Medical and Diagnostic Imaging Alert

Key Medical and Diagnostic Imaging Innovations in the European Union

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Analysis of Medical and Diagnostic Imaging Innovations in the European Union
Classic Tumor Targeting System for Advanced Radiotherapy–Elekta AB

VersaHD System
VersaHD is an exclusive offering from Elekta AB, a radiotherapy and radiosurgery diagnostic manufacturing company based in Sweden. The device is a convergence of traditional radiotherapy with advanced stereotactic precision to target tumor sites in the body. VersaHD has the ability to image during treatment delivery and improves clinical efficiency by reducing treatment time-slots. VersaHD has been designed with new ergonomic features, low mechanical noise, and softer streamlined shapes that creates a confident and relaxed treatment environment. The device, thus, has the option to deliver conventional and high dose rates without compromising the treatment time.

Market Readiness and Commercialization Strategy
Elekta has a number of key distribution partnerships worldwide to promote sales of its device. For instance, it has a key partnership with MSM-MEDIMPEX, a major distributor of medical technologies in Russia, to set up production of radiotherapy equipment in the Russian region.

Product Readiness Level

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**Attributes to the Product**
Key attributes of the product include VersaHD’s integration with the company’s software solutions to deliver immediate access to patient information. The device features Agility, Elekta’s revolutionary multi-leaf collimator that has a 40cm x 40 cm treatment field and provides extreme precision and reliability. The device has been designed with patient safety in mind. It decreases collision risks with touch-activated patient protection and reduces non-therapeutic doses with lowest radiation transmission.

Competing Aspects
One of the major competing aspects of the new system is the combination of imaging and treatment delivery. This reduces the likelihood of patient movement and changes in internal organ position during the treatment session. As a result, patient care is further enhanced while providing clinicians the flexibility to provide a patient-specific workflow.

Commercialization/ Wide-Scale Adoption
The VersaHD system received the 510(k) regulatory clearance from the US Food and Drug Administration (FDA) in 2013 and since then the company has witnessed a steep demand of the device. Wide-scale adoption of the device is expected in 2016.

Application Impact
The radiotherapy system from Elekta AB can accurately target tumor sites in the human body and protect critical structures during radiosurgery.

Market Potential /Opportunity
The global radiation therapy equipment market is a multi-billion dollar market and presents a huge potential for the VersaHD system.

Analyst Insights
The VersaHD system for both imaging and treatment delivery is an innovative solution that enables highly sophisticated therapies without compromising treatment times as well as patient comfort. It has the ability to provide dose rates as high as three times than previous generation linear accelerators and as a result takes advanced therapies to new levels.

Source: Frost & Sullivan
Fluorescent Light-based Video-Pill for Cancer Imaging
University of Glasgow, UK

Problem Statement
Fluorescence imaging has been traditionally considered a powerful diagnostic tool in medicine that can identify rich blood supplies that support the growth and progression of cancer in the human body, which are relatively easy to be missed under visible light. However, the traditional fluorescence imaging technologies have been expensive and bulky and consume substantial power, thus, limiting their use to laboratories and hospital examination rooms only.

Clinical Study Profile
- The project was conducted by the Electronic and Nanoscale Engineering at the University of Glasgow in UK.
- The research team has published a paper titled “Wireless fluorescence capsule for endoscopy using single photon-based detection,” in the journal Scientific Reports.

Innovation Attributes
Research at the University of Glasgow, led by David Cumming, has demonstrated that swallow able cameras can be tuned to make them more effective in detecting cancers of the throat and gut. Fluorescent light has been used for the first time to expand the diagnostic capabilities of the video-pill. The technique is expected to help clinicians make fewer false positives and negatives in cancer diagnosis.

Future Work and Funding
- The research team believes that the system could also be used to help track antibodies that are commonly used to label cancers in the human body. This can create a new pathway to detect cancer.
- The team is also interested in understanding and expanding the capabilities of the imaging technique to newer areas such as ultrasound imaging.
- The research group is in early talks with companies to put it to clinical testing and potential commercial use in the future.

Source: Frost & Sullivan
Ultrasound Tool for Robust Reproducibility to Cardiac Ultrasound Imaging—Koninklijke Philips NV

HeartModel System
The HeartModel system is an anatomically intelligent ultrasound (AIUS) tool that allows advanced quantification and robust reproducibility to cardiac ultrasound imaging. The ultrasound measurement method has been introduced on the existing EPIQ 7 ultrasound device, one of Philips’ top-of-the-line ultrasound devices, during the American Society of Echocardiography (ASE) annual meeting in Boston, Massachusetts, in 2015. The HeartModel tool has been launched by the company as one of the fastest 3D AIUS ultrasound measurement methods in the industry.

