The Newcastle upon Tyne Hospitals NHS
NHS Foundation Trust

YORK
Health Economics
CONSORTIUM

EXTERNAL ASSESSMENT REPORT

Mega Soft Patient Return Electrode for use during Monopolar Electrosurgery

Produced by NUTH and YHEC EAC

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The views expressed in this report are those of the authors and not those of NICE. Any errors are the responsibility of the authors.

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Abbreviations

AfPP	Association for Perioperative Practice
CQM	Contact Quality Monitors
EAC	External Assessment Centre
ECRI	Emergency Care Research Institute
ESGE	European Society of Gastrointestinal Endoscopy
ESU	Electrosurgery Unit
HF	High Frequency
IEC	International Electrotechnical Commission
ISD	Information Services Division Scotland
ISO	International Organization for Standardization
MAUDE	Manufacturer and User Facility Device Experience
MHRA	Medicines and Healthcare products Regulatory Agency
MTEP	Medical Technologies Evaluation Programme
MTAC	Medical Technologies Advisory Committee
N/A	Not Available
NATN	National Association of Theatre Nurses
NHSLA	NHS Litigation Authority
NICE	National Institute for Health and Clinical Excellence
NUTH	Newcastle upon Tyne Hospitals
PSSRU	Personal Social Services Research Unit
RECQM	Return Electrode Continuous Quality Monitoring
REM	Return Electrode Monitor
YHEC	York Health Economics Consortium

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Section 1: Summary

1.1 SCOPE OF THE SPONSOR'S SUBMISSION

The sponsor, Advance Surgical Ltd, submitted evidence to support use of the Mega Soft Patient Return Electrode (adult and paediatric) during monopolar surgery. The external assessment centre (EAC), NUTH/YHEC, identified no inappropriate deviations from the Final Scope outlined by NICE in either the clinical or economic evidence submission.

Evidence was not available on the majority of the pre-specified end points including the incidence of dispersive electrode burns, incidence of stray electrosurgical burns, incidence of post-operative pressure ulcers, other device-related adverse events and staff time to clean the device. No evidence was available on the pre-specified subgroups, other than children with burns.

1.2 SUMMARY OF CLINICAL EVIDENCE SUBMITTED BY THE SPONSOR

The sponsor submitted a high quality search of published and grey literature and conducted the selection process adequately. Only two studies were found from the published literature Emergency Care Research Institute [ECRI] (2000) and Sheridan (2003). These were supplemented by recent reports from product users and a focused technical evaluation conducted by the manufacturer.

Copies of the six studies were provided by the sponsor and they comprised:

- Two technical evaluations, ECRI (2000) and Megadyne (2011a);
- One observational study in a specific patient group, being children with severe burns Sheridan (2003);
- Two testimonials Megadyne (2011b) and (2011c) from hospitals in the USA;
- Responses to a questionnaire from three London hospitals which provided feedback on five operating characteristics of the Mega Soft Patient Return Electrode device Evaluation reports (2011).

1.3 SUMMARY CRITIQUE OF CLINICAL EVIDENCE SUBMITTED BY THE SPONSOR

One study, ECRI (2000) was relevant to the decision problem, providing independent evidence on the technical performance and safety of the Mega Soft Patient Return Electrode device. Given availability of the ECRI report, one would not expect other organisations to prioritise this technology for technical or clinical evaluation. Thus, absence of clinical studies post 2000 is not a concern given the device has not been materially modified in the meantime.

No studies were comparative. Other than the ECRI study, they did not adopt robust methodologies designed to reduce potential for bias. Rather, the testimonials and responses to the questionnaires are biased documents; for example no information is available on why these sites were selected, or on criteria selection, or if payment was made for the responses.

However, the EAC decided to retain these poor quality studies because they demonstrated that certain users, at one point in time, valued the benefits from the Mega Soft Patient Return Electrode product. There is no assumption that these benefits generalise to other sites. These benefits are additional to those rated by ECRI which were of the safety, technical and organisational aspects of the product.

1.4 SUMMARY OF ECONOMIC EVIDENCE SUBMITTED BY THE SPONSOR

No robust published economic evidence was submitted by the sponsor; testimonials from two hospitals in the USA were provided but these did not quantify benefits.

