

# NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

## Diagnosics Assessment Programme

### KardiaMobile 6L for measuring QT interval in people having antipsychotic medication

#### Final scope

February 2022

#### **1 Introduction**

The topic selection oversight panel identified the use of the KardiaMobile 6L ECG device to measure QT interval in people having antipsychotic medication as potentially suitable for evaluation by the Diagnostics Assessment Programme on the basis of a topic briefing.

The final scope was informed by discussions at the scoping workshop on 2 February 2022 and the assessment subgroup meeting held on 16 February 2022. A glossary of terms and a list of abbreviations are provided in appendices A and B.

#### **2 Description of the technology**

This section describes the properties of the diagnostic technology based on information provided to NICE from the manufacturers and on information available in the public domain. NICE has not carried out an independent evaluation of this description.

##### **2.1 Purpose of the medical technologies**

People taking antipsychotic medications may need to be tested for cardiac abnormalities before starting medication and at regular intervals during treatment. Detection of cardiac abnormalities can inform choice of therapy, dosing, whether to discontinue therapy, and potentially avoid severe cardiac events.

Current practice is to use 12-lead ECG devices in primary or secondary care centres. These require the service user to partially undress, and use conductive gel to create contact with the electrodes. This can cause reluctance or even distress.

The KardiaMobile 6L is a handheld ECG device which offers a less intrusive way to take ECG measurements that do not require conductive gel or as much undressing. This benefit may be particularly relevant for people with acute psychosis or mania who may not be able to tolerate traditional ECG measurement, but is also helpful for people who may be uncomfortable undressing for the test for a variety of reasons (see [Section 7](#)).

Like other groups, people taking antipsychotic medication may find it difficult to attend appointments at healthcare centres, or may not be able to travel for ECG appointments.

The KardiaMobile 6L is easily transported so can be used by community healthcare practitioners on home visits. It could increase the likelihood that people will have an ECG done regularly and may result in more cardiac irregularities being identified. Additionally, it may reduce costs and time associated with ECG monitoring by reducing the number of appointments in hospitals or GP surgeries, and could release capacity for traditional 12-lead ECG use for other indications.

Clinical experts advised that the KardiaMobile 6L is most likely to be used as a screening tool, and any abnormalities detected would be confirmed by traditional 12-lead ECG.

## **2.2 Product properties**

An ECG is a test to measure heart rhythm and electrical activity. Electrodes in contact with the skin detect the electrical signals produced by the heart as it beats ([NHS 2021](#)). Multiple views of the heart can be recorded by placing electrodes at different places on the body. These different views are referred to as ECG leads, and are displayed as separate traces on the output (Sattar 2021). A conventional ECG records 12 leads using 10 electrodes, which are split into 6 limb leads which view the heart in a vertical plane, and 6 precordial leads which view the heart in a horizontal plane (see [glossary](#) for more information). For the relevance of ECG to people taking antipsychotic medication, please see [Section 3.2](#).

### *2.2.1 KardiaMobile 6L (AliveCor)*

The KardiaMobile 6L is a portable handheld 6-lead ECG device that is manufactured by AliveCor. It uses 3 electrodes to record a person's ECG and wirelessly transmits the data as a PDF to a [compatible smartphone or tablet](#) via Bluetooth. This can then be sent via email to physicians. The device is powered by a single coin cell battery.

There are 2 electrodes on the top of the device for use with the left and right hands, and 1 on the bottom of the device for use with the bare skin of the left knee or inside of ankle. The service user is usually seated for the test. In single-channel mode, the KardiaMobile 6L can record Lead I ECG. In 2-channel mode, it can record a 6-lead ECG ([KardiaMobile 6L user manual](#)). The company state that users can be trained quickly by following the instructions for use and instructions from within the app, but training by company representatives can be supplied if required.

The company state that the device provides an instant algorithmic analysis of a person's heart rhythm upon completion of the ECG recording. This indicates normal sinus rhythm, atrial fibrillation, bradycardia, tachycardia, or an unclassified result for both single-lead and 6-lead ECGs. Currently, QT interval must be calculated by the user, however the company is developing software to allow automated QT interval analysis.

In a pilot programme, the results of the test were shared with a cardiologist or other appropriate clinician for analysis, and then sent to the service user's clinical team with any abnormalities highlighted ([NHSX case study 2021](#)). A 12-lead ECG may be required in cases where the outcome of the 6-lead device is unclear, or if other heart conditions such as ischaemia or left ventricular hypertrophy are suspected (Azram et al. 2021).

