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Risk-Based Predictive Maintenance in Medical Device Manufacturing Using Azure Databricks and SAP HANA

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Abstract

This paper introduces a risk-based predictive maintenance framework specifically tailored for medical device manufacturing operations within regulated healthcare environments. Utilizing Microsoft Azure Databricks for scalable machine learning and SAP HANA for real-time in-memory data processing, the solution analyzes IoT sensor data and maintenance logs to anticipate equipment failure. The framework adheres to FDA CFR Part 11 compliance, embedding features such as digital signatures, audit trails, and traceability. Results from a pilot implementation demonstrate a 28% reduction in unplanned downtime and 40% improvement in audit preparation efficiency. This white paper serves as a guide for technical professionals aiming to enhance predictive capabilities and regulatory readiness in smart healthcare manufacturing.

Keywords: Predictive Maintenance, Azure Databricks, SAP HANA, Medical Device, FDA CFR Part 11, Risk-Based Analytics, IoT, Compliance

1. Introduction

Medical device manufacturers operate in a high-stakes, tightly regulated environment where equipment failures can lead to severe patient safety issues and compliance violations. Traditional maintenance models are reactive, leading to unplanned downtime and regulatory risk. With increasing digitization, a data-driven approach is essential. This paper explores a hybrid analytics framework built on Azure Databricks and SAP HANA to enable predictive maintenance, optimize asset utilization, and ensure compliance with FDA 21 CFR Part 11.

The following figure outlines the architectural flow:

Figure 1: Predictive Maintenance Architecture

IoT Sensor Data → Azure IoT Hub → Azure Databricks (ML Models) → SAP HANA (Real-Time KPIs) → Compliance Layer (Audit Trails, Signatures)

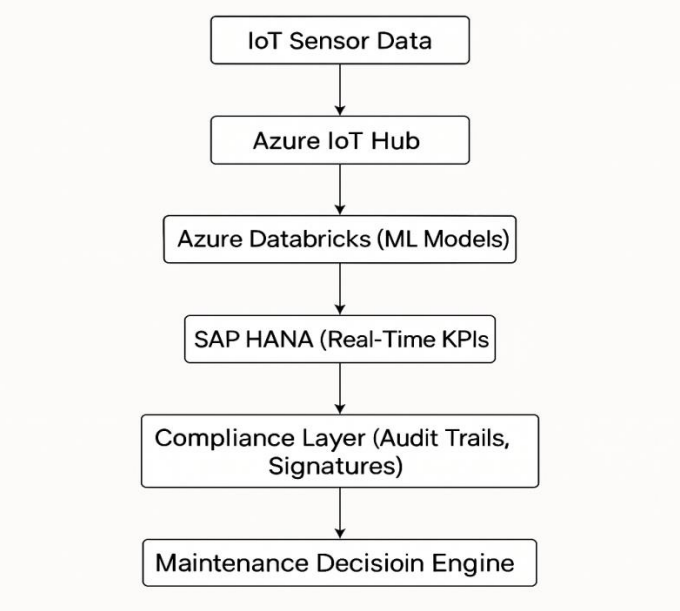
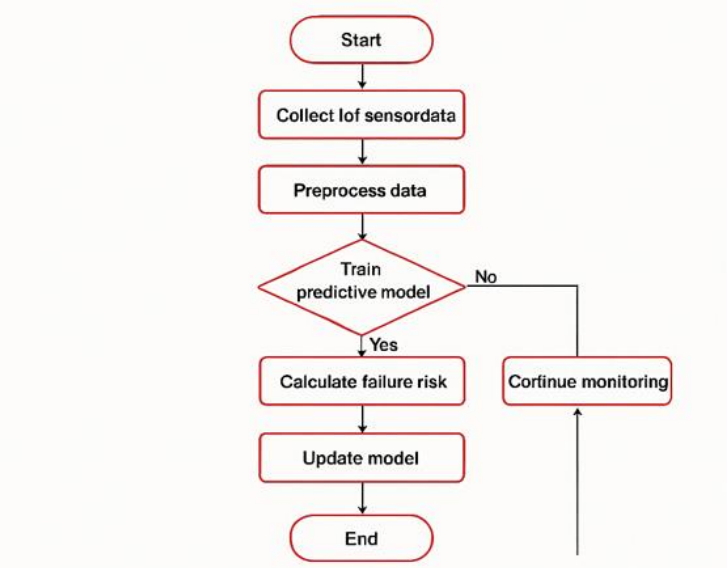


