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A contactless optical stethoscope for murmur detection compared to standard auscultation and using echocardiography as the clinical reference

Submission date 30/10/2025	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol
Registration date 26/11/2025	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 23/01/2026	**Condition category** Circulatory System	[_] Individual participant data [X] Record updated in last year

Plain English summary of protocol

Background and study aims
Doctors often listen to heart sounds using a stethoscope to check for problems like heart valve disease. These sounds, called heart murmurs, can sometimes be hard to interpret. A new device called LightScope uses laser technology to listen to the heart without touching the body. The aim of this study is to evaluate how well LightScope supports clinicians in detecting heart murmurs, compared with standard stethoscope auscultation, using transthoracic echocardiography as the clinical reference standard.

Who can participate?
Adults aged 18 years or older may take part in this study. This includes:
a) People with known or suspected valvular heart disease,
b) Individuals with atrial fibrillation, and
c) Participants with normal echocardiographic findings(control participants).

What does the study involve?
Participants will attend a single study visit. During this visit:
a) A trained clinician will listen to the participant's heart using a standard acoustic stethoscope.
b) The LightScope device will then record heart sounds in a fully contactless manner from specific areas of the chest and neck.
c) The heart sound recordings will be interpreted by clinicians and compared with the participant's existing echocardiogram results.

What are the possible benefits and risks of participating?
There are no direct health benefits for participants, but the study may help improve future heart diagnosis tools. The risks are very low. LightScope is safe, non-invasive, and does not use harmful radiation. The only small risk is if safety rules are not followed, the laser could accidentally shine into the eye.

Where is the study run from?
LightHearted AI Health Limited (UK)

When is the study starting and how long is it expected to run for?
March 2026 to July 2026

Who is funding the study?
LightHearted AI Health Limited (UK)

Who is the main contact?
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Contact information

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Public, Scientific, Principal investigator

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Additional identifiers

Integrated Research Application System (IRAS)
364868

Protocol serial number
CIP-LS-001

Study information

Scientific Title
Clinical validation of LightScope: a contactless optical stethoscope for murmur detection compared to standard auscultation and using echocardiography as the clinical reference

Study objectives
The purpose of this clinical investigation is to evaluate the diagnostic performance of the LightScope device, a non-contact optical stethoscope, in detecting cardiac murmurs associated with valvular heart disease. The primary objective is to determine the sensitivity and specificity of murmur detection using LightScope phonocardiograms, as interpreted by clinicians, compared to standard auscultation, with transthoracic echocardiography serving as the reference standard. The secondary objectives of the study shall include: assessing inter-rater agreement among clinicians, evaluating the repeatability and signal quality of LightScope recordings, and assessing repeatability of signal acquisition across user settings. The Exploratory endpoints aim to further characterize device performance based on subgroup analyses by valve lesion type, patient demographics (ethnicity, BMI, skin tone), and clinician experience; evaluation of usability metrics (time-to-use, error rates, ease-of-use, qualitative feedback); and a comparative assessment with the Eko Core500 device in a subset of participants. The study aims to generate clinical evidence to support regulatory approval and CE marking of the device under the EU Medical Device Regulation (MDR).

Ethics approval required
Ethics approval required

Ethics approval(s)
Submitted 09/01/2026, South East Scotland Research Ethics Committee 2 (South East Scotland Research Ethics Service Waverley Gate 2-4 Waterloo Place, Edinburgh, EH1 3EG, United Kingdom; -; Ruth.Fraser4@nhslothian.scot.nhs.uk), ref: -

Primary study design
Observational

Secondary study design
Prospective, observational, comparative, single-centre clinical investigation

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Detection of cardiac murmurs associated with normal and valvular heart disease in adult patients undergoing transthoracic echocardiography.

Interventions
This is an observational, comparative study. Each participant will undergo a single study visit during which a clinician will perform standard auscultation using a conventional stethoscope, followed by a non-contact phonocardiographic recording using the investigational LightScope

device. The LightScope system captures heart sounds through laser-based speckle vibrometry from the neck and chest region without physical contact. All participants will have undergone transthoracic echocardiography within the preceding 180 days, which will serve as the reference standard for murmur classification. Clinician interpretations of both standard auscultation and LightScope recordings will be compared against echocardiographic findings to assess diagnostic performance.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
LightScope (contactless optical phonocardiography device), Standard Acoustic Stethoscope, Transthoracic Echocardiography

