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SOFTWARE PROGRAMMES EMPLOYED AS MEDICAL DEVICES

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Abstract

The opportunity to successfully develop and roll out patient-centric digital health platforms is represented by Software as a medical device (SaMD). Software is now a crucial component of all products and is widely integrated into digital platforms that are used for medical purposes as technology in all areas of health care continues to progress. Artificial intelligence (AI) is a potent and currently evolving technology that has the potential to enhance capabilities in a wide range of sectors. Medical device companies have been fascinated in artificial intelligence. Nowadays Artificial intelligence based medical devices are gaining a lot of attention. Artificial intelligence-enabled medical devices have the potential to completely transform the way that healthcare is provided by enabling physicians to diagnose and treat their patients more precisely and successfully while also enhancing their overall level of care. The three primary objectives of the medical devices that are incorporated with AI are being developed by medical device companies as technology progresses are chronic disease management, medical imaging and Internet of Things (IoT). Quite apart from its advantages, artificial intelligence in medical devices also has drawbacks, such as the necessity for regulation to keep up with the rate of technological innovation. The softwares such as Eye Art and IDxDR for the identification of diabetic retinopathy, Quant X for breast abnormalities, Gleamer BoneView for fractures on X rays and software for the management of type 1 diabetes i.e., Dreamed Advisor Pro and as well as the AI-ECG platform are just a few instances of the artificial intelligence-infused software's that are discussed in this article.

Keywords: Digital health, Artificial intelligence, Diabetic retinopathy, Breast abnormalities, Fractures on X rays, Type 1 diabetes, AI-ECG platform.

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Introduction

The term "artificial intelligence," which refers to intellect created by humans, is made up of the phrases "artificial" and "intelligence." John McCarthy, an American computer scientist, first used the term "artificial intelligence" in 1956 at the Dartmouth Conference. The father of artificial intelligence is John McCarthy. A subfield of computer science called artificial intelligence focuses on creating intelligent machines that can think and act like people and are capable of making decisions on their own. Reasoning, knowledge representation, planning, learning natural language processing, perception, and the capacity to move and manipulate objects are the objectives of artificial intelligence [1].

Manufacturers of medical devices are employing these technologies to innovate their devices in order to better assist medical professionals and enhance patient care. A lot of data is employed in the disease detection, diagnosis, and treatment processes attributable to the ongoing development of assistive diagnostic technology. Clinical professionals may find it difficult to organize and analyze these data in a timely manner. In order to help physicians, anticipate diseases and treatment outcomes, AI is being applied in the field of medical devices more and more.

By gaining new and significant insights from the enormous quantity of data generated daily during the provision of healthcare, artificial intelligence (AI) and machine learning (ML) technologies have the potential to revolutionize the healthcare industry.One of the biggest advantages of AI/ML in software is its capacity to learn from actual use and experience and enhance performance [2].

Medical devices powered by AI in the healthcare sector could

- Synthesize data from many sources, automate activities, and identify trends
- Recognize disease or the beginning of medical disorders by processing and analyzing data from wearable sensors.

- Based on their medical histories, identify patients who are more likely to develop a disease, experience problems, or experience unfavorable results.
- Contribute to research by analyzing vast volumes of data and keeping track of treatment effectiveness.

Artificial Intelligence Trends in Medical Devices

Medical device manufacturers are creating AI-based medical devices that perform three primary tasks as technology develops:

1. Management of chronic diseases

Artificial intelligence-enabled medical equipment could keep track on patients and administer medicine or treatment as necessary.

2. Medical imaging

To conduct medical imaging with higher image quality and clarity, firms are creating medical devices integrating artificial intelligence. Additionally, these devices would lessen a patient's radiation exposure.

3. Internet of Things (IoT)

Medical professionals can manage data, keep patients informed, save money, monitor patients, and work more effectively and efficiently by using a system of wireless, interconnected, and connected digital devices. In order to improve patient outcomes, businesses are combining IoT with intelligent medical devices [3].