Market Readiness and Commercialization Strategy
Philips has an extremely strong brand name in the medical device industry, especially as a developer of innovative and top-of-the-line ultrasound systems globally. The company has its distributor offices globally in all major and minor markets of the world. With the integration of the HeartModel tool with EPIQ 7 ultrasound device, the tool will be made available globally.

Product Readiness Level

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Attributes to the Product
With the help of HeartModel tool, clinicians will be able to assess disease states quickly and easily and determine treatment and guide related therapies accordingly. Clinical comparison between conventional 2D scanning and ultrasound with HeartModel demonstrated a faster scanning of the left ventricular (LV) and left atrial (LA) dimensions. With access to advanced clinical information, the HeartModel is able to quickly adapt to variability in patient’s anatomy, which provides proven quantification of the LV and LA and displays routine apical views.

Competing Aspects
Analyzing heart measurements through conventional systems is a time-consuming process and as a result adds burden on the busy and constrained clinical environments. Three to six times faster scans with the HeartModel tool is a major game changer in this industry.

Commercialization/ Wide-Scale Adoption
HeartModel tool was made available in the United States in August 2015 and globally in all major market of Europe and Asia toward the end of 2015. However, the truest potential of the measurement tool will be utilized by late 2016 or early 2017, when it is widely adopted across hospitals and research centers.

Application Impact
The HeartModel anatomical intelligence ultrasound tool is expected to have the maximum impact on non-invasive cardiac imaging.

Market Potential /Opportunity
Philips is the first company to roll out an AIUS tool on any ultrasound device and thus the HeartModel has a good opportunity to impact the ultrasound market.

Analyst Insights
Overburdened health systems are constantly looking at innovative solutions that can reduce the treatment time. The HeartModel AIUS tool allows clinicians a better view at a fraction of scan time, thus making decisions early, fast, and more reproducible. With this innovation, the company will leverage its expertise to pioneer its range of ultrasound systems.

Source: Frost & Sullivan
Wound Healing Process to become Speedier
University of St. Andrews, UK

Problem Statement
Wound healing is a process in which the body tissue repairs itself after injury or trauma. It is a multi-stage process that involves inflammatory phase, proliferation phase, and maturation phase.

Wound healing process is a rather complex and slow process that can be further delayed if the person is suffering from other chronic diseases or on blood thinning medications. Thus, wound care speeds up the healing process and protects from infection.

Until recently, visible light has been used as a means to treat superficial wounds. Fiber-optic devices have been fabricated from glass for this process, however, they tend to stay permanently after the surgical process.

Innovation Attributes
The new method, called photochemical tissue bonding, involves light to be used to treat wounds. The research team has been able to develop a pathway through which biodegradable optical fibers can be inserted in the human body to deliver light to heal wounds internally (mostly post surgery). In this manner, the materials can be re-absorbed within the body, eliminating the need for removal and reducing the risk of tissue damage in the future, thus, providing doctors an approach to treat without scarring.

The lead researcher of the study, Malte Gather, believes that the innovative approach is expected to have dramatic implications in medicine. Optical techniques such as photochemical tissue bonding and photodynamic therapy essentially require efficient delivery of light deep into tissues. However, given the current limitations of light penetration through the tissues, their effective clinical use is hindered. Controlled delivery and collection of light is expected to boost the wound healing process.

Clinical Study Profile
- The research initiative has been undertaken by scientists at the University of St. Andrews (UK) and Harvard Medical School (USA).
- The research has demonstrated treatment of deep wounds using light to help heal wounds faster and this has been published in the journal, Nature Communications.

Future Work and Funding
- The research undertaken by the team is expected to be clinically tested before it can enter clinical trials to prove its safety and efficacy in humans. Although, the procedure holds promise, it will take a number of years to be commercialized.
- The research team believes that the photodynamic therapy could be used in other areas such as in cancer treatment and implanted endoscopy after surgery for repeated imaging or the wound healing process.

