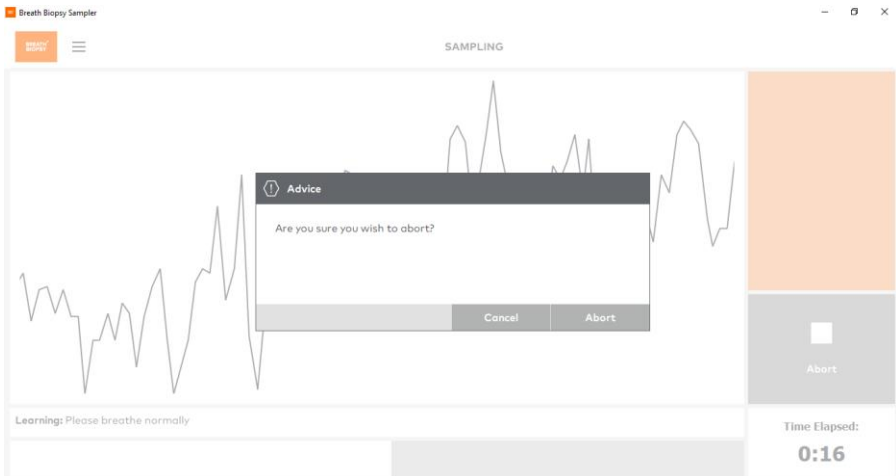


Remove the ReCIVA Breath Sampler from the subject as soon as possible after the **Collection Complete** message is shown. If using the CASPER clean air supply, please refer to its user manual for disconnection instructions.

Select **Continue** to complete the breath collect and return to the initial screen, ready for a subsequent collect (a new Data Entry pop-up will show). A H5 file containing the collected breath data will be saved in the defined folder (see section 8 for settings).

If running multiple collects with the same subject, remove and reattach the ReCIVA Breath Sampler from/to the subject between collections. Before starting a subsequent collect, check the subject remains comfortable.

During breath collection, pressing the **Abort** button will end the current collect. A pop-up window will ask for confirmation of the abort before ending the collect.



7 Instructions – Advanced View

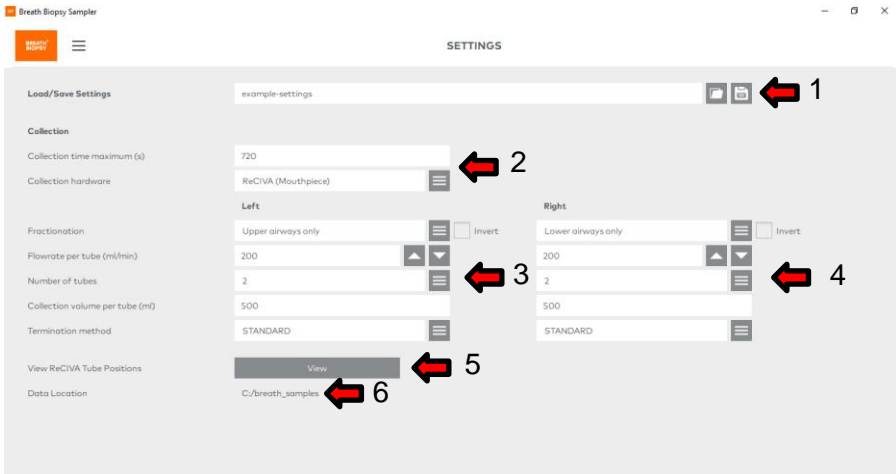
Enter the Advanced view by clicking the menu button in the top left corner of the BSC software – represented by three horizontal lines – and selecting **Advanced**.

The Advanced view can be switched to during (or before) a collect and shows additional metrics and data traces in contrast to the standard view. The metrics available are CO2, Pressure, Left Pump Flow Rate and Right Pump Flow Rate. These different metrics can be toggled on/off by clicking the buttons show under the graph:



8 Instructions – Settings View

Enter the Settings view by clicking the menu button in the top left corner of the BSC software – represented by three horizontal lines – and selecting **Settings**.



- 1 = settings file name with save/load buttons;
- 2 = overall collection settings – time and hardware;
- 3 = left pump collection settings;
- 4 = right pump collection settings;
- 5 = view tube positions (see appendix 2);
- 6 = data location (destination of H5 data files)

The ReCIVA Breath Sampler has two pumps that can be configured independently. Pump A is on the subject's left and Pump B on the subject's right when they are wearing ReCIVA Breath Sampler (see appendix 2 for tube positions).

