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Clinical Rationale and Protocol for AI-Assisted Digital Auscultation in Hospitalised Patients: The STETHO-HUS Phase 1 Study

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Abstract

Background*: Conventional acoustic auscultation is limited by subjectivity and marked inter-observer variability. Valvular heart disease is missed by standard auscultation in more than half of cases, and in the United Kingdom over 70% of heart failure diagnoses are made only after an unplanned hospital admission despite prior consultations at which symptoms were already present [1-3]. Digital stethoscopes coupled to artificial-intelligence (AI) classification algorithms have been proposed as a means of narrowing this diagnostic gap, but prospective clinical evidence in hospitalised internal medicine and cardiology populations remains limited.*

Methods: *We describe the clinical rationale, design, and protocol of the Phase 1 investigational clinical validation of an AI-assisted digital stethoscope (STETHO-HUS), conducted within the Service de Médecine Interne and Département de Cardiologie of the Hôpitaux Universitaires de Strasbourg (HUS). Consecutive adult inpatients and outpatients undergo standardised auscultation with the investigational device, benchmarked against transthoracic echocardiography and high-resolution CT/pulmonary function testing as reference standards, under an approved Comité de Protection des Personnes (CPP) protocol.*

Findings: *Enrolment is ongoing; no diagnostic accuracy data are yet available. An interim analysis is planned after 100 complete cases.*

Interpretation: *This report should be read as a description of the clinical rationale and study protocol for an investigational device. Diagnostic accuracy, clinical utility, and impact on patient management remain to be established through the ongoing, adequately powered validation study.*

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Introduction

The acoustic stethoscope, introduced by Laennec in 1819, remains the global standard for bedside cardiopulmonary examination, yet its diagnostic performance is constrained by subjectivity and substantial inter- and intra-observer variability [4]. Auscultatory skill is heterogeneous across clinicians and, in the case of valvular heart disease, standard auscultation fails to detect more than half of cases subsequently confirmed by echocardiography [1]. Heart failure follows a similar pattern of late recognition: in the United Kingdom, over 70% of incident diagnoses are made only after an unplanned hospital admission, despite antecedent consultations at which relevant symptoms were already present [2]. Both examples illustrate a recurring clinical problem — disease that is, in principle, detectable at the bedside but is frequently missed until a later, more costly, and more morbid stage of presentation.

Artificial-intelligence (AI)-assisted digital stethoscopes have emerged as a candidate solution to this gap. By recording and quantitatively analysing heart and lung sounds, these devices aim to support — rather than replace — clinical judgement, flagging findings that may otherwise be under-recognised [3]. Evidence for this approach is accumulating: a deep-learning algorithm applied to a commercial digital stethoscope platform achieved a sensitivity of 76.3% and specificity of 91.4% for murmur detection in a prospective cohort of 962 patients against echocardiographic ground truth, and a UK multicentre point-of-care screening study using an ECG-enabled digital stethoscope demonstrated feasibility for identifying reduced left ventricular ejection fraction in routine practice [5,6]. A recent large-scale primary-care implementation trial reported that consistent use of an AI-enabled stethoscope increased detection of heart failure, atrial fibrillation, and valvular heart disease relative to usual care, while also showing that technical accuracy alone did not guarantee sustained clinical adoption [7].

The Hôpitaux Universitaires de Strasbourg (HUS) have an established programme in digital auscultation research. Building on this experience, we initiated a prospective, single-centre clinical validation programme — STETHO-HUS — to evaluate an investigational AI-assisted digital stethoscope against reference-standard imaging and functional testing in hospitalised internal medicine and cardiology patients. This report describes the clinical rationale, protocol, and regulatory framework of the Phase 1 investigational study. It deliberately omits the engineering and signal-processing architecture of the device, which is described separately in a companion technical report, and instead focuses on the clinical question the study is designed to answer: whether AI-assisted auscultation can improve detection of cardiac and pulmonary pathology in hospitalised patients.

Methods

Study Design and Setting

STETHO-HUS Phase 1 is a prospective, single-centre, single-arm observational clinical validation study conducted within the Service de Médecine Interne and Département de Cardiologie of the Hôpitaux Universitaires de Strasbourg, France. The study is conducted under an approved Comité de Protection des Personnes (CPP) protocol in accordance with the French Loi Jardé (Law No. 2012-300), with data handling compliant with CNIL requirements and the ethical principles of the Declaration of Helsinki [8]. The investigational device is classified as a Class IIa active medical device under the EU Medical Device Regulation (2017/745); its embedded AI classification module falls within the high-risk category of the EU AI Act (Regulation (EU) 2024/1689) by virtue of its status as a component of a Notified-Body-assessed Class IIa device. Clinical use during this investigational phase is restricted to the approved protocol described here.

