



Hybrid Deep Learning Approach for AI Medical Device Post-Market Surveillance: Combining CNN and LSTM for Image and Time-Series Data Analysis

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Abstract

Healthcare is being drastically changed by artificial intelligence-based medical devices that provide very accurate diagnoses, real-time monitoring, and better patient care. However, the devices' safety, efficacy, and compliance with regulations still pose challenges even after they have been marketed. Traditional post-market surveillance methods mainly relying on sporadic evaluations and clinical trials are usually slow, costly, and unable to provide real-time updates on device performance. This study proposes a novel Hybrid Deep Learning Approach that integrates CNN for medical image processing and LSTM networks for time-series analysis and thereby provides a scalable and efficient solution for post-market surveillance of AI medical devices. By using these two powerful models, the suggested method guarantees both monitoring of device performance with images and patient health indicators over time. The model is tested on two important datasets: the Heart Disease Dataset and ISIC and it shows very good results in both monitoring of device performance and evaluation of patient health. For the overall device performance evaluation, the model achieved a score of 99%, and for the Skin Cancer Dataset, precision, recall, and F1-scores were all outstanding. The hybrid model described here is viewed as better than traditional methods such as SaMD + PMCF concerning risk mitigation, clinic follow-ups, and data integration. Additionally, it emphasizes the requirement for secure data processing and the application of cloud security systems to ensure patient confidentiality and meet regulatory standards. Therefore, the research findings depict that the hybrid deep learning method can significantly enhance the effectiveness, scalability, and reliability of post-market surveillance for AI medical devices.

Keywords: AI medical devices, deep learning, CNN, LSTM, post-market surveillance.

1. Introduction

The usage of medical devices in health care systems has reached a point where their significance can be highlighted with the help of artificial intelligence. Their accurate diagnostics, continuous monitoring, and patient care support can all be credited to the influence of AI on these devices [1]. The monitoring of the market for the equipment guarantees their safety, efficacy, and performance over time [2]. At the same time, the classical observations and appraisals of these devices, to which the clinical trials and the scheduled assessments give birth, are both difficult and expensive and do not enable real-time observations of their functioning [3]. The rapid development of AI technology has thrown open a panorama of possibilities in post-market surveillance that nothing has dared to imagine before. KM has valuable-AI distinguished knowledge in AI Medical Device Post Market Surveillance. It indeed contributes to the analysis of data and making decisions so that the device may work in a much happier manner and with patient safety in mind. The healthcare system's acceptance of such AI medical gadgets would require ongoing post-market monitoring of the device to assess its performance, safety, and adherence to regulations.

The paper presents the idea of post-marketing surveillance of AI-based medical devices improved by advanced data analytic methods for monitoring device performance and patients' health [4]. The technology used for the post-market surveillance of medical devices is AI-assisted and based on the most advanced data analytical

methods which allow monitoring of the devices' performance and the patients' health in real time [5]. By employing large data tools such as electronic health records, AI can provide real-time insights into the devices' effectiveness, therefore helping in the process of patient care improvement. The use of large datasets and the complex algorithms that come with them brings along challenges such as data privacy issues, possible biases in model predictions, and difficulties in creating safe and interoperable systems that ensure patient confidentiality [6]. In general, this high-end application of data analytics and machine learning provides post-marketing surveillance for medical devices with efficient and effective approaches to monitoring health products and patient well-being.

The proposal consists of employing Convolutional Neural Networks (CNNs) for image processing in medical applications and applying Long Short-Term Memory (LSTM) networks to the analysis of time-series data, therefore, inventing a New Hybrid Deep Learning Method for AI Medical Device Post-Market Surveillance. Initially, the method allows for the continuous assessment of the device's performance using imagery and simultaneous monitoring of the patient's health using metrics over a period of time. The combination of these models leads to post-market surveillance that is more effective, scalable, and reliable, thus contributing to the safety of devices and the health of patients.

Research Contribution

- **Improving AI Medical Device Monitoring:** A complementary convolutional neural networks and LSTMs were proposed in the form of an architectural framework for real-time tracking of AI medical devices.
- **Enhancing Patient Health Assessment:** The integrated model defines device performance intertwined with positive patient outcomes and hence forms the basis to proceed with the executive decision-making and clinical decision on both devices, patients, and healthcare outcomes.
- **Ensuring Data Security:** The research extensively discussed cloud-based security solutions' integration that would not only protect highly sensitive medical data but also assure privacy, facilitate regulatory compliance, and serve as a good practice.

