

EarlySense for heart and respiratory monitoring and predicting patient deterioration

Medtech innovation briefing

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Summary

The EarlySense system, using the Vitals software option, is used to continuously monitor heart rate and respiratory rate for patients in hospital. A sensor placed under the mattress continuously collects data while the patient is in bed and the system alerts healthcare professionals if rates change, indicating patient deterioration. Validation studies suggest that the EarlySense system records heart and respiratory rate accurately, and that its alerts are predictive of clinical deterioration. One non-randomised comparative study reported reduced length of stay and fewer intensive care transfers compared with standard monitoring. The system, together with the Vitals software option, costs about £35,000 for a 10-bed unit and the sensor must be replaced annually at a cost of £475.00 per bed (excluding VAT).

<p>Product summary and likely place in therapy</p> <ul style="list-style-type: none"> • The EarlySense system is a contact-free continuous measurement system used for routine monitoring of non-intensive care unit (ICU) hospital patients. • Using the Vitals software module, it measures heart rate and respiratory rate and alerts healthcare professionals if these measurements change, helping early identification of patient deterioration. • It would be used in non-critical care wards, in place of manual or separate measurements of heart rate and respiratory rate, where patients may be at risk of deterioration. This can include general (internal) medicine wards, surgical wards, acute medical wards or care wards for older people. 	<p>Effectiveness and safety</p> <ul style="list-style-type: none"> • The published evidence summarised in the briefing comes from 6 studies including a total of 41 children and 8093 adults. • Two studies assessed diagnostic accuracy for heart and respiratory rates against standard approaches. In 1 non-controlled case series with 41 children and 58 adults, EarlySense heart rate accuracy was 91.5% in children and 94.4% in adults in a sleep laboratory setting and 94% in ICU. Respiratory rate accuracy was 91.8% in children and 93.1% in adults in a sleep laboratory setting, and 82.0% in adults in ICU. • In another case series of 38 patients in ICU, the heart rate accuracy was 92.1% compared with ECG and the respiratory rate accuracy was 80.1% compared with manual measurements. • 1 prospective study including 37 critically ill patients reported that unstable respiration precedes and correlates with respiratory failure. The EarlySense system indicated which patients would have a major clinical event in the following 24 hours with 90% specificity and 50% sensitivity. • 1 prospective study in 204 patients found that deterioration in clinical condition was detected in 88.6% of incidences and in 100% of major events using EarlySense. • 1 prospective study of 113 patients found that EarlySense alerts were infrequent (2.7 and 0.2 alerts per patient-day for threshold and trend alert respectively). For the threshold alerts, sensitivity and specificity in predicting deterioration was 82% and 67% respectively, for heart rate (HR) and 64% and 81%, respectively, for respiratory rate (RR). For trend
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	<p>alerts, sensitivity and specificity were 78% and 90% for HR, and 100% and 64% for RR respectively.</p> <ul style="list-style-type: none"> • 1 prospective study of 7643 patients found that use of EarlySense resulted in statistically significant reductions in mean days in ICU and major clinical events compared with a standard care ward.
<p>Technical and patient factors</p> <ul style="list-style-type: none"> • The system is based on a piezoelectric sensor that is placed under the patient's mattress or inside a chair seat cushion and is sensitive to applied mechanical strain. It does not need direct patient-device contact to function. • Measurements and trends in the data are displayed at the bedside and on central displays. High and low threshold alerts for both heart rate and respiration rate can be set for each patient. The system alerts healthcare professionals if these thresholds are exceeded. 	<p>Cost and resource use</p> <ul style="list-style-type: none"> • The guideline cost for the EarlySense system using the Vitals software is £35,000 for 10 units (1 unit is needed per bed). This cost includes all sensors, bedside units, a nurse station computer and screen, a gateway computer, software and 4 pagers (with transmitter) for nurse or clinician alerts. • The piezoelectric sensor must be replaced annually at a cost of £475.00 per bed.

Introduction

Admission into an intensive care unit (ICU) is reserved for those people who are critically ill or in an unstable condition. People in ICU are usually monitored using specialist equipment by clinical staff with a high level of expertise in order to help recovery from, or prevention of, a severe clinical event (NHS Choices 2015).

Monitoring people's vital signs outside an ICU often relies on nursing staff conducting checks at set intervals. However, if the patient deteriorates between monitoring times, there may be a delay in

detecting the change in their condition. Continuous monitoring of people's vital signs, in particular heart rate (HR) and respiratory rate (RR), may provide a mechanism to alert doctors or nurses of an imminent severe clinical event. The NICE guideline on [acute illness in adults in hospital](#) recommends that physiological parameters, including HR and RR, should be monitored at least every 12 hours. These physiological observations provide the basis for risk stratification of patients using systems such as the National Early Warning Score System (which uses respiratory rate, oxygen saturation, temperature, systolic blood pressure, pulse rate and level of consciousness; Royal College of Physicians 2012). Patients are assessed upon admission and those with low deterioration risk scores have at least 12-hourly monitoring (as recommended in the NICE guideline on [acute illness in adults in hospital](#), section 1.3). Higher scores necessitate more extensive monitoring.

The EarlySense system has a potentially broad range of applications, 1 of which would be in non-critical care hospital settings for continuous monitoring of patients' HR and RR, which is the focus of this briefing. Continuous monitoring could provide medical staff with the means to identify patients at risk of clinical deterioration, leading to fewer adverse events such as cardiac arrest, respiratory failure and death (Landrigan et al. 2010). Additional modular software, which can monitor patient movement in bed, as well as bed exit (fall risk) is outside the scope of this briefing.

Technology overview

This briefing describes the regulated use of the technology for the indication specified, in the setting described, and with any other specific equipment referred to. It is the responsibility of health care professionals to check the regulatory status of any intended use of the technology in other indications and settings.

About the technology

CE marking

EarlySense was awarded CE marks for the following components in April 2009:

- Class IIb for the EarlySense 1.0S (supervision of heart rate, respiration rate, bed exit, motion, patient rotation, and oxygen saturation). This covers the bedside unit and sensor.
- Class IIa for the EarlySense CDS1.0S (EarlySense Central Display Station Software). This covers the software.

- Class IIb for the EarlySense 2.0S (supervision of heart rate, respiration rate, bed exit, chair exit, motion, patient rotation, and oxygen saturation). This covers the bedside unit and sensor.

