

Advisory Notice CONFIDENTIAL

Date: June 9, 2020 **To:** External Partners

From: Kylie Gilberg, Marketing Manager, Midmark Corporation

Topic: Medical – IQspiro® + SARS-CoV-2

Dear Valued Partner:

Midmark places patient and provider safety at top priority for all of our clinical solutions. For this reason, Midmark would like to provide additional details on how to safely perform spirometry using the IQspiro during the SARS-CoV-2 pandemic.

The Midmark® IQspiro has a clear record of clinical efficacy and safety. We do not currently have a filtered mouthpiece offering and have not validated any alternative supplier offerings. Midmark can only warrant product performance and accuracy if the IQspiro is used as intended in its unaltered form, and when recommended practice guidelines are followed. Any modification to the Midmark IQspiro mouthpiece, including but not limited to the use of an adapter or filter, is considered an alteration to the design of the product.

Midmark recommends using the proper personal protective equipment as recommended by the Centers for Disease Control and Prevention (CDC) and the American Thoracic Society while performing spirometry. This may include, but is not limited to, the use of gloves and a mask. Midmark also recommends following CDC guidelines for disinfecting the exam room space.

Should disinfecting beyond the methods outlined in the IQspiro manual be required given the current situation with SARS-CoV-2, an EPA-approved (see list here), premoistened disposable wipe containing low concentrations (< 3%) of hydrogen peroxide as the only active ingredient is the preferred and recommended method. If hydrogen peroxide-based products are unavailable, premoistened disposable wipes containing low concentrations (1:10 dilution) of sodium hypochlorite (chloride bleach) may also be used. After the EPA-recommended contact time, remove any excess cleaning solution from the surface of the instrument using a clean cloth wetted with water. Verify that all equipment including accessories are completely dry before using.

Notice: These recommendations are based on available technical literature understood to be reliable and not on actual compatibility testing. The cleaning guidelines as established by the product manual shall be the preferred method for cleaning the IQspiro. Customers assume the risk when cleaning Midmark products with disinfecting solutions not outlined in the product manual.

Designing better care.™

Kylie Gilberg

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