

**Category**

Best Medical Technology

**Drug / Device Name**

LungVision

**Compound/ Tech Name**

AI-powered, real-time intraoperative CT imaging

**Trade Name**

LungVision

**Date of Approval**

2019-04-18

**Indications**

The LungVision system is intended to enable users to segment previously acquired 3D CT datasets and overlay and register these 3D segmented data sets with fluoroscopic live X-ray images of the same anatomy in order to support catheter/device navigation during pulmonary procedures.

**Therapeutic Categories**

Lung cancer diagnostics

**Attached Files:**

- Body Vision Lung Vision Final 63 Subtitles.mp4
- Body Vision Medical Procedural Workflow.mp4
- MSM 00029 Rev 01 2023 Reduced.pdf

**Background information and need for drug/device**

The first area Body Vision has decided to tackle is lung cancer. 2.2 million new lung cancer cases are diagnosed annually and lung cancer accounts for 25% of all lung cancer deaths annually, more than colon, breast and prostate cancers combined. Despite improved medical technology, smoking cessation in the population and increased lung cancer screening, 5-year survival remains ~20% in the United States and only 10% worldwide. The reason why lung cancer remains the leading cause of cancer-related deaths worldwide is two-fold. One, systematic screening for lung cancer does not exist, as exemplified by the fact that less than 5 percent of persons in the U.S. identified as high-risk for lung cancer underwent lung cancer screening. As a result, most lung cancer patients are diagnosed at a late stage; only 16% are detected at stage 1 where patients have better than 50% chance of living 5 or more years. Second, even if a suspicious lesion is found through screening or incidental imaging, the ability to definitively diagnose or rule out lung cancer in these patients has been less than optimal.

Typically, suspicious pulmonary lesions are either detected on low-dose CT screens or incidentally during chest x-rays. Once a suspicious lesion is identified, a biopsy of the tissue from within that lesion

is needed to definitively diagnose whether cancer is present. The least invasive technique for doing this is diagnostic bronchoscopy. While this method is minimally-invasive and comes with few potential complications, the diagnostic success rate generally does not exceed 70% due to the lack of intraoperative imaging to help guide the procedure.

Body Vision Medical is changing this paradigm with its AI-driven, intraoperative CT imaging platform, LungVision™.

LungVision™, uses AI-driven algorithms to transform 2D X-ray images from any C-arm – a common piece of X-ray imaging equipment accessible to every bronchoscopy suite -- into intraoperative 3D CT scans in real time. This enables clinicians that are performing diagnostic bronchoscopy to see intraprocedurally exactly where the lesion is so that they can accurately navigate to it and visually confirm that they are taking tissue samples from within the lesion. Bronchoscopists can thus be empowered to biopsy from smaller, more difficult-to-access lung lesions at an earlier stage, boosting diagnostic yield of the procedure to 90%+ and dramatically increasing the likelihood of an early diagnosis for lung cancer patients and improving odds for survival.

Body Vision Medical's approach of focusing on our core strengths in AI and imaging to leverage existing equipment in the bronchoscopy ecosystem rather than supplant them, is a novel one and is in line with our ethos of democratizing innovative technology so that it is accessible. Other technologies have been introduced to address the issue of low diagnostic yield, but most of them such as robotic bronchoscopy platforms and cone-beam CT (CBCT) are far too expensive to be viable outside of major academic centers and metropolitan hospitals in the United States and will be a barrier to entry in more cost-sensitive markets outside the United States. One of the key design requirements for Body Vision's solution was that it had to enhance the quintuple aim for lung cancer diagnostics—improve patient care, boost provider performance, and enhance patient outcomes while simultaneously lowering the cost of care and increasing the number of patients with access to the technology.

Body Vision Medical's approach helps drive superior clinical outcomes by providing intraoperative imaging at significantly reduced cost so that it is an option for rural and community hospitals in the United States as well as globally where a much greater emphasis is placed on health economics.

### **History of the development of the drug/device**

Excerpt from blog by Body Vision Medical founder, Dorian Averbuch:

As a pioneer in the field of Navigation Bronchoscopy since 2013, I spent the big majority of my career leading the development of electromagnetic navigation bronchoscopy (ENB). At one point, ENB represented a major advancement in pulmonary medicine, however, gradually I recognized its limitations and knew we needed to take a wholly different approach if we were to address the fundamental challenge of enabling reliable, minimally-invasive diagnosis of small pulmonary nodules. This was why I founded Body Vision Medical.

From day one, I was certain that we wouldn't use electromagnetic sensing because of its limitations, including the well-known, CT-to-Body divergence problem. If we wanted to solve this deficiency, designing a MedTech that would be easy for doctors to adopt and preferably based on some real-time technology they were already using was critical. In our case, this meant conventional fluoroscopy.

Although, fluoroscopy was a challenging choice because, on one hand, it's a familiar and widely used

imaging modality during biopsy but on the other hand, pulmonary lesions are typically invisible on fluoroscopy. The fundamental question and first hurdle we had to overcome was, “How can we make pulmonary lesions visible on fluoroscopy?”

This was not a trivial task because part of the solution we contemplated was, ultimately, implementing computational tomography algorithms to run on a conventional C-arm. While this is possible in theory, since the C-arm is an x-ray device similar to a CT scanner and has the ability to rotate and take multiple 2D x-ray images from multiple angles that are a prerequisite for tomographic imaging, we had to overcome the fact that a C-arm is an inherently less precise device than an actual CT scanner. Also, many different C-Arm models exist on the market, each very different from the other. Luckily, Body Vision had (and continues to have) a very talented R&D team that is skilled to invent and develop a revolutionary hardware-agnostic technology that not only overcame this significant technical challenge but, because the solution was artificial intelligence (AI)-driven, laid the foundation for a system that could continue to improve accuracy and tomographic imaging quality as we fed it additional clinical data.

