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Executive Summary

> *The NHS spends hundreds of millions annually on diagnostic imaging for head and neck conditions, many of which could be identified faster, cheaper, and more accurately through an entirely different modality: sound.*

The Acoustic Diagnostic Mesh System (ADMS) is a flexible, wearable device that listens to the body as it moves. Using an array of MEMS microphones, inertial sensors, and real-time AI analysis, it captures the acoustic signatures of bones, joints, tendons, arteries, nerves, and fluids — precisely located in 3D space and tagged to the exact movement that produced them. A standard session takes 5–10 minutes. No radiation. No specialist at point of screening. No invasive procedure.

PRIMARY BENEFIT

First-line triage tool replacing unnecessary CT/MRI referrals at primary and secondary care level

FINANCIAL CASE

£2M–£8M annual saving per Trust; system-wide adoption could reclaim hundreds of millions per year

LONGER-TERM VALUE

Generates a living biomechanical atlas — a population-scale dataset for predictive and preventative medicine

Non-invasive diagnostics | Head & neck | AI-powered | Acoustic medicine | NHS triage

Cost reduction | MHRA Class II | Patient-driven innovation

01

Clinical Need & Problem Definition

The NHS faces sustained pressure across diagnostic pathways for musculoskeletal, neurological, and vascular conditions of the head and neck. A fundamental diagnostic gap exists: conditions that are dynamic — only presenting under specific movement — remain invisible to static imaging technologies.

Static Imaging Blindspot

CT and MRI are excellent for anatomical snapshots but systematically miss movement-triggered dysfunction. A cervical joint that misaligns only at 35° of rotation will appear entirely normal at rest.

Disproportionate Cost

A single MRI costs £350–£800; a CT £250–£500. Radiology departments are operating near or at capacity. Referrals for head and neck imaging have increased 23% over five years.

Subjective Symptom Reporting

Clinicians depend on patient-described symptoms to initiate diagnostic pathways. Vague or unusual presentations lead to repeated consultations, misclassification, and inappropriate mental health referrals.

Diagnostic Delay

Patients with hidden mechanical or vascular causes — ligament instability, arterial compression, CSF flow anomalies — can wait months or years for a correct diagnosis while harm accumulates.

System-Wide Backlog

Every unnecessary imaging referral displaces a case that genuinely requires it. Diagnostic backlog reduction is a stated NHS priority — and demands upstream triage innovation.

Hidden Vascular Events

Partial arterial blockages, vascular compression, and early vascular events in the head and neck are notoriously difficult to detect without specialised imaging — yet acoustic changes precede visible structural change.

NHS Context: The Diagnostic Economy

NHS England spends an estimated £1.3 billion annually on diagnostic imaging. Head and neck presentations account for a significant and growing proportion. Primary care GPs have limited first-line tools beyond clinical examination, creating a binary choice between watchful waiting and expensive imaging. The ADMS fills this gap.

02

Proposed Diagnostic Solution

The ADMS is grounded in a simple but profound physical principle: different biological structures transmit and reflect sound differently. This is already exploited in geophysics to map underground formations. Applied passively to the human head and neck, it becomes a precision diagnostic instrument.

The Acoustic Palette of the Human Body

SOUND SIGNATURE	TISSUE / STRUCTURE	CLINICAL INDICATOR	FREQUENCY RANGE
Crisp crack / crunch	Bone · Joint	Misalignment, degeneration, bone-on-bone contact	200–2,000 Hz
High-pitched snap / ping	Tendon · Ligament	Laxity, micro-tear, instability, stretch injury	500–5,000 Hz
Pulsating pop · pressure burst	Artery · Vessel	Stenosis, compression, partial blockage, vascular anomaly	20–500 Hz
Squish · squelch · low rumble	Fluid · Soft Tissue	CSF flow issues, oedema, soft tissue stress	10–200 Hz
Sustained vibration / thud	Muscle Fibre	Tone abnormalities, spasm, nerve-related tension	50–400 Hz

SOUND SIGNATURE	TISSUE / STRUCTURE	CLINICAL INDICATOR	FREQUENCY RANGE
Explosive pressure · detonation	Cranial · Intracranial	Intracranial pressure change, CSF event, vascular collapse	5–100 Hz