Description

The EarlySense system is based on a piezoelectric sensor integrated into a membrane plate (300 mm wide × 210 mm high × 2.5 mm deep), which is placed under the patient's mattress to detect mechanical vibrations. The sensor collects the signal and the system algorithms analyse it to extract the following:

- Heart rate – by identifying the motion signal transmitted to the surface of the body resulting from the sudden ejection of blood from the heart with each beat.
- Respiratory rate – by identifying the motion signal generated by movement of the chest during respiration.

The system can, with additional components, also analyse patient movement, bed exit and peripheral capillary oxygen saturation (SpO₂); these uses are outside the scope of this briefing.

The sensor is connected to a wall-mounted bedside unit (260 mm wide × 250 mm high × 110 mm deep) with a touch screen, which uses software to display the readings from the sensor and allows system configuration. This can display numerical values or graphical data for viewing trends. This software can also be installed on a 'gateway computer', which transfers the alerts to a pager or other handheld devices (such as mobile phones) and acts as a file server for archiving reports. The software is available in 3 packages, which each have specific features: All-in-One (early detection of patient deterioration, fall prevention and pressure ulcer prevention), Safety (fall prevention and pressure ulcer prevention) and Vitals (early detection of patient deterioration). The last of these, Vitals, is the focus of this briefing. Vitals continuously monitors heart and respiratory rate and displays the rates that have been averaged over the previous minute. The software generates trends that can be used to detect patient deterioration. It has both visible and audible alarms and the high and low threshold of each parameter can be adjusted for each patient.

EarlySense also offers these optional components and accessories:

- A patient management centre, comprising a standard desktop computer with a 22-inch touch-screen and Vitals software. This displays the EarlySense readings from up to 36 bedside units at the nurse's station.
- A hallway display, which is a 42-inch LCD screen to display EarlySense readings.

- A contact-free chair sensor that uses the same technology as the sensor in the EarlySense system but which can be placed inside a specified chair seat cushion.
- Transmitter and pager devices, which allow healthcare professionals to get direct alerts for their assigned patients.

The EarlySense system can be used with both passive and active mattresses. Before installation, on-site testing is carried out on the different mattress types used by a facility to ensure proper performance of the system.

Setting and intended use

The EarlySense system is intended for use on non-critical care wards where patients may be at risk of deterioration. This can include general (internal) medicine, surgical, acute medical or care wards for older people. This briefing does not cover the use of this device for pressure ulcer risk assessment and monitoring, fall risk or bed exiting.

Current NHS options

Current NHS monitoring for general internal medicine patients or patients recovering from surgery is standard nurse-led monitoring. This does not include continuous monitoring with a device, but will be done as part of the ward's standard procedures. The Royal College of Physicians (2012) recommends that wards use the National Early Warning System (NEWS), which uses the following measurements: respiratory rate (observed manually over 1 minute by a nurse), oxygen saturation (measured by pulse oximeter), temperature (via ear thermometer), systolic blood pressure (using an electronic blood pressure monitor), pulse rate (observed manually over 1 minute by a nurse) and level of consciousness (patient response monitored by a nurse and classified as fully alert, voice responsive, pain responsive or unresponsive). Patients are assessed on admission and those with low deterioration risk scores have at least 12-hourly monitoring. People with higher NEWS scores need monitoring from half-hourly to 4-hourly intervals, depending on the score.

Many acute medical wards have telemetry monitoring already in place, enabling continuous distant ECG monitoring. Specialist commentators have also stated that many acute wards already have bedside monitors for continuous monitoring.

Costs and use of the technology

The distributor (BES Healthcare, a division of BES Rehab) has confirmed that the EarlySense system can be bought in single-unit packages, but offers packages tailored to individual NHS trust needs (for example in packs of 10 devices). Each device serves 1 bed.

The manufacturer used the example of 10 EarlySense systems (sensor and bedside unit) loaded with Vitals software package, which costs £35,000 (10 units at £3500 each, excluding VAT). This 10-unit package also includes the components needed for full device functionality, namely a desktop PC (including the Vitals software), central display station, pager transmitter and 4 pagers.

Individual unit prices for the devices and components are as follows (excluding VAT):

- The EarlySense system (with Vitals software) – £3500, including both a bedside unit and sensor.
- EarlySense sensor – £475; the distributor notes that the sensor must be replaced annually.
- Desktop PC loaded with EarlySense software (listed as 'gateway computer bridge') – £2250.
- Central display station – £2450.
- Pager transmitter – £1950.
- Pager – £135.

The PC can be supplied by the hospital, but is included free of charge with the software. The LCD touch screen and the pagers can also be supplied by the hospital.

Maintenance and training packages are available. The distributor has stated that these are negotiable and will vary between NHS trusts according to their needs.

Likely place in therapy

The EarlySense system could be used for patients who are at risk of clinical deterioration but are not constantly monitored, for example, patients recovering after surgery.

Specialist commentator comments

Two specialist commentators were concerned that the upfront cost of the EarlySense system might be prohibitive for the NHS without clear data on the likely downstream savings, and noted that ongoing costs such as maintenance and calibration would further increase this. One commentator also noted that the device might be more suited to wards where each patient's bed is situated in an individual cubicle or private room, which is not typical in the NHS.

Two specialist commentators noted that the EarlySense system needed patients to be in bed for monitoring, pointing out that many patients are not nursed in bed continuously and this may limit the device's utility. One specialist commentator identified monitoring in patients who have recently had surgery and night-time monitoring as situations where EarlySense might be useful.

Two specialist commentators pointed out that the NHS already uses the NEWS system, a manually administered assessment in which heart and respiratory rate, blood pressure, temperature, oxygen saturation and level of consciousness are periodically collated to detect patient deterioration.

One specialist commentator noted that they supported the use of a deterioration-monitoring device in the NHS, but would like to see more robust data and a comparative study of the current devices and systems available.

In terms of costs to the NHS, 1 specialist commentator noted that more frequent monitoring of heart and respiratory rate alone might lead to more physiological measurements being made (such as temperature and blood pressure) and so increase the number of clinical interactions.

One commentator noted the risk of 'alarm fatigue' from early warning systems in general, in which staff ignore monitor alerts because of the perceived number of false alarms.

