

Clinical review

Adult ECG Electrodes

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Guidance for use

This clinical evaluation report is aimed primarily at the NHS and all those working to support patient care. If you would like to talk through how this report can be used in your setting, please contact the team by emailing:

clinical.evaluationteam@nhs.net

Please note that the product assessment results should only be read and used in conjunction with the full text of this clinical review.

1. Introduction

The NHS Clinical Evaluation Team (CET) was established in April 2016. The team's remit is to add independent clinical review to 'everyday healthcare consumables' used by the NHS.

Everyday healthcare consumables are products that are found in the majority of wards, clinics, health centres, treatment rooms and district nurses' bags across the NHS. The purpose of this report is two-fold: firstly, to provide a clinical assessment of the usability and requirements from the NHS for Adult Electrocardiogram (ECG) Electrodes that are available to the NHS from the national procurement provider (NHS Supply Chain) and secondly, to provide a clinical overview of functions and properties that the clinicians in the NHS require of Adult ECG Electrodes.

It is apparent that Adult ECG Electrodes, featured in this report, are everyday healthcare consumables which can be found in clinics, wards and within mobile health services. They would certainly be items included in any stock list to set up a new clinical service. On that basis, the project was approved by the Clinical Reference Board and culminates in the production of this report for their approval in November 2017.

Based on data collected over a period of 12 months, supplied by the current national provider, NHS Supply Chain, who have approximately 40% of the market share, the NHS purchases more than 152 million Adult ECG Electrodes annually.

There are 242 Adult ECG Electrodes in this category reviewed by the NHS CET which are provided by 11 different suppliers. There are many different types of Adult ECG Electrodes on the market, with new products being launched to the UK market on a regular basis, however, for the purposes of this evaluation, only those products currently available through NHS Supply Chain have been included in the evaluation. This report covers the range of products available as of April 2017.

Information on Adult ECG Electrodes was collated from a variety of sources to provide further details on the current evidence available to support the way in which the devices are designed and clinically evaluated.

Following this information gathering, clinical conversations were held nationwide with the aim to define important clinical criteria for Adult ECG Electrodes from frontline NHS clinicians; identifying what was important, and what was unnecessary, together with additional factors that can truly only be identified by clinicians using these products in everyday practice. With each conversation this clinical criteria was further reviewed, developed and refined to reflect the national opinion.

The national clinical conversation events provided a lot of rich information from generalists and specialists from diverse clinical fields. It was recognised that cardiac physiologists, amongst others, are key clinical stakeholders in this project. Further conversations took place with individual specialists from various backgrounds and

the Society for Cardiological Science and Technology (SCST), the British Heart Foundation (BHF) and the British Heart Rhythm Society (BHRS). This information was reviewed and used to develop clinical criteria for Adult ECG Electrodes, against which all brands available from the national procurement provider were reviewed.

Findings from these clinical reviews are collated into a product assessment report to allow users to identify products and see how they performed against the agreed clinical criteria.

A more detailed description of the team, our pathway approach and clinical criteria is available in the NHS Clinical Evaluation Team Operating Manual, which can be found on our website at: www.nhsbsa.nhs.uk/cet.

2. Clinical review

2.1 Clinical definition and scope

This report is concerned with Adult ECG Electrodes only. This removed the more specialist areas of Paediatric, Neonate or Neurological in which different types of electrodes are used or supported consumables such as gels and monitoring leads.

The electrodes are categorised into 3 sections within the NHS Supply Chain catalogue:

- Diagnostic
- Monitoring
- Stress/Holter

Within these 3 groups it is possible that the electrodes can be used in different clinical settings and are not restricted by the section they are listed in. However, products have been categorised by component parts for comparison purposes.

2.2 Intended clinical use

An ECG is a medical test which is used to check for and diagnose possible cardiac conditions and arrhythmias.

The ECG electrode is a device which is applied to the skin and transfers the electrical activity produced by the heart to a monitoring or diagnostic devices which is capable of visualising the data. The location where electrodes are placed, the quantity used, shape, size and material properties can all vary, yet the functionality is the same (Society of Cardiological Science and Technology (SCST), 2014).

ECGs are an important and integral part of a patient's initial clinical diagnosis, monitoring and the decision making process relating to treatment, particularly life-saving treatment.

2.3 Clinical practice

Performing an ECG is part of the basic clinical observations and documenting of vital signs that should be carried out for any acutely unwell patient (Royal College of Nursing, 2017) (Resuscitation Council (UK), 2017).

2.4. Clinical impact

Poorly performing products can lead to a delayed reading and therefore misinterpretation, misdiagnosis and substandard patient experiences.

2.5. Other clinical considerations

If clinicians follow the best practice guidelines as described in section 3.2 and utilise correct skin preparation, there may be less need for stronger adhesives and advanced gels.

The quality of an ECG is influenced by several factors which can affect the ECG results:

- Immediate environment in which ECG is being recorded
- Patient preparation (see best practice guidelines)
- Type of ECG electrode chosen
- Attachment to the lead wires and connection to the monitor
- The positioning of lead wires
- Correct functioning of the leads
- Service status, age and condition of the ECG monitor