Once we developed the technology for tomographically visualizing radiolucent lesions with a conventional C-arm, which we dubbed C-Arm-Based Tomography, or CABT for short, the question was how best to present this data to bronchoscopists to be of greatest use to them during a diagnostic endobronchial procedure. The decision was to show the CABT images juxtaposed to the pre-operative CTs. This was so physicians had the ability to reference the preoperative plan and confirm the relationship between the lesion and the tool in multiple planes for true visual tool-in-lesion confirmation while also injecting it through augmented fluoroscopy to assist with real-time navigation to the tumor and to visualize tool-in-lesion in real-time prior to and during biopsy.

While the concept of augmented fluoroscopy is nothing new, the innovation that our technology introduces is that the augmentation is done with actual lesion location as captured by real-time CABT imaging while the patient is on the table, rather than images derived from the pre-operative CT. For this reason, unlike other forms of augmented fluoroscopy and navigational systems, Body Vision's solution doesn't suffer from CT-to-body divergence. This was a seemingly elegant solution, but one that required many years of research and collaborative development with pulmonary clinicians to achieve.

The resulting solution we developed, which we have branded as LungVision™, merges the 3D imaging capability of intraoperative computational tomography (CT) with real-time imaging of fluoroscopy, providing similar to cone-beam CT (CBCT) to enable reliable, accurate, real-time imaging of both lesion and tools during a diagnostic endobronchial procedure. These are characteristics that ENB and all other navigation technologies, up until this point, lacked. That this can be accomplished with very little incremental equipment beyond a conventional C-arm, a ubiquitous and underutilized piece of imaging equipment readily accessible to every bronchoscopist is an absolute game-changer.

**Why this drug or device is innovative, the broad implications for future research, and/or how it will improve the human condition**

Body Vision Medical's LungVision™ solution is critical as the healthcare industry faces challenges from rising costs and the resulting shift towards more health economics and outcomes-driven decision-making. LungVision enables bronchoscopists to see exactly where the lesion is and where their bronchoscope and biopsy tools are relative to the lesion in real-time, providing the critical image

guidance they need to accurately navigate to the lesion, biopsy, and, if needed, to make informed clinical decisions during the procedure. This maximizes the likelihood that a sufficient sample of lesional tissue is obtained from which a definitive diagnosis can be achieved, saving the lung patient from the worry of not knowing or potentially undergoing additional procedures in pursuit of a diagnosis.

LungVision™ also empowers both clinicians and healthcare institutions to build their practice and program with maximum flexibility. It can serve as a standalone platform that provides both image-guided navigation and real-time intraoperative imaging during the diagnostic bronchoscopy procedure or as an adjunct that augments robotic bronchoscopy platforms with the critical, outcomes-enhancing intraoperative imaging they lack.

LungVision seamlessly integrates into the existing procedural workflow, leverages existing equipment the hospital already has in order to reduce the cost of implementation, and comes at a fraction of the cost of electromagnetic navigation (EMN), robotics, or cone-beam CT (CBCT).

This is very much in line with Body Vision's ethos of delivering clinically effective and economically sound solutions that help hospitals achieve their goals of providing the best possible care while preserving their financial stability. Body Vision Medical's recent release of a unique subscription model that allows hospitals to acquire LungVision™ without depleting their capital budgets further increases the accessibility of AI-powered imaging for both healthcare providers and the lung patients they treat.

Body Vision Medical is committed to pushing the boundaries of what is possible in lung cancer diagnostics and is constantly striving to further leverage their expertise in AI-powered imaging to improve patient care worldwide. While it's AI-powered imaging is currently only being leveraged in the lung nodule biopsy and diagnostic space today, the technology can potentially be expanded into both lung cancer therapy -- today, all trials for minimally-invasive, localized lung cancer therapy delivery utilize cone-beam CT, a real-time imaging solution too cost-prohibitive to be a broad-based solution for the masses -- as well as the intraoperative imaging of other endoluminal structures such as kidney, liver, etc.

**Please provide appropriate references (ie Pubmed links)**

Ravikumar N, Ho E, Wagh A, Murgu S. (2023) Advanced Imaging for Robotic Bronchoscopy: A Review. Diagnostics. 13. 990. <https://www.mdpi.com/2075-4418/13/5/990>

Hedstrom G, Wagh A. Combining Real-Time 3-D Imaging and Augmented Fluoroscopy with Robotic Bronchoscopy for the Diagnosis of Peripheral Lung Nodules. Chest, Volume 162, Issue 4, Supplement, 2022, Page A2082. <https://doi.org/10.1016/j.chest.2022.08.1720>

Pritchett MA. Prospective Analysis of a Novel Endobronchial Augmented Fluoroscopic Navigation System for Diagnosis of Peripheral Pulmonary Lesions. J Bronchology Interv Pulmonol. 2021 Apr 1;28(2):107-115. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8132897/>

**Attached Files:**

- Grady BV Abstract from CHEST 2022.pdf
- Prospective\_Analysis\_of\_a\_Novel\_Endobronchial.pdf
- diagnostics1300990.pdf