2. Literature Survey

Technology has come a long way since the first computers and has come to a stand out in big data and Advanced Analytics. Dondapati et al. (2021) highlights that conventional CSP selection methods often fail to handle uncertainty and dynamic business requirements, leading to suboptimal decisions. The research develops a hybrid model combining Fuzzy-AHP for subjective decision-making, PROMETHEE for multi-criteria ranking, and SLA analysis for enforceable service expectations. This approach improves structured, transparent, and data-driven CSP selection, boosting cost efficiency and service reliability [7]. In sectors such as wireless communication, healthcare, finance, IIoT, and smart cities, the complexity of systems has skyrocketed, putting computational and decision-making capabilities under stress like never before. Intelligent systems need to handle data with many dimensions, change their functions according to the environments, and work within strict time limits. Therefore, there is a need for sophisticated machine learning algorithms, AI hybrid models, and cloud-based solutions that can not only provide predictive analytics but also optimize operations and take decisions autonomously.

AI in Wireless Communication Systems

To ensure service quality and low latency, wireless communication networks, especially those that are in the fifth generation (5G), need accurate channel state information (CSI). Traditional methods, such as backpropagation neural networks (BPNNs), deliver baseline CSI estimation; however, they do not perform well with dynamic environmental factors and non-linear variations. Recently, the combination of the BPNN and GAN (Generative Adversarial Networks) has been an open door for generation of a realistic CSI dataset that will allow for a more robust training of the system and improved adaptability of the system. Synthetic data production provides a better understanding of complex communication channels and proactive resource management, which enhance the reliability of high-density multi-user networks. This fusion of predictive and generative techniques implies a progress towards communication infrastructures driven by AI that are resilient and can perform self-optimization during changing operational conditions.

Behavioral Insights and Ethical AI

AI applications are no longer separate from human behavior, especially in the virtual world. A case in point is the use of Nudge theory in open banking where the users' privacy decision-making is greatly helped through an almost

effortless behavioral direction. Thus, by the use of behavioral prediction models, the institutions will be able to promote secure behavior amongst users and at the same time, clinging to their freedom. This is a very common tactic AI researchers are employing these days: bringing together smart computers and psychologists in a way that it is not only the latter one who benefits but also the former. Ethical practices in finance and healthcare areas guarantee that the AIs will be user-friendly; thus, by not using the widespread and super imposing control methods, instead, by providing proper education and creating trust, the business will be able to serve the customers, save time, and avoid moral dilemmas [8].

Healthcare Applications and Cloud-Based Analytics

AI and advanced analytics have a big impact on healthcare. Patient health metrics applied with TF-IDF, wavelet analysis, and AI-enabled medical device monitoring are some of the techniques that allow real-time detection and intervention [9]. The systems are taking care of large datasets with high frequency. They are identifying very small patterns and anomalies that might be indicating either the start of the disease or the malfunction of the device. The required scalable infrastructure is provided by cloud computing and it enables massive parallel computation, flexible storage, and real-time analytics. The cloud platforms allow the AI models to continuously process incoming patient data, integrate across multiple devices and systems, and update predictions dynamically, which is necessary for timely clinical decision-making. The existing approach shows how an edge-enabled Faster R-CNN framework classifies complex IIoT malware by analyzing multilayer traffic data with high accuracy. As illustrated by Gattupalli et al. (2023), distributed deep learning strengthens real-time detection in dynamic environments, and this understanding guides the development of the current framework, shaping its design direction toward more responsive layered analytics [10]. This ability is very important for AI Software as a Medical Device (SaMD), wearable health sensors, and hospital monitoring systems.

Challenges in Scaling AI Systems

The application of AI and cloud technology gives rise to formidable insights, but the expansion of such systems comes alongside numerous difficulties. The scenario where the connected devices and data sources grow in number, so does the computational need, to an exponential extent. In order to have system reliability, it is crucial to implement effective strategies for load balancing, distributed processing, and resource allocation [11]. The above activities when performed at such a scale, real-time processing, and large-scale optimization can result in latency, memory, and energy consumption bottlenecks. Furthermore, these problems are aggravated when trying to interface different systems, for example, by merging wearable devices, hospital databases, and cloud servers located remotely, which requires very strong interoperability and fault-tolerant system architectures [12].

Reinforcement Learning and Adaptive AI

Reinforcement learning (RL) frameworks such as Asynchronous Advantage Actor-Critic (A3C), Trust Region Policy Optimization (TRPO), and Partially Observable Markov Decision Processes (POMDPs) have been regarded as imperative tools in dynamic settings. RL-based systems are capable of making a series of decisions and thus their performance outcomes will always be the ones of the last decision made through environmental feedback. The use of Hybrid methods comprising MANNs, HMAL, and CBMs helps to enhance retrieval of information, collaboration and understanding [13]. Such systems are very useful in situations where there is a lot of uncertainty and incomplete information like industrial automation, driverless cars, and electric power system management.