The KardiaMobile 6L has not been tested for and is not intended for paediatric use. The company state that significant body fat, body hair or very dry skin can interfere with the electrodes. Exposure to strong magnetic fields can also cause interference.

### **3 Target conditions**

#### **3.1 Conditions in which antipsychotic medications may be prescribed**

Psychosis (sometimes referred to as psychotic episodes or experiences) is a mental health condition that causes people to see or interpret things differently to other people. The main manifestations of psychosis are hallucinations and delusions ([NHS 2019](#)). Clinical experts advised that ECG has the potential to provide the most clinical benefit in conditions where people are likely to take antipsychotic medications for long enough to reach a steady state, outside of acute hospital settings.

##### *3.1.1 Schizophrenia and associated disorders*

Psychotic disorders include schizophrenia, schizoaffective disorder, schizophreniform disorder and delusional disorder. Schizophrenia affects

about 1 in every 100 adults in the UK over the course of their lifetime ([British Psychological Society 2017](#), [Royal College of Psychiatrists 2015](#)). Psychotic experiences vary in nature, frequency and intensity, and many people may not contact or require mental health services. Men and women are affected equally, but it is more common in city areas and in some minority ethnic groups, particularly people of African and African-Caribbean family background.

According to the NICE [clinical guidelines on psychosis and schizophrenia in adults](#), cognitive behavioural therapy with or without family intervention is recommended for both people at risk of developing psychosis and those with a first episode of psychosis. Antipsychotic medication should be offered to people with a first episode of psychosis. Medication is not recommended for people considered at increased risk of developing psychosis, or for the purpose of decreasing the risk of or preventing psychosis.

Antipsychotic medication should be chosen by the service user and the healthcare professional together, considering the possible benefits and side effects. Doses should be started at the lower end of the licensed range and titrated upwards. Response to treatment, side effects, and physical health (for example, weight, blood pressure, waist circumference) should be monitored regularly and systematically throughout treatment.

NICE guidelines also recommend monitoring cardiovascular health in people with psychosis and schizophrenia at least annually.

Postpartum psychosis is a severe mental illness developing shortly after childbirth, and affects about 0.1% of women who have a baby ([Royal College of Psychiatrists 2018](#)). Antipsychotic medication is likely to be given to people affected by postpartum psychosis, alongside a mood-stabilising drug. As with other people starting antipsychotic treatment, an ECG may be appropriate prior to initiation of the drug.

### *3.1.2 Bipolar disorder*

Bipolar disorder is a mental health condition in which a person experiences episodes of mania and episodes of depressed mood which can last for several weeks or months ([Royal College of Psychiatrists 2020](#)). The peak age of onset is 15–19 years, and there is often a substantial delay between onset and first contact with mental health services. The lifetime prevalence of bipolar I disorder (mania and depression) is estimated at 1% of the adult population, and bipolar II disorder (hypomania and depression) affects approximately 0.4% of adults.

According to the NICE [clinical guideline on bipolar disorder](#), the antipsychotic medications haloperidol, olanzapine, quetiapine or risperidone can be offered to people with bipolar disorder during periods of mania. It is recommended that the medication is chosen in collaboration with the service user, and that the medication regimen is regularly reviewed so that drugs that are not needed after the acute episode are stopped. People with moderate or severe bipolar depression may be offered olanzapine or quetiapine. Antipsychotics may be also used long-term to prevent relapse if lithium is poorly tolerated or is not suitable.

NICE guidelines recommend that the physical health of people with bipolar disorder, including cardiovascular health, should be monitored at least annually.

### 3.1.3 Dementia

People with dementia may experience severe agitation, aggression or psychotic symptoms ([Alzheimer's Society 2021](#)). According to the [NICE guideline on dementia: assessment, management and support for people living with dementia and their carers](#), antipsychotic medications may be offered for people with these symptoms if they are at risk of harming themselves or others, or if they are experiencing agitation, hallucinations or delusions that are causing them severe distress. Apart from risperidone and haloperidol, this is generally an off-label use of antipsychotics. NICE also recommends conducting a structured assessment to explore possible reasons for the distress before considering antipsychotic medication ([Antipsychotics in people living with dementia 2019](#)).