Software as medical device

The International Medical Device Regulators Forum (IMDRF) defines software as a medical device as "software designed to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device."

The use of software as a medical device is on the rise. It can be applied to a wide range of technological platforms, including virtual networks, commercial "off-the-shelf" platforms, and platforms for medical devices, to mention a few.Previously, such software was referred to as"standalone software," "medical device software," and/or "health software" by the industry, international authorities, and healthcare providers [4].

Advantages of SaMDs

- Faster drug development and manufacturing will spur innovation. The use of AI software may be essential for identifying potential therapeutic treatments due to its capacity to boost productivity.
- Data-driven improvements in health outcomes can shorten diagnosis times by doing data analysis more quickly. (For example, ML algorithms may find patterns in datasets to estimate risks, and autonomous diagnostic decision-making systems can recognize symptoms of certain diseases.)
- Improved effectiveness and efficiency in the delivery of healthcare
- Algorithms can be used to speed up time-consuming operations, such as computer-aided detection (CAD) systems for interpreting medical pictures, to help those with limited access to healthcare and a staff shortage [5].

INSTANCE

1 AI -ECG PLATFORM

Recent research has demonstrated the effectiveness of artificial intelligence (AI) used to analyze digital ECGs in identifying and forecasting cardiovascular diseases [6]. The AI-ECG Platform is an analysis system incorporating Ai technologies that assists physiciansmonitor and interpret ECGs fast and accurately. The interpretation generated by the software program can then be evaluated, modified, or deleted by the physician [1]. The FDA has approved and CE has certified China's AI-ECG platform as the country's first AI-powered ECG product. The platform for AI-ECG is developed to be utilized in hospitals and other health care institutions for the detection of common cardiac problems [7]. As a tool for thorough human-like interpretation of the ECG as well as a potent one for phenotyping cardiac health and disease that can be used at the point of care, the AI-ECG is proving to be quite useful [8].

Components of AI ECG Platform

1. AI ECG Workstation: With a powerful GPU, AI-ECG workstation can support fast AI computation and deliver more rapid and accurate waveform analysis, interpretation, and diagnosis for ECG examinations.

2. Management portal: Users can manage company settings, access security and daily ECG test tasks, run work statistics, or read and print ECG reports via the web-based administration interface.

3. Diagnostic client: It assists the physicians in diagnosing and analyzing ECGs more quickly with wide range of features such as ECG review, waveform measurement, heartbeat annotation, interpretation, electrical signature, and report generation [9].

Functioning

The programme receives ECG waveform data directly from the device or from the user who manually uploads it. It then analyses the ECG data and automatically interprets it on the computer server. The ECG measurement, interpretation, and waveform data are then downloaded to a PC-based physician's diagnosis client application so that the physician can review, edit, and confirm the analysis statements and print the report. Secure permanent storage of the original ECG waveform data is provided by the server computer [10].

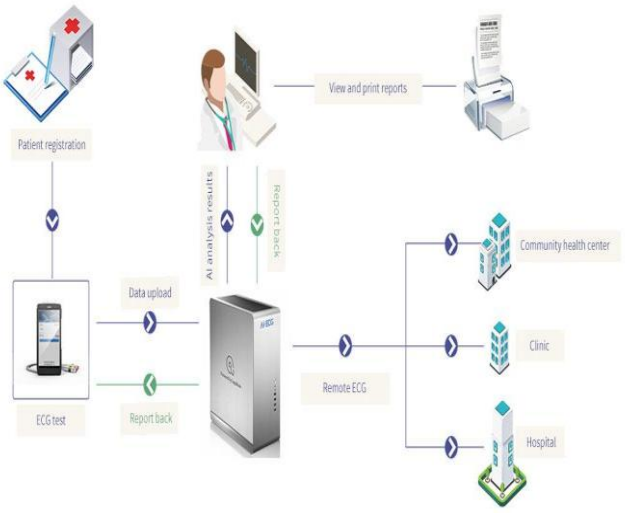

Figure 1: Procedure of AI-ECG Platform [7].

