

# Kendall DL for ECG monitoring in people having cardiac surgery

Medtech innovation briefing

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## Summary

- The **technology** described in this briefing is Kendall DL, a single-patient-use electrocardiogram (ECG) cable and lead wire system. It is used for diagnostic and ongoing patient monitoring. This briefing focuses on its use for people having cardiac surgery.
- The **innovative aspects** are the single-use design of the ECG cable and lead wire, which decreases the risk of cross-contamination, and allows patients to use a single set of ECG cables when in acute care. The system also has a button to secure the lead wire to the electrode, to reduce the chance of 'lead-off' false alarms.
- The intended **place in therapy** would be for anyone who needs ECG monitoring in acute care.

- The **main points from the evidence** summarised in this briefing are from 3 studies (2 randomised controlled trials and 1 observational study) with a total of 36,146 surgery cases in the US. They show that Kendall DL is associated with fewer false alarms. The studies also show fewer surgical site infections at 90 days after coronary artery bypass graft procedures, compared with reusable ECG leads.
- **Key uncertainties** around the technology are that clinical evidence is limited and may not be generalisable to the NHS.
- The **cost** of Kendall DL is £11.10 for a 3-lead system and £12.68 for a 5-lead system (inclusive of VAT). The **resource impact** would be greater than reusable ECG cable and lead wire systems. These costs might be offset by reducing surgical site infections but the evidence for this is limited.

## The technology

The Kendall DL is a single-patient-use electrocardiogram (ECG) cable and lead wire system. It is used to assess and monitor cardiac health for people having cardiac surgery. The Kendall DL comprises:

- disposable 3-, 5-, 6- and 10-lead wires that connect directly to electrodes
- a cable that connects the leads to an ECG monitor
- a universal adaptor for compatibility with different models of ECG monitoring equipment.

The disposable design of the technology minimises the risk of cross-contamination between people, especially those having cardiac surgery with large incisions, or those at high risk of infection. The system's push button reduces the risk of false alarms. Kendall DL has 2 connection options that allow patients to move between bedside and telemetry monitoring.

If Kendall DL was adopted, it could replace reusable ECG cable and lead wires.

## Innovations

Kendall DL provides both disposable ECG lead wires and cables, whereas other similar technologies provide only disposable ECG lead wires. The company claims that Kendall DL

is the only single-patient-use ECG cable and lead wire set that can be used throughout a patient's hospital stay. The system uses a patented push button technology to secure the lead wire to the electrode.

## Current care pathway

NICE's guideline on [routine preoperative tests for elective surgery](#) recommends that ECG is considered for people with cardiovascular, renal or diabetes comorbidities before their surgery. However, there are no recommendations on standards of ECG cable and lead wire. Clinical guidelines on [recording a standard 12-lead ECG](#) from the Society for Cardiological Science and Technology recommend equipment specification for ECG including the need for disposable electrodes. There is currently no national standard of care for cleaning ECG cable and lead wires in the NHS. There may be cleaning protocols at an individual hospital level.

## Population, setting and intended user

Kendall DL is for people who need ECG monitoring, with a focus on those having cardiac surgery and those at risk of healthcare-associated infection. The company claims the technology would be used in preoperative assessment, during the operation, and in recovery in an intensive care unit.

## Costs

### Technology costs

Table 1 Cost of the Kendall DL Cable and Lead Wire System

Description	Cost (inclusive of VAT)
3-lead Kendall DL	£11.10 per unit
5-lead Kendall DL	£12.68 per unit

### Costs of standard care

The company estimates the cost of reusable ECG leads to be £5.49 for an average lifetime

of 30 to 40 uses.

## Resource consequences

The technology is currently used in 15 hospitals in England. It could reduce cross-contaminations between patients who are at high risk of developing healthcare-associated infection.

A US budget impact analysis ([Saunders and Lankiewicz, 2018a](#)) showed that yearly costs for patients who had coronary artery bypass grafting were \$12.2 million. This included 605 days in intensive care unit and 9 readmissions because of surgical site infections. The use of disposable leads resulted in savings of \$16,780. Savings included 3.2 days shorter stay in intensive care and 2.4 fewer readmissions.