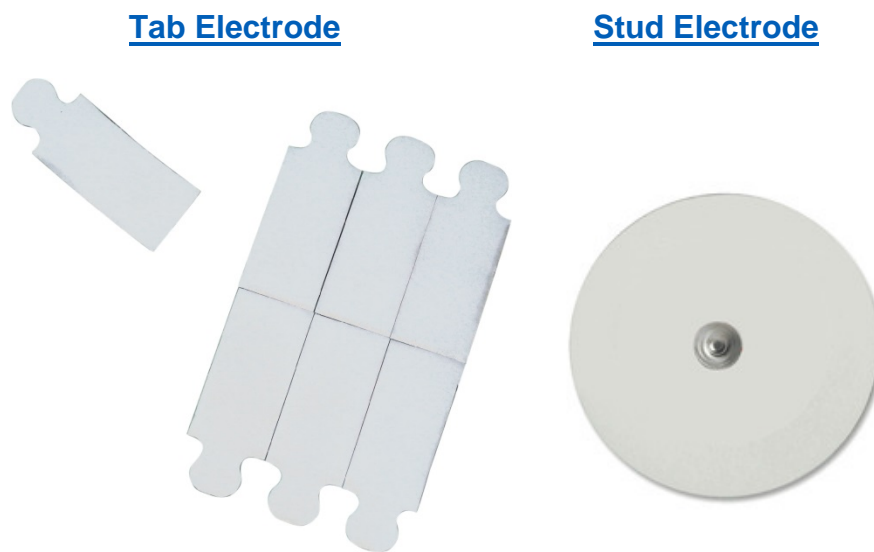
Whilst there are many well trained and qualified personnel, there is evidence that there is lack of competence amongst those who record ECGs. Studies from several countries repeatedly show that practitioners lack essential knowledge and skills and as a consequence, ECGs can be incorrectly recorded resulting in erroneous diagnosis and inappropriate treatment (Society of Cardiological Science & Technology (SCST), 2014).

Often, the ECG electrode is the first component to be criticised as this is the obvious variable in the process of undertaking an ECG. However, it is essential that all the above factors are taken into account prior to making this assumption.

2.6. Product technical design

Each ECG electrode is attached by a wire to an ECG monitor. The electrical activity of the heart is transmitted via this wire to the monitor, which translates the electrical impulses into a waveform that the machine then displays on a monitor and/or records on graph paper. The ECG records in such detail that the results can be used to diagnose a broad range of heart conditions by a trained clinician.

There are 2 main types of electrodes:



Tab electrodes

These are generally polymer-based products with a conductive adhesive covering the whole surface of the underside. Tab electrodes are generally used in the acquisition of routine assessment ECGs. Although these electrodes can remain on the skin for several hours, they are more commonly used to acquire a single ECG trace before being removed. They connect via a clip that does not offer a secure fix. Patients who require on-going monitoring would have an ECG electrode with a stud fixing or similar applied.

Stud electrodes

Stud electrodes can be produced from a variety of materials. It is important for a user to understand what will work best for the procedure and patient.

2.6.1. Connections

Adult ECG electrodes can be connected to an ECG monitor by various types of connections:

- Crocodile Clip Connector – Tab
- Snap Connectors – Stud
- 4mm Banana Connector – 4mm Banana Stud
- Universal (Snap & Tab)

Some electrodes have a Dual Connection (Snap & Tab) feature removing the need to replace electrodes when transferring between ECG devices. Alternatively, universal leads can be used.

2.6.2 Offset vs onset

The terms 'offset' and 'onset' refer to the position of the stud connection placement. 'Onset' has the connector placed in the centre of an electrode and 'offset' off-centre, usually in a teardrop shaped electrode.

There is a lack of evidence to support benefits of one type over another. Clinicians have observed that when the ECG lead wires are pulled whilst being attached to an onset stud electrode this causes the electrode gel to lose contact with the skin and the signal of the ECG is interrupted. However, with the offset electrode this pulling movement occurs away from the gel interface and minimises the risk of the signal being interrupted.

2.6.3 Material

i. Foam

Foams make up the majority of the stud electrodes which are used in everyday settings as they are versatile in their use. The electrode has an adhesive outer ring which adheres to the skin. A gel centre transmits the electrical signal through the connector. Foam electrodes have a protective barrier to prevent fluid interfering and a supplier sticker as a top layer. They can be used for the initial assessment of patients and kept on the skin for several days. There are a variety of different foams, gels and adhesives which are combined by the manufacturer as required. It has not been possible to determine foam or adhesive properties from the data that is available from suppliers.

ii. Cloth and tape

These are both designed for long term use (24 hours up to 7 days). Tape can follow the body's contours easily and is breathable, whilst cloth offers (in addition to tape features) increased flexibility, allowing the skin to move reducing the risk of damage.

Some adhesives become stronger over time, building a bond with the skin. It is worth noting that if these types of electrodes are removed too soon or incorrectly they can potentially cause skin damage.

Some products have features which allow the user to shower or wash with the electrode in place. Patients have indicated that, where clinically appropriate and with guidance, they would happily replace electrodes that came off themselves.

During this evaluation of products, a number of newer cloth / silicone type electrodes were highlighted as being significantly different to other products offering a pleasant and pain free experience on removal. Although these have some limitations, e.g. slide off in contact with water, they could offer a better clinical option for patients with high risk of skin damage. The evaluation results of these products have remained in the cloth matrix as information was not available to accurately separate them at this stage.

2.6.4 Gel types

There are 3 types of gel products available:

i. Solid gel

The majority of gels used in practice are classed as a solid gel. These provide a stable and constant performance over time.

ii. Wet gel

These products have the ability to obtain a clear and enhanced ECG trace quicker. The research evidence to support this is limited. Wet gel electrodes are also at risk of drying out as the moisture evaporates.

iii. Tac /sticky gel

There are newer, hybrid electrodes which are looking to achieve the rapid and clear ECG trace of wet gel and the duration of solid gel electrodes.

2.6.5. XRAY/MRI

Electrodes that meet this requirement have the metal stud fixing replaced by a carbon version which is more expensive to produce. No evidence has been found by the author that suggests that carbon electrodes perform differently to standard electrodes.

