

Testing a breathing app for patients in the paediatric emergency room: a diagnostic accuracy study

Submission date 30/07/2026	Recruitment status Recruiting	☐ Prospectively registered ☐ Protocol
Registration date 09/09/2026	Overall study status Ongoing	☐ Statistical analysis plan ☐ Results
Last Edited 03/09/2026	Condition category Respiratory	☐ Individual participant data ☒ Record updated in last year

Plain English summary of protocol

Background and study aims

Respiratory rate is a key physiological parameter in children and forms an integral component of the Paediatric Early Warning Score (PEWS) used throughout the NHS. An abnormal respiratory rate is an early indicator of clinical deterioration in respiratory illness and is also associated with adverse outcomes in conditions such as sepsis, diabetic ketoacidosis, and other acute systemic illnesses. Despite its clinical importance, respiratory rate remains one of the least reliably measured vital signs in routine practice, particularly in infants and young children where manual counting can be challenging and is frequently abbreviated.

electronRx has developed purpleDx Paediatric, a smartphone-based application that derives respiratory rate and heart rate from a short, contactless video recording. The clinical objective of the technology is to support the accurate classification of a child's respiratory rate as being within or outside the normal age-specific range, thereby assisting the identification of children who may require further clinical assessment.

CLEAR Junior is a prospective, observational clinical investigation designed to evaluate the performance of purpleDx Paediatric. The primary objective is to determine the positive percent agreement (PPA) and negative percent agreement (NPA) of the device for classifying respiratory rate as within or outside the age-specific 10th to 90th centile range, compared with a blinded reference respiratory rate determined from the same video recording by trained independent reviewers. Secondary objectives include assessment of respiratory rate measurement agreement, heart rate classification, concordance with the respiratory component of the Paediatric Early Warning Score (PEWS), comparison of the video-derived reference count with an independent physiological measurement in a monitored sub-study, evaluation of reference standard reliability, nurse usability, and assessment of performance across predefined participant subgroups, including skin pigmentation.

Who can participate?

Children aged 0–12 years presenting to paediatric acute care settings.

What does the study involve?

Participants will attend a single study visit during which handheld video recordings will be

obtained using the purpleDx application while routine pulse oximetry measurements are performed as part of standard clinical care. Video recordings will include sequential recordings of the chest and abdomen, the face, and a combined view of the chest, abdomen and face. Recording duration will be determined during the internal pilot phase within a predefined range of 15 to 60 seconds, allowing optimisation of the recording protocol before progression to the main clinical investigation. The study is observational and does not alter routine clinical management or treatment. All reference respiratory rate measurements will be determined retrospectively by trained raters who are blinded to the device output.

What are the possible benefits and risks of participating?

There are no particular clinical benefits for the children who take part in this clinical investigation, and there is no financial inducement to participate. The device output is not used in the child's care. Families may feel a sense of altruism from taking part in research that could improve the recognition of deterioration in sick children in future.

The benefit to future patients rests on the accuracy of the measurement. If a contactless measurement can classify a child's respiratory rate against the normal range for age with sufficient accuracy, it would address a vital sign that is difficult to obtain reliably in the children who are hardest to assess.

No clinically significant risks are expected to occur to participants from the use of purpleDx Paediatric in this investigation. The measurement is non-invasive and involves no contact with the child. No fiducial markers, adhesives or mouthpieces are used.

Where is the study run from?

electronRx Ltd

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

September 2026 to September 2027.

Who is funding the study?

electronRx Ltd

Who is the main contact?

Bipin Patel, admin@electronrx.com

Contact information

Type(s)

Principal investigator, Public, Scientific

Contact name

Dr Adrian Boyle

Contact details

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Additional identifiers

Integrated Research Application System (IRAS)
375713

Study information

Scientific Title

A multi-site paediatric clinical investigation of a smartphone-based, contactless respiratory rate measurement: positive and negative percent agreement for detecting abnormal respiratory rate in sick children up to 12 years of age, against age-specific centile normal ranges

Acronym

CLEAR-Junior

Study objectives

Ethics approval required

Ethics approval required

Ethics approval(s)

Submitted 02/09/2026, East of England - Cambridge South Research Ethics Committee (-, -, -, United Kingdom; -; cambridgesouth.rec@hra.nhs.uk), ref: 26/EE/0221

Primary study design

Observational

Secondary study design

Prospective diagnostic accuracy study

Study type(s)

Health condition(s) or problem(s) studied

Respiratory disease in children

Interventions

Participants will attend a single study visit during which handheld video recordings will be obtained using the purpleDx application while routine pulse oximetry measurements are performed as part of standard clinical care. Video recordings will include sequential recordings of the chest and abdomen, the face, and a combined view of the chest, abdomen and face. Recording duration will be determined during the internal pilot phase within a predefined range of 15 to 60 seconds, allowing optimisation of the recording protocol before progression to the main clinical investigation. The study is observational and does not alter routine clinical management or treatment. All reference respiratory rate measurements will be determined retrospectively by trained raters who are blinded to the device output.

1. Screening and approach
2. Taking informed consent and assent
3. Study encounter, capture and completion of source documentation in the application
4. Blinded comparator count by two independent raters
5. Third-rater adjudication, where required
6. Extraction of monitor-derived respiratory rate, sub-study participants only
7. Input of data into the electronic case report form and Principal Investigator sign-off

Intervention Type

Device

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

purpleDx Paediatric smartphone application

Primary outcome(s)

1. Positive and negative percent agreement of purpleDx Paediatric for classifying respiratory rate as inside or outside the age-specific 10th to 90th centile range against a blinded video-derived count of the same recording classified by the same rule, measured using a single device to capture respiratory rate, heart rate and oxygen saturation (SpO2) at one study encounter

Key secondary outcome(s)**Completion date**

30/09/2027

Eligibility**Key inclusion criteria**

1. Child presenting to a paediatric ED or inpatient ward at either site with an acute medical illness
2. Age from newborn (0 days) up to and including 12 years
3. Caregiver with parental responsibility present and able to provide informed consent

Healthy volunteers allowed

Yes

Age group

Mixed

Lower age limit

0 Years

Upper age limit

12 Years

Sex

All

Total final enrolment

0

Key exclusion criteria

1. Child presenting with trauma or injury as the primary complaint (fractures, wounds, burns, head injury, other traumatic presentations)
2. A primarily mental illness presentation
3. Critical illness requiring resuscitation at presentation
4. High-frequency oscillatory ventilation
5. Infant presenting before their expected date of delivery
6. Long-term tracheostomy
7. Long-term ventilation, whether invasive or non-invasive
8. Known underlying condition with a fixed abnormal breathing pattern that would compromise interpretation, including congenital airway anomaly, neuromuscular disease, and congenital cardiac disease with fixed tachypnoea
9. A looked-after child, unless local safeguarding arrangements permit inclusion with appropriate consent
10. Any child for whom video capture would be inappropriate on safeguarding, information governance or family preference grounds
11. The child's age stratum has already met its abnormal-case quota and is closed to recruitment
12. Any further ground at the discretion of the Principal Investigator, recorded with the reason

Date of first enrolment

01/09/2026

Date of final enrolment

31/08/2027

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre

Cambridge University Hospitals NHS Foundation Trust

Cambridge Biomedical Campus

Hills Road

Cambridge

England

CB2 0QQ

Study participating centre

The Children's Hospital School

Leicester Royal Infirmary

Infirmary Square

Leicester
England
LE1 5WW

Sponsor information

Organisation
electronRx Ltd

Funder(s)

Funder type

Funder Name
electronRx Ltd

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available