Equality considerations

NICE is committed to promoting equality, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. In producing guidance, NICE aims to comply fully with all legal obligations to:

- promote race and disability equality and equality of opportunity between men and women
- eliminate unlawful discrimination on grounds of race, disability, age, sex, gender reassignment, marriage and civil partnership, pregnancy and maternity (including women post-delivery),

sexual orientation, and religion or belief (these are protected characteristics under the Equality Act 2010).

This device could be used in care wards for older people. Age is a protected characteristic under the Equality Act 2010.

Evidence review

Clinical and technical evidence

Regulatory bodies

A search of the Medicines and Healthcare Products Regulatory Agency website revealed no manufacturer Field Safety Notices or Medical Device Alerts for this device. No reports of adverse events were identified from a search of the US Food and Drug Administration (FDA) database: Manufacturer and User Device Facility Experience (MAUDE).

Clinical evidence

Fifteen relevant studies were identified, which took the form of journal publications, technical reports, conference abstracts and posters. Five of these were excluded because they were either out of scope for this briefing, were editorial or comment articles, or no results were presented. Four of the studies were excluded because they repeated data already found in the selected studies presented below. In these cases, peer-reviewed journal publications, more recent publications and studies with larger cohort sizes (in ongoing studies with updates) were selected for inclusion. As a result, 6 studies are summarised in the briefing, of which 2 were available as abstracts and 1 was a company internal report. All included studies are tabulated in the appendix.

Validation and diagnostic accuracy studies

The study by Ben-Ari (2010; table 1) compared the EarlySense system in both sleep laboratory and ICU settings in Israel with standard monitoring systems for each setting.

In the sleep laboratory, the standard comparative measuring device for respiratory rate (RR) was the Embla N7000 with Somnologica Studio Software System (Embla Systems Iceland). The standard measuring system for heart rate (HR) was the Embla Sleep Lab System. Patients included 16 adults (8 men, 8 women) and 41 children (32 boys, 9 girls). For HR, the EarlySense accuracy was 91.5% in children (5% absolute relative error [aRE] $\pm 3\%$) and 94.4% in adults (3% aRE $\pm 3\%$) when compared with the HR data points collected by the standard measuring systems. For RR, accuracy

was 91.8% in children (4% aRE \pm 2%) and 93.1% in adults (4% aRE \pm 1%) compared with standard RR measurement systems.

In the ICU setting, the standard method for HR was ECG monitoring (Datex/Ohmeda, GE Medical). Measurement of respiration for ventilated patients was done by end-tidal CO₂ (ET CO₂) module, or was measured manually by trained research assistants. The study enrolled 42 adult patients (25 men, 17 women). The EarlySense system had 94% accuracy (3% aRE \pm 0.3%) compared with the HR data points collected by the standard monitoring system, and an 82% accuracy (7% aRE \pm 6%) for RR against ET CO₂. EarlySense had 75% accuracy (8% aRE \pm 8%) compared with RR manually monitored by research assistants.

The conference abstract by Sorkine (2008) describes an accuracy evaluation of the EarlySense system against standard ICU monitoring systems. Thirty-eight critically ill patients (23 men and 15 women, aged 16–87 years) were recruited and simultaneously monitored with the EarlySense and the ICU's standard of care of ECG for HR and electrical plethysmography or ET CO₂ for RR. Trained technicians also manually measured RR. The EarlySense system had a HR accuracy of 92.1% (aRE 3.6%). RR accuracy compared with ET CO₂ and manual RR counts was 79.4% (aRE 9.6%) and 80.1% (aRE 12.6%) respectively.

The conference abstract by Frenzl et al. (2013) describes an observational study to assess respiratory patterns, which may be used to predict respiratory failure. In the study, 37 adult critically ill surgical patients were continuously monitored while intubated or mechanically ventilated. Patients were retrospectively studied in 2 groups: those who were successfully extubated and those with failed extubation. EarlySense alerts were considered to be true positives if they were followed by a major clinical event within 24 hours. After extubation, abnormal respiratory patterns identified patients likely to need additional ventilatory support with 90% specificity, 50% sensitivity (positive predictive value [PPV]: 60%, negative predictive value [NPV]: 86%). Abnormal respiratory patterns prior to extubation showed 91% specificity, 44% sensitivity, a PPV of 78% and a NPV of 71%, where abnormal respiratory patterns are predictive of a failed extubation. The authors concluded that the EarlySense system can indicate which ventilated patients are not yet ready for extubation.

The Zimlichman (2012) study aimed to define cut-off points for alarms using the EarlySense system, and assessed the predictive value of the alerts to detect clinical deterioration in a general (internal) medicine ward setting. The study enrolled 149 patients and data from patients with at least 30 hours of monitoring were used for the analysis (n=113). Major clinical events (defined as ICU transfer, intubation or cardiac arrest) were recorded, and the patients were constantly monitored with the EarlySense system. RR and HR alerts were based on the vital signs recorded

and analysed retrospectively, and were set on a threshold basis. Trend analysis used grouped HR and RR readings for 6-hour periods throughout the day with data collected every 3 minutes. The study authors compared the median of the readings for each period with the corresponding period of the previous day. Retrospective analysis showed that the optimal cut-offs for the threshold alerts were HR below 40 or above 115 beats/min, and RR below 8 or above 40 breaths/min. Only 6-hour time windows with at least 420 valid RR or HR results were included in the analysis. Staff did not make clinical decisions based on the EarlySense readings. EarlySense alerts were considered to be true positives if they were followed by a major clinical event within 24 hours. For the trend alerts, when comparing between time periods, retrospective analysis showed that a rise of 20 or more beats/min and 5 or more breaths/min corresponded with a maximal sensitivity and specificity. Nine out of 113 patients had a major clinical event. For HR threshold alerts, the sensitivity was 82% and the specificity was 67%. For RR, threshold alerts had a sensitivity of 64% and the specificity was 81%. For trend alerts, HR sensitivity was 78% and specificity was 90%. For RR trend alerts, sensitivity was 100% and specificity was 64%. The authors concluded that the EarlySense system is able to continuously measure RR and HR with low alert frequency, and provide timely prediction of patient deterioration.