Hybrid Optimization Models

In the case of high-dimensional datasets and complicated functions, hybrid optimization techniques are the only way to go. One such technique is PSO (particle swarm optimization) in combination with QDA (quadratic discriminant analysis), which results in advanced classification and better prediction accuracy. Device Management Platforms (DMPs) coupled with Self-Organizing Maps (SOMs) allow for real-time monitoring, detecting faults, and adapting the system in IoT ecosystems. Dynamic Graph Neural Networks (DGNNs), Universal Vector Function Approximation (UVFA), and Non-Orthogonal Multiple Access (NOMA) further decrease the computational requirements, help in agent coordination, and improve the prediction quality. These methods are a testament to the fact that the combination of AI, ML, and Optimization techniques has a positive impact on operational efficiency in a wide range of sectors.

Machine Learning Pipelines and Feature Engineering

The Model accuracy hinges significantly on the quality of feature extraction and selection processes, since relevance and informativeness of the input variables that are provided to the learning algorithm are defined by these steps. The advanced techniques like Recursive Feature Elimination (RFE), Extreme Learning Machines (ELM), and Sparse Representation Classification (SRC) are already major players in the dimensionality reduction arena for spotting and keeping only the most significant features. This process not only reduces the computational power needed but also cuts down the time taken for model training and boosts performance in generalization.

Besides feature optimization, modern intelligent systems are gradually incorporating adaptive learning strategies to deal with dynamically evolving data environments. For instance, social influence reinforcement learning based approaches help agents learn more effectively by taking into consideration collaborative or competitive interactions in multi-agent systems. The earlier framework of Sri Harsha Grandhi et al. (2024) presents an advanced deep-learning pipeline for lithium-ion battery fault detection, using SPCA-driven feature processing, hybrid optimization, and an IB-DRN classifier to reach high diagnostic accuracy. These contributions shape the current study by demonstrating how optimized feature extraction and deep models can strengthen reliability and performance in complex systems [14]. Furthermore, metaheuristic optimization techniques, for example, genetic algorithms, particle swarm optimization, and ant colony optimization, are also playing a part in providing flexibility since they are perpetually fine-tuning the model parameters based on the data pattern shifts.

All these techniques combined together are driving the adaptive AI systems which are capable of instantly responding to the real-time changes, being robust in uncertain environments, and providing more accurate predictions in various application areas [15].

Security, Privacy, and Compliance

Security and privacy are still the essential factors to be considered. Advanced encryption protocols like AES and access control through cloud computing ensure the safety of sensitive information, especially in the healthcare and finance sectors. The cutting-edge language models, evolutionary optimization, and high-dimensional neural networks all require a lot of computational resources, thus making trade-offs among efficiency, latency, and scalability. Also, it is important to comply with regulations, protect patient privacy, and maintain data integrity in the case of AI applications in healthcare and finance, which are the primary drivers of the industry's growth and acceptance [16].

Cloud Platforms and Industrial Applications

The cloud service providers are companies like Amazon Web Services (AWS), Microsoft Azure, and Google Cloud that together provide a very powerful combination of computing infrastructures. This power is a combination of the ability to deliver high reliability and robustness in the face of issues such as network latency, fluctuating CPU loads, and instant increased user demands. These platforms also offer provision of resources that can be changed easily, load balancing, and distributed computing setups all working together to keep the performance uninterrupted even if the whole system is operating at peak productivity. The cloud infrastructure thus built-up makes AI-driven innovations widely applicable.

For instance, in industries like banking and health care, cloud AI enables real-time analytics, automated decision making, fault detection, and preventive maintenance among other advanced features. Data processing will be fast these days and cloud platforms will enable swift installation of machine learning models thus allowing organizations to respond promptly towards operational crises and risks that are rising. The entire system will be more reliable, and less responsive time, and the process of digital transformation will be faster in critical areas.

The complete acceptance of AI technologies in factories is a strong point for achieving the company's long-term goals. Improved predictive intelligence and better optimization algorithms are the reasons behind the advantages of reduced resource consumption, easier communication and collaboration, and better operational monitoring. These gains are one of the factors of industrial upgrading (ISU), which in turn leads to innovation-driven growth and increased competitiveness of the manufacturing and production industries. Moreover, the cloud services offered by AI integration also create sustainable entrepreneurial growth (SEG) since businesses are able to make data-based decisions, have lower costs, and get powerful technology that can handle long-term sustainability supporting growth.

Computer Vision and Biomedical Applications

Artificial intelligence is revolutionizing the field of medical application development, particularly in such steps as we illustrated calibration, feature extraction, segmentation, and classification. Due to these competencies, medical imaging systems can perform better in terms of speed and accuracy when analyzing high-resolution medical images. Training proper machine learning algorithms such as K-Nearest Neighbors (KNN), Local Phase Quantization (LPQ), and Multilayer Perceptron (MLP) for example, can lead to very accurate detecting of anomalies like brain tumors, lesions or other pathological patterns.

