



GE Healthcare Receives FDA Clearance for First X-ray AI to Help Assess Endotracheal Tube Placement

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- *Critical Care Suite 2.0 helps clinicians assess Endotracheal Tube (ETT) placement for intubated patients, including critical COVID-19 patients*
- *The AI suite also includes algorithms that help radiologists prioritize critical cases and automate processes to help cut average review time from up to eight hours¹*

CHICAGO – November 15, 2021 – GE Healthcare today announced it has received Food and Drug Administration (FDA) 510(k) clearance for an artificial intelligence (AI) algorithm to help clinicians assess Endotracheal Tube (ETT) placements. The AI solution is one of five included in GE Healthcare's Critical Care Suite 2.0, an industry-first collection of AI algorithms embedded on a mobile x-ray device for automated measurements, case prioritization and quality control.

GE has distributed this solution under the FDA COVID-19 imaging guidance since November 2020, citing its potential to impact clinicians who were experiencing an influx of critically ill COVID-19 patients who required ventilation. Research shows that up to 25 percent^{3,4,5,6,7} of patients intubated outside of the operating room have misplaced ETTs on chest x-rays, which can lead to severe complications for patients, including hyperinflation, pneumothorax, cardiac arrest and death. Moreover, as COVID-19 cases climb, with more than 250 million confirmed worldwide⁸, anywhere from 5-15 percent require intensive care surveillance and intubation for ventilatory support⁹. Over the past year, 200 hospitals have deployed the technology to assist with ETT placements. The FDA has now granted 510(k) clearance for this solution allowing its continued sale outside of the public health emergency.

"At GE Healthcare, we saw the potential role of Critical Care Suite 2.0 in helping hospitals manage the crisis caused by the number of patients who needed ETT placements during the pandemic, requiring accelerated innovation, and we quickly worked with the FDA to make the solution available to clinicians. We are pleased to now have the FDA's clearance for this important solution," said Jan Makela, President and CEO, Imaging at GE Healthcare. "The pandemic has proven what we already knew – that data, AI and connectivity are central to helping front line clinicians deliver intelligently efficient care. GE Healthcare is not only accelerating the development and access of new tools to help hospital staff keep up with demand, but also leading the way on COVID-era advancements that will transform the industry and have a long-lasting impact after the pandemic."

Up to 45% of ICU patients, including severe COVID-19 cases, receive ETT intubation for ventilation^{10,11,12}. While proper ETT placement can be difficult, Critical Care Suite 2.0 uses AI to automatically detect ETTs in chest x-ray images and provides an accurate and automated measurement of ETT positioning to clinicians within seconds of image acquisition, displaying the results on the monitor of the x-ray system. The AI generated measurements – along with an image overlay – are then made accessible in picture archiving and communication systems (PACS). The average error is less than 1.0mm when calculating the endotracheal tube tip-to-carina vertical distance¹³. With these measurements, clinicians can determine if the ETT is placed correctly or if additional attention is required for proper placement.

Improper positioning of the ETT during intubation can lead to various complications, including a pneumothorax, a type of collapsed lung. While the chest x-ray images of a suspected pneumothorax patient are often marked "STAT," they can sit waiting for up to eight hours for a radiologist's review¹⁴. However, when a patient is scanned on a device with Critical Care Suite 2.0,¹⁵ the system automatically analyzes images and sends an alert for cases with a suspected pneumothorax – along with the original chest x-ray – to the radiologist for review in PACS. The technologist also receives a subsequent on-device notification¹⁶ to provide awareness of the prioritized cases.

"Seconds and minutes matter when dealing with a collapsed lung or assessing endotracheal tube positioning in a critically ill patient," explains Dr. Amit Gupta, Modality Director of Diagnostic Radiography at University Hospital Cleveland Medical Center and Assistant Professor of Radiology at Case Western Reserve University, Cleveland. "In several COVID-19 patient cases, the pneumothorax AI algorithm has proved prophetic – accurately identifying pneumothoraces/barotrauma in intubated COVID-19 patients, flagging them to radiologist and radiology residents, and enabling expedited patient treatment. Altogether, this technology is a game changer, helping us operate more efficiently as a practice, without compromising diagnostic precision.

To make the AI suite more accessible, Critical Care Suite 2.0 is embedded on a mobile x-ray device – offering hospitals an opportunity to try AI without making investments into additional IT infrastructure, security assessments or cybersecurity precautions for routing images offsite.

Furthermore, the on-device AI offers several benefits to radiologists and technologists:

- **ETT positioning and critical findings:** GE Healthcare's algorithms are a fast and reliable way to ensure AI results are generated within seconds of image acquisition, without any dependency on connectivity or transfer speeds to produce the AI results.
- **Eliminating processing delays:** AI results are then sent to the radiologist while the device sends the original diagnostic image, ensuring no additional processing delay.
- **Ensuring quality:** The AI suite also includes several quality-focused AI algorithms to analyze and flag protocol and field of view errors as well as auto rotate the images on-device. By automatically running these quality checks on-device, it

integrates them into the technologist's standard workflow and enables technologist actions – such as rejections or reprocessing – to occur at the patient's bedside and before the images are sent to PACS.