How the ADMS Works

Mesh Applied

Flexible MEMS array placed over head and neck — full movement retained

Patient Moves

Reproduces symptomatic movements — triggers real-world acoustic events

Sensors Capture

Microphones + IMU sensors log every sound with precise 3D location and motion tag

AI Analyses

Triangulates source, classifies tissue type, maps against anatomical model

Clinician Output

Visual map: structure, sound type, movement trigger — actionable triage guidance

Technology Precedent: This Is Not Speculative

> Geophysicists map underground cities using seismic sound waves. Smartphone IMUs already track motion at sub-degree precision. Medical ultrasound proves that sound reveals internal anatomy non-invasively. The ADMS combines these established domains in a novel configuration — passive acoustic listening, synchronised with motion data, analysed by AI trained on anatomical ground truth.

03

Clinical Safety, Risk & Governance

As a passive listening device that emits no energy into the body, the ADMS presents an inherently low direct-harm profile. However, governance and clinical safety frameworks must address diagnostic accuracy risks, device hygiene, and the consequences of false-negative outputs.

HIGH PRIORITY

False Negative: Missed Serious Pathology

ADMS must not be used to rule out serious conditions. It is a triage and supplementary tool — not a replacement for indicated imaging. Clinical protocols must mandate escalation thresholds.

HIGH PRIORITY

AI Misclassification

Machine learning outputs carry inherent uncertainty. Clinician override must always be possible. Confidence intervals and explainability requirements must be embedded in software design.

MED

Infection Control

Mesh components must meet IPC standards. Single-use liners or validated decontamination protocols required. Device materials must be compatible with standard NHS cleaning agents.

MED

Patient Harm During Movement Replication

Patients with acute or unstable cervical pathology should not reproduce provocative movements without clinical supervision. Contraindication screening protocol required before session.

LOW

Skin and Comfort

Mesh must be made from hypoallergenic materials. Session duration is short; prolonged pressure unlikely to cause harm. Paediatric and elderly variants may require modified sizing.

LOW

Electromagnetic Interference

Device must be tested for EMC compliance in clinical environments. Particular attention required in settings near MRI suites or active medical equipment.

Governance Framework

ADMS deployment must be governed by a Clinical Oversight Committee including radiologists, neurologists, ENT surgeons, and a patient safety lead. A formal Clinical Safety Case must be produced under DCB0129 / DCB0160 before any clinical deployment. Adverse event reporting must integrate with the NHS National Reporting and Learning System (NRLS).

04

Evidence Requirements

Before clinical commissioning, ADMS must demonstrate diagnostic accuracy against established reference standards. A phased evidence programme is proposed, moving from laboratory validation to large-scale comparative trials.

1

Acoustic Signature Laboratory Validation

Controlled cadaveric and phantom studies to characterise frequency-specific signatures for each tissue type. Establish repeatability and inter-device variability. Target: coefficient of variation <10% across 3 prototype units.

2

Healthy Volunteer Baseline Study (n=100)

Establish population-level acoustic baselines stratified by age, sex, BMI, and anatomical variation. Required to train AI classification models and define "normal" reference ranges for each tissue category.

3

Prospective Comparative Study vs. MRI/CT (n=500+)

Patients referred for head/neck imaging undergo ADMS assessment prior to scan. ADMS outputs compared against confirmed radiological diagnoses. Primary endpoints: sensitivity ≥85%, specificity ≥80% for major diagnostic categories. Pre-registered on ISRCTN.

4

Inter-Rater Reliability Study

Multiple trained clinicians interpret identical ADMS outputs independently. Agreement coefficient (Cohen's κ) target >0.75. Informs standardisation of output interpretation and training requirements.

5

Longitudinal Monitoring Study (12 months)

Patients with known conditions (e.g., cervical spondylosis, TMJ dysfunction, vascular stenosis) assessed monthly. Demonstrates ADMS utility for disease progression monitoring and treatment response tracking.

6

Health Technology Assessment (NICE)

Full HTA submission to NICE for Medical Technologies guidance or Diagnostics Guidance. Requires completed trial data, cost-effectiveness modelling (ICER per QALY), and submission through the Medical Technologies Evaluation Programme (MTEP).

Minimum Acceptable Performance Thresholds

For safe first-line triage use: sensitivity ≥85% (to protect against false negatives); specificity ≥75% (to prevent unnecessary escalation); negative predictive value ≥90% for serious pathology categories (vascular, neurological). These thresholds must be demonstrated across demographic subgroups including age >65, high BMI, and paediatric populations.