Source: Frost & Sullivan
High Performance Diagnostic Displays to help Radiologists—Barco NV

Coronis Fusion
Barco NV, a company that manufactures and globally distributes mammography, diagnostic, clinical, surgical and dentistry displays, unveiled the next generation of its successful product line, the Coronis Fusion, at the European Congress of Radiology that was held in Vienna from March 2 to March 6, 2016. Globally, the Coronia Fusion 6MP has become the preferred choice of radiologists and the new generation diagnostic displays further boosts diagnostic accuracy as well as radiologist productivity. The new line of Coronis displays ensures that radiologists are able to interface more with the patients and work more efficiently.

Market Readiness and Commercialization Strategy
Barco NV has its own facilities for sales and marketing of its healthcare market products that also includes a customer support and manufacturing base in Europe, North America and APAC. The company is active in over 90 countries and thus has a strong distribution model to commercialize its new line of displays.

Product Readiness Level

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Attributes to the Product
The new line of Coronis Fusion displays is built on the latest IPS (in-plane switching) panel technology, which includes a screen area that is 100% compliant with the American College of Radiology (ACR) guidelines for luminance ratio. To improve radiologists workflow, the displays offer 50% more calibrated light for faster and accurate diagnosis of subtle details. The displays also include SpotView technology that is able to focus the light on lesions and abnormalities that require extra detail. To improve efficiency in workflow, VirtualView and DimView features allow the removal of light pollution coming from surrounding displays, allowing the radiologists to focus better on important details.

Competing Aspects
Coronis Fusion allows radiologists to double the size of the image in the focal spot to prevent loss of any detail in the image. The display system also has a warranty of 40,000 hours.

Commercialization/ Wide-Scale Adoption
Barco is expected to commercialize the new line of Coronis Fusion displays in 2016 as it has already started showcasing its new range in major events worldwide. Wide-scale adoption is expected by 2017, considering the strong global network of Barco NV.

Application Impact
The Coronis Fusion line of displays has been primarily developed to cater to the growing need of radiologists to improve workflow efficiency and reduce the burden and discomfort of using three display units at the same time.

Market Potential /Opportunity
Being a one-stop-shop solution, the Coronis Fusion line of displays has a huge potential in the multi-billion dollar radiology market.

Analyst Insights
The previous Coronis Fusion display units have received a good response globally and the new range of its diagnostic displays will boost the diagnostic accuracy that is expected from Barco products. With ultra-fast display controllers and seamlessly integrated technologies that improve workflow, the new range of Coronis displays will ensure a reduction in operational expenditure at the radiology division in a clinic.

Source: Frost & Sullivan
Irritable Bowel Syndrome to have a Breakthrough Diagnostic—University of Nottingham, UK

**Problem Statement**
Irritable bowel syndrome (IBS) is a common disorder that affects the colon or the large intestine and is associated with a number of symptoms such as cramping, abdominal pain, diarrhea, etc.

Diagnosis of IBS is a difficult process as physical signs or symptoms can confirm the prevalence of the disease. As a result, physicians tend to rule out other gastro-intestinal disorders and arrive at the conclusion of a person suffering with IBS.

Additional tests such as sigmoidoscopy, colonoscopy, radiography, CT scans, etc. can be performed including stool studies to rule out other causes of the symptoms.

**Clinical Study Profile**

- The research has been led by the University of Nottingham at the Digestive Diseases Center (NDDC) and scientists from the Sir peter Mansfield Magnetic Resonance Center at the University.
- Three separate studies have been published that examine the disease in detail and determined a new approach in investigating the illness.

**Future Work and Funding**

- The work at the University of Nottingham is being funded by Medical Research Council (MRC), Wellcome Trust, the National Institute for Health Research (NIHR), the Biotechnology and Biological Science Research Council (BBSRC) and the industry.
- The research team was also able to understand the link between the chemistry of food and its impact on the bowel technique.

Thus, the scientists used MRI and MRI visible biomarkers that were ingested by the patient to ascertain the time frame of the bowel movement. Using MRI, the scientists were able to visualize normal and delayed transit in their bowel, that can potentially be used for the management and treatment of IBS. The research work is far better than what the clinicians used to rely on for diagnosis – the patient’s themselves explaining the illness without any diagnostic evidence.

Source: Frost & Sullivan
Patients with Osteoporosis get a New Diagnostic Tool
Med Imaging Limited

Stratos DR
Med Imaging Limited, one of UK’s independent diagnostic imaging firms, has released its novel diagnostic tool for the diagnosis and follow-up of patients suffering with osteoporosis. The company has been in business in UK for the past 20 years and has been delivering service to the National Health Service (NHS) Trusts and private health organizations. The Stratos DR is a dual-energy X-ray absorptometry (DXA) solution for practicing surgeons and bone health specialists that require a fast, powerful yet cost-effective diagnostic procedure.