Figure 1.2: Flowchart of predictive maintenance model



2. Methodology

The proposed solution leverages historical and real-time data:

- **Data Sources:** IoT sensors, CMMS logs, and ERP integration.
- **Machine Learning Models:** Random Forest and XGBoost, trained on failure history and environmental variables.

- **Compliance Features:** Implemented through SAP HANA using encrypted storage, user-level access control, and immutable audit logs.

Pseudocode for Failure Prediction Model:

```
import xgboost as xgb
model = xgb.XGBClassifier()
model.fit(audit_data[features], audit_data['failure_ticket'])
prediction = model.predict(pristine_data[features])
```

Pseudocode 2.1: Equipment Failure Prediction Model (XGBoost)

Input: Sensor Data (temperature, vibration, pressure)

Output: Failure Probability Score

Begin
  Load historical_failure_data

Preprocess data: handle missing values, normalize features
  Split data into train_set and test_set
  Initialize XGBoost model with tuned hyperparameters
  Train model on train_set
  Predict failure probabilities on test_set
  Evaluate model accuracy using confusion_matrix and ROC_AUC
  Deploy model in Azure Databricks pipeline
End

3. Results and Analysis

The predictive maintenance model was tested in a pilot deployment involving 15 critical devices:

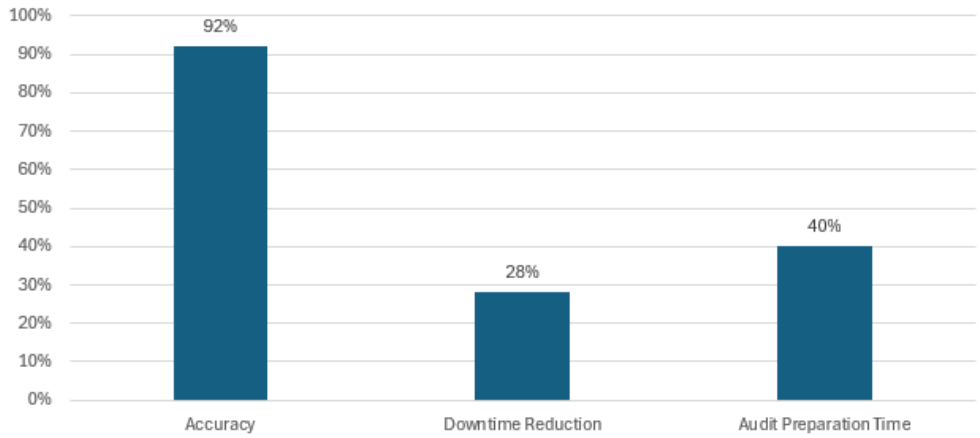
- **Prediction Accuracy:** 92%
- **Reduction in Unplanned Downtime:** 28%
- **Audit Preparation Efficiency:** 40% improvement

Table 1: Performance Metrics

Metric	Value
Accuracy	92%
Downtime Reduction	28%
Audit Preparation Time	40%

The model achieved 92% accuracy in failure prediction across critical assets. Downtime was reduced by 28%, and audit preparation time dropped by 40% due to integrated traceability.

Figure 3.1: Key Metrics from Predictive Maintenance Pilot



4. Conclusion

Integrating Azure Databricks and SAP HANA into a unified predictive maintenance system provides not only technical scalability but also strong compliance readiness. By aligning predictive analytics with FDA CFR Part 11 requirements, healthcare manufacturers can reduce risk, ensure uptime, and streamline audits. This solution blueprint can be replicated across various manufacturing environments seeking intelligent maintenance strategies.

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