Participants

Consecutive adult inpatients and outpatients (≥18 years) of the Service de Médecine Interne and Département de

Cardiologie are eligible for enrolment, following written informed consent. Patients unable to provide informed consent or with a clinical condition precluding standardised examination are not enrolled.

Procedures

Each participant undergoes a standardised ten-site auscultation examination (four cardiac and six pulmonary sites) using the investigational AI-assisted digital stethoscope, performed in addition to — and independently of — usual clinical care. The examining clinician is blinded to the device's AI-derived confidence output at the time of examination. Reference-standard assessment is obtained independently of the device output: transthoracic echocardiography (TTE) within 72 hours, interpreted by a senior cardiologist blinded to the AI output, for cardiac findings; and high-resolution CT and/or pulmonary function testing, interpreted by a senior pulmonologist blinded to the AI output, for pulmonary findings. Moderate or greater valvulopathy on TTE, and interstitial lung disease, COPD (GOLD ≥2), or heart-failure-pattern crackles/wheezes on the pulmonary reference standard, define ground-truth positive status.

Outcomes

The primary endpoints are: (1) sensitivity and specificity of the device's binary classification output, with 95% confidence intervals; (2) the area under the receiver operating characteristic curve (AUROC) of the continuous AI confidence score as a discriminator of confirmed pathology; and (3) agreement between the AI output and blinded expert reference assessment (Cohen's κ). Pre-specified secondary endpoints include performance stratified by auscultation site and pathology type (cardiac versus pulmonary), performance across AI confidence strata, the false-negative rate within the high-confidence subgroup, and the proportion of recordings meeting a pre-defined signal-quality threshold on first acquisition.

Sample Size

Assuming an anticipated sensitivity and specificity of at least 80%, a prevalence of clinically significant pathology of 40%, a two-sided α of 0.05, and 80% power, the study requires at least 97 patients with confirmed pathology and 146 without (n=243 evaluable) to estimate sensitivity and specificity to within ±8 percentage points. Allowing for an estimated 15% attrition due to incomplete reference-standard data, the target enrolment is 285 patients.

Statistical Analysis

Sensitivity, specificity, positive and negative predictive values, and AUROC will be calculated with 95% confidence intervals (Wilson method for proportions). Inter-observer and AI–expert agreement will be assessed using Cohen's κ, interpreted as: <0.20 poor, 0.21–0.40 fair, 0.41–0.60 moderate, 0.61–0.80 good, 0.81–1.00 excellent. All pre-specified endpoints will be analysed on the evaluable population (all participants completing both the index examination and reference-standard assessment), with no post-hoc threshold adjustment. An interim analysis is planned after 100 complete cases.

Current Status

Enrolment is ongoing under the approved CPP protocol. As of the current report, no diagnostic accuracy data are available; the findings and interpretation sections of this report will be completed once Phase 1 enrolment and reference-standard adjudication are complete.

Table 1: STETHO-HUS Phase 1 clinical validation protocol.

Parameter	Specification
Study design	Prospective, single-centre, single-arm observational; examining clinician blinded to AI confidence output
Site	Service de Médecine Interne et Département de Cardiologie, HUS, France

Population	Adults ≥18 years, inpatients and outpatients, consecutively enrolled, written informed consent (CPP approved)
Reference standard (cardiac)	TTE within 72 h; senior cardiologist blinded to AI output; ≥moderate valvulopathy = ground-truth positive
Reference standard (pulmonary)	HRCT and/or PFT; senior pulmonologist blinded to AI output; ILD, COPD (GOLD ≥2), or heart-failure crackles/wheezes = ground-truth positive
Primary endpoints	Sensitivity, specificity, AUROC of AI classifier; Cohen's κ vs blinded expert
Target performance	Sensitivity ≥80%, specificity ≥80%, AUROC ≥0.80; κ ≥0.60 (substantial agreement)
Target enrolment	n=285 (n=243 evaluable; α=0.05, power=80%, 15% dropout allowance)
Regulatory framework	Loi Jardé; CPP approved; CNIL compliant; Declaration of Helsinki; MDR Annex X
Status	Enrolment ongoing; interim analysis planned after 100 complete cases; no results yet available