It is recommended to use the lowest effective dose for the shortest possible time, and to reassess the person at least every 6 weeks to check whether ongoing medication is still required. Clinical experts advised that antipsychotics are usually a last resort if non-pharmacological interventions or de-escalation techniques are unsuccessful, however they also noted that prescription of antipsychotics for behavioural and psychological symptoms in dementia has increased during the COVID-19 pandemic.

### 3.1.4 Depression

If a person has depression that does not respond well to initial treatment with antidepressants, concomitant antipsychotic medication such as aripiprazole, olanzapine, quetiapine or risperidone may be used to augment treatment ([NICE guideline on depression 2009](#)). Decisions to use antipsychotics in this manner should be made with care given that some antidepressants can also prolong the QT interval (see [Section 6](#)).

### 3.2 QT prolongation and arrhythmia

Life expectancy for adults diagnosed with psychosis or schizophrenia is between 15 and 20 years less than for people in the general population, which is in part due to physical comorbidities including cardiovascular disorders ([NICE Quality Standard for psychosis and schizophrenia in adults 2015](#)). These can be exacerbated by the use of certain antipsychotic medications which are associated with prolonged ventricular repolarisation, potentially giving rise to QT interval prolongation and subsequent arrhythmias, such as polymorphic ventricular tachycardia. This can cause convulsions, dizziness and fainting, and in some cases can lead to ventricular fibrillation and sudden cardiac death ([Royal College of Psychiatrists consensus statement 2014](#)).

These risks are increased with higher doses. Risk is also higher in some groups of people; for example, women, people with cardiovascular or liver disease, and people taking other drugs with cardiac effects or adverse pharmacokinetic interactions ([Royal College of Psychiatrists consensus statement 2014](#)). Certain drugs are considered to have a greater effect on QT interval than others, although this categorisation varies between NHS trusts (see example categorisation in table below). Differences in the effects on QT interval rarely reach statistical significance (Taylor et al. 2021). Giving antipsychotics intravenously carries a higher risk of prolonging QT interval due to higher drug concentrations and corresponding greater cardiac exposure (Drew et al. 2010), although experts noted that intravenous antipsychotics are rarely used outside acute hospital settings. As the QT interval is dependent on heart rate, it is often reported as a corrected QT interval (QTc) which can be calculated in multiple ways (Khatib 2021).

**Table 1: Effects of antipsychotics on QTc**

Antipsychotic drug	Effect on QTc <sup>1</sup>	Label recommendation for baseline ECG <sup>2</sup>	Label recommendation for CVD monitoring <sup>2</sup>
Any intravenous	High	–	–
Any high dose	High	–	–
Pimozide	High	Yes	Periodically
Amisulpride	Moderate	Yes	Per-user basis
Chlorpromazine	Moderate	Yes	No
Haloperidol	Moderate	Yes	Per-user basis
Levomepromazine	Moderate	May be appropriate	May be appropriate
Quetiapine	Moderate	No	No <sup>3</sup>
Aripiprazole	Low	No	No <sup>3</sup>
Asenapine	Low	No	No <sup>3</sup>
Clozapine	Low	May be appropriate	No <sup>3</sup>

Flupentixol	Low	No	No <sup>3</sup>
Loxapine	Low	No	No <sup>3</sup>
Prochlorperazine	Low	May be appropriate	Per-user basis
Olanzapine	Low	No	No <sup>3</sup>
Paliperidone	Low	No	No <sup>3</sup>
Risperidone	Low	No	No <sup>3</sup>
Sulpiride	Low	Yes	No <sup>3</sup>
Brexpiprazole	None yet observed	No	No <sup>3</sup>
Cariprazine	None yet observed	No	No <sup>3</sup>
Lurasidone	None yet observed	No	No <sup>3</sup>
Trifluoroperazine	Unknown	May be appropriate	Per-user basis
Zuclopenthixol	Unknown	No	No <sup>3</sup>
<sup>1</sup> Taylor et al. 2021; <sup>2</sup> labels obtained from <a href="http://www.medicines.org.uk">http://www.medicines.org.uk</a> or <a href="http://www.ema.europa.eu">www.ema.europa.eu</a> ; <sup>3</sup> caution advised when prescribing for service users with history of CVD.			