A recent conference abstract reported a budget impact analysis for the NHS. This suggested that a single-use ECG system reduced the cost of care for patients having coronary artery bypass grafting by £73 (1%), mainly because of a decrease in surgical site infections. Savings included 3.7 days shorter stay in intensive care and 1.5 fewer readmissions per 100 patients ([Saunders and Lankiewicz, 2018b](#)).

There would be no other resource or infrastructure changes needed to use the technology.

## Regulatory information

Kendall DL is CE marked as a class I medical device. This system meets the requirements of the [American National Standards Institute \(ANSI\)](#) and the [Association for the Advancement of Medical Instrumentation \(AAMI\)](#). No medical device alerts for this technology have been identified.

## 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 and advice, 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).

There are many different types of heart diseases. Many heart diseases develop over the course of time, and can be long-term conditions. This may mean someone is disabled if cardiovascular conditions have a substantial and long-term effect on their ability to do daily activities. Disability is a protected characteristic under the Equality Act. NICE's clinical guideline on [surgical site infections](#) lists risk factors that are associated with surgical site infection including age, underlying conditions and the complexity of procedure.

## Clinical and technical evidence

A literature search was carried out for this briefing in accordance with the [interim process and methods statement](#). This briefing includes the most relevant or best available published evidence relating to the clinical effectiveness of the technology. Further information about how the evidence for this briefing was selected is available on request by contacting [mibs@nice.org.uk](mailto:mibs@nice.org.uk).

## Published evidence

There are 3 studies summarised in this briefing. The evidence for Kendall DL includes 2 randomised controlled trials and 1 retrospective observational study, with a total of 36,146 surgery cases including cardiovascular surgery, general surgery and neurological surgery.

[Table 2](#) summarises the clinical evidence as well as its strengths and limitations.

## Overall assessment of the evidence

The studies compared the rates of surgical site infections and false alarms between disposable (Kendall DL) and reusable electrocardiogram (ECG) cable and lead systems. Of the 3 included studies, 2 were randomised controlled trials, both of which recruited patients from a single medical centre in the US. The randomisation was by care units not patients (cluster study design). One trial was not blinded because of the colour of the ECG cables.

Both randomised controlled trials were funded by the company.

## Table 2 Summary of selected studies

<u>Albert et al. (2014)</u>	
Study size, design and location	A cluster randomised controlled trial of 7,939 patients who had cardiovascular surgery, general surgery or neurological surgery, and 7,240 were included in study analysis.
Intervention and comparator(s)	Disposable ECG LWs. Cleaned reusable ECG LWs.
Key outcomes	In a 12-month study period, there was no difference in total infection rate between disposable and reusable ECG LW based on 100 patient days. Also, there was no difference in rates of BSI, VAP and SSI between the intervention and control group.
Strengths and limitations	A large number of people were included but these patients were recruited from a single medical centre. This trial was not blinded. Randomisation was by intensive care units not patients (a cluster study design). The study was funded by the company.
<u>Albert et al. (2015)</u>	
Study size, design and location	A cluster randomised controlled trial of 1,611 patients having cardiac surgery in the US.
Intervention and comparator(s)	The Kendall DL disposable cable and LW system. Reusable ECG LWs.
Key outcomes	A total of 1,611 patients had 233 admissions (each of which counted as 1 case).  The analysis based on all alarms recorded, showed that disposable ECG LWs led to a 29% reduction in no-telemetry, leads-fail and leads-off alarms (RR=0.71, 95% CI 0.53 to 0.96) during the 4-month period and showed statistical non-inferiority in monitoring alarms and false alarms (p=0.002).