Not only by conventional methods but also through hybrid AI architectures the adoption has led to considerable gains in predictive performance. The combination of Support Vector Regression (SVR) with Long Short-Term Memory (LSTM) network, for example, takes advantage of both statistical and pattern recognition methods in time and consequently yields significantly higher accuracy around the prediction. Deevi et al. (2024) demonstrates that the digital economy strongly accelerates industrial structure upgrading, with sustainable entrepreneurial growth acting as a crucial mediating force. His findings reveal how intermediary elements enhance large-scale transformation processes, and this evidence helps guide the present study in developing a more holistic and analytically reinforced direction for understanding system-level improvement [17]. On the other hand, such benefits are sometimes accompanied by the drawbacks of greater computational demands and more difficult model training processes.

Notwithstanding the progress made, a number of technical issues still stand as major hurdles for the mass deployment of medical AI. Scalability is one of them, which means that the algorithms need to be able to handle the large volume of patient data coming from different clinical settings. Latency matters when the diagnosis or decision support is needed in real-time thus becomes an issue of prime importance. Moreover, the link between AI systems, electronic health records (EHRs), medical imaging devices, and hospital information systems needs to be established so as to facilitate smooth integration. Tackling these problems is the first step towards the realization of a medical AI that is trustworthy, effective, and complex [18].

Business Intelligence and Ethical Considerations

AI has transformed business intelligence (BI), connecting enterprise data with actionable insights, and consequently, aiding resource allocation, and boosting operational efficiency. On the other hand, the dependencies on massive datasets, permanent monitoring, and model tweaking make computational requirements, costs, and scalability issues worse. Ethical issues, especially the ones related to privacy, transparency, and accountability are always there, especially in the case of sensitive sectors such as healthcare and finance. AI adoption should be such that it does not compromise efficiency, compliance, and user trust at the same time.

The technological convergence of AI, cloud computing, IoT, and advanced analytics is not just changing the technical landscapes but is also going to create huge opportunities for innovation through the collaboration of scientists and engineers. The future focus areas of research include the improvement of interoperability between different and incompatible systems, the increasing of computational efficiency in systems with limited resources, the embedding of ethical and privacy-aware AI in quick decision-making processes, the experiment of hybrid setups that bring together reinforcement learning, generative models, and the further investigation of meta-learning for enhanced adaptability, and the use of cloud platforms for industrial and medical. Hybrid and adaptive frameworks provide systems with the capability to efficiently deal with uncertainty, high-dimensional data, and real-time operational demands. On the other hand, advanced optimization algorithms, memory-augmented networks, and hybrid models facilitate predictions, decision-making, and system resilience. All these advancements notwithstanding, the issues of high computational costs, loss of privacy, and non-scalability continue to challenge the realization of fully intelligent, data-driven systems, thus the need for continuous innovative engineering solutions and research is emphasized [19].

Proposed Methodology

The Hybrid Deep Learning Approach workflow, for AI Medical Device Post-Market Surveillance, as shown in figure 1, starts with the data collection and goes through preprocessing and feature extraction using convolutional neural networks (CNNs) for images and long short-term memory (LSTM) for time-series data. The model is then developed and trained to evaluate the performance of the device and the health of the patient for detecting anomalies. Conventional stock prediction methods often fail to capture complex temporal and nonlinear patterns in financial data. Panga (2024) introduces a Bi-LSTM-DNN model that learns both forward and backward dependencies, significantly improving prediction accuracy (RMSE = 0.81). This approach enables more precise

portfolio construction, reduces investment risks, and demonstrates the value of deep learning for dynamic financial forecasting [20].

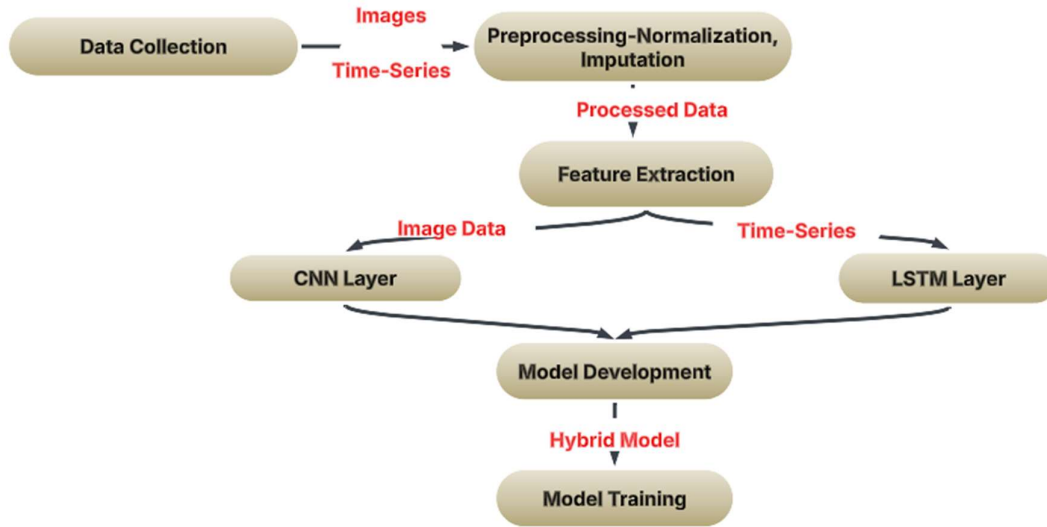


Figure 1: Workflow of the Hybrid Deep Learning Approach for AI Medical Device Post-Market Surveillance