Clinical utility studies

The Brown et al. (2014) study compared 2 similar medical-surgical units in the USA, 1 which used the EarlySense system as a monitoring system on all beds and the other which served as a control using standard nurse-led monitoring. Outcomes from both wards were assessed for 9 months before and after the EarlySense system was deployed in 1 of the wards. Outcomes included ICU transfers, length of stay (total and ICU only), code blue events (a US hospital code used to indicate a patient needing immediate resuscitation), and Acute Physiology and Chronic Health Evaluation (APACHE II; Knaus et al. 1985) score. The APACHE II score is calculated from a patient's age, blood oxygen saturation, temperature, mean arterial pressure, arterial pH, HR, RR, serum sodium and potassium, creatinine and haematocrit levels, white cell count and Glasgow Coma Scale score. There were no statistically significant differences in ICU transfers or APACHE II scores between the 2 wards after the EarlySense system was introduced. A three-armed comparison showed a significant reduction in days in ICU in the intervention unit post-implementation (63.5 days/1000 patients compared with 120.1 and 85.36 days/1000 patients, for the implementation and control unit before implementation respectively; $p=0.04$). Length of stay in ICU for the control unit actually increased from 32.69 days per 1000 patients before implementation to 85.36 days per 1000 patients after implementation ($p=0.01$). The EarlySense-equipped intervention unit had 6.3 code blue events per 1000 patients before implementation, improving to 0.9 events per 1000 patients after implementation ($p<0.01$). The control unit had 3.9 events per 1000 patients before implementation compared to 2.1 events per 1000 patients after implementation ($p=0.36$).

A company internal report (Zimlichman et al. 2009) describes an unpublished study in which the EarlySense system was used to detect clinical deterioration in medical-surgical wards, and the system's level of false alarms. A total of 204 adult patients (99 men and 105 women) were continuously monitored in 3 hospitals (1 in the USA, 2 in Israel) for over 14,000 cumulative hours. Worsening of clinical conditions which led to interventions occurred in 29 patients (14%), with a total of 35 events of deterioration. Signs of worsening were detected by monitoring heart or respiratory rates (alerts and trends) in 31 of these events (88.6%). Of the 35 total events, 11 were defined as major. The EarlySense system detected signs of worsening in 100% of these major events.

Recent and ongoing studies

Eight ongoing, completed or in-development trials on the EarlySense system were identified in the preparation of this briefing.

- [NCT00361426](#) in patients with chronic obstructive pulmonary disease. Status: unknown.
- [NCT00382746](#) in patients with congestive heart failure. Status: completed.
- [NCT00361608](#) in patients with type 1 diabetes. Status: completed.
- [NCT01978340](#) in patients with obesity, sleep apnoea, obstructive central apnoea, sleep disorders, poor quality sleep. Status: not yet recruiting.
- [NCT02036996](#) in patients with overweight, sleep disorders. Status: not yet recruiting.
- [NCT02318004](#) in patient with myocardial infarction, cardiac surgery. Status: not yet recruiting.
- [NCT00640718](#) in patients post-operatively, patients needing patient-controlled analgesia, patients with respiratory conditions, patients at risk of falls. Status: unknown.
- [NCT01774708](#) in sleep (prediction of bed exit and fall prevention). Status: active but not recruiting.

Costs and resource consequences

During 2013–14, basic and advanced cardiovascular support accounted for 904,093 support days in England, whereas people needing basic and advanced critical respiratory support totalled 766,632 support days (HSCIC 2015). Some support days for cardiovascular and respiratory care may have been incurred concurrently, because people often need multiple system support. For

non-specific critical care, [NHS reference costs 2013–14](#) state a range between £696 (XC07Z – adult critical care, 0 organs supported) and £1947 (XC01Z – adult critical care, 6 or more organs supported), based on generalised 'best case' and 'worst case' ICU referral costs. Adopting an effective early warning system could reduce the number of ICU transfers, cardiac arrests and other life-threatening emergencies through detecting clinical deterioration.

Adopting an automated monitoring system could change the way that non-critical care wards are organised, in that clinicians may need to do fewer scheduled rounds in order to monitor patients. This would be balanced by the time spent assessing alarm triggers and performing additional tests in response to alerts.

Setting up the EarlySense may need additional infrastructure such as networked computer terminals and wireless networking.

Strengths and limitations of the evidence

The currently available evidence for the clinical effectiveness of the EarlySense system was limited in both quantity and quality, and comprised 3 peer-reviewed journal articles, 3 conference poster abstracts and 1 technical report. These studies were situated either in the USA or Israel, and no large UK-based comparative studies were identified. The results may not be generalisable to the UK setting, because the hospitals in Israel or the USA may not be organised in the same way. They also may not use the NEWS system, and may therefore have less robust current patient monitoring in place.

The Ben-Ari et al. (2010) study employed the EarlySense system in a sleep laboratory setting, which is not the intended setting for the use of the device. The patients were not randomised, which may lead to bias. The EarlySense system was compared with standard monitoring systems in both the sleep laboratory and ICU setting, which is an appropriate comparison for HR and RR accuracy measurements. Patient numbers were quite low, with 67 sleep laboratory participants and 42 ICU patients enrolled. The ICU patients were highly variable in their age (16–86 years), which could lead to a high level of variance in the results. This is a basic accuracy study and so does not show the effect of the device on patient outcomes such as ICU transfers or critical events.

Sorkine et al. (2008) is a conference poster abstract describing an accuracy evaluation of the EarlySense system compared with standard ICU monitoring systems. As an abstract, it lacks detail in both methodology and results reporting. The sample size was small, with 38 patients recruited and no control group or randomisation. The EarlySense system was compared with standard monitoring systems in the ICU setting, which is an appropriate comparison for HR and RR accuracy

measurements. This was a basic accuracy study and so did not explore the effect of the device on patient outcomes such as ICU transfers or critical events.

Frendl et al. (2013) is a conference poster abstract describing an observational study to assess respiratory patterns, which may indicate an upcoming respiratory failure event. As a conference abstract, it lacks detail in both methodology and results reporting. The sample size was small, with only 37 patients recruited. There was no randomisation, but patients were split into 2 groups: those who were successfully extubated and those who were not. Only 16 unsuccessful extubations were available for analysis. This study does assess the EarlySense system's ability to predict respiratory failure, which is a possible application of this device in the NHS.