Threats

- If the programme does not receive ECG waveform data accurately, it results in the wrong interpretation of results which worsens the disease condition of the patient.
- Data transfer security breach causes patient damage.

Merits

- The AI-ECG platform is built on waveform image input, which can accurately capture the complete waveform.
- Convolutional neural networks' multilayer processing efficiently reduces the impact of irrelevant information on ECG diagnosis.
- The 12 different types of arrhythmic events may be detected by the AI-ECG platform with a sensitivity of 99%, and the positive predictive value for detecting atrial fibrillation is 98.67%.
- More than 7,000 applications and 14 million ECG service volumes are combined on the AI-ECG platform, improving the reliability of analysis results [11].

INSTANCE: 2 EYEART

The Eye Art system is an automated, cloud-based artificial intelligence (AI) eye screening software created to identify more severe and potentially dangerous diabetic retinopathy (DR) in the eyes of persons with diabetes who have not previously been identified with more severe DR [12,13]. It is the first autonomous AI system that has received FDA clearance and generates diagnostic results for each patient's eye [14]. EyeArt has also received a Health Canada license, and is CE-marked in the European Union as a class IIa medical device [15].

Components of EyeArt

1. EyeArt Client: The EyeArt operator's PC has this component installed (working under supervision of a healthcare provider). The EyeArt Analysis Computation Engine can be used to transfer images, and the operator can then get results.It needs an internet connection to work. If photographs from a patient encounter cannot be analyzed because of low image quality or because all necessary image fields are missing, feedback is sent to the operator to assist in successfully obtaining results upon resubmitting the images.
2. EyeArt Server: This part of the system offers a user interface that securely handles incoming requests and maintains user data, including images and outcomes, in a secure manner.Through an application programming interface (API), it allows the EyeArt Client to use the EyeArt Analysis Computation Engine.
3. EyeArt Analysis Computation Engine: Exam quality is assessed using the EyeArt Analysis Computation Engine, which also detects mtmDR and vtDR. It comprises of a collection of machine learning (deep learning) algorithms that have been clinically synchronized [16].

Functioning

A computer with the EyeArt Client programme installed is connected to a retinal fundus camera, which is used to take pictures of the patient's retinal fundus.

Two non-mydriatic, 45-degree images of each eye are taken of the patient.

The EyeArt operator can transfer the required fundus images to and get findings from the remote EyeArt Analysis Computation Engine through the EyeArt Server using the graphical user interface (GUI) provided by the EyeArt Client software.

The EyeArt Analysis Computation Engine uses artificial intelligence algorithms to analyze the fundus images. It is installed on one or more distant computers in a secure data center.

The AI will suggest dilation if the image isn't good enough, however most of the time dilation isn't required.

As soon as the patient photographs are submitted, a report is created in less than 60 seconds.

Results of the DR screening can be downloaded as a PDF report [16].

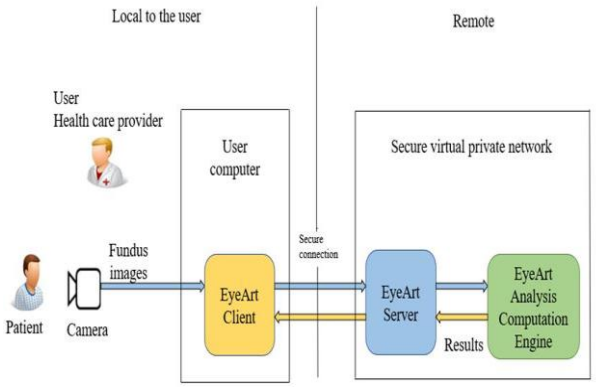

Figure 2: Components of EyeArt [16].

Threats

- One of the biggest risks is false negative outcomes. Though the probability of a false negative finding is thought to be very low, it may take longer to diagnose the condition and start treatment if the patient is not referred to an eye care specialist by the healthcare provider after receiving a false negative result for the vision-threatening diabetic retinopathy.
- A false positive test result might imply disease in a patient who does not show clinical signs of diabetic retinopathy, leading an eye care professional to refer the patient for additional testing and increasing the risk of alarm fatigue [14].