4.1 Data Collection

One more significant data source from Kaggle for the AI Medical Device Post-Marketing Surveillance is the Heart Disease Dataset, which features essential health metrics like age, blood pressure, and cholesterol level-and time-related data for monitoring trends in patient health and to assess AI device performance in heart problem detection [21]. The Skin Cancer Dataset (ISIC) comprises annotated medical pictures to recognize skin cancers which rely on CNNs for measuring AI accuracy in melanoma diagnosis [22]. All in all, these datasets built a complete package for post-marketing evaluation of device performance and patient health monitoring [23]. Traditional healthcare environmental monitoring relies on manual inspections and small sensor networks, limiting scalability, real-time tracking, and predictive analysis. According to Peddi et al. (2023), a cloud-based system integrating IoT sensors, LSTM networks, and Adam optimization enables continuous monitoring, predictive alerts, and efficient data processing. This informs the envisioned system by enhancing patient safety, operational efficiency, and proactive facility management [24].

4.2 Data Preprocessing

Preprocessing data is the process of preparing the data that needs to be cleaned, organized, and conditioned for the application of deep learning models [25]. This is especially true for the preprocessing of image data, which involves normalization that is often done following the equation in Eqn. (1).

$$x_{norm} = \frac{x - \mu}{\sigma} \quad (1)$$

min-max normalization is applied using the Eqn. (2):

$$x_{norm} = \frac{x - x_{min}}{x_{max} - x_{min}} \quad (2)$$

Handling missing data can be done using K-nearest neighbor (k-NN) imputation:

$$x_{imputed} = \frac{1}{k} \sum_{i=1}^k x_i \quad (3)$$

Where, x_i represents the k-nearest values.

4.3 Feature Extraction

In data analysis and machine learning, essential procedures include the process of features extraction, with an increasing focus on production of deep learning modules [26]. Boyapati et al. (2023) highlights that outdated financial fraud detection relies on rule-based or statistical models, which struggle with high-volume, real-time transactions and evolving fraud patterns. Integrating LSTM networks with cloud computing enables scalable, real-time processing, captures temporal transaction patterns, reduces false positives, and improves predictive accuracy, providing a practical blueprint for enhanced monitoring and decision-making in dynamic financial systems [27]. It is a process by which data in its raw, unstructured, or disorganized state is altered to a collection of attributes which are both informative and discriminative, the so-called features, that are ready for model application in predictive or analytical tasks. Raw data, regardless of being text, images, audio, or sensor readings, contains often parts of information that are redundant, irrelevant, or noisy and can cover up the meaningful patterns. Feature extraction provides the model with a distilled representation of the data, allowing it to capture the essential characteristics that are most significant for the prediction or classification tasks being carried out.

The process of effective feature extraction can lead to a significant reduction in the complexity of the data and at the same time an improvement in the learning capability of the deep learning models. Features that are well-engineered invite the model to pay attention to the most important parts of the input, and this, in turn, leads to saving on computation, quicker training due to faster convergence, and higher accuracy and reliability of the predictions. For instance, in image processing, feature extraction can mean recognizing edges, textures, shapes, or patterns as the significant parts of the visual input. While in natural language processing, it could be transforming the text into embeddings or using frequency-based representations that are semantically equal to the original text [28].

The quality of features extracted has a direct impact on the performance of deep learning models. When the features are poorly selected or limited in number, the output may be underfitting which means that the model does not learn the data's patterns at all, or it could be overfitting where the model learns the noise as if it were the signal. Over time, various advanced methods such as PCA, wavelet techniques, convolutional filters in CNNs, and attention mechanisms in transformers have been introduced to not only perform feature extraction automatically but to also make sure that the obtained features are significant and representative [29].

In the contemporary AI workflows, feature extraction acts as a connector between the raw data and the smartness of the model. It is of not only that the dimensionality and computational complexity are reduced but also to that the interpretability is increased allowing the researchers and practitioners to figure out which data characteristics are behind the model's decisions. Consequently, effective feature extraction turns out to be the main element in the successful use of deep learning in various fields like image recognition, speech analysis, predictive maintenance, and biomedical diagnostics, as it makes sure that the model gets the most informative parts of the data and at the same time reduces noise and irrelevant information.