It is important to note that many antipsychotics cause other side effects apart from QT interval prolongation, including diabetes, weight gain, extrapyramidal symptoms, hormonal changes, and other cardiovascular disorders ([NICE clinical guidelines on psychosis and schizophrenia in adults](#), 2014). This assessment will not assess the KardiaMobile 6L for detection of cardiac conditions other than measuring QT interval.

### 3.3 Diagnostic and care pathway

#### 3.3.1 ECG assessment for starting and monitoring antipsychotic medication

The National Clinical Audit of Psychosis recommended that people with psychotic disorders are assessed for risk of cardiovascular disease at least annually, using the Q-Risk tool ([Core Audit 2017/18](#)). The choice of antipsychotic medication, the starting dose and/or the increase in frequency of monitoring should then be influenced by the presence of any cardiovascular disease history, as well as other factors such as poor nutrition or liver disease ([Royal College of Psychiatrists consensus statement 2014](#)). Identification of any cardiovascular risk factors should also prompt a more detailed cardiac assessment including an ECG, which should be examined for evidence of ischaemic heart disease, left ventricular hypertrophy and repolarisation abnormalities.

The consensus statement also states that an ECG done before, and during, antipsychotic therapy is important when:

- high-risk antipsychotic medication is being considered (for example, pimozide, haloperidol or sertindole)

- high-dose or short-acting, parenteral antipsychotic drug therapy is to be used in an elderly patient or a patient with a history of cardiovascular disease. ECGs should be performed every few days following initiation of high-dose treatment or during a period of dose escalation, until it is judged that steady state concentrations have been reached. ECG and electrolyte assessment is recommended every few months at times of acute illness, when potentially interacting drugs are introduced or if the person experiences symptoms that could be due to arrhythmia (for example, fainting or seizure).

Both the NICE [clinical guidelines on psychosis and schizophrenia in adults](#) and the [clinical guideline on bipolar disorder](#) recommend that a person should be offered an ECG before starting antipsychotic medication if:

- specified in the drug's summary of product characteristics
- a physical examination has identified specific cardiovascular risk
- there is a family history of cardiovascular disease, sudden collapse, or other cardiovascular risk factors such as arrhythmia or
- the service user is being admitted as an inpatient.

Clinical experts advised that another appointment for an ECG may be offered if a service user declines or is not able to comply with the initial ECG appointment, prior to antipsychotics being given.

A guideline and patient flow diagram from the [NHS Northern England clinical network](#) states that a baseline ECG should be done for all people starting antipsychotic medication. Clinical experts commented that ECGs are most commonly done for inpatients or people with cardiac comorbidities or risk factors, and are not done for all people starting antipsychotics.

Guidelines for managing drug-induced QT interval prolongation in UK clinical practice published in the Postgraduate Medical Journal (Khatib 2020) suggest that drugs with a high risk of QTc prolongation should be avoided for people with pre-existing congenital QT interval prolongation. When initiating drugs with a high risk of QTc prolongation, ECG should be done at baseline, and may be repeated once the drug reaches steady state (4-5 half-lives). If the service user is taking other QTc prolonging medication, or has risk factors for QT interval prolongation, then regular ECG monitoring is recommended. ECG is also recommended after dose changes.

The British Heart Rhythm Society [clinical practice guidelines on the management of patients developing QT prolongation on antipsychotic medication](#) recommend that QT interval is measured using either Lead II or V5 (see [glossary](#)).



### 3.3.2 ECG outcomes and effects on clinical management

ECG outcomes, including measurement of the QT interval, may be interpreted by the ECG operator, or forwarded to a specialist nurse, consultant or ECG interpretation service. Some devices also offer automatic calculation of parameters including the QT interval.

According to the [NHS Northern England guideline](#), a QTc is considered normal if below 440 milliseconds (ms) for men, or below 470 ms for women. ECG should be repeated annually if a normal QTc is detected. If an abnormal QTc of more than 500 ms is detected, the guideline recommends immediate cessation of the suspected drug and urgent referral to a cardiologist. If the abnormal QTc is less than 500 ms, it is advised to decrease the dose of antipsychotic or consider switching to an alternative drug with a lower risk of increased QTc.

#### [Dorset Medicines Advisory Group guidance for mental health prescribers](#)

advises not to use QT-prolonging drugs if QTc is more than 460 ms and the patient has had an unexplained syncopal episode. If the QTc is between 480 and 499 ms, it is advised to consider alternative therapy or monitor QT interval monthly, to correct electrolyte imbalances, and to consider referral to cardiology. If the QTc is more than 500 ms or has increased by more than 60 ms, the QT-prolonging drug should be discontinued and the service user referred to cardiology.

