MonitorMed: Non-Intrusive Performance Monitoring for FDA-Approved Medical AI

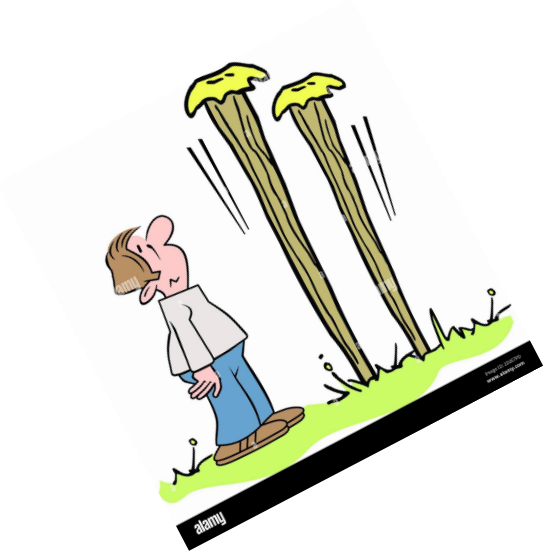
MonitorMed AI
(Jules, Cheng, Johnny, & Daniel)

950 AI medical devices have been approved .....

but how do we ensure they maintain performance without compromising their validation?

The Stakes are high:

- Patient Safety
- Model Reliability
- Regulatory Compliance



1. Current Challenges

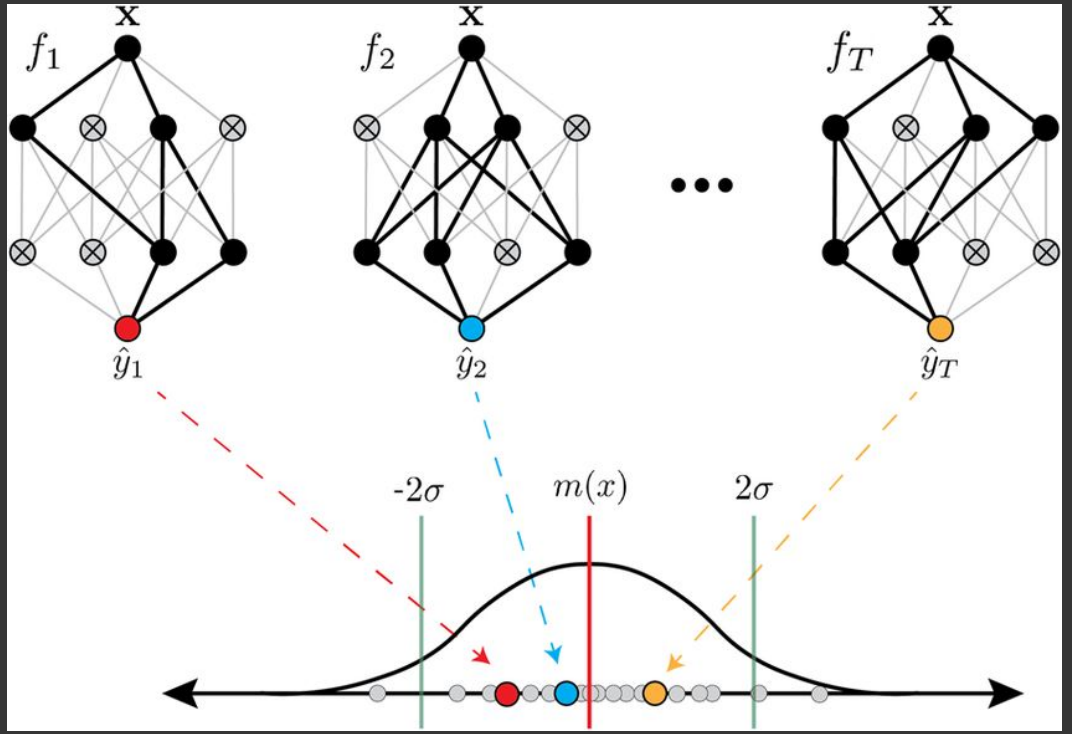
FDA-Approved AI Models:

- ➔ Can't modify validated models
- ➔ Black box predictions
- ➔ No uncertainty measures

Critical Issues:

- ➔ Performance degradation unknown
- ➔ No traditional MLOps possible
- ➔ Hard to detect unreliability

Our Technical Solution: Monte Carlo Dropout



Why! Monte Carlo Dropout.