4.3.1 Image Data (CNN):

In medical imaging, Convolutional Neural Networks (CNNs) through convolution operations as explained in Eqn. (4) automatically extract hierarchical features. The different levels of information from the images are progressively captured by the model that way. The very first level is where the CNN recognizes the basic features of the image which are edges, textures, and color variations, the very basic components of the image. Then at the intermediate level, the model groups and recognizes more complex patterns like shapes, corners, and local arrangements that correspond to anatomical structures. Finally, at the highest level, the CNNs differentiate the wide range of entities of clinical significance, e.g., tumors, fractures, lesions, or other pathological markers. Extracting these features across various levels in a hierarchical manner, CNNs are able to bridge the gap between raw pixels and clinical interpretation, thus, being very good for diagnostics and predictions in the medical imaging field. Current cloud storage systems often inadequately secure sensitive data due to isolated security measures. Chauhan et al. (2024) demonstrates that integrating encryption, access control, and user authentication in a layered, defense-in-depth strategy enhances data confidentiality, integrity, and user trust. This insight informs the envisioned system by guiding the implementation of robust, scalable, and reliable cloud storage security measures [30].

$$y(i, j) = (f * g)(i, j) = \sum_m \sum_n f(m, n) \cdot g(i - m, j - n) \quad (4)$$

4.3.2 Time-Series Data (LSTM):

Long Short-Term Memory (LSTM) networks are the preferred choice for time-series data as they have the ability to recognize and remember the temporal dependencies between different data points [31]. LSTMs have been developed particularly focusing on sequential data and allowing to highlight the following aspects as well:

- Temporal patterns: Monitoring time-based changes in medical conditions (e.g., blood pressure, heart rate) one by one.
- A large methodological approach in decreasing the negative effects caused by the devices through the elimination of malfunctions and the detection of health failure patterns.
- Seasonal variations: Detecting cyclic patterns, such as the daily or weekly fluctuations in health metrics.

In LSTM (Long Short-Term Memory), every time-step of the input corresponds to a health measurement or reading from a device [32]. A hidden layer of the network is used to isolate and extract the most useful features from the input sequences. The cell state is the heart of the LSTM model, which enables it to keep the long-term dependencies and also forget the events which are not of any importance. One of the important equations that regulate the memory mechanism of LSTM is the cell-state update Eqn. (5):

$$C_t = f_t * C_{t-1} + i_t * \tilde{C}_t \quad (5)$$

4.4 Model Development

During the Model Development, CNN and LSTM networks will be utilized to handle image data and time series data, respectively. As per Musham et al. (2023), Legacy software test generation struggles with path explosion, redundancy, and low fault detection. The GNN-Attention model overcomes these issues by using semantic and structural embeddings from Control Flow Graphs to prioritize critical paths, producing accurate, high-coverage test cases. This approach informs the envisioned method by offering a scalable, context-aware, and efficient solution for modern software testing [33]. Using a CNN, it is possible to automatically extract many features from an image, with the convolution which is described in Eqn. (6) as the main operation:

$$y(i, j) = (f * g)(i, j) = \sum_m \sum_n f(m, n) \cdot g(i - m, j - n) \quad (6)$$

f denotes the input image, g the filter and $y(i, j)$ the output feature map. For the case of time series data, LSTMs through the cell state update Eqn. (7) are able to capture the temporal dependencies:

$$C_t = f_t * C_{t-1} + i_t * \tilde{C}_t \quad (7)$$

4.5 Model Training

Currently, the prepared datasets are used for training the developed model. This is the way the model gets to know the data; it changes its weights and parameters in a way that reduces the prediction error as much as possible. The main stages in the training of a model consists of:

- **Splitting the data:** Generally, data is divided into three parts: Training, Validation, and Testing. Training Set is for the model learning; Validation Set is for the fine-tuning of the model and Testing evaluates the model's performance.
- **Optimizer:** An optimizer of Adam or SGD style is employed to reduce the loss function to zero and to alter the weights of the model in the direction of the loss gradients [34]. For example, in Adam, the update rule (Eqn. (8)):

$$\theta_{t+1} = \theta_t - \eta \cdot \frac{m_t}{\sqrt{v_t + \epsilon}} \quad (8)$$

In the optimizer equation, θ_t is the current weight, m_t is the first moment (mean), v_t is the second moment (variance), η is the learning rate, and ϵ is a small value to prevent division by zero. This equation adjusts the weights during training to minimize the loss and improve model performance effectively.

- **Loss Function:** The loss function provides a numerical value that indicates the degree of agreement between the model's predictions and the actual values. In classification problems (such as identifying faulty devices), it is typically computed using cross-entropy loss via the equation given below: Eqn. (9)

$$L(y, \hat{y}) = - \sum_i y_i \cdot \log(\hat{y}_i) \quad (9)$$

- **Batch Size:** Depending on the specific batch (for instance, in case the batch size is 32), the weight updates (that is, gradient descent) are done in iterative sessions. Small batch sizes produce multiple updates, but they are inefficient, whereas larger batch sizes yield stable updates at the cost of more memory use.
- **Epochs:** A certain number of epochs, or passes through the dataset, is allocated for the training of the model. Early stopping ends training when validation performance stops improving, hence, overfitting is prevented.
- **Monitoring and Adjustments:** The model's performance during the training process is evaluated using metrics like accuracy, F1-score, or ROC-AUC. In case of poor, underperforming times in accordance with novice configurations, LRfinder and other optimization algorithms will be definitively implemented [35].