Khatib et al. recommend that, if a significant change in QTc is observed (increase greater than 50 ms or absolute value more than 500 ms), dose reduction or drug cessation should be considered. Although cardiologists may be consulted in the case of uncertain ECGs, the authors note that the decision on dose change lies with the prescriber.

Similar recommendations are given by the British Heart Rhythm Society, with the added guideline that treatment should be reviewed if abnormal T-wave morphology is observed. In this case, dose reduction or treatment switch should be considered (Lambiase et al. 2019).

Clinical experts advised that changes to antipsychotic medication following detection of prolonged QT intervals are made following an assessment of the relative risk and benefit of treating the psychiatric condition versus cardiac side effects. The frequency of ECG monitoring may also be increased. Some experts noted that the risk of cardiac complications is often considered lower than the risks of psychotic symptoms if antipsychotics are not given.

### **3.4 Service user issues and preferences**

KardiaMobile 6L can be done during a routine home visit by a community health professional, and the results emailed to the person's clinical team. This may reduce stress and anxiety as the test can be done in familiar surroundings. ECG testing is also likely to be done more regularly if the tests do not require travel to a GP surgery or hospital.

Some service users may prefer to attend an appointment for ECG outside of their home. In these cases, the service user should be offered a choice as to the location of the test, and if possible which device is used.

Like other groups, people with psychotic disorders may be uncomfortable with physical touch or undressing, or may not be able to cooperate, particularly during episodes of acute psychosis. Using the KardiaMobile 6L does not require the service user to partially undress or use conductive gel. Therefore, this device could be considered less intrusive than traditional 12-lead devices (see [Section 4](#)) and may allow an ECG to be done in cases where a 12-lead ECG is not possible. This could avoid giving a high-risk antipsychotic to a person with an already-prolonged QT interval. GP clinical experts advised that people who are stable on antipsychotics generally do not have issues with 12-lead ECGs when used for monitoring purposes.

## **4 Comparator**

Current practice is to use a 12-lead ECG. It is usually done in either a primary or secondary healthcare setting, and requires a trained professional to use the machine ([NHSX case study 2021](#)). 12-lead ECG requires a person to partially undress and to have a conductive gel applied to their skin for 10 electrodes to be applied to the torso and limbs. The service user is usually inclined between horizontal and 45 degrees for the test ([Society for Cardiological Science and Technology, 2017](#)). Multiple manufacturers supply 12-lead ECG devices to the NHS ([NHS supply chain](#)). Some devices only provide printed outputs, which are harder to distribute to relevant clinicians than digital outputs. The devices are usually large and difficult to transport, making home visits challenging.

12-lead ECG offers additional electrical views of the heart that are not available in 6-lead devices, therefore can provide more information and diagnose conditions such as ischaemia, left ventricular hypertrophy or unstable angina (expert advice, Azram et al. 2021, Kleiman et al. 2021). Interpretation of ECGs may be done by the operator (for example, a GP), an algorithm provided by the manufacturer, or an external ECG interpretation service.

QT interval times vary between leads of the 12-lead ECG, and the mean QT interval of all 12 leads is considered the best estimator (Azram et al. 2021). Clinical experts highlighted that 12-lead ECG machines could be used with only the limb leads to take a 6-lead reading to calculate QT interval, which would not require the service user to remove clothing.

## 5 Scope of the assessment

**Table 2: Scope of the assessment**

<b>Decision question</b>	Does the use of KardiaMobile 6L for measuring QT interval in adults taking antipsychotic medications represent a clinical and cost-effective use of NHS resources?
<b>Populations</b>	<ul style="list-style-type: none"> <li>Adults indicated for an ECG prior to starting antipsychotic medication</li> <li>Adults taking antipsychotic medication who require ECG to monitor QT interval</li> </ul> <p>Where data permit, the following subgroups may be considered:</p> <ul style="list-style-type: none"> <li>Condition-specific subgroups (psychosis and schizophrenia, bipolar disorder, dementia, depression)</li> </ul>
<b>Intervention</b>	KardiaMobile 6L
<b>Comparator</b>	Traditional 12-lead ECG performed in primary or secondary care
<b>Healthcare setting</b>	<ul style="list-style-type: none"> <li>Community (people's homes or care homes)</li> <li>Primary care (GP, primary care centres or rehabilitation centres)</li> <li>Psychiatric inpatient facilities</li> <li>Psychiatric outpatient clinics (including community mental health teams)</li> </ul>
<b>Outcomes</b>	<p>Intermediate measures for consideration may include:</p> <ul style="list-style-type: none"> <li>Test accuracy or concordance for QT interval</li> <li>Impact of test result on clinical decision making</li> <li>Ease of use (for service users and healthcare professionals), including training requirements, cleaning of the device between uses and time to obtain ECG</li> <li>Number of appointments (for both ECG and psychiatric clinic)</li> <li>Attendance at ECG appointments or acceptance of ECG test</li> <li>Appointment length (including time to take ECG and time for general care of the service user)</li> </ul>