The settings page allows you to configure zero, one or two sorbent tubes for each pump. If using less than four tubes, please use a cover for the unused slots on the ReCIVA.

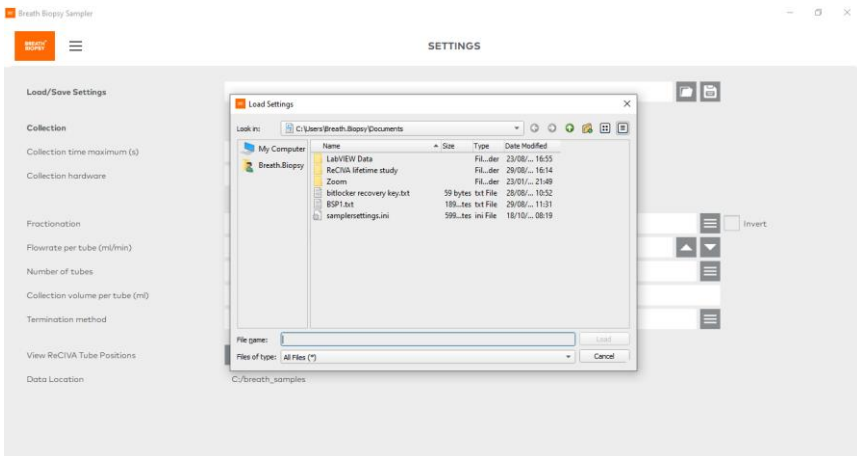
The following can be adjusted: collection time, collection hardware, collection volume, number of tubes, termination method and which portion of the subject's breath (fractionation) to collect.

Breath portions are based on pressure and should be used as a systematic guide to the origin of the breath (some mixing within airways will occur).

To adjust the breath sampling parameters, enter new values as required for each pump in the settings page. Certain fields allow data entry (e.g. volume) whereas others allow selection from a pre-defined drop-down list (e.g. fractionation).

The collection hardware setting allows the user to specify whether collects are to be performed using a ReCIVA with mouthpiece (default) or a ReCIVA with mask. This setting will only update images and text to refer to mouthpiece or mask respectively and does not affect the underlying collection functionality.

Settings must be defined before starting the collect and cannot be modified whilst sampling is in progress. Settings will remain as defined over subsequent collects until changed by the user.



Settings can also be saved and loaded. A save and load button are present at the top of the settings page. This feature can be used to easily run samples with consistent settings and to quickly change between pre-defined sets of parameters. For subsequent collects, the last saved used settings will be automatically loaded.

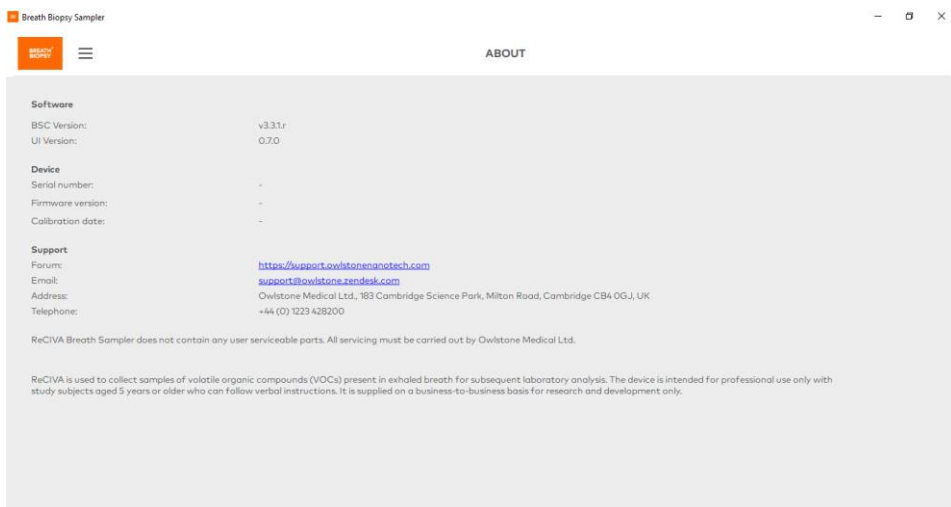
Please contact Owlstone Medical Ltd if you are in any doubt about the collection settings that you require.