GE Healthcare worked with multiple academic research partners including UC San Francisco and the University Hospitals Cleveland Medical Center to develop the Critical Care Suite using GE Healthcare's Edison platform, which helps deploy AI algorithms quickly and securely. Critical Care Suite 2.0 is available on the company's AMX 240 and AMX Navigate mobile x-ray systems.

For more information on GE Healthcare and Critical Care Suite 2.0 visit the company's virtual [RSNA booth](#) or [gehealthcare.com](#). Clinicians can also test the Critical Care Suite 2.0 algorithms by uploading their own anonymized chest x-ray images to [gexray.ai](#).

About GE Healthcare:

GE Healthcare is the \$18 billion healthcare business of GE (NYSE: GE). As a leading global medical technology, pharmaceutical diagnostics and digital solutions innovator, GE Healthcare enables clinicians to make faster, more informed decisions through intelligent devices, data analytics, applications and services, supported by its Edison intelligence platform. With over 100 years of healthcare industry experience and around 47,000 employees globally, the company operates at the center of an ecosystem working toward precision health, digitizing healthcare, helping drive productivity and improve outcomes for patients, providers, health systems and researchers around the world.

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¹ Rachh, Pratik et al. "Reducing STAT Portable Chest Radiograph Turnaround Times: A Pilot Study." *Current Problems in Diagnostic Radiology* Vol. 47, No. 3 (n.d.): 156–60. <https://www.sciencedirect.com/science/article/abs/pii/S0363018817300312?via=ihub>.

² FDA 510(k) K211161 and CE-mark.

³ Jemmett ME, Kendal KM, Fourre MW, Burton JH. Unrecognized misplacement of endotracheal tubes in a mixed urban to rural emergency medical services setting. *Acad Emerg Med* 2003;10:961–5.

⁴ Katz SH, Falk JL. Misplaced endotracheal tubes by paramedics in an urban emergency medical services system. *Ann Emerg Med* 2001;37:32–7.

⁵ Lotano R, Gerber D, Aseron C, Santarelli R, Pratter M. Utility of postintubation chest radiographs in the intensive care unit. *Crit Care* 2000;4:50–3.

⁶ McGillicuddy DC, Babineau MR, Fisher J, Ban K, Sanchez LD.

⁷ Is a postintubation chest radiograph necessary in the emergency department? *Int J Emerg Med* 2009;2:247–9.

⁸ WHO Coronavirus Disease (COVID-19) Dashboard. Retrieved November 8, 2020, from <https://covid19.who.int/>.

⁹ Möhlenkamp S, Thiele H. "Ventilation of COVID-19 patients in intensive care units." *Nature Public Health Emergency Collection*. 2020 Apr 20 :1–3

¹⁰ Hannah Wunsch, Jason Wagner, Maximilian Herlim, David Chong, Andrew Kramer, and Scott D. Halpern. ICU Occupancy and mechanical ventilator use in the United States. *Crit Care Med*. 2013 Dec; 41(12): 10.1097/CCM.0b013e318298a139.

¹¹ Dawei Wang, Bo Hu, Chang Hu, et al. Clinical Characteristics of 138 Hospitalized Patients With 2019 Novel Coronavirus–Infected Pneumonia in Wuhan, China. *JAMA*. 2020;323(11):1061-1069. doi:10.1001/jama.2020.1585

¹² Lingzhong Meng, M.D.; Haibo Qiu, M.D.; Li Wan, M.D.; Yuhang Ai, M.D.; Zhanggang Xue, M.D.; et al. Intubation and Ventilation amid the COVID-19 Outbreak: Wuhan's Experience. *Anesthesiology* 6 2020, Vol.132, 1317-1332.

¹³ GE Healthcare data on file.

¹⁴ Rachh, Pratik et al. "Reducing STAT Portable Chest Radiograph Turnaround Times: A Pilot Study." *Current Problems in Diagnostic Radiology* Vol. 47, No. 3 (n.d.): 156–60. <https://www.sciencedirect.com/science/article/abs/pii/S0363018817300312?via=ihub>.

¹⁵ The Pneumothorax AI algorithm is also available with GE Healthcare's Critical Care Suite 1.0 on the Definium Tempo, Definium 646 HD and Definium 656 HD digital radiography systems.

¹⁶ The technologist on-device notification is generated after a delay, post exam closure, and it does not provide any diagnostic information, nor is it intended to inform any clinical decision, prioritization, or action.

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