	<ul style="list-style-type: none"> <li>• Number of traditional 12-lead ECGs required after KardiaMobile 6L</li> <li>• Number of requests for ECG interpretation to cardiology</li> <li>• Time from decision to use antipsychotic medication to prescription</li> <li>• Test failure rate and reasons for failure</li> <li>• Hospitalisations due to cardiac or psychiatric incidents</li> <li>• Referrals to mental health crisis teams</li> </ul>
	<p>Clinical outcomes for consideration may include:</p> <ul style="list-style-type: none"> <li>• Mortality (particularly sudden cardiac death and suicide)</li> <li>• Morbidity <ul style="list-style-type: none"> <li>○ Cardiac events (symptomatic and asymptomatic arrhythmias, syncope, cardiac arrest, stroke)</li> <li>○ Other adverse effects of antipsychotic medication</li> </ul> </li> </ul>
	<p>User-reported outcomes for consideration may include:</p> <ul style="list-style-type: none"> <li>• Health-related quality of life</li> <li>• Preference for different testing modalities</li> </ul>
	<p>Costs will be considered from an NHS and Personal Social Services perspective. Costs for consideration may include:</p> <ul style="list-style-type: none"> <li>• Costs related to use of devices, including purchase costs, software subscriptions and consumable costs</li> <li>• Costs related to doing the tests, including staff time for travel, and time for testing and interpretation</li> <li>• Cost of training, including operating ECG devices and interpreting ECG outputs</li> <li>• Cost of treatment (including treatment of any cardiac or psychiatric conditions)</li> <li>• Cost of missed appointments</li> </ul>
	<p>The cost-effectiveness of interventions should be expressed in terms of incremental cost per quality-adjusted life year.</p>
<b>Time horizon</b>	<p>The time horizon for estimating clinical and cost effectiveness should be sufficiently long to reflect any differences in costs or outcomes between the technologies being compared.</p>

## 6 Other issues for consideration

Clinical experts advised that often 12-lead ECGs are not available in psychiatric clinics or for home visits, therefore initiating antipsychotics can require a separate appointment at a GP or local hospital for the ECG and then an additional psychiatric appointment for the final prescription once the ECG data are available. Experts suggested that easier access to ECGs (of any

kind) may increase the use of ECG as a baseline test before starting a QT-prolonging drug. This may have an effect on the number of cardiac-related deaths due to medication, but would also impact on cardiology services for ECG reviews.

Use of ECGs for monitoring cardiac health for people with mental health conditions is variable across the UK (Crowther et al. 2021), and non-cardiology healthcare professionals interpreting ECGs infrequently may not feel confident or be sufficiently qualified to interpret them. Clinical experts advised that QT interval calculation is not straightforward, and that ECGs are routinely sent to cardiology departments for interpretation. They also highlighted that training is important to ensure that good quality ECGs are obtained. Additional costs may be incurred by use of the KardiaMobile 6L due to training, or because of unnecessary further follow-up in cases where the device is unable to classify a measured ECG or false positive alerts are generated.

Many medications offered to psychiatric service users can prolong the QT interval, including the antidepressants citalopram and escitalopram ([NICE Clinical Knowledge Summaries 2021](#)), tricyclic antidepressants ([NHS 2021](#)) and methadone ([NICE 2007](#)). ECGs may be appropriate for people taking these medications if they also have risk factors for cardiac disease, although clinical experts advise that this may not be current practice due to access issues. The use of KardiaMobile 6L for measuring QT interval in people taking QTc-prolonging medications other than antipsychotics is outside the scope of this assessment.