Strengths and limitations	<p>Randomisation was described in the study. A large number of patients were included but these patients were recruited from a single medical centre. Data were obtained by remote monitoring personnel who recorded alarm event occurrence and types of events, and this may affect the accuracy and completeness of data due to errors.</p> <p>Randomisation was by medical units not patients (a cluster study design). Study data collection and analysis were funded by the company.</p>
<u>Lankiewicz et al. (2018)</u>	
Study size, design and location	A retrospective case-control study of 316 facilities where a total of 27,296 CABG procedures were done.
Intervention and comparator(s)	<p>Kendall DL disposable cable and LW system.</p> <p>Reusable ECG lead wire.</p>
Key outcomes	<p>During the 12-month study period, 42 hospitals did 4,450 (16.3%) CABG procedures using single-use ECG cable and lead systems and 274 hospitals did 22,846 (83.7%) CABG procedures using reusable ECG leads.</p> <p>The incidence rates of SSIs were significantly lower in the single-patient-use ECG cable and lead wire group compared with reusable ECG lead wire group (3.3% compared with 4.4%, <math>p=0.0403</math>). There was a significant 25% reduction with the single-patient-use ECG cable and lead wire at 90 days after CABG (<math>p=0.04</math>) but a non-significant 14% and 21% reduction at 30 days (<math>p=0.48</math>) and 60 days (<math>p=0.14</math>) after CABG respectively. The incidence rates between 2 groups were not significantly different at 30 days (1.3% in single use ECG group compared with 1.6% in reusable ECG group, <math>p=0.488</math>) and 60 days (2.7% compared with 3.4%, <math>p=0.1383</math>).</p>
Strengths and limitations	This is a retrospective study. The analysis was not patient level, but on the basis of the number CABG procedures performed at hospital level.
<p>Abbreviations: BSI, bloodstream infection; CABG, coronary artery bypass grafting; CI, confidence interval; ECG, electrocardiogram; LW, lead wire; RR, relative risk; SSI, surgical site infection; VAP, ventilator associated pneumonia.</p>	

## Recent and ongoing studies

No ongoing or in-development trials were identified.

## Specialist commentator comments

Comments on this technology were invited from clinical specialists working in the field and relevant patient organisations. The comments received are individual opinions and do not represent NICE's view.

Four specialists were familiar with or had used this technology before.

## Level of innovation

Commentators considered that the disposable concept and design of Kendall DL was novel. One commentator thought it was a modification of current standard care because reusable ECG cable and lead are used in the NHS. Other experts commented that Kendall DL was not widely used in the NHS.

## Potential patient impact

Two commentators thought disposable ECG cables and leads would reduce the possibility of cross-contamination between patients. They also thought that using the new technology with its disposable design would reduce the risk of equipment failure associated with repeated use of cables and leads. One of the experts stated that the technology would most benefit patients who have surgery associated with a long hospital stay. One commentator noted that Kendall DL may be associated with reduced infection rates, but evidence was weak and this clinical benefit might be offset by substantial increase in the cost of Kendall DL.

One commentator said that the technology could improve the accuracy of ECG monitoring by decreasing the risk of 'lead-off' false alarms because of the push button.

## Potential system impact

Fewer healthcare-associated infections and less staff time for responding to false alarms



were identified as potential system benefits. But all commentators agreed that more good quality research was needed to give robust clinical and economic evidence.

## General comments

One commentator noted that Kendall DL would probably be used for major surgery in different specialities. Using the technology in patients who have cardiac surgery may not show clinical or economic benefits because the length of hospital stay could be too short. Another commentator suggested that the evidence base for the use of Kendall DL was weak and the cost of the technology could prevent its use in the NHS.

## Specialist commentators

The following clinicians contributed to this briefing:

- Muzahir Tayebjee, consultant in cardiology and cardiac electrophysiology, Leeds Teaching Hospitals NHS Trust, did not declare any interests.
- Nick Curzen, consultant interventional cardiologist and professor of interventional cardiology, University Hospital Southampton NHS Foundation Trust, did not declare any interests.
- Nicholas Gall, consultant cardiologist, King's College Hospital NHS Foundation Trust, did not declare any interests.
- Steven Knight, consultant in anaesthesia, Wythenshawe Hospital, Manchester University NHS Foundation Trust, did not declare any interests.

## Development of this briefing

This briefing was developed by NICE. The [interim process and 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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