2.6.6 Storage

Pouches are designed to protect electrodes from sunlight, moisture and temperature. Once opened the remaining electrodes will have a limited shelf life which can be further influenced by extremes of high and low temperatures. To ensure that the electrodes continue to function correctly, users should store them away from heat sources and reseal or fold over the packaging to prevent the gel and adhesive from drying out. This is to prevent poor performance and failure to acquire a suitable trace.

It is recommended that the electrodes remain stored in the pouch and once opened the new expiry date shall be written on the pouch.

3. Pathway methods

Collated evidence has been used as a basis, alongside supplier submitted evidence, to help form initial ideas about product use, performance and requirements. This contributed to the development of the initial clinical criteria for Adult ECG Electrodes which was then taken to frontline clinical staff at national engagement events for development and validation.

3.1. Intelligence gathering

In preparation of the criteria, account has been taken of academic and related clinical evidence, known guidance and nationally recognised publications as further described in Section 3.

All suppliers listed within the national framework were invited to submit relevant evidence, product information and testing data to help support the review.

Account has also been taken of appropriate international and other standards as they pertain to the devices (e.g. ISO, EN and/or BSI). A review of MHRA alerts has also been carried out.

Finally, the specification used by NHS Supply Chain has been reviewed to understand what has previously been asked of suppliers of these devices.

Evidence from these sources has then been used as a basis to help form initial ideas around suitable clinically based statements of what clinical staff need from an Adult ECG Electrode and how it should perform in order to satisfy those identified clinical requirements.

3.1.1. Literature search

A literature search has been undertaken to establish what current academic knowledge exists on the products for evaluation. It should be noted that the team have not conducted a comprehensive or systematic review of literature. However, the team have interrogated the information to look for common themes which supported the development of the clinical criteria.

Initially, an evidence search was performed across the NICE service using the generic term (ECG, Electrocardiogram) in the following areas;

- Pathways - <https://pathways.nice.org.uk/>
- Guidance - <https://www.nice.org.uk/guidance/published>
- Clinical Knowledge Summaries <https://cks.nice.org.uk>

All searches returned no results.

Whilst this is not a full academic literature search, the principles applied had the same structured method when searching the online academic databases of CINAHL.

On the basis that our initial searches returned no results we then utilised a PIO framework as developed by Sackett (Sackett & al, 2000). This helped to break down the search question into 3 essential elements - **PIO** (**P**opulation or **P**roblem, **I**ntervention, **O**utcome/s).

Keywords were carefully chosen to retrieve the maximum number of relevant returns. Keywords were checked to ensure possible alternatives were included and the truncated symbol was used to include all possible spellings both US and UK and alternative word endings.

POI - Search Term		
Population	Intervention	Outcome
ECG	Electrode	Quality
EKG	Dot	Comparison
Electrocardiogram		Compare
		Adhesive
		Reaction
		Trace
		Problem
		Defect

These search terms produced no relevant results.

These and similar searches were independently verified by a third party experienced clinical librarian confirming the hypothesis that there is a fundamental lack of evidence based research or even low level research in which to support the electrode market.

3.1.2. National procurement provider specification

The current national procurement provider's (NHS Supply Chain) framework specification for the current framework combines ECG monitoring electrodes and ECG diagnostic electrodes in 2 lots. Suppliers can bid for either or both of these lots.

As the national procurement provider, NHS Supply Chain manages a framework of suppliers who are then listed in the national catalogue. The framework covers a wider selection of products than just ECG electrodes.

The specification, as used by NHS Supply Chain (2016), has been reviewed to understand what has previously been asked of suppliers of Adult ECG electrodes.

The specification includes, for example, the following:

- Electrodes should peel from their backing and affix to the skin with no slippage. They must also be removable without causing damage to the skin of the patient.
- Gel on the electrodes must be non-irritant and suitable for use on patients with sensitive skin.
- Tab electrodes must fix securely to the lead wire and should also be easily and cleanly peeled from their backing.
- Electrodes:
 - are for long or short term monitoring
 - can be either solid gel or wet gel
 - should have backings to be manufactured from foam, micro-porous tape, paper, carbon or cloth
 - can be either stud and/or tab style.

This has resulted in a framework that is significant in size with manufacturers producing electrodes for multiple suppliers. There can be minor differences between products which are not readily identifiable even when they are from the same supplier. It was difficult to find data on electrodes as not all products are listed in supplier catalogues or on company websites.

3.1.3. National and international safety and quality standards

The Medicines and Healthcare products Regulatory Agency (MHRA) website (<https://www.gov.uk/drug-device-alerts>) returned 1 result of limited importance to this case.

Account has also been taken of appropriate international and other standards as they pertain to ECG Electrodes (e.g. from the International Organisation for Standardisation (ISO), European Standards (EN) and/or British Standards Institution (BSI)).

Medical Device Directive 93/42/EEC as amended, currently in transition to the new Medical Device Regulation MDR 2017/745

- All products classified as a Medical Device must have their CE marking clearly evident on the product and/or packaging and meet the requirements set out within the standard(s) related to labelling.

BS EN ISO 15223-1-2016

- Symbols to be used with Medical Device Labels

BS EN ISO 10993-1: October 2009 Biological evaluation of medical devices.

- The primary aim is the protection of humans from potential biological risks arising from the use of medical devices. i.e. gels and adhesives

BS EN 60601-1:2006+A12:2014

- Medical electrical equipment, Part 1: General requirements for basic safety and essential performance

ANSI/AAMI EC12:2000 (R)2010 - Disposable ECG Electrodes

- This standard contains minimum labelling, safety and performance requirements; test methods; and terminology for disposable ECG electrodes.