The Brown et al. (2014) paper describes a comparative study with the EarlySense system set up in 1 ward and a 'similar' control ward without the system. Various patient outcomes in both wards were also compared in the 9 months before the EarlySense was introduced. The sample size was large, with 2314 patients monitored in the EarlySense ward and 5329 across the 3 control arms. The authors state that the patients were referred alternately to the EarlySense or non-EarlySense ward, but this is not true randomisation and the study was not blinded. The authors also note that the alarm thresholds for the EarlySense system could be altered by nurses if the patient was frequently triggering alarms. This could lead to bias. There is also an issue with the baseline similarities of the 2 selected wards. The baseline length of stay in ICU for the control unit was 32.69 days per 1000 patients, and the ward that subsequently introduced the EarlySense system had a baseline of 120.11 days in ICU per 1000 patients ($p=0.06$). Although not calculated as statistically significant, this is a large difference in ICU length of stay between the 2 wards at baseline, and may have caused bias.

The Zimlichman et al. (2009) publication is an unpublished report that has not, therefore, been peer-reviewed. The sample size was reasonable, with 204 patients monitored, but only 29 patients had events that needed intervention. The results were based on a requirement for clinicians to set the system's high and low HR and RR thresholds. Although this allows tailoring of the device to suit an individual's specific HR and RR, it also has the potential to introduce a high degree of variability (because 1 clinician's concept of what constitutes a high or low RR and HR may differ from that of another). There was no randomisation because all enrolled patients were monitored with the EarlySense system.

The Zimlichman et al. (2012) study aimed to define cut-off points for alarms using the EarlySense system and assess the usefulness of the alerts to predict clinical deterioration in a general (internal) medicine ward setting. Of the 149 patients enrolled, data from only 113 were analysed because 30 hours of monitoring was needed for analysis. The study recruited patients at an increased risk

for respiratory failure, so the results from this study may not be applicable to a general medical ward. There was no randomisation because all enrolled patients were monitored with the EarlySense system. This study comprised a prospective data collection period, followed by retrospective data analysis. Therefore, trend analysis was carried out post-hoc and was modelled to provide the optimal sensitivity and specificity. The authors showed that the modelled cut-off values could predict clinical events, but the analysis was done on the same patients from which the thresholds were modelled. In order to prove the validity of these findings, these modelled thresholds should have been prospectively tested on a new patient cohort.

Relevance to NICE guidance programmes

NICE has issued the following guidance:

- [Acute illness in adults in hospital: recognising and responding to deterioration \(2007\) NICE guideline CG50](#)
- [Acute heart failure: diagnosis and management \(2014\) NICE guideline CG187](#)

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Appendix

Contents

Data tables

Table 1: Summary of the Ben-Ari et al. (2010) study

Table 2: Summary of the Sorkine et al. (2008) abstract

Table 3: Summary of the Frenzl et al. (2013) abstract

Table 4: Summary of the Zimlichman et al. (2012) study

Table 5: Summary of the Brown et al. (2014) study

Table 6: Summary of the Zimlichman et al. (2009) company report

Table 1 Summary of the Ben-Ari et al. (2010) study

Study component	Description
Objectives hypotheses	To study the accuracy of the EarlySense system for heart and respiratory rate measurements.
Study design	Non-controlled case series.
Intervention	EarlySense.
Setting	Sleep laboratory and ICU settings.
Inclusion/exclusion criteria	<p>Sleep laboratory inclusion: Adults (age above 18 years) referred to the sleep laboratory for any indication and who were willing to sign an informed consent. Children (aged 4–18 years) referred to the sleep laboratory for any indication and consented by legal guardian. Exclusions not stated.</p> <p>ICU inclusion: Hospitalisation in critical care unit and consent obtained from patients or their next of kin (for intubated and ventilated patients).</p> <p>ICU exclusion: Missing or compromised data (due to noise from external sources).</p>
Primary outcomes	Respiratory rate and heart rate.

<p>Methods</p>	<p>Sleep laboratory:</p> <p>Reference standards: RR - Embla N7000 with Somnologica Studio Software System (Embla Systems Inc. Iceland). HR - Embla Sleep Lab System. RR and HR were measured simultaneously using the reference device and the EarlySense for the entire night (21:00–06:00 hours).</p> <p>ICU:</p> <p>HR measured with standard ECG monitoring (Datex/Ohmeda GE Medical). RR for ventilated patients was measured by end-tidal CO₂ (ET CO₂) module. The RR of non-ventilated patients was measured manually by trained research assistants. RR was also measured using a standard impedance technique (Datex-Ohmeda GE Medical).</p> <p>Data and statistical analysis:</p> <p>EarlySense and standard measurements were compared to calculate the accuracy and the detection rate of EarlySense. The absolute relative error rate (aRE) was computed as: $aRE = (\text{reference} - \text{EarlySense}) / \text{reference}$. For the linear regression and for the BMI-accuracy correlation, Pearson correlation coefficient was used.</p>
<p>Participants</p>	<p>Sleep laboratory: 16 adults (8 men, 8 women); mean age \pm SD=30.6\pm5.3 years; BMI (\pm SD)=24.2\pm4.7 kg/m²</p> <p>41 children (32 boys, 9 girls); mean age \pm SD=7.6\pm3.6 years; BMI \pm SD=18.4\pm5.7 kg/m²</p> <p>ICU: 42 adults (25 men, 17 women); mean age \pm SD=54.8\pm17.4 years; BMI \pm SD=26.9\pm6.6 kg/m²</p>

<p>Results</p>	<p>Comparison of EarlySense readings with the standard device for HR and RR in the sleep laboratory patients:</p> <p>RR:</p> <p>Adults (n=16): 1249/1341 (93.1%) accurate data points; aRE±SD=0.04±0.01 Children (n=37): 3346/3646 (91.8%) accurate data points; aRE±SD=0.04±0.02. Correlation=0.93</p> <p>HR:</p> <p>Adults (n=16) 5475/5792 (94.4%) accurate data points; aRE±SD=0.03±0.03 Children (n=37):10,348/11309 (91.5%) accurate data points; aRE±SD=0.05±0.03. Correlation=0.97</p> <p>Comparison of EarlySense and standard impedance readings with the standard device for HR and RR in the ICU:</p> <p>EarlySense compared with reference standard</p> <p>HR:</p> <p>42 patients; 42,752/45,470 (94%) accurate data points; aRE±SD=0.03±0.003; correlation=0.91</p> <p>RR (ET CO₂):</p> <p>13 patients; 6288/7625 (82%) accurate points; aRE±SD=0.07±0.06; correlation=0.82</p> <p>RR (manual):</p> <p>35 patients; 547/734 (75%) accurate points; aRE±SD=0.08±0.08; correlation=0.93</p> <p>Impedance compared with reference standard</p> <p>RR (ET CO₂):</p> <p>13 patients; 3310/6388 (52%) accurate points, aRE±SD=0.22±0.11;correlation=0.37</p> <p>RR (manual):</p> <p>35* patients; 352/635 (55%) accurate points; aRE±SD=0.16±0.14; correlation=0.81</p>
<p>Adverse events</p>	<p>No adverse events occurring in the sleep laboratory or ICU were related to EarlySense.</p>