Non-Intrusive Solution:

- No model modification
- Maintains FDA compliance
- Mathematically sound

How It Works:

- Enable dropout during inference
- Multiple predictions = Uncertainty estimate
- Statistical analysis for confidence


LIVE
DEMO

Analysis Results

Analysis Results

- Is It Pneumonia?: False
- Standard Deviation: 6.777259707450867
- Mean Probability: 58.16918611526489
- High Confidence: True

Patient History

Patient ID: P0000

Age: 62

Gender: Female

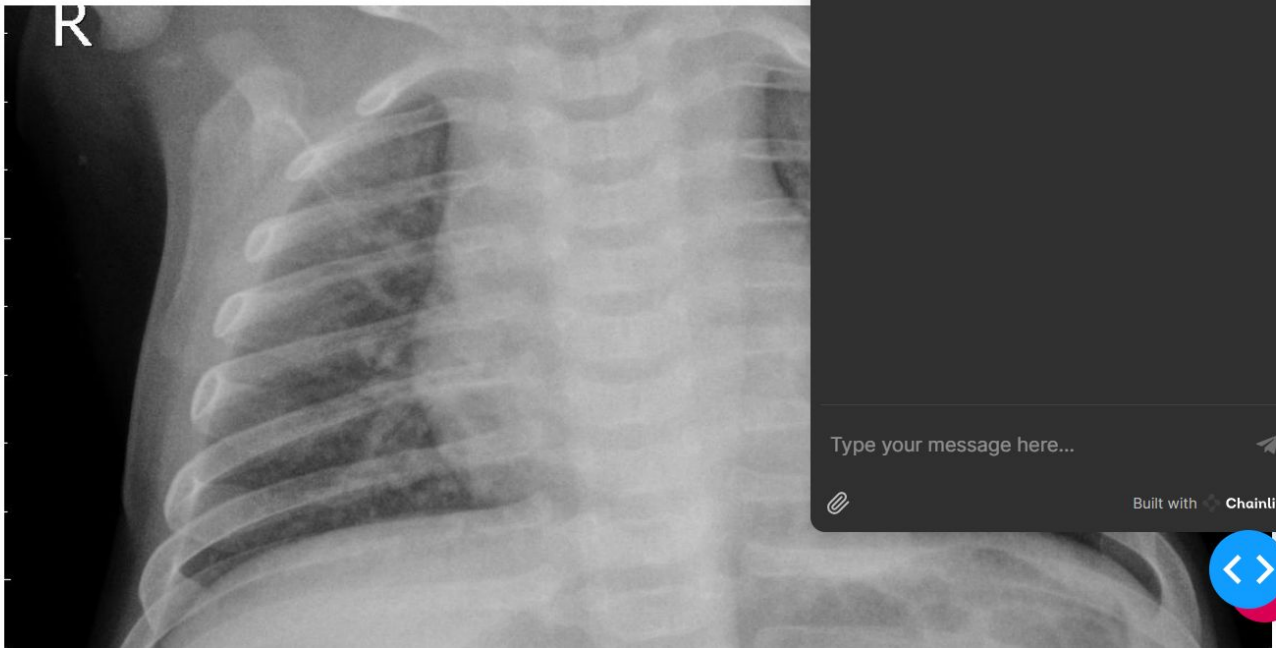
Vital Signs

- Temperature: 38.7°C
- Heart Rate: 119 bpm
- Respiratory Rate: 25 /min
- Blood Pressure: 131/90
- Oxygen Saturation: 88%

Symptoms

Drag and Drop or Select X-Ray Image

Supported formats: DICOM, PNG, JPEG



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PROBLEM → SOLUTION → IMPACT

Uncertainty in AI Decisions to Monte Carlo Analysis

92% accurate uncertainty estimation

Clear confidence bounds for each case

Immediate trust indicators

No Performance Monitoring to Non-Intrusive Tracking

Real-time degradation detection

Zero modification to FDA models

Early warning system

Disconnected Clinical Context to Integrated Risk Assessment

23% reduction in false positives

Automated case prioritization

Enhanced radiologist workflow

Primary Users

Radiology Departments

8,000+ radiology practices in US

Growing adoption of AI tools

Need for quality assurance

Hospital AI Safety Teams

Many hospitals are using AI systems

Responsible for patient safety

Need monitoring solutions

Medical Device Manufacturers

950+ FDA-approved AI devices

Need post-market surveillance

Regulatory compliance requirements

Before

Radiologist Uncertainty: **“Is this AI prediction reliable?"**

No Performance Monitoring: **"Is our model still accurate?"**

FDA Compliance Risk: **"How do we monitor without invalidating approval?"**

After

Clear Decision Support:

- Confidence Score: 92%
- Clinical Context Match: High
- Risk-Adjusted Assessment

Real-Time Monitoring:

- Trend Analysis
- Anomaly Detection
- Distribution Shift Alerts

Maintained Compliance:

- Non-intrusive monitoring
- No model modification
- Complete audit trail

THANKS

MonitorMed AI