9 Instructions – About View

Enter the About view by clicking the menu button in the top left corner of the BSC software – represented by three horizontal lines – and selecting **About**.

The About view lists information about the version of BSC software and the connected headset (if any).

Support and contact information for Owlstone Medical Ltd can also be found on this view.



Return to the default collection view by clicking the menu and selecting **Home**. Note, the BSC version may not exactly match the image above.

To close the software, click the 'X' in the top right corner of the window.

10 Troubleshooting

Errors, warnings, and advice messages can occur during use and will be displayed as a pop-up within the UI. These pop-ups inform of the message severity (error/warning/advice in decreasing severity). The following tables show cause and relevant actions for each of these messages.

10.1 Errors

Error Indication	Possible Cause	Action
Exit Breather Application	Operator has requested to exit the application	Cancel to continue the collect, Confirm to exit the software
Are you sure you wish to abort?	Operator has pressed abort	Cancel to continue the collect, Confirm to abort
Sampler settings not found	Collection settings not defined	Define collection settings on the settings view
No valid sampler settings file found	Collection settings defined are not valid	Check for errors in settings definition. Contact Owlstone for valid settings.
Unable to communicate with breath sampler	Headset has become unplugged	Stop the collect, reconnect the headset and start a new collect
Invalid breath sampler calibration	ReCIVA headset calibrated incorrectly	Contact Owlstone to determine if headset should be returned for servicing.
Breath sampler is incompatible with the software	Out of date ReCIVA model	Contact Owlstone to determine if headset should be returned for servicing.

Multiple breath samplers found	More than one headset has been detected	Disconnect all and just connect the one which is to be used.
Unable to create a log file	Software installation issue.	Contact Owlstone for reinstallation of software.
Pressure sensor self test failed	Potential ReCIVA headset fault.	Contact Owlstone to determine if headset should be returned for servicing.
CO2 sensor self test failed	Potential ReCIVA headset fault.	Contact Owlstone to determine if headset should be returned for servicing.
Left sampling pump self test failed	Potential ReCIVA headset fault.	Contact Owlstone to determine if headset should be returned for servicing.
Right sampling pump self test failed	Potential ReCIVA headset fault.	Contact Owlstone to determine if headset should be returned for servicing.
Left sampling pump pre-collect training failed	Potential ReCIVA headset fault.	Contact Owlstone to determine if headset should be returned for servicing.
Right sampling pump pre-collect training failed	Potential ReCIVA headset fault.	Contact Owlstone to determine if headset should be returned for servicing.
Pressure sensor failed	Potential ReCIVA headset fault.	Contact Owlstone to determine if headset should be returned for servicing.
Power Supply Unit (PSU) failed	Potential ReCIVA headset fault.	Contact Owlstone to determine if headset

		should be returned for servicing.
Internal communication failed	Software installation issue.	Contact Owlstone for reinstallation of software.
Unable to start core application	Software installation issue.	Contact Owlstone for reinstallation of software.
Unable to connect to socket of core application	Software installation issue.	Contact Owlstone for reinstallation of software.
Unable to start core application as collection storage path not created	Collection storage path does not exist	Make sure the folder defined on settings for data storage exists. If problem persists contact Owlstone.
Unable to start core application as log file path not created	Software installation issue.	Contact Owlstone for reinstallation of software.
Unable to write to data socket	Software installation issue.	Contact Owlstone for reinstallation of software.
Invalid Automated Test	Software installation issue.	Contact Owlstone for reinstallation of software.
Unexpected pressure sensor reading	One of the pressure sensors is malfunctioning. This could affect collection quality.	If error consistently appears contact Owlstone to determine if headset should be returned for servicing.
Unexpected temperature sensor reading	One of the temperature sensors is malfunctioning. This could affect collection quality.	If error consistently appears contact Owlstone to determine if headset should be returned for servicing.