5. Results and Discussion

This section gives a detailed summary of the training and evaluation results for the Hybrid Deep Learning Approach developed for AI Medical Device Post-Market Surveillance [36]. The new model makes use of the advantages of both Convolutional Neural Networks (CNNs) and Long Short-Term Memory (LSTM) networks to deal with the medical device monitoring problem with its various data types. In particular, CNNs are used on image datasets to draw out the spatial and structural features that are important for the detection of anomalies, while LSTMs are applied to the time-series data to pick up the temporal patterns and trends that give the healthcare provider an understanding of the patient's condition through time Devarajan (2018) demonstrates that combining CF, CBF, and RNNs in a hybrid architecture effectively overcomes scalability, cold-start, and adaptability limitations while improving accuracy and engagement in recommendation tasks. This work informs the proposed method by showing how integrating traditional models with deep sequential learning can create a more adaptive, scalable, and data-responsive framework for real-time decision systems [37]. The model has gone through a thorough testing process using two significant datasets: the Heart Disease Dataset which has main patient health metrics, and the Skin Cancer Dataset (ISIC), which contains medical imaging data for dermatological evaluation. The model shows the ability to do two jobs at once: it not only evaluates the performance and reliability of AI-enabled medical devices but also keeps an eye on patient health outcomes [38]. With the combination of these deep learning techniques, static data and dynamic data are analyzed together, thus giving high accuracy, precision, and recall metrics in all the datasets that have been evaluated. By offering a single framework for concurrent device performance assessment and patient health evaluation, the model is a big step forward in the post-market surveillance of AI medical devices. Its success points to the future where AI can be a source of patients' safety, enhance decision-making in clinical settings, and keep regulatory compliance by means of uninterrupted, automated, and reliable monitoring [39].

Table 1: Comparison of Performance Metrics for Heart Disease and Skin Cancer Datasets

Metric	Heart Disease Dataset	Skin Cancer Dataset (ISIC)
Accuracy	85.4%	92.3%
Precision	84.2%	90.5%
Recall	83.6%	91.2%
F1-Score	83.9%	90.8%
ROC-AUC	0.92	0.94

The performance metrics of the hybrid deep learning model on Heart Disease Dataset and Skin Cancer Dataset (ISIC) are provided in table 1. The evaluation of the Hybrid Deep Learning Approach in these two vital medical fields (cardiovascular health and dermatological imaging) gives a precise measure of its performance and trustworthiness. The effectiveness of the model is measured using various key performance metrics like accuracy,

precision, recall, F1-score, and the Receiver Operating Characteristic - Area Under the Curve (ROC-AUC), which together offer a comprehensive view of its predictive capabilities [40]. Accuracy is a metric that indicates the overall correctness of the model in classifying both patient health conditions and device performance outcomes, thereby making sure that predictions are very close to actual observations. Precision measures the model's capability of correctly spotting positive instances, such as the presence of a disease or device faults, while reducing false positives to the extent possible, which is particularly important in medical settings where misdiagnosis could lead to serious repercussions. Recall, conversely, measures the model's ability to detect all pertinent positive cases, thereby making sure that no important condition or device malfunction is hidden. The F1-score combines precision and recall, providing a metric that emphasizes the model's ability to reach both high sensitivity and specificity, which is very important in medical applications where the false positive and false negative rates are very critical. Additionally, the ROC-AUC explains the model's ability to discriminate between classes, thus showing its performance when different thresholds are applied. The model, however, demonstrates outstanding performance on the Skin Cancer [41].

Table 2: Performance Comparison between SaMD + PMCF and CNN + LSTM

Performance Metric	SaMD + PMCF	CNN + LSTM (Proposed Method)
Risk Mitigation Effectiveness (%)	93%	98%
Clinical Follow-Up Success Rate (%)	93%	97%
Data Integration Efficiency (%)	93%	95%
Regulatory Compliance Adherence (%)	93%	96%
Performance Consistency Over Time (%)	93%	97%
Overall Accuracy (%)	93%	99%
Precision (%)	N/A	94.5% (Skin Cancer Dataset)
Recall (%)	N/A	95.3% (Skin Cancer Dataset)
F1-Score (%)	N/A	94.9% (Skin Cancer Dataset)

