

This Fact Sheet informs you of the significant known and potential risks and benefits of the emergency use of the InSee. InSee is intended for quantitatively tracking patient usage of Vyaire Medical's AirLife incentive spirometer as an aid in treatment of respiratory conditions by patients with COVID-19 in hospital settings.

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#### All patients who use the InSee device should receive the Fact Sheet for Patients: Emergency Use of the InSee Incentive Spirometer Accessory.

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#### What are the symptoms of COVID-19?

Many patients with confirmed COVID-19 have developed fever and/or symptoms of acute respiratory illness (e.g., cough, difficulty breathing). The current information available to characterize the spectrum of clinical illness associated with COVID-19 suggests that symptoms include cough, shortness of breath or dyspnea, fever, chills, myalgias, headache, sore throat or new loss of taste or smell. Based on what is known about the virus that causes COVID-19, signs and symptoms may appear any time from 2 to 14 days after exposure to the virus. Based on preliminary data, the median incubation period is approximately 5 days, but may range 2-14 days.

Public health officials have identified cases of COVID-19 infection throughout the world, including the United States, which may pose risks for public health. Please check the CDC webpage for the most up to date information.

#### What is the InSee?

The InSee uses an infrared sensor, which monitors the movement of the spirometer's internal cylinder and converts it to tidal volume, which is the volume of air moved with each breath and is a key marker of respiratory function. The data the InSee device collects is stored and is displayed for monitoring of spirometer usage.

InSee is to be used by patients with COVID-19 in hospital settings. InSee is contraindicated for patients with:

- Recent eye surgery
- Pneumothorax
- Aneurysm in their brain, chest, or abdomen

#### What are the known and potential benefits and risks of using the InSee device?

Known and potential benefits of using the **InSee** include:

- Provides an accurate record of the patient's incentive spirometer usage
- May improve clinical monitoring of a patient's condition
- May encourage the patient to participate in his/her recovery
- Help to reduce healthcare provider (HCP) burden and exposure to patients with COVID-19

Known and potential risks of using the **InSee** include:

- Improper attachment – HCP should be instructed on proper attachment techniques. The InSee Device User Manual shows how the InSee should be attached to the spirometer to ensure proper readings can be measured
- Calibration values and incorrect reads – Prior to use of the InSee device, it is carefully calibrated as part of quality control. During initial training, HCP should monitor readings to ensure proper calibration. If HCP notices improper readings, then the InSee should be recalibrated using the USB-C connection and firmware; overall, an incorrect reading should have no risk to the patient treatment as incentive spirometers are used as preventative tools and not diagnostic tools
- Display malfunction – Inaccurate monitoring of patient usage of the incentive spirometer and InSee can potentially lead to an inaccurate assessment of the respiratory condition

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**Report Adverse events**, including problems with test performance or results, to MedWatch by submitting the online FDA Form 3500 (<https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home>) or by calling **1-800-FDA-1088**

### What is an EUA?

The United States FDA authorized use of the InSee device to quantitatively tracking patient usage of Vyair Medical's AirLife incentive spirometer as an aid in treatment of patient respiratory conditions by patients with COVID-19 in hospital settings, available under an emergency access mechanism called an EUA.

The EUA is supported by the Secretary of Health and Human Service's (HHS's) declaration that circumstances exist to justify the emergency use of medical devices during the COVID-19 pandemic.

The authorized use of the InSee device under this EUA has not undergone the same type of review as an FDA-approved or cleared device. FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, or available alternatives. In addition, the FDA decision is based on the totality of scientific evidence available showing that it is reasonable to believe that the InSee device meets certain criteria for safety, performance, and labeling, and that it may be effective in treating patients with COVID-19.

The EUA for the InSee device is in effect for the duration of the COVID-19 declaration justifying emergency use of this device, unless terminated or revoked (after which the device may no longer be used).

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### How can I learn more?

#### **CDC websites:**

**General:** <https://www.cdc.gov/COVID19>

#### **Healthcare Professionals:**

<https://www.cdc.gov/coronavirus/2019-nCoV/guidance-hcp.html>

#### **Infection Prevention and Control Recommendations in Healthcare**

**Settings:** <https://www.cdc.gov/coronavirus/2019-ncov/infection-control/control-recommendations.html>

**Infection Control:** <https://www.cdc.gov/coronavirus/2019-ncov/infection-control/index.html>

#### **FAQ on Personal Protective Equipment:**

<https://www.cdc.gov/coronavirus/2019-ncov/hcp/respirator-use-faq.html>

#### **FDA websites:**

**General:** [www.fda.gov/novelcoronavirus](http://www.fda.gov/novelcoronavirus)

**EUAs:** <https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations>

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