Primary outcome(s)
1. Murmur detection performance (sensitivity and specificity) measured using clinicians' interpretation of LightScope phonocardiograms, compared with standard auscultation, using transthoracic echocardiography (TTE) as the clinical reference at a single study visit

Previous primary outcome(s):
Murmur detection performance (sensitivity and specificity) measured using clinicians' interpretation of LightScope phonocardiograms, compared with standard auscultation, using transthoracic echocardiography (TTE) as the clinical reference at a single study visit

Key secondary outcome(s)
1. Inter-rater agreement between clinicians interpreting LightScope phonocardiograms measured using Cohen’s or Fleiss’ kappa statistics at baseline

2. Signal quality of LightScope recordings measured using a 5-point Likert scale rated by clinicians at baseline

3. Clinician diagnostic confidence in murmur assessment using LightScope measured using a 5-point Likert scale at baseline

4. Repeatability of signal acquisition across users and settings measured using the calculation of intra- and inter-user Intraclass Correlation Coefficients (ICC) from repeat recordings within the same session at baseline

5. Ethnicity and body habitus subgroup performance diagnostic outcomes measured using LightScope phonocardiograms and compared with standard auscultation and transthoracic echocardiography (TTE) at baseline

6. Atrial fibrillation subgroup performance diagnostic outcomes measured using LightScope phonocardiograms and compared with TTE once at baseline

7. Device performance across valve types of murmur measured using detection results from LightScope phonocardiograms compared with echocardiographic valve findings at baseline

8. Classification of murmurs by type (systolic, diastolic, ejection, holosystolic) measured using clinician interpretation of LightScope phonocardiograms and validated against echocardiography at baseline

9. Clinician experience-related interpretation differences measured using diagnostic assessments compared across clinician experience levels at baseline

10. Usability feedback from clinicians and participants measured using data collected via structured usability questionnaire and a brief interview at baseline

11. Usability assessment in self-directed or booth-based workflow (subset of approximately 60 participants) — time-to-use, error rate, and user feedback measured using data recorded through observation and structured questionnaire at baseline

12. Comparative signal quality and murmur detection LightScope performance compared with Eko Core500 digital stethoscope measured using blinded clinician rating at baseline

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Completion date
15/07/2026

Eligibility

Key inclusion criteria
1. Aged 18 years or older at the time of consent.
2. Undergoing or having undergone transthoracic echocardiography within the past 180 days, with documentation available.
3. Able and willing to provide written informed consent prior to participation.
4. Able to comply with study procedures and optional follow-up requirements, if applicable.

Participant type(s)
Healthy volunteer, Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
100 Years

Sex
All

Total final enrolment

0

Key exclusion criteria
Current key exclusion criteria as of 23/01/2026:

1. Presence of an active skin infection, open wound, or dermatological condition over the neck or chest areas where the LightScope measurements would be performed.
2.Known diagnosis of congenital heart disease
3.Any cognitive, psychiatric, or physical condition that, in the opinion of the investigator, would impair the participant’s ability to comply with study procedures or provide reliable informed consent.
4. Pregnancy
5. Any previous surgical procedure or anatomical abnormality that prevents reliable recording of heart sounds from the standard measurement sites
6. Participants who are currently or have recently been involved in other research studies may be recruited, provided that their participation does not conflict with this investigation or pose any additional safety risk. As this is a non-invasive, observational study involving only contactless recording of heart sounds, clinical echocardiography and digital stethoscope auscultation, there are no overlapping safety or design considerations that would preclude co-enrolment. Each participant’s eligibility will be confirmed by the investigator prior to inclusion to ensure there are no protocol or safety conflicts with concurrent studies.

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Previous key exclusion criteria:

1. Presence of an active skin infection, open wound, or dermatological condition over the neck or chest areas where the LightScope measurements would be performed.
2. Known diagnosis of congenital heart disease, unless a specific subgroup analysis for congenital lesions is planned.
3. Any cognitive, psychiatric, or physical condition that, in the opinion of the investigator, would impair the participant’s ability to comply with study procedures or provide reliable informed consent.
4. Any previous surgical procedure or anatomical abnormality that prevents reliable recording of heart sounds from the standard measurement sites.

Date of first enrolment
24/03/2026

Date of final enrolment
17/06/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Healthcare Central London Ltd
South Westminster Center for Health, St George's House, 82 Vincent Square
London
England
SW1P 2PF

Sponsor information

Organisation
LightHearted AI Health Limited

Funder(s)

Funder type
Industry

Funder Name
LightHearted AI Health Limited

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Data sharing statement to be made available at a later date