Merits

- In addition to detecting diabetic retinopathy, EyeArt may also evaluate whether there is clinically significant macular edema [14].
- 60 second report
- Simple to use
- For DR screening, no expertise is required.
- It automatically detects photographs that are of poor quality or that do not display the necessary retinal fields (protocol deviations).

- Supports various Camera Brands & ModelsE I N 6 0 S E C O N D N O
- Showed in a major, prospective, multicenter clinical trial great sensitivity (96% for more severe DR and 97% for vision-threatening DR) and good specificity (88% for more severe DR and 90% for vision-threatening DR) [15].

INSTANCE: 3 IDxDR-DR

The first AI algorithm for the identification of Diabetic Retinopathy in the offices of healthcare professionals who are not ophthalmologists is IDxDR-DR which was approved by FDA[17].Based on the results of a clinical research that used retinal scans from 900 diabetes patients at ten primary care facilities, the FDA made its decision[18].The cloud-based IDxDR-DR programme can identify vision loss from retinal pictures, which can assist diabetic patients avoid going blind[19].It is a part of an emerging trend in which algorithms are trained to recognize and identify disease[20].

Components of IDx-DR

1. IDx-DR Analysis: Using the patient's images as input, the analytic programme examines the quality of the exam and the existence or absence of diabetic retinopathy
2. IDx-DR Client: a part of a computer programme running on a device at the client's location that is typically connected to the fundus camera. With the aid of this software, the client can send photos via IDx-Service to IDx-DR Analysis and receive the findings. IDx-DR Client performs without needing to be installed, and it works locally on all Windows machines. An internet connection is necessary for it to function. When an exam cannot be analyzed because of poor picture quality or an image acquisition protocol mistake, quality feedback is sent to the operator to assist in acquiring high-quality exams and obtaining a successful result after resubmitting the exam.
3. IDx-Service: A database that maintains customer information, a logging system, and a webserver front-end are all included in IDx-Service. Device cybersecurity is also mostly handled by IDx-Service [21].

Functioning

The device is paired with a non-mydriatic retinal camera, such as the Topcon NW400, which takes pictures of the back of the eye, the operator takes two shots of each eye.

The patient's retinal digital images are subsequently uploaded to a cloud server running the IDx-DR programme.

After that, the server employs IDx-DR software and a "deep-learning" algorithm to identify retinal findings consistent with DR by autonomous comparison with a huge dataset of sample fundus images.

The IDx-DR system, which is projected to run the algorithm in 20 seconds, generates a screening conclusion within a few minutes.

When the device receives photos of good enough quality and sends them to the IDx-DR system to determine whether the patient has diabetic retinopathy, one of two outcomes is generated:

Either the patient tests "negative" for the condition and needs to be rescreened in 12 months, or the patient is found to have more severe diabetic retinopathy and needs to be referred to an eye care professional for treatment [17].

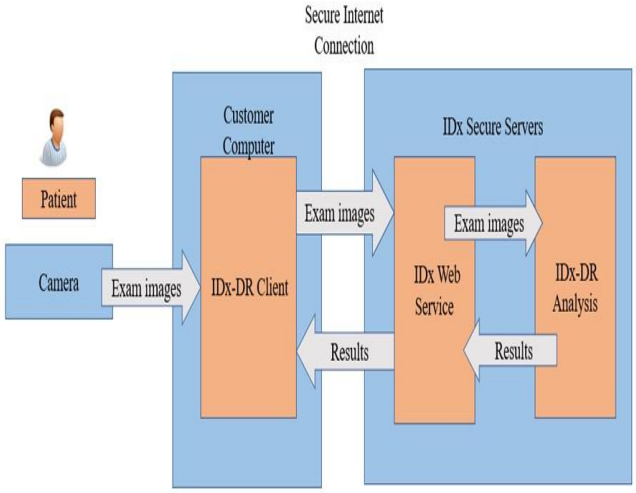

Figure 3: Components of IDx-DR[21].