Market Readiness and Commercialization Strategy
Med Imaging Limited has an established network of hospitals across the United Kingdom where the device is available. This includes NHS SBS (Shared Business Services), NHS Supply Chain, NHS Scotland and North of England Commercial Procurement Collaborative (NOE CPC).

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Attributes to the Product
Some of the key attributes of the product include faster examination scan times (up to 60 seconds) that can examine the whole body or even multiple sites in the human body. The two-dimensional (2D) fan-beam in the device provides the highest image resolution with the help of a 4 linear, 64 element multi-array detector. The Stratos DR has been designed to enhance performance by improving reliability and image quality and optimize investment for the practitioner.

Competing Aspects
Key competing aspects of the Stratos DR system from other densitometry devices include automatic selection of the region of interest (ROI), where the examination needs to be performed. In addition, the device comprises morphometric tools that have the ability to define the fracture risk, for example, hip structural analysis.

Commercialization/ Wide-Scale Adoption
Med Imaging Limited has made available the Stratos DR densitometry device in the whole of UK, especially to the NHS service. The device is also available for purchase from a number of online stores globally. Wide-scale adoption is expected in late 2016.

Application Impact
In addition to routine exams for osteoporosis diagnosis of hip, spine, and forearms, the device can cater to a wide range of applications including lateral spine, pediatrics, whole body, and so on.

Market Potential/Opportunity
The bone densitometry market is estimated to be a billion dollar market globally and this presents a huge opportunity for the Stratos DR system.

Analyst Insights
Med Imaging Limited has been at the forefront of introducing innovative densitometry technologies in the past too. The Stratos DR is a complete DXA solution that will certainly benefit clinicians as well as patients suffering with osteoporosis, who require follow-up diagnosis.

Source: Frost & Sullivan
New Diagnostic for 3D Breast Imaging
Planmed OY

Clarity 3D
Planmed Oy is a medical device company based in Finland that develops, manufactures and markets innovative mammography units. The company has introduced its new Digital Breast Tomosynthesis (DBT) system, Clarity 3D, at the European Congress of Radiology, held in Vienna, Austria in March 2016. Globally, digital breast tomosynthesis is a relatively newer yet effective technology for breast cancer screening. The company aims to offer the device to breast cancer clinics around the world, ensuring the people in developing markets are able to get a proper diagnosis at a reduced cost.

Market Readiness and Commercialization Strategy
The Finland-based company, Planmed Oy, has signed an exclusive distributor partnership with Xograph Imaging Systems (UK), to distribute and support Planmed’s line of digital mammography equipment. This will ensure the product receives the wide-scale adoption in major countries of Europe.

Competing Aspects
The device offers full field Flex-AEC, i.e., large AEC area coverage for optimal imaging in every imaging mode. MaxView breast positioning system allows maximal tissue visibility for better diagnostics. The device also offers SideAccess feature that allows for comfortable patient positioning during breast examination.

Attributes to the Product
Planmed’s Clarity 3D system is able to provide crisp images due to two unique technologies offered by the company—TomoMarker technology and Continuous Sync-and-Shoot technology. The TomoMarker technology allows for improved tomographic image quality and accuracy, and superior acquisition geometry detection. The Continuous Sync-and-Shoot imaging sequence enables sharp, motion-blur-free images that is able to highlight delicate structures.

Product Readiness Level

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Commercialization/ Wide-Scale Adoption
Planmed Oy has attained CE mark for the Clarity 3D system before launching the device in the European region. As a result, the company is ready to roll out the device in all countries of Europe. Wide-scale adoption of the device is expected toward the first half of 2017.

Application Impact
The Clarity 3D system offered by the company has been specially designed for breast examinations including screening for tumors.

Market Potential/Opportunity
The breast imaging technologies market is multi-billion dollar market globally. However, there is a huge potential for the device as it offers a number of key features that limit the use of other systems in the same category.

Analyst Insights
Clarity 3D is a complete digital breast tomosynthesis unit that features a new type of mammography unit that allows fast screening and even stereotactic procedures while ensuring patient care and comfort at all times.

Source: Frost & Sullivan
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