



ReCIVA® Disinfection Protocol



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1 General Information

This document provides instructions on how to disinfect the ReCIVA® Breath Sampler. These instructions replace the general cleaning instructions provided in the ReCIVA User Manual. For full instructions on the use of ReCIVA, please refer to the User Manual.

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.



Clean nitrile gloves must always be worn when handling ReCIVA, including during the disinfection process described in this document.



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

2 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 will be supplied with ReCIVA. Additional supplies are available on request.

3 Disinfection 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 tube holder 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.

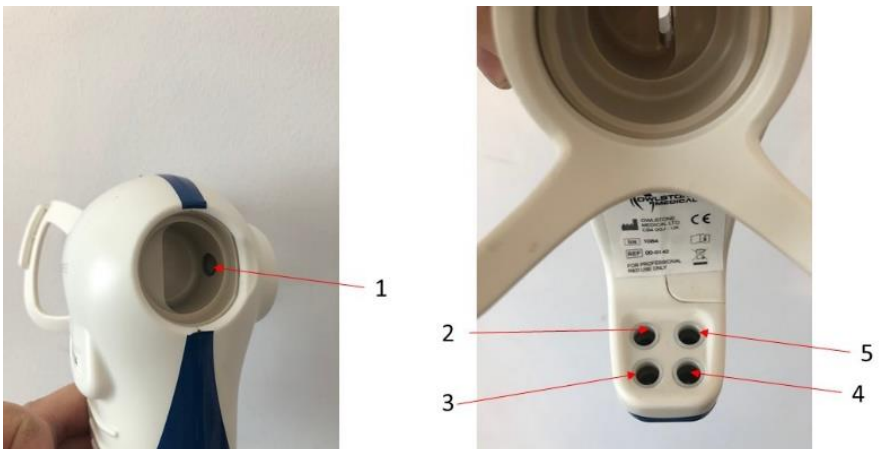


Figure 4

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.

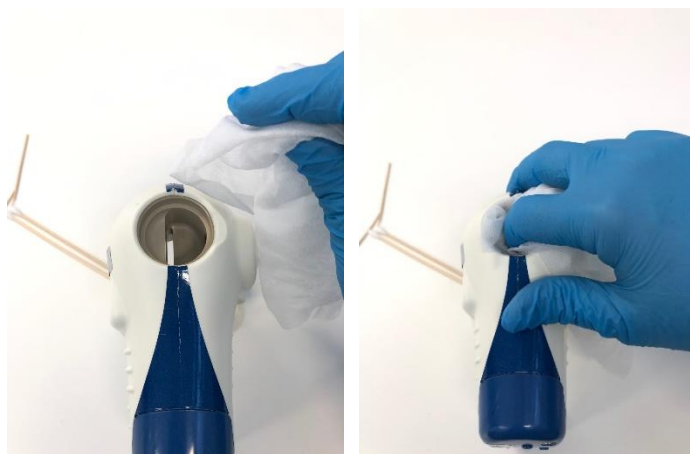


Figure 8

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



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

4 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 clean nitrile gloves for the study subjects to wear, so that they can hold or touch ReCIVA without additional risk of introducing contamination. Note: the ReCIVA user manual requires the operator, but not the subject, to wear clean nitrile gloves.
- Ensure that the sorbent tube assembly containing the breath sample is removed from ReCIVA and bagged as soon as possible after completing the breath collection. The sorbent tubes are exposed to the subject's breath so it is imperative to follow our existing advice to always handle them 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 (including its integral biological filter) and the yellow exhaust 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 will be shipped with each Breath Biopsy[®] Kit. Please contact us if you require additional valves.

- 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.

5 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:



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