Threats

- False negative outcomes are one of the main hazards. If the patient is not referred to an eye care specialist by the healthcare practitioner after receiving a false negative result for the mtmDR, it may take longer to diagnose the condition and begin therapy.
- A false positive test result would indicate the presence of illness in a patient who does not exhibit clinical indications of diabetic retinopathy, prompting an eye care practitioner to refer the patient for additional testing, raising the risk of alarm fatigue. The probability of a false positive finding is thought to be low [21].

Merits

- It independently makes the clinical decision.
- Makes diagnosis more accessible because the technology can be utilized by a physician or nurse who is not an eye specialist [19].
- Easy to use
- Individualized solutions for workflow integration [22].
- Instead of being limited to ophthalmology clinics, IDx-DR makes it possible to do diagnostic tests in easily accessible locations.
- It doesn't require medical supervision [23].

INSTANCE: 4 DREAMED ADVISOR PRO

The utilization of AI/ML has the potential to significantly expand the accessibility of diabetes care, thereby increasing its effectiveness [24]. DreaMed Advisor Pro is an AI powered insulin dosing software designed for people with Type 1 diabetes using insulin pump therapy with continuous glucose sensors or blood glucose meters. The software previously acquired CE Mark approval and FDA authorization for usage with a pump and CGM. This is the first decision support tool that has been approved to help medical professionals manage Type1diabetic patients who use insulin pumps or BGM [25].

MD Logic Algorithm

MD-Logic is a closed-loop remote monitoring system. Fuzzy logic and a Self-adaptive learning algorithm are the basis of the analysis [26]. Over a ten-year period, hundreds of diabetics' data sets were used to test the MD Logic technology that powers Advisor Pro. It employs AI algorithms to mimic how skilled endocrinologists assess their patients, personalizing their understanding for each patient while employing accumulated information, such as gathering, cross-referencing, and evaluating all that crucial, patient-specific data - both in real-time and in the past. MD Logic makes it possible to quickly and thoroughly analyze information on insulin administration, blood glucose levels (CGM, SMBG, insulin pump), and patient reporting in order to develop the best possible treatment.

Functioning

The qualified third-party Diabetes Management Systems (DMS), which collects biological input data from various diabetes devices, are how the DreaMed Advisor Pro acquires and evaluates data inputted.

Diabetes management system downloads patient data from an insulin pump, a CGM, and a blood glucose meter.

An advisor retrieves this information and uses the MD Logic algorithm to evaluate it.

Processing and analyzing the information, dreamed advisor pro looks for trends in highs and lows as well as insulin dosage occurrences.

To produce individualized advice for improving glucose control, dreamed advisor pro examines each insulin dosage event as well as the tendencies of highs and lows. Personalized diabetes management advice may be included with the recommendations, which could also include basal rate, carb ratio, and correction factor

The suggestions are sent to the diabetic management system by dreamed advisor pro. The patient report with recommendations is given to the healthcare provider, who is able to alter it and provide it to the patient.

Patient gets specific suggestions to enhance their insulin pump settings and manage their diabetes treatment [27].

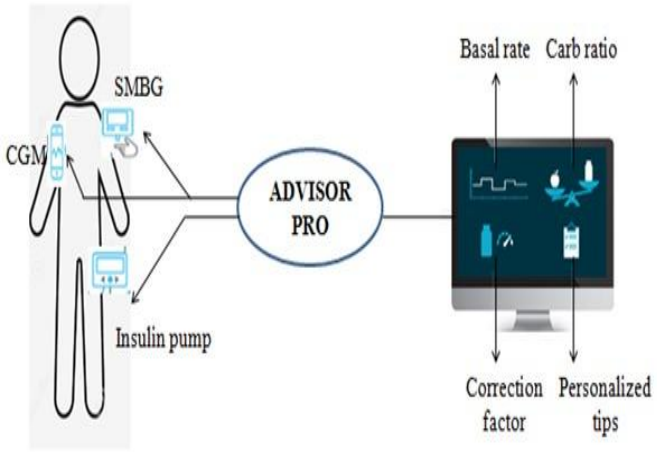

Figure 4: Functioning of DreaMed Advisor Pro [27].