Discussion

STETHO-HUS addresses a well-documented clinical gap: the limited sensitivity of unassisted acoustic auscultation for valvular and pulmonary pathology, and the frequent late recognition of heart failure at the point of unplanned hospital admission [9]. The clinical premise for AI-assisted auscultation is supported by external benchmark evidence rather than by data generated within the present protocol, which remains ongoing. In a prospective cohort of 962 patients, a deep-learning murmur-detection algorithm applied to digital stethoscope recordings achieved 76.3% sensitivity and 91.4% specificity against echocardiographic ground truth, rising to 90.0% sensitivity when trivial grade-1 murmurs were excluded [5]. A subsequent point-of-care screening study using an AI-augmented stethoscope for valvular heart disease reported a sensitivity of 92.3% versus 46.2% for conventional auscultation, at the cost of reduced specificity (86.9% versus 95.6%), identifying twice as many previously undiagnosed cases [10]. A UK national implementation trial similarly found that consistent device use increased detection of heart failure, atrial fibrillation, and valvular disease in primary care, but that technical accuracy alone did not translate into a measurable population-level effect on intention-to-treat heart failure diagnosis rates — approximately 40% of participating practices had discontinued device use by 12 months, citing workload and lack of electronic health record integration as principal barriers [7, 11-14].

These findings frame both the opportunity and the constraints relevant to STETHO-HUS. The sensitivity gains reported for AI-assisted auscultation are frequently accompanied by reduced specificity, implying a trade-off between earlier detection and an increased downstream burden of confirmatory investigation — a trade-off that the pre-specified secondary endpoints of this protocol (performance across confidence strata, false-negative rate in the high-confidence subgroup) are designed to characterise rather than assume. Equally, the implementation experience from large-scale primary-care deployment indicates that diagnostic accuracy is a necessary but not sufficient condition for clinical impact; workflow integration and sustained use are independent determinants of effectiveness that a single-centre investigational study cannot, by itself, resolve.

Within the hospital setting, an AI-assisted digital stethoscope is best conceived as a screening adjunct to — rather than a replacement for — clinical auscultation, providing a second, quantitative layer of support for a skill that is known to be heterogeneous across clinicians and increasingly time-constrained in busy inpatient services.[3] Its clinical value will ultimately depend on whether the sensitivity and specificity achieved in this hospitalised population approach the benchmark figures reported in the comparator literature cited above, and on whether AI-flagged findings translate into earlier, appropriately targeted confirmatory investigation rather

than indiscriminate additional testing.

Limitations

This report has several limitations that should inform its interpretation. First, and most importantly, no diagnostic accuracy data are yet available: Phase 1 enrolment is ongoing, and all sensitivity, specificity, and AUROC figures cited from the literature are external benchmark comparators, not results of the STETHO-HUS protocol itself. Second, the study is single-centre and conducted at a tertiary academic hospital, which may limit generalisability to primary care or community settings with different disease prevalence and clinician experience. Third, reference-standard interpretation, while blinded to AI output, is performed by senior specialists, which may not reflect performance benchmarks achievable with less experienced examiners. Fourth, the study does not evaluate downstream clinical outcomes (subsequent management change, hospitalisation, mortality); diagnostic accuracy does not by itself establish clinical utility, and this will require dedicated outcome-focused research once Phase 1 is complete.

Conclusion

STETHO-HUS is a prospective, adequately powered clinical validation programme designed to determine whether an AI-assisted digital stethoscope improves detection of cardiac and pulmonary pathology in hospitalised internal medicine and cardiology patients, benchmarked against echocardiography and pulmonary functional imaging. Consistent with the current investigational status of the device, this report presents the clinical rationale, protocol, and regulatory framework of the study rather than diagnostic performance data, which remain to be established through ongoing enrolment and blinded reference-standard adjudication. Findings will be reported once the pre-specified interim and final analyses are complete.

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Contributors

EA and CB conceived and coordinated the STETHO-HUS clinical programme and drafted this manuscript. CB, ST, NLV, BG and AHEH contributed to protocol design and critical revision of the manuscript. All authors approved the final version.

Declaration of Interests

The authors declare no competing interests relevant to this work.

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