10.2 Warnings

Warning Indication	Possible Cause	Action
Breath sample complete (maximum collection time reached)	Sample completed, but requested volume was not reached in the time allowed	Confirm to complete this collect. Increase the collect time in the settings page and collect again if required.
Rapid breathing detected	Subject breathing rapidly	Advise subject to breathe more slowly
Shallow breathing detected	Subject breathing shallow	Check the mouthpiece (or head strap and mask fitting) before advising the subject to breathe deeply.
Insufficient power supply	The USB port that the headset is connected to may not provide sufficient power to allow collection.	Proceed with collection. There is a risk to collection quality. For subsequent collects try a different USB port.
Unexpected CO2 sensor reading (high)	Possible condensation in the breath sampler. This has no effect on collection quality.	If warning consistently appears contact Owlstone to determine if headset should be returned for servicing.
Unexpected CO2 sensor reading (low)	Possible CO2 sensor malfunction.	If warning consistently appears contact Owlstone to determine if headset should be returned for servicing.
CO2 sensor failed	Possible CO2 sensor malfunction.	If warning consistently appears contact Owlstone to determine if headset should be returned for servicing.

Sampling pump unable to reach target flow rate	Possible port blockage.	Check that the operator or subject are not blocking the exhaust ports of the headset.
Unable to detect breathing pattern	Software cannot detect breathing pattern. Could affect collection quality	Advise subject to breathe consistently.
Sampling flow inconsistency	Exhaust ports possibly blocked or tubes not fitted correctly	If warning consistently appears contact Owlstone to determine if headset should be returned for servicing.

10.3 Advice

Advice Indication	Possible Cause	Action
Breath sample complete	Sample completed on volume.	Confirm to complete this collect.

11 Appendix 1 - Default Settings for BSC

Breath Sample Collect (BSC) can be configured to collect different portions of breath as described above. The choice of breath will vary from application to application. Below are the Owlstone Medical Ltd default collection settings. They are provided here as a guide only.

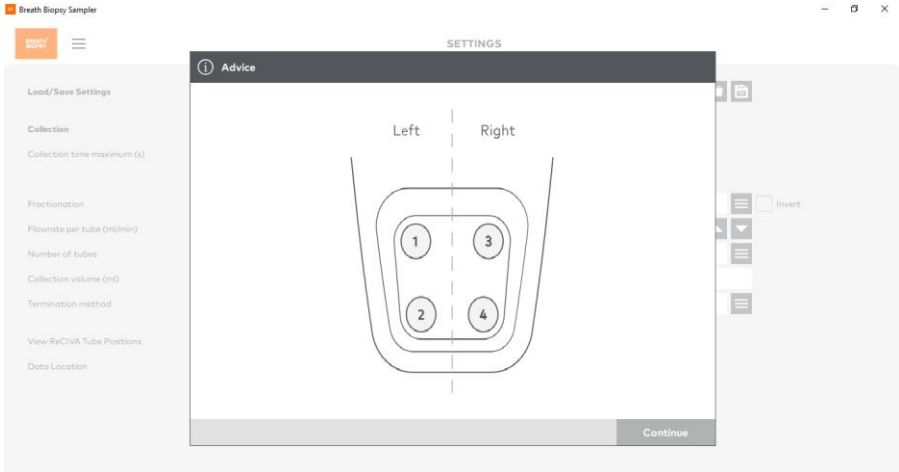
Setting	Default Value	Minimum	Maximum
Collection time	300 s	0 s	1200 s
Number of Tubes – Left Pump	2	0	2
Number of Tubes – Right Pump	2	0	2
Flow Rate – Left Pump	200 mL/min per tube	50	250
Flow Rate – Right Pump	200 mL/min per tube	50	250
Collection Volume – Left Pump	500 mL	0	N/A
Collection Volume – Right Pump	500 mL	0	N/A
Fractionation – Left Pump	Upper	N/A	N/A
Fractionation – Right Pump	Lower	N/A	N/A

In addition to the customisable settings above, the following settings are fixed and cannot be changed within the BSC UI:

- Initial wait before learning phase: 3 seconds
- Threshold values used in fractionation calculation:
 - End bronchial enriched threshold: 1
 - Start bronchial enriched threshold: 5
 - Start-end tidal enriched threshold: 7

12 Appendix 2 – Tube Positions

The layout of the ReCIVA tube holder can be viewed on the Settings page by pressing the **View** button next to **View ReCIVA tube positions**:



13 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:

support@owlstone.com



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14 Warranty Statement

Owlstone Medical Ltd. 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 Ltd.
- Accessories and reagents which have not been approved by Owlstone Medical Ltd are used.
- The instrument is not operated or maintained in accordance with instructions.