Threats

- Hypoglycemia or hyperglycemia may result from incorrect or drastic changes in insulin dose recommendations.
- Inappropriate clinical decision-making may result from incorrect interpretation of the results.
- Inadequate knowledge on how to operate a technology properly could result in poor treatment choices.
- Data transfer security breach causes patient damage.
- Inappropriate treatment suggestions may be caused by data corruption [28].

Merits

- Simple and user-friendly
- The Advisor Pro will make it easier and faster for the physician to examine the insulin and glucose data, which could lead to more focused clinic sessions.
- Any clinic can use the Advisor to develop telemedicine services, provide patients with remote consultation, and frequently adjust titrations [27].
- Convenience to patients
- Providing an opportunity for the patients to undergo more frequent insulin pump adjustments [28].

INSTANCE:5 QUANTX

According to a significant new study in Radiology, artificial intelligence (AI) is a viable technique for breast cancer diagnosis in screening mammography programmes [29]. Computer-aided detection is one method that machine learning has been used in breast imaging (CAD) [30]. QuantX is a computer-aided diagnosis (CADx) software tool that helps radiologists evaluate and characterize breast abnormalities using MR image data [31]. It is the first computer-aided breast cancer diagnostic system in radiology to receive FDA clearance [32].

Functioning

A third-party acquisition equipment is used to get MR images.

When linked to a DICOM capable equipment, the QuantX device can load the images either manually or automatically.

To examine the photos with the QuantX software tools, users select and load the patient case. It is possible to see mammography or ultrasound pictures from the same patient with various MR sequences (T1, DCE, T2, DWI, etc.).

Based on a user-specified seed point, QuantX offers automated segmentation and analysis tools as well as image registration.

For usage as input in the QuantX analytics, users can manually choose a ROI from the MR image or get and accept a ROI automatically using a segmentation tool.

QuantX analytics show the volume of the chosen region as well as the QI Most Enhancing Curve and Average Enhancing Curve.

Based on the physical and enhancing properties of the region of interest, QuantX gives users the QI Score

Using an image atlas and histogram display format, the QuantX programme compares the QI score and its component element features to lesions with known ground truth (either biopsy-proven diagnosis or minimum one year follow-up negative scan for non-biopsied lesions).

A user familiar with the relevance of such data will be able to evaluate and analyze this additional data while diagnosing breast lesions.

The QI Score is used to organize an online atlas (reference database) that is made available to the user as the Similar Case Database; it is not a "probability of malignancy." Based on a machine learning algorithm trained on a subset of features

computed from segmented lesions, the QI score is generated. A combined feature score algorithm based on the literature that is thoroughly detailed in the submission is used to calculate the QI Score [31].

Threats

- Improper lesion(s) characterization leading to false positive results may cause inappropriate patient management with potential side effects such unwarranted extra diagnostic workup, such as biopsy, and/or additional medical imaging. Unnecessary therapy would be less likely but still possible.
- False negative results brought on by erroneous lesion(s) characterization might result in consequences including wrong diagnosis and a delay in the treatment of the disease.
- Inappropriate diagnostic information could be given to the user as a result of the device being used improperly to analyze images from an undesired patient population, on images collected with incompatible imaging hardware, or on images acquired using incompatible image acquisition parameters.
- Failure of the device could result in incomplete, delayed, or wrong results, which could also cause patient evaluation to be incorrect.