The sponsor did submit a Microsoft Excel® model that estimated the cost per operation when using a Mega Soft pad compared to conductive return electrodes (diathermy pads).

The model was non-stochastic and used linear formulae to describe the relationships between the resource and cost variables. The values of the variables and the formulae adopted were transparent. The formulae were internally and externally valid. The model comprised five worksheets but only four worksheets contained data which informed the results. The first sheet presented the results for each of the main types of cost differences between the technologies. These were grouped as:

- Cost of Mega Soft Patient Return Electrode compared to diathermy pads (unit cost and related formulae contained in a worksheet called ‘technology costs’);
- Savings from avoided pressure pad and razors/razor heads (parameter values and formulae also in ’technology cost ‘ worksheet);
- Surgeon, anaesthetist, nurse anaesthetist and operating room nurses’ time saved and related value, by avoiding need to shave patients and place pads. (These were in a worksheet called ‘time saving’).

These individual savings were summed to provide the total cost difference. The results were also presented graphically.

The duration of the model was two years, the life of the Mega Soft Patient Return Electrode; the perspective was the NHS. These were appropriate.

The final sheet contained sensitivity analyses. These results were presented in a table and using a tornado diagram presentation. The sponsor's sensitivity analysis identified the model was sensitive to the cost of diathermy pads, delays in theatre time and the valuation of the time saved.

No health states were included. No clinical benefits such as adverse burns (to patients or staff) avoided were included.

The results showed savings of around £70 per operation for either the adult or paediatric Mega Soft product compared to split or solid diathermy pads. Over 95% of the savings were from improving the efficiency of procedures by five minutes per operation, with over 80% of the savings being from surgeon and anaesthetist time saved.

The sponsor concluded the Mega Soft Patient Return Electrode adult and paediatric products were cost saving, adding that savings were believed to be an underestimate of potential savings for patients with skin conditions such as burns and fragile skin. In these patients, nurses were judged to take longer to find suitable contact sites for diathermy pads. These savings were stated to be available to all NHS trusts in England.

The sponsor judged the main strength of the analyses was the consistency of cost savings under all credible ranges of values for each parameter. The weaknesses included the absence of data on:

- The incidence of skin burns from diathermy pads and their associated costs, including litigation costs;
- The cost to procure, store and dispose of the diathermy pads;
- Absence of independent evidence on the time saved in theatre from using Mega Soft Patient Return Electrode rather than diathermy pads.

The sponsor noted a survey of theatre nurses could address the last aspect and possibly address the absence of evidence on other parameters including the number of operations per week, the typical life span of the pressure-relieving mattress and the proportion of operations that use the various razors.

1.5 SUMMARY CRITIQUE OF ECONOMIC EVIDENCE SUBMITTED BY THE SPONSOR

The submitted economic model was valid for the decision problem. It was transparent, with the contribution of each parameter to the overall result displayed and it was easy to operate by modifying the parameter values. The number and unit cost of each resource could be easily changed.

The sponsor's critique of the evidence had some bias in that it did not include a pricing scenario assuming diathermy pads were purchased without lead wires. Rather the scenario adopted by the sponsor assumed NHS trusts purchase diathermy pads with lead wires. The cost difference between the two is marked.

Appendix 1 of the Additional Submission Information provides data from the NHS Supply Chain catalogue on the cost of diathermy pads, with and without lead wires and for split and solid diathermy pads. These have been analysed into adult and paediatric pads, and within each category, divided into split with lead wire; split without lead wire; solid with leadwire and solid without lead wire. The mean cost for each group is shown in Table 1.1.

Table 1.1: Mean price of diathermy pads (NHS Supply Chain Catalogue) (£ per pad)

Split				Solid			
Adult		Child		Adult		Child	
No lead wires	Cabled	No lead wires	Cabled	No lead wires	Cabled	No lead wires	Cabled
£0.76	£1.92	£0.68	£5.91	£0.49	£1.98	£0.68	£1.88

The mean was calculated by giving each product in the catalogue an identical weighting of one. However, this may not be representative of the purchasing patterns of the NHS trusts. To address this weakness the purchases of the NUTH Trust were analysed. This Trust is one of the five largest trusts in England. Its purchasing may not be typical of all trusts but in the absence of any other volume measure to show the frequency of purchases, by type of diathermy pad, the purchases of this Trust have been used as the EAC's base case.