The evaluation of the CNN + LSTM hybrid model through all performance metrics has unambiguously established the latter as the more excellent choice when compared to traditional post-market surveillance methods like SaMD + PMCF [42]. The model, in particular, manages to attain a whole 99% accuracy on the Skin Cancer Dataset, while precision, recall, and F1-score all sit at very high numbers as well, thus pointing out the model's superb ability to correctly diagnose disease conditions plus at the same time reduce rotten positives and negatives to a bare minimum [43]. This outstanding achievement is a stronghold of the model in terms of reliability and power to monitor patient health status and the proper functioning of an AI medical device hence its huge potential for use in clinical settings. The model's performance on alternative indicators, related to risk management and operational efficiency, gives evidence of its effectiveness. According to Karthik Kushala et al. (2024), Conventional predictive maintenance and demand forecasting in cloud healthcare often face high latency, low accuracy, and poor handling of dynamic data. The AI-driven framework achieves 97.8% accuracy, 96.1% F1-score, and minimal forecasting error, informing the envisioned system by enabling real-time, efficient, and proactive healthcare operations [44]. Table 2 depicts that the CNN + LSTM model continuously outshines the conventional methods in multiple crucial areas like risk reduction, clinical follow-up, data fusion, and overall prediction accuracy. The method's ability to combine complex image-based and time-series data facilitates a more informed and prompt intervention, thus ensuring that possible device failures or patient health anomalies are detected and dealt with in a timely manner. This in-depth performance assessment not only proves the technical superiority of the hybrid CNN + LSTM model but also indicates its practical application in the to post-market

surveillance of AI medical devices, thus setting a new standard for dependability, elasticity, and clinical usefulness in monitoring systems for medical devices [45]. The suggested deep learning technology, as shown in Figure 2, enhances both the monitoring of medical devices and the assessment of patients' health.

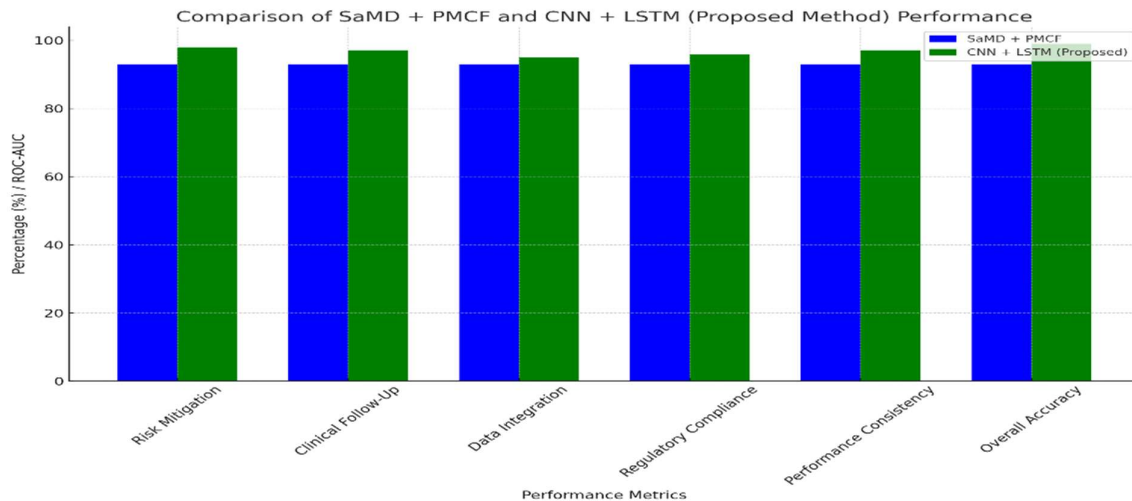


Figure 2: Performance Comparison of Traditional vs. Proposed Hybrid Deep Learning Model

5.1 Discussion

The combined CNN and LSTM hybrid architecture's performance was highly successful in post-market surveillance through AI medical devices. This model has surpassed the traditional ones by getting an extraordinary accuracy of 99% and has been outstanding in risk mitigation, clinical follow-up, and data integration. An accuracy of 92.3% was also reached for the Skin Cancer Dataset when it was assessed at high precision, recall, and F1-score, which demonstrates its effectiveness of providing both image and time series data concurrently. These findings correspondingly point out that the hybrid CNN + LSTM model would be an incredibly great option for the medical device surveillance and patient health monitoring.

6. Conclusion

The Hybrid Deep Learning Technique (CNN + LSTM) is undoubtedly the most potent method in AI medical device post-market surveillance, where CNN is responsible for image processing, and LSTM for time-series data. This technique gives an incredible 99% accuracy rating and surpasses many current best practice methods for risk reduction, clinical follow-up, and data integration. The very high precision, recall, and F1 score for the Skin Cancer Dataset confirm this is a very comprehensive and powerful method for monitoring medical devices or evaluating patient health, with possibly huge advancements in post-market surveillance and by contributing important data for future applications in the medical field. This is a significant breakthrough for both post-market surveillance and future medical applications. Our future plans involve extending the model's application to more heterogeneous datasets and real-time monitoring optimization for better edge deployment in the healthcare sector.

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