3.1.4. Product suppliers and manufacturers

Requests for information were sent to all suppliers on the framework. A limited amount of information was received back which was reviewed and considered when designing clinical criteria and is summarised here:

- Effective skin preparation can reduce alarm fatigue by up to 77%.
- Changing of electrodes on a daily basis decreases the number of alarms requiring staff intervention (Cvach, et al., 2013) (Sendelbach, et al., 2015). The increased cost of electrodes easily outweighs the staff costs dealing with alarms.
- Offset electrodes help prevent wet gel dispersal when connecting to lead wires compared to onset.

The most common form of intelligence provided was individual data sheets for each different electrode. These supported the development of the matrix, allowing for the product elements to be developed and built upon.

No supplier provided any details on the type or level of adhesives used. As this information could not be found online either, this particular information was not pursued further for the purpose of this review.

This report recognises that some manufacturers of monitoring and diagnostic equipment only recommend the use of connector cabling and electrodes that they approve. These are often those which they supply themselves.

3.1.5. Quality of evidence

Hierarchy of evidence: Levels of evidence sometimes referred to as hierarchy of evidence are assigned to studies based on the methodological quality of their design, validity, and applicability to patient care.

All the evidence for Adult ECG Electrodes collected by the methods previously described, at best, scored Level 4 while most would be classed as Level 6 or 7.

(Melnyk & Fineout-Overholt, 2005, p. 10)

Hierarchy ranking	Description
Level 1	A systematic review of all relevant randomised controlled trials (RCT) or evidence-based clinical practice guidelines based on systematic reviews of RCT evidence
Level 2	Evidence from at least one well designed RCT
Level 3	Evidence from well-designed controlled trials; non-randomised, quasi experimental
Level 4	Well-designed case control & cohort studies
Level 5	Systematic reviews of descriptive and qualitative studies
Level 6	Evidence from a single, descriptive or qualitative study
Level 7	Evidence from the opinion of authorities and/or reports of expert committees

3.2. Best practice guidelines

The Society of Cardiological Science and Technology represents the Profession of Cardiac Physiologists and the subject specialists. They have produced a Clinical Guidelines by Consensus Report* which, in the absence of other national evidence, has been used as the basis for the summarised key points in relation to the use of electrodes (Society of Cardiological Science & Technology (SCST), 2014).

- In pre-planned assessments patients should be given advice (a leaflet) on how to prepare for an ECG. This includes information and instructions not to wear body creams or powders in the locations where electrodes are going to be placed and to clip (not shave) chest hair.
- Ensure that the patient understands what is happening during the examination. This reduces anxiety and muscle tremor. Consent for assessment is obtained.
- Where possible patients are examined in a private, walled room with the addition of a curtain. This provides dignity as “do not enter” signs do not always prevent staff entering and patients remain anxious.
- The room is at a comfortable temperature for someone in a state of undress and they are provided with a gown or blanket to preserve their dignity.
- Correct skin preparation:
 - clip chest hair (not to shave)
 - avoid alcohol-based products (inhibits electrical trace)
 - gently abrade the skin (gauze swabs or non-alcohol wipe)
 - ensure the area is as dry as possible
- Patient is positioned in the correct 45° semi recumbent position.
- Choose the right electrode for the right clinical requirement and the right patient type e.g. a patient with delicate tissue-like skin will need a different electrode to a young healthy adult.
- Attach leads to Centre Stud electrodes prior to electrode backing removal and applying to patient, thus protecting the adhesive border.
- Ensure that lead wires are correctly positioned to minimise distortion.

These extracts are designed to ensure that the patient is as relaxed as possible and the conditions are such that the ECG procedure can be done quickly, efficiently and produce the best trace possible without the need to utilise electrodes with extra adhesives, or replace electrodes due to grease and/or patient tremor. This offers a better patient perspective and clearer trace on which to base important treatment decisions.* Correct at date of publication

3.3. Patient perspectives

The British Heart Foundation has kindly provided access to its patient networks which has allowed the capture of vital patient perspectives on the subject which have been collated and support the best practice guidelines.

4. NHS clinical engagement

In order to develop a shared vision of what an Adult ECG Electrode should offer various methods of engagement were used.

Mapping exercises were undertaken to determine personnel that should be involved and/or consulted regarding these products. This stage of the report focused on NHS clinical staff who are either:

- a) recognised by peers as subject experts, and/or
- b) recognised regular users of the devices in their clinical practice.

Various methods of engagement were undertaken to ensure these clinical opinions were robust, and validated by peers from around the country, options of engagement included:

Regional and national face-to-face events with NHS clinical colleagues;

- Focussed visits to NHS clinicians regional and national face-to-face events;
- Website subscription;
- Attendance at specialist network events;
- Attendance at NHS Business Services Authority events;
- Web-based surveys and e-engagement tools (e.g. email, WebEx, portal-based surveys).

4.1. Clinical conversations

To build a broad spectrum of attendees at our events, letters were sent inviting Trusts to nominate clinical colleagues to attend a series of regional group events. These were hosted by NHS organisations throughout England to enable the widest possible access for all invited. This aimed to set aside any pre-existing regional variance.

Details of the information gathered were recorded in workbook form from the open events, transcribed and then used together with the evidence gathered at the previous project stage to inform a list of clinical criteria against which the product has been tested.

The questions used to stimulate discussion and further information gathering were developed following a questionnaire sent to the clinical procurement specialist network (CPSN), which represents nurses and other clinicians working in procurement roles at NHS Trusts, regional procurement hubs and NHS Supply Chain.

It is understood that electrodes are used in a variety of departments with a range of requirements based upon patient conditions (e.g. sweat levels or patient movement) and level of analysis of the produced ECG.