05

Integration into NHS Workflow

The ADMS is designed as a first-line triage tool, not a replacement for specialist assessment or confirmed imaging. Integration is envisioned across three care settings, with clear escalation pathways.

Primary Care (GP / PCN)

ADMS deployed as a rapid first-line tool when a patient presents with unexplained head or neck symptoms. Replaces the binary choice between watchful waiting and immediate imaging referral. GP receives structured output; makes evidence-based triage decision.

Secondary Care (Outpatient / A&E)

ENT, neurology, and vascular surgery outpatient clinics use ADMS to characterise presentations before ordering specialist imaging. In A&E, ADMS assists rapid triage of neck and head trauma presentations where dynamic testing is feasible.

Pathology & Radiology Interface

ADMS outputs are structured and exportable as HL7 FHIR-compatible data. Radiology referrals include ADMS findings as pre-test context, improving request quality and reducing inappropriate referrals. ADMS does not replace but informs the radiologist.

Digital Systems Integration

Full integration with NHS Spine, EMIS, SystmOne, and Lorenzo EPR systems. ADMS output stored as a structured clinical note, accessible across care settings. Supports NHS data standards: SNOMED CT coding, NHS number linkage, and Information Governance Toolkit compliance.

Clinical Pathway: ADMS-Guided Triage

Patient Presents

GP / ENT / ED — head or neck complaint

ADMS Session

5–10 min. Structured acoustic-motion map generated

Low Complexity

Discharge / physio / conservative management

Moderate Complexity

Targeted specialist referral — informed by ADMS output

High Risk Flags

Immediate imaging / urgent pathway — clinician-confirmed

06

Regulatory Pathway

The ADMS is classified as an active medical device under UK Medical Devices Regulations 2002 (as amended). As a diagnostic device that does not emit energy into the body but processes and presents diagnostic information, it is expected to qualify as a Class IIa device under UKCA marking requirements — requiring involvement of a UK Approved Body.

UKCA / MHRA Regulatory Route

Four-stage pathway from concept to clinical deployment

01

MHRA Innovation Office

Pre-submission meeting to confirm classification and identify applicable standards (IEC 62304, IEC 60601-1, ISO 14971)

02

Technical Documentation

Compile clinical evaluation, risk management file, QMS (ISO 13485), software lifecycle documentation

03

UK Approved Body Review

Conformity assessment by MHRA-designated Approved Body; quality system audit; technical file review

04

UKCA Mark & UDI Registration

UKCA mark affixed; device registered on MHRA device registration system; post-market surveillance plan activated

Software as a Medical Device (SaMD)

The AI analysis component of ADMS constitutes Software as a Medical Device and will require separate MHRA/UKCA assessment under the IMDRF SaMD framework. The AI model must be validated as a locked algorithm (or with a defined change management procedure if adaptive)

> and must provide explainable outputs that clinicians can interrogate and override. NICE Evidence Standards Framework for Digital Health Technologies (Tier D) will apply.

07

Data Protection & GDPR Compliance

ADMS generates novel biometric data — acoustic signatures of internal anatomy — which constitutes special category health data under UK GDPR Article 9. A comprehensive data governance framework is a prerequisite for any clinical deployment.

Lawful Basis

Processing under Article 9(2)(h) — medical diagnosis and treatment — with explicit patient consent. Research use governed by separate ethics approval and data sharing agreements.

Data Architecture

Acoustic data stored pseudonymously on NHS-approved cloud infrastructure (NHS Digital / NHSX compliant). Raw audio never transmitted externally; only processed feature vectors exported for AI training.

DPIA Requirement

A Data Protection Impact Assessment is mandatory before deployment. Novel biometric data type means high-risk processing classification under ICO guidance. DPO sign-off required at each Trust.

NHS DSPT Compliance

Device and associated software must meet NHS Data Security and Protection Toolkit standards. Annual certification required for any system accessing NHS patient data or networks.

Research Data Atlas

Anonymised acoustic data contributed to a population-level biomechanics atlas must be governed by an NHS Research Ethics Committee approval, a Data Access Agreement, and a published data governance policy.

Retention & Deletion

Clinical data retained per NHS Records Management Code of Practice (8 years post-episode). Research atlas data governed by separate retention schedule. Patient right to erasure applied where technically feasible.