

# Digital Pathology Tool to Grade Breast Cancer Histological Images

*Our patented digital pathology tool provides pattern recognition of biological samples represented as digital images to quantitatively grade cancer types by translating the American Joint Commission on Cancer (AJCC) and the College of American Pathology (CAP) guidelines into computational algorithms capable of accurately and consistently grading cancer. This tool offers a computer-implemented analysis framework that enables individual pathologists to scan slides at a touch of a button and could be integrated with specialized software to establish a one-stop workflow for reliable cancer imaging, diagnosis, quantification, storage and sharing of their own digital pathology library. The device can grade breast cancer using the Nottingham grading system into grade I, II, and III and further classify into 16 diagnostic categories of invasive ductal carcinoma. This companion diagnostic tool aids physicians in decision making to edit, confirm, document and report diagnostic data.*

## COMMERCIAL OPPORTUNITY

- The American Cancer Society estimated that there were 1.6 million new cases of cancer and over 600,000 cancer related deaths in 2017. Breast cancer is the most common cancer in women worldwide, with over 250,000 new diagnoses each year in the U.S. Invasive ductal carcinoma is the most common form of breast cancer, representing 80% of all breast cancer diagnoses. 10,000 breast cancer cases per year may be under diagnosed due to the failure to resolve discordant radiology and pathology findings.
- According to National Patient Safety Agency, decision making delays in pathology account for 41% of delays in cancer diagnosis. The accurate quantitative assessment of cancer involvement and scale is a central and challenging task for pathologists. Due to increasing caseloads, there is a need for digital pathology solutions and smart analysis software to reduce pathologists' routine workload, improve diagnostic accuracy and precision, and reduce error rates.
- In 2017, the FDA approved the Philips Intellisite Pathology Solution for primary diagnostic use. Companies like Philips are also partnering with others such as Inspirata in joint agreements to develop advanced image analytics and automated workflows.

## TECHNOLOGY

The patented technology is a computer implemented method for determining and grading features of a digitally imaged tissue sample by performing the following functions: (1) a hematoxylin and eosin (H&E) nucleus identification by segmenting a nucleus based on RGB values and selecting the nucleus with predetermined area, roundness criteria and an eosin cytoplasm identification to determine a nucleus to cytoplasmic ratio, followed by applying a pattern recognition algorithm to identify the number of tumor cells, 2D area of tumor cells and a ratio of tumor cells to non-tumor cells; (2) surveying a tumor region to assess disease state for cancer cell classification to assess nuclear pleomorphism by determining nuclear parameter size, hematoxylin counterstain, shape, texture, nucleus to cytoplasmic ratio and comparing these features with normal nuclei; (3) grading the cancer cell classification by mitotic density, nuclear waterfall and region fractal analysis of tissue structure; and (4) creating a simplified report of the graded tissue sample by comparing the classification with a standard scoring algorithm. The software and algorithms have been designed and optimized by using an extensive database of well over 15,000 tissue samples and complex histology.

## PUBLICATION/PATENT

- US Patent 9,760,760 filed on 01/18/2013 and issued to Moffitt for inventors Drs. Lloyd and Bui.

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### LICENSING OPPORTUNITY