In order to capture the different requirements at the conversation events the following classification was created and clinical staff were asked to validate:

- Ambulance
- 12-lead diagnostic ECG
- General patient monitoring (includes theatres, labour wards etc.)
- Emergency trolley (crash cart)
- Long term monitoring
- Stress tests
- Ambulance
- Special requirements and cardiac specialists

Based upon the information received in the intelligence gathering phase of the project a series of questions were developed for NHS clinical colleagues to answer.

Examples of the evidence gathering criteria questions posed are:

PACKAGING

How important is

1. Design of the external packaging
2. Design of the internal packaging
3. The quantity of electrodes in a pouch (Please specify any requirements)
4. Wastage, due to incorrect package size
5. The shelf life of the product'

OPENING

How important is

6. Removal from the backing strip
7. A single backing strip
8. Individual backing pieces
9. Backing strip has colour / pattern
10. Guide to accurate placement

CLINICAL USE

How important is

11. That we have a range of different gel products?
12. Is having an abrasive skin prep feature?
13. Shape (note: round, square, oval products available)?
14. Size (any specific requirements)?
15. How long do electrodes need to adhere for? <1hr, 1 to 12hrs, 12 to 24hrs, >24hrs
16. How should the electrode connect to monitor (stud, clip, other, please specify)?
17. Is it to have clear (see-through) electrodes?
18. To have different colour electrodes?
19. Removal of the electrodes after use? What factors influence this?

DISPOSAL

How important is

20. Any specific disposal criteria for this product?
21. What would make a 'perfect' product if you could design your own based on your clinical experience and knowledge? What features would it have?

Clinicians who contributed were also given the opportunity to provide their own comments and narrative.

4.1.1. Clinical conversation insights

With regards to packaging, manufacturers must meet all the required standards; however clinicians expressed the view that it would be helpful if the pouch packaging was improved. Some suppliers include the mandatory information on the external box or accompanying leaflets. In clinical practice, products generally get decanted from the case and placed in drawers, on shelves or in cupboards and crash carts. Any accompanying information therefore gets lost when the outer packaging is disposed of.












Language / symbols used in the industry

It had become obvious that the language used in the market was not understood by the majority of those either using or purchasing the electrodes. Clinicians did not understand for example when a wet gel product should be used or why you would need to consider an offset connector.

Symbols have become commonplace on packaging and serve a vital purpose to clearly identify key information, particularly when supplying to multiple countries which require instructions in their native language. Less common was the use of bespoke symbols by individual manufacturers to denote properties (e.g. material composition cloth, tape or foam). These symbols were found to be confusing to users and delay choosing the correct product or identifying the information they need.

These are some of the more common symbols seen on packaging

:

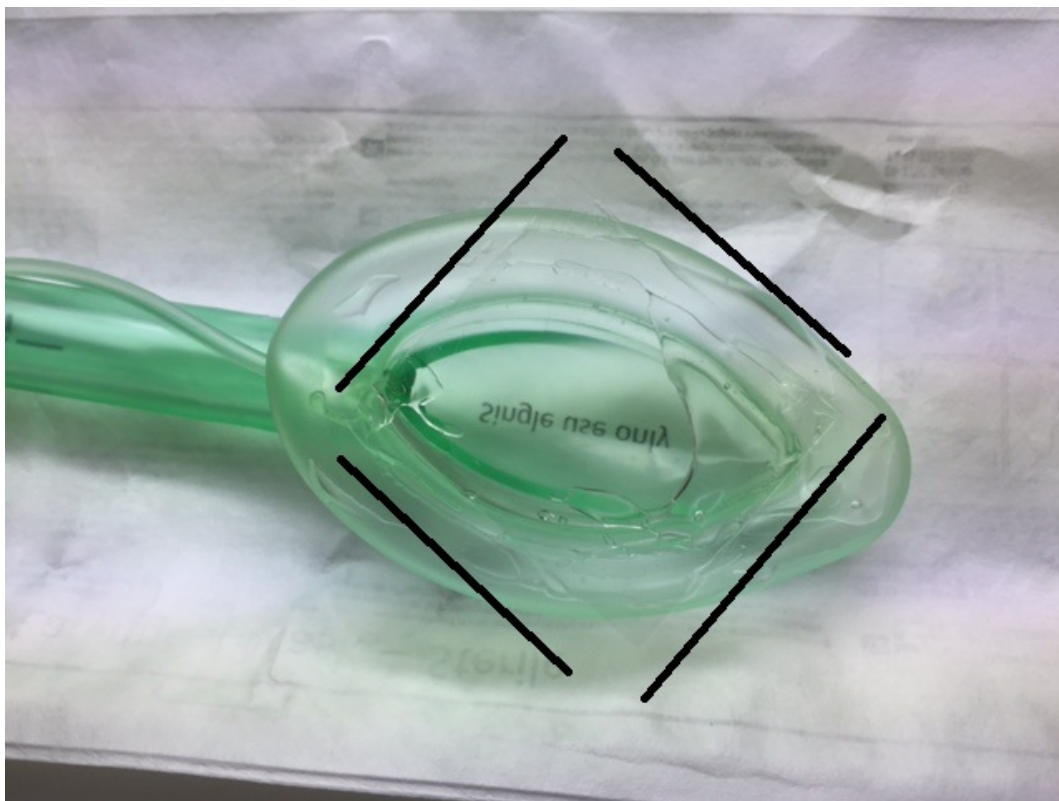
	Catalog Number
QTY	Quantity
Rx Only	Caution: U.S. Federal law restricts this device to sale by or on the order of a physician.
	Batch Code
	Refer to Instructions for Use
	Attention: See Instructions for Use
	Manufacturer
	Irradiation Sterilization
	Latex Free
	Expiration Date YYYY-MM
	Do Not Reuse

Observed hazards

One area identified through the clinical conversations that caused concern in clinical use was in relation to the plastic discs that protected the adhesive surface of the electrode prior to application. Multiple clinicians had either witnessed or they had slipped on the transparent disc that had fallen on the floor and could not be seen. This is widely recognised as being a trip/slip hazard by regular users particularly when each electrode has its own plastic backing disk.

