

Guidance for clinicians on the use of noninvasive, point-of-care, pulmonary gas exchange monitoring (using the MediPines AGM100®) in patients with suspected or confirmed COVID-19

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Introduction

On February 21st, 2020 the Center for Disease Control (CDC) updated their interim infection prevention and control recommendations entitled, *Interim Infection Prevention and Control Recommendations for patients with confirmed Corona Virus Disease 2019 (COVID-19) or Persons under Investigation for COVID-19 in Healthcare Settings*¹. Additionally, on January 28th, 2020, the World Health Organization (WHO) released a guidance entitled, *Clinical management of severe acute respiratory infection when novel coronavirus (2019-n-CoV) infection is suspected*.²

It is estimated that approximately 90%³ of hospitalized patients with *COVID-19* develop pneumonia or other lower respiratory tract complications which results in inefficient gas exchange of the lungs. MediPines Gas Exchange Monitor, [AGM100®](#) compares the oxygen level of the lungs and blood simultaneously, providing a measure of gas exchange inefficiency,⁴ along with other respiratory parameters, noninvasively.

This guidance is designed to assist clinicians with integrating the use of MediPines Gas Exchange Monitor (AGM100®) to implement CDC and WHO recommendations, as well as recommendations provided by other health authorities. This guidance is not intended to replace clinical judgement, nor modify current FDA approved labeling of the device. It should also not be considered a complete summary of the recommendations from the CDC, WHO, and other regulatory authorities.

This document is organized into the following sections:

1. Triage and Recognition of Patients with Symptoms of Acute Respiratory Illness (SARI)
2. Infection Prevention and Control (IPC) Measures
3. Early Monitoring of Suspected and Confirmed COVID-19 Cases

The recommendations in this guidance can be applied to both hospital and outpatient clinical settings and are derived from Health Authority guidance, evidence-based guidelines, and clinical experience (expert opinion). For questions, please email: info@medipines.com.

Triage and Recognition of Patients with Symptoms of Acute Respiratory Illness (SARI)

In their recommendations for handling suspected or confirmed COVID-19 patients on arrival, the CDC requires providers to recognize patients that have symptoms of suspected COVID-19 or other respiratory infections. In an attempt to take measures to separate them from the general patient population:

“Ensure that patients with symptoms of suspected COVID-19 or other respiratory infection (e.g., fever, cough) are not allowed to wait among other patients seeking care. Identify a separate, well-ventilated space that allows waiting patients to be separated by 6 or more feet, with easy access to respiratory hygiene supplies.”¹

1. **Recommendation:** When using the AGM100® as a frontline assessment tool for triage, respiratory panel results provided by the AGM100® that may be consistent with symptoms of suspected COVID-19 or other respiratory infection in adults include: SpO₂% < 90%², RR > 30² breath per minute, gPaO₂ < 80 mmHg^{5,6}. These values need to be taken into consideration with the overall assessment of patient history and presentation.
2. **Recommendation:** Oxygen Deficit, a measurement of a patient's gas exchange inefficiency,⁴ provided by the AGM100®, may be useful in monitoring the respiratory status of patients with suspected or confirmed COVID-19. Published studies have established that in normal healthy subjects, an Oxygen Deficit measurement is usually less than 10, though it does increase slightly as subjects age^{6,7}. In patients with known pulmonary disease, such as COPD, Oxygen Deficit is usually greater than 30. Although Oxygen Deficit may be used in a similar fashion to a traditional alveolar-arterial PO₂ difference (AaDO₂), it is not currently known what the normal values are in early COVID-19 cases. Therefore, it is recommended that Oxygen Deficit be used as an individualized, objective trend of pulmonary gas exchange in patients with suspected or confirmed COVID-19 to monitor progression of the respiratory impairment (i.e. gas exchange inefficiency) of the patient.

Infection Prevention and Control (IPC) Measures

When making recommendations on patient placement and isolation, the CDC states:

“Only essential personnel should enter the room. Implement staffing policies to minimize the number of HCP who enter the room. Facilities should consider caring for these patients with dedicated HCP to minimize risk of transmission and exposure to other patients and other HCP.”¹

The CDC recommendation goes on to state:

“Facilities should keep a log of all persons who care for or enter the rooms or care area of these patients.”¹

3. **Recommendation:** The AGM100®, a point-of-care gas exchange monitor, can be used to reduce the number of personnel that should enter a patient room or care area treating suspected or confirmed

COVID-19 cases. It requires minimal training to use and can be safely operated by any appropriately trained medical team member that already has a need enter a patient room or care area.

- 4. Recommendation:** To further reduce unnecessary exposure, it is recommended that AGM100® measurements be taken with other scheduled vital assessments, and when a possible change in respiratory status of a patient needs to be evaluated.

The CDC recommendations for standard, contact, and airborne precautions in suspected and confirmed COVID-19 cases also state:

“Use dedicated or disposable noncritical patient-care equipment (e.g., blood pressure cuffs). If equipment will be used for more than one patient, clean and disinfect such equipment before use on another patient according to manufacturer’s instructions.”¹

- 5. Recommendation:** When using the AGM100 to monitor patients with suspected or confirmed COVID-19 cases, the device should be dedicated to the patient whenever possible. AGM100® breathing circuits are disposable single-patient use and should **never** be shared between patients. If any equipment will be used for more than one patient, clean and disinfect the AGM100® before use on another patient according to the instructions provided in the user manual.

Early Monitoring of Suspected and Confirmed COVID-19 Cases

According to the recommendations provided by the WHO:

“Closely monitor patients with SARI for signs of clinical deterioration, such as rapidly progressive respiratory failure and sepsis, and apply supportive care interventions immediately. Remarks: Application of timely, effective, and safe supportive therapies is the cornerstone of therapy for patients that develop severe manifestations of 2019-nCoV.”²

- 6. Recommendation:** A trend of the AGM100® measurements should be maintained to provide the care team with an individualized reference for deterioration and possible respiratory failure, as well as to monitor effectiveness of therapy. For patients with suspected or confirmed COVID-19, AGM100® panel measurements should be taken with each scheduled vital sign assessments (usually every 4 hours) to monitor for rapidly progressive respiratory failure. As previously recommended, whenever possible, tasks including AGM100® measurements, should be grouped together to reduce the number of times providers enter suspected or confirmed COVID-19 patient rooms and care areas.

References:

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