Conclusions	The monitoring system was considered to be sufficiently accurate in accordance with standard regulatory and industry criteria. Specifically, RR measured using EarlySense was more accurate than impedance-based technologies widely used currently. The authors noted that further research is needed, but that this device could allow earlier recognition and response to changes in a hospitalised patient's condition.
Abbreviations: aRE, absolute relative error rate; BMI, body mass index; BPM, beats per minute; Br, breaths; ECG, electrocardiogram; ET CO ₂ , end tidal CO ₂ ; HR, heart rate; ICU, intensive care unit; RR, respiratory rate; SD, standard deviation.	

Table 2 Summary of the Sorkine et al. (2008) abstract

Study component	Description
Objectives/hypotheses	To evaluate the accuracy of EarlySense for measuring HR and RR and its ability to alert staff to significant changes, in comparison to standard ICU methods.
Study design	Case series.
Intervention	EarlySense.
Setting	Hospital ICU.
Inclusion/exclusion criteria	No inclusion/exclusion criteria were stated.
Primary outcomes	HR and RR.
Methods	EarlySense's sensor was placed under the mattress with the data displayed on its control unit. Patients were simultaneously monitored using the ICU's standard of care of ECG for HR and electrical plethysmography/end tidal CO ₂ for RR (makes and models of these comparator devices not given). Trained technicians also manually measured RR.
Participants	38 critically ill patients (23 male and 15 female, age 16–87 years).

Results	Range was 35–180 BPM for HR and 6–45 breaths/min for RR. Paired data points (n=40,719) were evaluated for HR accuracy. EarlySense had a 92.1% accuracy with an aRE=3.6%. RR compared with end-tidal and manual RR counts showed an accuracy of 79.4% and 80.1% with an aRE=9.6% and 12.6%, respectively. The number of alerts relating to extreme changes in HR (for example atrial fibrillation and arrhythmia) and RR were consistent between the 2 methods.
Adverse events	None reported by the authors.
Conclusions	EarlySense is accurate and easy to use for measuring HR, RR and trends. It enables staff to continuously assess patients that are currently not monitored, without interfering with their comfort.
Abbreviations: aRE, absolute relative error rate; BPM, beats per minute; Br, breaths; ECG, electrocardiogram; HR, heart rate; ICU, intensive care unit; RR, respiratory rate.	

Table 3 Summary of the Frenzl et al. (2013) abstract

Study component	Description
Objectives/hypotheses	To identify respiratory patterns characteristic or predictive of respiratory failure.
Study design	Prospective, observational study.
Intervention	EarlySense.
Setting	Not stated however ICU in hospital seems likely.
Inclusion/exclusion criteria	Inclusion: Adult, critically ill surgical patients. Exclusion: No exclusion criteria were noted.
Primary outcomes	Respiratory patterns.

Methods	<p>HR and RR were recorded continuously with EarlySense while the patients were intubated/mechanically ventilated with PSV and followed for up to 24 hours after extubation.</p> <p>Two patient cohorts were studied: those who successfully extubated and those who were not (end-points of failure: reintubation, tracheostomy or death). The periods (6.5–24 hours) prior to extubation and 9–24 hours following extubation were studied. The abstract does not clarify whether this was the range studied for all patients individually or whether it is the range of periods studied across the cohort. The recordings were analysed by an algorithm to detect abnormal patterns that correlate with respiratory outcomes and were confirmed by visual examination of the raw signals.</p>
Participants	37 adult critically ill surgical patients (consent taken by surrogates).
Results	<p>A healthy respiratory pattern (normal rate, minimally variable depth) was observed in those patients who were later successfully extubated. Three forms of non-reassuring respiratory patterns were seen with those who failed extubation:</p> <ol style="list-style-type: none"> 1. Generalised disorganised respirations; 2. Frequent occurrences (every 30–120 seconds) of a single deep gasping breath; 3. Multiple periods of apnea >30 seconds. <p>Patients were considered to have abnormal respiration when their non-reassuring respiration patterns were at least twice as long as their periods with normal respiratory patterns. After extubation, abnormal respiratory patterns identified those patients requiring additional ventilatory support (90% specificity, 50% sensitivity, PPV: 60%, NPV: 86%). Abnormal respiratory patterns prior to extubation showed 91% specificity, 44% sensitivity, PPV: 78%, NPV: 71%.</p>
Adverse events	None reported by the authors.
Conclusions	<p>A pattern of unstable respirations (apparent in inconsistent chest wall motion amplitude) was found to precede and correlate with respiratory failure. For ventilated patients this abnormal pattern (seen in PSV mode) may indicate that a patient is not ready for extubation. In the case of recently extubated patients, the pattern may indicate a need for interventions to prevent re-intubation.</p>

Abbreviations: ICU, intensive care unit; NPV, negative predictive value; PPV, positive predictive value; PSV, pressure support ventilation.