An added concern has been a report of a plastic disc going unnoticed until it had entered a patient's airway attached to the surface of an LMA (Laryngeal Mask) and the anaesthetist spotting it before damage could be done. This is a recent incident which has been reported. The pictures below illustrate clearly how this could occur and therefore the impact of design on clinical practice

(The black lines in the image below help identify the backing)



Multiple clinicians observed that they had treated patients who had developed skin damage from the plastic discs going unnoticed amongst the sheets of a patient's bed and becoming stuck to the skin, particularly amongst the elderly and patients who were unconscious and therefore unable to raise concerns.

A small change to making these backing discs coloured or with prominent markings would make significant improvements reducing the risk of slips and staff injury and more importantly eliminate these types of incident.

4.2. Choosing the correct Adult ECG Electrode

In order to determine the evaluation criteria and to provide end users with data that helps inform clinical procurement decisions, it was important to first understand how the electrodes would be used and the features that are needed.

Clinicians and specialists provided details and helped to verify these groupings.

Function	Important features	Recommend
12-lead diagnostic ECG and routine examination	<ul style="list-style-type: none"> • Pouch design, information and ease of opening • Shelf life of an opened pouch (low use areas) • Multiple electrodes attached to backing card which are easily removed • Ease of removal from patient 	Tab Electrode Solid gel
General patient monitoring (includes theatres, labour wards etc.)	<ul style="list-style-type: none"> • Design of the pouch • Shelf life once opened • Electrodes are easy to remove from the backing and that backing has colour or pattern • Electrodes last up to 24hrs • Ease of removal 	Foam onset Solid gel
Emergency Trolley (Crash cart)	<ul style="list-style-type: none"> • Pouch quantity = 3pk • Multiple electrodes attached to backing card which is easily identified and electrodes are easy to remove • Last up to 12 hours • Stud connector 	Foam onset Solid gel (3 pack)
Long Term Monitoring	<ul style="list-style-type: none"> • Pouch shelf life • Colour / pattern to backing card • Up to 7 days • Removal • Ability for skin to breathe 	Cloth and tape (not wet gel)
Stress Tests	<ul style="list-style-type: none"> • Offset • Stud connector • Wet gel 	Foam offset
Ambulance	<ul style="list-style-type: none"> • Pouch quantity between 10 and 30 to minimise waste • Ease of opening robust pouch • Date easy to identify • Single electrode to backing piece • Wet gel, offset • Dual connection 	Foam dual connection Wet gel
Special requirements and cardiac specialists	<ul style="list-style-type: none"> • Pouch design so that properties and features are easy to spot 	

Long-term electrode feedback indicated that colour and shape were unimportant. Patients explained that they were more concerned with the bulky equipment and the removal of electrodes than how they looked.

4.3. Report limitations

Specialist independent laboratory advice was sought regarding the possibility of developing suitable tests which would add information to aid users with an appropriate and legitimate comparison option.

The evidence discovered was that, at the time of writing, there is yet to be a standard skin adhesion test developed which will be accepted as a benchmark for evaluation of products.

As part of the ISO standards / Medical Devices Directives a decision was taken by the Clinical Evaluation Team, in conjunction with experts, not to re-test standards relating to adhesion and electrical performance as manufacturers have already met the requirements to enter the NHS Supply Chain framework.

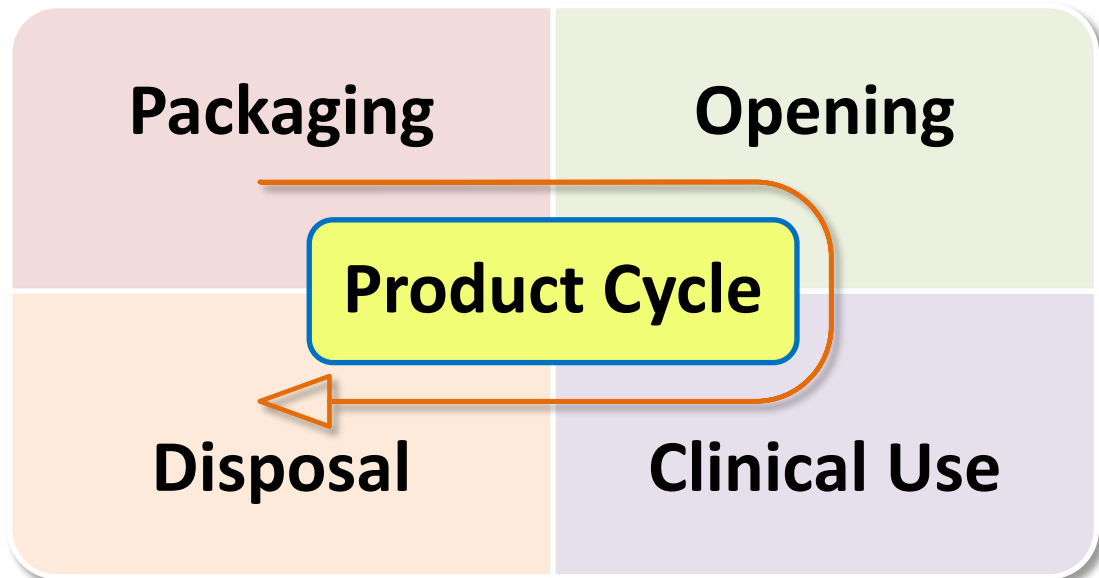
Clinical in-situ testing was considered, however, to acquire sufficient patient data (which would capture the variety of skin types, clinical environments and conditions to have validity) was prohibitive due to the number of products in the report.