Merits

- This software offers users a systematic automated analysis of breast MRI data to help them characterize breast lesions as a concurrent read of breast MRI.
- When QuantX is employed during breast MRI interpretation as opposed to conventional MRI interpretation without the use of QuantX, reader performance in diagnosing breast cancer is shown to be marginally statistically significant better.
- When several abnormalities are present, QuantX can be used to evaluate each anomaly separately [31].
- Compared to existing technologies, the QuantX system for radiologists will let them diagnose breast cancer with a 20% higher degree of accuracy [32].
- QuantX boosted overall diagnostic improvement by 20% and raised the detection of malignant breast cancers by 39% [33].

INSTANCE:6 BONEVIEW

Fracture diagnosis on X-rays that is missed or delayed might have serious consequences for the patient. As the increase in imaging volumes continues to outstrip the recruitment of radiologists, the issue is only made worse by a lack of timely access to expert advice. According to a Radiology study, artificial intelligence (AI) is a useful tool for identifying fractures more quickly and accurately, which could help solve this issue [34].

BoneView is a revolutionary AI software that enables to diagnose fractures and traumatic injuries on X-rays, developed by the company named Gleamer [35]. It received FDA clearance and the CE mark class 2a certification in the European Union. With the help of BoneView, radiologists and non-radiologists were better able to identify fractures in many different anatomical regions, including the foot/ankle, knee/leg, hip/pelvis, hand/wrist, elbow/arm, shoulder/clavicle, rib cage, and thoracolumbar spine [36]. Fujifilm partners with Gleamer, uses advanced algorithms to detect and localize lesions on X-rays. The Bone View programme can be connected to Fujifilm X-ray equipment via a new image processing box called EX-Mobile [37].

Functioning

The X-ray is taken and automatically forwarded to a server on which the algorithm is installed. The software will analyze the pictures [38]. After analyzing, it gives 3 different pre-diagnosis labels on the images:

- POSITIVE when the confidence for the presence of a lesion is above 90%
- DOUBT when the confidence for the presence of a lesion is between 50% and 90%
- NEGATIVE otherwise [39].

In the vast majority of assessments, the algorithm is certain of a fracture. In that case, the software shows with a fixed line on the picture where the fracture is located. If there is a suspicion, the fracture will be marked by the software with a dotted line. After detecting a fracture, Gleamer's platform prioritizes that report and submits its findings to a radiologist for confirmation [38].

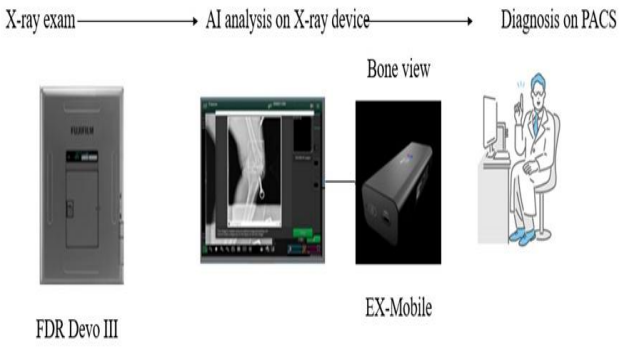

Figure 5: Functioning of Gleamer BoneView [37].

Threats

If the software is tampered with, it might lead to inaccurate diagnoses or even wrong or unneeded medical operations.

Merits

- A time-saving, trustworthy, and user-friendly tool [36].
- At the point of care, results are available in less than 30 seconds, giving medical personnel more assistance in managing patients [37].
- The algorithm is quick; it takes less than three minutes for BoneView to analyze a test [38].
- In a clinical investigation involving appendicular skeletal fractures, BoneView was demonstrated to increase fracture detection sensitivity and specificity while reducing false positives by 41.9% [40].
- Radiograph reading times were 6.3 seconds faster with AI assistance for each patient [41].

Conclusion

Medical device development processes that incorporate AI systems can forecast performance and lower failure rates. Under correctly crafted regulatory monitoring, AI will provide secure and useful software functionality that raises the standard of patient care. Users and manufacturers of medical

devices can benefit from new functionality, innovative approaches to managing doctor-patient relationships, and better healthcare delivery.

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Declaration of conflicting interests

The Author(s) declares(s) that there is no conflict of interest'.

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