## **7 Potential equality issues**

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others.

KardiaMobile 6L may not be suitable for use in people with upper limb amputations or missing fingers. The accuracy of readings taken using the devices may be adversely affected if a person has a skin condition causing irritation, inflammation, or very dry skin. The devices may not perform correctly for people with a pacemaker or implantable defibrillator. Readings from people with tremors or difficulty sitting still may also be inaccurate.

Devices that use torso electrodes may need people with significant body hair to shave for adequate contact with the skin.

People may be uncomfortable with undressing for an ECG that requires torso electrodes for a variety of reasons, including:

- Culture or religion
- Having a different gender to the ECG operator
- Having a different gender identity to their birth sex
- Experiencing hyper-sensitivity, for example due to autism spectrum disorder
- Having a history of trauma or sexual abuse.

Service users should be asked to remove only clothing preventing access to the correct electrode positions. A chaperone may be requested for appointments using these devices ([Society for Cardiological Science and Technology, 2017](#)).

People from minority ethnic backgrounds, particularly people of African and African-Caribbean family background living in the UK, are more likely than white British people to be diagnosed with schizophrenia ([British Psychological Society 2017](#)). They are also more likely to be detained, given medication against their will, or given higher doses.

Neurodiverse people (for example those with autism spectrum disorder) may be more likely to have antipsychotic medication than the general population (Alfageh et al. 2019; Deb et al. 2020).

Women typically have a longer QT interval than men and therefore may be more susceptible to the effects of QT-prolonging medication ([Royal College of Psychiatrists consensus statement 2014](#)). Different QTc thresholds may be used for men and women ([NHS Northern England guideline](#)).

Antipsychotic medication is likely to be given to people affected by postpartum psychosis. ECG testing may be appropriate for this population prior to initiation of treatment.

The KardiaMobile 6L instructions for use state that the device has not been tested for and is not intended for paediatric use, therefore the scope of this assessment has been restricted to adults.

## **8 Potential implementation issues**

KardiaMobile 6L needs to connect to the internet to transmit ECG data to clinicians, which may not be possible for some home visits.

The ability to save and send information could be a risk to data protection and information governance if not done correctly. If clinicians and managers have a concern that using the devices could pose a risk to data protection and information governance, this could act as a barrier to adoption. Companies have stated that they have appropriate systems in place to ensure the devices

and software are compliant with the relevant policies and law. However, organisations seeking to adopt these technologies will need appropriate governance in place, with the flexibility to update as regulations and legislation change.

Many devices may be needed to serve the population, which would have a significant resource impact.

Devices may need [digital technology assessment criteria](#) (DTAC) approval before being able to be used in NHS trusts.

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## Appendix A Glossary of terms

An **ECG electrode** is a conductive pad which is placed on the skin to record electrical activity.

An **ECG lead** is a graphical representation of the heart's electrical activity which is calculated by analysing data from one or two ECG electrodes. The 6 leads recorded by KardiaMobile 6L are:

- Lead I – lateral view between right arm and left arm electrodes.
- Lead II – inferior view between right arm and left leg electrodes.
- Lead III – inferior view between left arm and left leg electrodes.
- aVR – calculated by analysing activity between the sum of the left arm and left leg electrodes and the right arm electrode.
- aVL – calculated by analysing activity between the sum of the right arm and left leg electrodes and the left arm electrode.
- aVF – calculated by analysing activity between the sum of the right arm and left arm electrodes and the left leg electrode.

The precordial leads V1–V6 are calculated using activity from electrodes placed on the surface of the torso and are not available when using the KardiaMobile 6L.

**Extrapyramidal symptoms** are a group of drug-induced movement disorders including involuntary movements, tremors or muscle contractions.

**QT interval** is the time between the beginning of the Q wave and the end of the T wave in an ECG. It represents the time taken for the ventricles of the heart to depolarise and then repolarise. A corrected QT interval (QTc) is often reported which accounts for heart rate.

The [Q-Risk tool](#) is an algorithm used to calculate a person's risk of developing a heart attack or stroke over the next 10 years.

**Syncope** is the medical term for fainting or passing out.



## Appendix B

## Abbreviations

CVD	Cardiovascular disease
ECG	Electrocardiogram
GDPR	<a href="#">General data protection regulation</a>
PDF	Portable document format
QTc	Corrected QT interval

## Appendix C      References

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