Table 4 Summary of the Zimlichman et al. (2012) study

Study component	Description
Objectives/ hypotheses	To establish the accuracy of the EarlySense continuous monitoring system in predicting clinical deterioration.
Study design	Non-interventional prospective study with retrospective data analysis.
Intervention	EarlySense.
Setting	2 hospitals: Sheba and Sapir Medical Centres in Israel.
Inclusion/ exclusion criteria	<p>Inclusion: Patients hospitalised with an acute respiratory condition including pneumonia, chronic obstructive pulmonary disease or asthma exacerbation, congestive heart failure with pulmonary oedema or congestion, and patients who needed supplemental oxygen on admission. Patients were enrolled only if they were initially assessed within 24 hours of hospitalisation.</p> <p>Exclusion: Dementia and inability to sign informed consent.</p>
Primary outcomes	HR and RR

<p>Methods</p>	<p>Patient enrolment took place during the period of January to December of 2008 in Sheba Medical Center and July to November of 2008 in Sapir Medical Center. Since the study was non-interventional, and the EarlySense monitor alarms were not responded to by healthcare professionals during the study, patients were also monitored by other monitoring devices, such as telemetry and pulse oximeter, as indicated clinically.</p> <p>Patients were monitored for the full extent of their stay in the 2 medical departments. Only 2 monitors were available at each site, so in cases where patients stayed for more than 2 weeks, a decision was made by the principal investigator whether to continue monitoring or disconnect the sensor and enrol another patient. This was based on an assessment of clinical stability and on how much longer patients were expected to stay in the unit, in an attempt to avoid a situation where a patient was utilising 1 monitor for a very long period of time. This was done to boost patient recruitment numbers.</p>
<p>Participants</p>	<p>One hundred and forty nine patients were enrolled, mean age 69 ± 6 years, 45.1% were female. Mean BMI 27 (17–52.7), mean Charlson comorbidity score 1.58, mean LOS 7.3 ± 5.9 days. No significant differences were seen in the groups in any of these parameters. One hundred and thirteen had the required ≥ 30 hours monitoring required for this study.</p>

<p>Results</p>	<p>9/113 (8.0%) patients had a major clinical event, including 2 patients who were transferred to an ICU, 1 patient who was intubated and ventilated in the study unit and later had a cardiac arrest and died, and 6 more patients who had cardiac arrests and died in the study units (overall, 10 major clinical events).</p> <p>The only significant difference between patients with and without major clinical events was length of stay: 6.9±6.0 days without a major clinician event, compared to 11.9±7.8 days with a major clinical event (p=0.02).</p> <p>Threshold alerts:</p> <p>HR: sensitivity (sens) 82%, specificity (spec) 67 %, positive predictive value (PPV) 21%, negative predictive value (NPV) 97%</p> <p>RR: sens 64%, spec 81%, PPV 26%, NPV 95%</p> <p>HR and RR: sens 55%, spec 94%, PPV 50%, NPV 95%</p> <p>Trend alerts:</p> <p>Change in HR ≥20 beats/minute: sensitivity 78%, specificity 90%, PPV 41%, NPV 97%</p> <p>Change in RR ≥5 breaths/minute: sensitivity 100%, specificity 64%, PPV 20%, NPV 100%</p> <p>Change in both HR ≥20 beats/minute and RR ≥5 breaths/minute: sensitivity 78%, specificity 94%, PPV 54%, NPV 98%</p> <p>Sensitivity and specificity were reasonably high for all threshold and trend alerts, and negative predictive value was very high for EarlySense. However, positive predictive value was consistently low for all types of alerts studied. Retrospective analysis showed that the optimal cut-offs for the threshold alerts were HR below 40 or above 115 beats/min, and RR below 8 or above 40 breaths/min.</p>
<p>Adverse events</p>	<p>None reported by the authors.</p>
<p>Conclusions</p>	<p>This study found that the EarlySense monitor is able to continuously measure RR and HR, providing low alert frequency. The current study demonstrates the potential of this system to provide timely prediction of patient deterioration. Utilising a trend algorithm has been shown to improve the device's accuracy and reduce associated alert burden and false-positive alerts.</p>

Abbreviations: CHF, congestive heart failure; COPD, chronic obstructive pulmonary disease; HR, heart rate; ICU, intensive care unit; LOS, length of stay; NPV, negative predictive value; PPV, positive predictive value; RR, respiratory rate; SD, standard deviation.

Table 5 Summary of the Brown et al. (2014) study

Study component	Description
Objectives/ hypotheses	To assess the effects of continuous heart rate and respiration rate monitoring in a medical-surgical unit on unplanned transfers, length of stay in the intensive care unit and length of stay in the medical-surgical unit.
Study design	Controlled 9 month prospective intervention period and a 9 month retrospective baseline period.
Intervention	EarlySense system.
Setting	Medical-surgical unit.
Inclusion/exclusion criteria	None stated by the authors.
Primary outcomes	Unplanned ICU transfers, average ICU length of stay (LOS) for transferred patients, medical-surgical unit LOS.
Methods	A 33-bed medical-surgical unit (intervention unit, using EarlySense monitoring) was compared to a similar 'sister' control unit, and patients were monitored over a 9 month period. Results were also compared with 9 months of retrospective patient data for each ward, referred to as 'the pre-implementation phase'. Patients were admitted to the 2 units by the hospital's admissions office in an alternating manner (the authors state that the similar patient populations, supervision and service levels make this 'almost random'). Following the intervention, all beds in the intervention unit were equipped with monitors that allowed for continuous assessment of heart and respiration rate.
Participants	Participants were compared using their mean age, sex, baseline acuity levels and Charlson scores, with no statistically significant differences.

Results	The study population included 7643 patients, of which 2314 patients in the intervention unit were placed under continuous monitoring using EarlySense. The remaining 5329 patients were in the control arms. Results are presented in a 3-armed fashion with control unit and intervention unit arms both compared to pre-implementation baseline and each other. Statistically significant differences in favour of EarlySense were seen in mean length of stay on the medical/surgical ward, the mean length of stay in ICU and the improvement in the numbers of code blue events.							
	Control unit (CU)			Intervention unit (IU)			p values	
	Pre	Post	p	Pre	Post	p	CU-IU Pre	CU-IU Post
LOS in medical/surgical unit, mean (25%-75% IQR)	3.80 (1.26-4.25)	3.61 (1.19-4.12)	0.07	4.00 (1.26-4.66)	3.63 (1.19-4.22)	0.02	0.19	0.37
ICU transfers/1000 patients	18.89	19.06	1.00	26.52	25.93	0.92	0.17	0.12
Days in ICU/1000 patients	32.69	85.36	0.01	120.11	63.44	0.10	0.06	0.02
ICU LOS, mean (25%-75% IQR)	1.73 (1.06-2.28)	4.48 (0.94-4.09)		4.53 (0.91-4.39)	2.45 (0.86-2.82)			
APACHE II score, mean (25-75% IQR)	13.08 (7.75-18.00)	14.0 (6.00-19.00)	0.59	15.19 (10.00-18.00)	13.38 (7.00-18.25)	0.25	0.29	0.61

LOS in unit before transfer to ICU, mean (25%–75% IQR)	13.07 (7.26–19.46)	17.03 (6.97–19.9)	0.29	16.82 (5.97–19.95)	11.94 (5.77–14.40)	0.07	0.19	0.13
Code blue events/1000 patients	3.9	2.1	0.36	6.3	0.9	<0.01	0.44	0.45
Adverse events	None reported by the authors.							
Conclusions	Continuous monitoring on a medical-surgical unit was associated with a significant decrease in total length of stay in the hospital and in intensive care unit days for transferred patients, as well as lower rates of code blue events.							
Abbreviations: APACHE, acute physiology and chronic health evaluation; ICU, intensive care unit; IQR, interquartile range; LOS, length of stay; p, p value; SD, standard deviation.								