It is therefore recommended that this report is used as a guide only.

4.4. Clinical criteria

The data received from all the NHS clinical conversation events, alongside the data collected from individual experts, was assimilated into a series of clinical criteria.

The clinical criteria were formulated to move through the key aspects of product use using the NHS Clinical Evaluation Team product cycle:



NHS Clinical Evaluation Team Product Cycle

A clinical criterion is defined for the purposes of this report as a principle or standard by which products may be evaluated. It is a statement which describes the clinician's requirements for the product.

The proposed criteria were validated by workshop attendees and all other clinical experts engaged in the development process. In addition, other clinical experts who are likely to add further useful insight were also included, leading to the finalised clinical criteria listed on the next page.

Pouch Labelling	Is the Expiry Date & Lot Number Or Manufacturing Date & Shelf Life clearly visible?
	Does the pouch clearly identify product wear time?
	Does the pouch clearly identify the shelf life once pouch opened?
	Are there clear instructions for use, including skin-preparation procedures and electrode preparation?
	Is the manufacturing product code clearly displayed?
	Does the Description clearly identify the electrode properties inside?
	Do the pouch / packet indicate clinical use?
Opening & Preparation:	Does the pouch / packet have a space to record date it was opened or new expiry date?
	Can the pouch / packet be easily opened without splitting or damaging the packaging using hands only?
Clinical Use	Do the electrodes remove easily from the backing piece?
	Does the product apply to the skin correctly and efficiently without wastage?
	Does the backing card have a colour or pattern which would make it visible on a floor or in the bedsheets?
	Is the electrode comfortable on the skin for the wearer?
	Any indications / aids for removal on the product?
	Discomfort or skin reaction on removal?
Disposal	Is there any indication that the pouch can be recycled?

4.5. Product evaluation

Evaluation methodologies are defined for each and every clinical criterion. They reflect the clinical environment.

Wherever possible, products were supplied in a 'ward-ready' unit of issue as would be found by clinical staff on accessing a store area in their clinical environment. Where this has not been possible it was acknowledged as part of the product assessment results matrix.

The evaluation product was ordered and supplied from NHS distribution centres. Products evaluated have been stored post evaluation for a period of three months after publication of this review.

NHS clinical staff, were invited to review the current range of ECG electrodes available through NHS Supply Chain in accordance with the developed criteria. It was not possible to 'blind' the evaluations; in the sense that the evaluators were aware of the product brand; however, the products to be evaluated were independently picked and prepared for evaluation by colleagues who were not otherwise involved in the process.

Each clinical evaluator entered data independently and without inter-rater comparison into their own workbook. These were then collated, reviewed and summarised by the clinical specialist lead for the project.

The defined criteria either prompted a 'yes/no' answer, or a subjective score was given from 0-3 as follows:

As part of the evaluation preparation, each evaluator was given a more detailed and product specific definition for each of the scores

Score	Meaning
0	This does not meet the criteria
1	This partially meets the criteria
2	This meets the criteria
3	This exceeds the criteria

NHS Clinical Evaluation Team scoring methods

These numerical scores across all evaluators were totalled and a mean value determined. This mean value has then been converted into a star rating (see matrix below).

The mean values convert to a star rating in accordance with the following table:

Point scored	Star value
0 to 0.99	0 Stars
1 to 1.24	1 Star
1.25 to 1.74	1.5 Stars
1.75 to 2.24	2 Stars
2.25 to 2.74	2.5 Stars
2.75 to 3	3 Stars

Conversion of mean scores to star rating

Evaluators were also encouraged to record comments where they felt it necessary to provide rationale for their scoring and answers.

The results obtained have been validated by the NHS Clinical Evaluation Team moderation committee for consistency of scoring and interpretation. These results are presented in the product assessment reports herein.