Table 6 Summary of the Zimlichman et al. (2009) company report

Study component	Description
Objectives/hypotheses	The study objectives were to evaluate the capability of the EarlySense to monitor and alert staff to deteriorations in patient condition and to evaluate the usability of the EarlySense device during routine activities in sub-acute care units such as medical/surgical wards. Specifically, it sought to identify if and how clinical deterioration was detected by the EarlySense device in medical/surgical departments and to evaluate the system's level of false alarms.
Study design	Multi-centre, prospective study.
Intervention	EarlySense.
Setting	Hospitals in the USA (Metro West, Massachusetts) and Israel (Sheba, Tel Aviv District and Sapir, Centre District).

<p>Inclusion/exclusion criteria</p>	<p>Inclusion: None.</p> <p>Exclusion: Patients who were unwilling to sign the consent form, patients with Parkinson's disease, intubated patients or patients who regularly used a CPAP or BIPAP device during the night, were excluded from the study.</p>
<p>Primary outcomes</p>	<p>HR and RR.</p>
<p>Methods</p>	<p>Clinicians set 'high' and 'low' heart and respiration rate thresholds for each patient individually, so EarlySense would alert staff if the patient's heart or respiratory rate crossed the pre-defined threshold. For each alert in the US site, the nurses indicated whether it was a true alert or a false alarm, allowing analysis of the false alarm rate. In addition, the system displayed the trends of the measured parameters enabling clinicians to identify unexpected increases or decreases in heart or respiratory rate. Patients' clinical conditions were recorded on CRFs as well as logged in the patients' clinical charts.</p> <p>EarlySense reports were reviewed and compared with patients' CRFs and clinical charts. Three levels of deterioration severity were defined: 'major/severe', 'moderate' and 'minor'. The severity level of each deterioration event was assessed mainly according to the medical intervention required, for example ICU transferral or intubation was classified as a 'major' intervention. Utilisation of BIPAP was considered as a moderate intervention. EarlySense reports of the patients whose condition deteriorated were reviewed. Heart and respiratory rate trends as well as system's alerts were reviewed and compared to the patients' condition.</p>
<p>Participants</p>	<p>Participant demographics: 204 patients (99 males, 105 females), mean age 66.1±18.5 years, mean weight 78.6±20.2 kg, mean BMI 28.7±7.8 kg/m². Patients were not compared for statistical significance at baseline.</p>

Results	A total of 204 patients (99 males and 105 females) from all sites were continuously monitored for over 14,000 cumulative hours. Worsening of clinical conditions (where an intervention of any level was necessary) occurred in 29 patients (14%), with a total of 35 deterioration events. By monitoring heart or respiratory rates using EarlySense, signs of worsening (alerts and trends) were detected in 31 (88.6%) of these events. Of the 35 total events, 11 were defined as major. EarlySense detected signs of worsening in 100% of these major events.
Adverse events	None reported by the authors.
Conclusions	These are preliminary results. The authors suggest that continuous monitoring of RR and HR for patients hospitalised in general medical/surgical units can provide an early warning for deterioration and to allow better clinical data-driven decisions.
Abbreviations: BIPAP, bilevel positive airway pressure; BMI, body mass index; CPAP, continuous positive airway pressure; CRF(s), case report forms; HR, heart rate; ICU, intensive care unit; RR, respiratory rate; SD, standard deviation.	

Search strategy and evidence selection

Search strategy

The following search strategy was used to search Ovid MEDLINE (R) 1946 to May week 2 2015:

"earlysense.tw" or "everon.tw"

Similar search strategies were adapted for Medline in Process, Embase, PsycInfo, Cochrane Library (all components), Pubmed, HEED, NHS Evidence and Web of Science. The searches returned a total of 15 references after duplicate removal.

Evidence selection

Retrieved results were independently sifted by two researchers using the selection criteria below, and disagreements discussed and resolved.

- Population: Non-critical care patients who may deteriorate and are not constantly monitored

- Intervention: EarlySense monitoring system
- Comparator: Standard ICU monitoring systems for heart rate (e.g. ECG) and respiratory rate (e.g. plethysmography/end tidal CO₂)

Outcomes:

- Heart and respiratory rate diagnostic accuracy – sensitivity, specificity, PPV, NPV
- Prediction of patient deterioration/medical events using heart and respiratory rate, and rate of false alarms
- Rate of code blue events and ICU transfers

Following the first sift, 9 records were removed based on the following criteria:

- Not relevant to selection criteria (out-of-scope setting)
- Review articles, protocols or editorials
- Duplicate results with other publications found. In these cases, peer-reviewed journal publications, more recent publications, and larger cohort sizes (in ongoing studies with updates) were selected for inclusion.

Full articles were retrieved for the remaining 7 studies. Due to the paucity of data, all studies meeting the selection criteria were considered for inclusion. Ultimately, 6 references met the criteria and were included in this briefing.

About this briefing

Medtech innovation briefings summarise the published evidence and information available for individual medical technologies. The briefings provide information to aid local decision-making by clinicians, managers and procurement professionals.

Medtech innovation briefings aim to present information and critically review the strengths and weaknesses of the relevant evidence, but contain no recommendations and are **not formal NICE guidance**.

Development of this briefing

This briefing was developed for NICE by Cedar. The [Interim process & methods statement](#) sets out the process NICE uses to select topics, and how the briefings are developed, quality-assured and approved for publication.

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- Elaine Grainger (South Manchester NHS Trust) – Emergency and Critical Care, Lead Nurse
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Declarations of interest

No relevant interests declared.

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