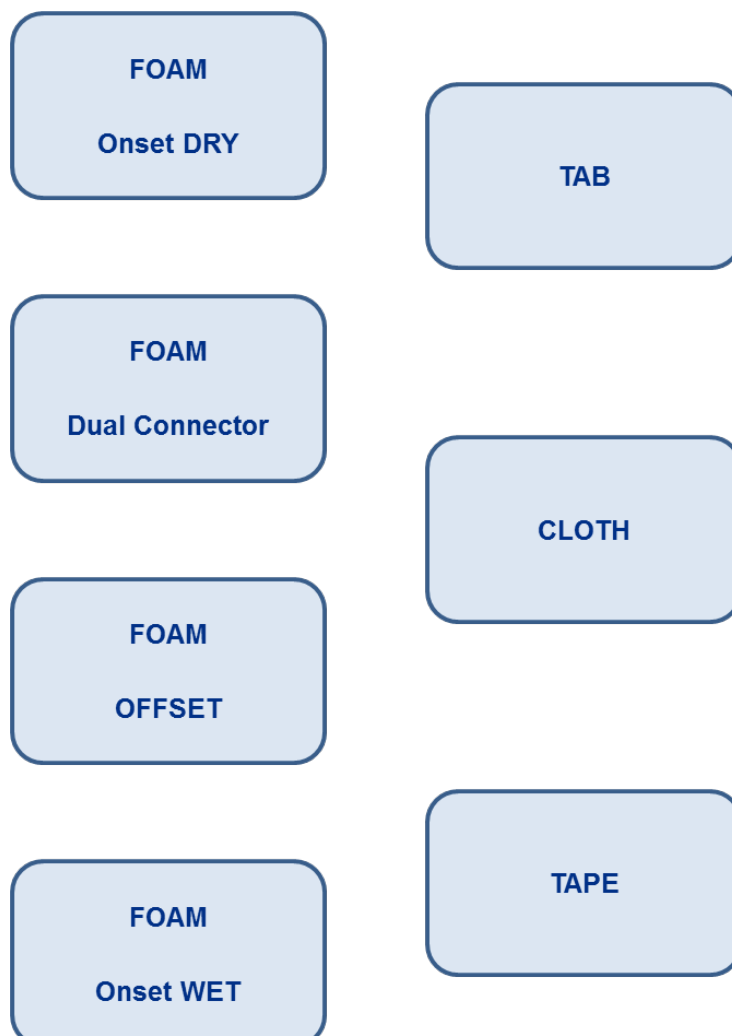
5. Product assessment results

The following product assessment results pages show the tested clinical criteria listed vertically on the left-hand side of the page with the tested device found horizontally across the top of the matrix. The accompanying photographs were taken during evaluation. These photographs are of sample products provided for evaluation. Lot numbers were recorded and samples have been retained in storage following the completion of evaluation for at least 3 months.

The products represented are the range of suppliers and brands available through the NHS national procurement provider's framework as of December 2016.

Results can be seen within the product matrix. Each clinical product has been given a star rating.

The product assessment results have been divided into 7 sub-categories of Adult ECG Electrodes based upon their characteristics, as illustrated below:



6. Using the Product Assessment Results Matrix

The clinical criteria displayed are designed to capture key clinical elements that health professionals may wish to consider when reviewing/selecting products for their own clinical practice. The report is intended as a guidance tool to aid product selection and is not intended to be a universal determination of the clinical effectiveness of any particular product. Each clinical practitioner should therefore make their own assessments taking into account all relevant considerations for their particular situation.

Not all clinical criteria cited in the report will be relevant or important in all environments,

E.g. does the pouch / packet have a space to record date it was opened or new expiry date?

A cardiology clinic seeing large numbers of patients may not need to record the date the pouch was opened, however a low usage GP practice may identify this as being a benefit to prevent using expired stock.

Likewise not all clinical criteria will be relevant or important for all patient groups.

Clinicians may identify the criteria that most represent their clinical environment and patient demographic, and may choose to build their own hierarchy of importance to aid product(s) selection for patient outcome goals using the matrix presented in this report, their own clinical knowledge, as well as any other resources (including publications) to provide informed choice and transparency of their decision for product(s) being used.

7. Further considerations and recommendations

7.1. Future recommendations

7.1.1. Packaging

- Pouch packaging should include all the mandatory information as specified by the relevant standards.
- Standard symbols with text to be used by suppliers to identify material type. Existing symbols are not understood and inconsistent.
- RX only symbol should have '(USA only)' clearly marked on the packaging to avoid potential confusion as language and symbols are easily adopted in other countries.

7.1.2. Opening

- All backing plastic to be differentially coloured or display a pattern as described in the report.
- Where pouches contain at least 30 electrodes they should be able to be resealed or closed (folded) so they protect electrodes and maintain shelf life.
- Packaging for pouches with more than 10 electrodes should have space and be made of material that allows a standard black ink pen to record the new expiry date once they have been opened.

7.1.3. Clinical use

- Functioning electrodes which are correctly located should not be routinely replaced as patients transfer through their care pathway.
- Suppliers are to improve information so that linked products and variants can be identified. Manufacturing product codes and descriptions rarely show a connection between products.

7.1.4. Disposal

- Whilst suppliers informed us that the packaging was recyclable there needs to be clear recycling instructions on the pouch packaging.

7.1.5. NHS Supply Chain

- Product data sheets which includes information on adhesive properties to be published on the NHS Supply Chain online catalogue and supplier websites for ease of review when required.
- Consideration to a new category for silicon-based products which can be used as an alternative when they are clinically required.

7.2. Barcodes

The CET are aware of the Scan4Safety project and are aligned with the ambitions of the programme, which will deliver significant benefits in terms of patient safety and efficiency, to the NHS. The adoption of standards, driven by Scan4Safety, enables patient, product and location identification and traceability from the supply chain to the patient.

Adoption of these standards has also been shown to improve the quality of care by minimising the risk of human error.

The CET will be considering the inclusion of an evaluation criteria relating to the presence of GS1 compliant barcodes in future reports, as following our clinical conversations we have seen clinical staff asking for it to be included, but further information will be issued by the CET on this to stakeholders in advance.

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9. Disclaimer

Reports published by the NHS Clinical Evaluation Team represent general guidance and the team's opinions on products are based on the clinical evaluations undertaken, using the information and clinical criteria generated from extensive stakeholder engagement in line with the team's requirements and evaluation pathway. Reports will be reviewed and updated at the team's discretion as deemed appropriate to reflect any changes.

You should make your own assessment and not take or rely on the opinions expressed by the NHS Clinical Evaluation Team, as contained in the reports, as recommendations or advice to buy or not buy (as the case may be) particular products.

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Reports are accurate at the time of publication, any recommendations or best practice guidance should be checked for updates.

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‘Quality, safety and value are at the heart of our work and it’s important that we use our clinical experience to deliver high standards of care while reducing cost and waste in the NHS.’

Mandie Sunderland
Chair, Clinical Reference Board
(Governing body of the NHS Clinical Evaluation Team)