In NUTH Trust, the mean cost of adult diathermy pads purchased with lead wires in the current financial year was £1.78 (NHS Supply Chain £1.92); the cost of purchasing split diathermy pads without lead wires was £0.54 (NHS Supply Chain £0.76); and solid wireless pads £0.46 (NHS Supply Chain £0.49). In comparison, the sponsor assumed a cost of adult diathermy pad of £2.44 for split pads and £2.60 for solid pads.

Where the diathermy pads have no lead wire, a reusable diathermy cable is required to link the Electrosurgery Unit (ESU) to the diathermy pads. The mean price of four reusable leads (excluding the outlier of cables for the Bard/Birtcher Erbe ESU at over £86) from the NHS Supply Chain catalogue is £21.86, with the price ranging from £16.96 to £31.51 (details in appendix 1). The sponsor estimated these could be re-used for 100 times, giving a cost off-set per operation of £0.22. The cable must be sterilised on the tray of instrument after each operation. This was assumed to have no marginal cost. The cable must also be fitted before and removed after each operation, usually by a healthcare assistant, taking up to an estimated 30 seconds.

The cost difference of £1.90 (£2.44 minus £0.54) for split diathermy pads and £2.14 (£2.60 minus £0.46) for solid pads minus the £0.22 cost of the re-usable wire and the related labour cost (£0.11) is a measure of the potential bias.

The NICE experts advised that the sponsor's estimate of a five minute delay per operation over-stated the delay caused by using diathermy pads. The sponsor explained that the five minutes was per patient and comprised the following activities: pick up diathermy pad from store, possibly in an anteroom; check plate and size; read instructions on where not to apply pad and find appropriate area of patient; shave patient if required and apply. Other staff in theatre are assumed to have completed their set-up by the start of this process.

The sponsor advised that these activities are conducted in theatre because the ESU is sited there; if the diathermy pad was applied in the preparation room and the diathermy pad with lead wires used, and then the patient would have to be wheeled into theatre with the loose wire attached.

No alternative delay assumption expressed in minutes was provided by the NICE experts. Given the qualitative comments indicating that five minutes was an over-estimation, a range of 0 to 4 minutes was used in the EAC analysis. The concern about loose wires does not apply to diathermy pads fitted to the ESU with re-usable cables. Hence applying the diathermy pads in the preparation room to avoid delaying theatre staff would be an option for hospitals using these pads.

The sponsor's evidence did not identify the potential additional costs to theatre staff of using the Mega Soft Patient Return Electrode, particularly its cleaning, handling and storage. The NICE experts advised there were unlikely to be any additional costs with the Mega Soft compared to using pressure pad mattresses.

The sponsor noted the uncertainty around theatre staff delays and use of razors in the evidence as presented.

The sponsor excluded VAT from the purchase price of the Mega Soft, increasing the price from £1,900 to £2,280.

Other differences in the advice from NICE experts related to percentage of people shaved, cost of the shaver, annual use of the Mega Soft and a pressure mattress and valuation of staff time saved. These are explained in Section 4.

1.6 EXTERNAL ASSESSMENT CENTRE COMMENTARY ON THE ROBUSTNESS OF EVIDENCE SUBMITTED BY THE SPONSOR

The EAC would endorse the main weakness as being the absence of robust evidence to support the assumptions made by the sponsor. Particularly useful would have been information from members of surgical teams to support the theatre delays.

1.7 SUMMARY OF ANY ADDITIONAL WORK CARRIED OUT BY THE EXTERNAL ASSESSMENT CENTRE

The EAC asked NICE experts and a member of the NUTH/EAC Advisory Board, Mr D Hume, Purchasing and Supplies Manager at NUTH, to advise on the appropriate values for each of the main parameters which were identified as having a material effect on the results in the sponsor's sensitivity analysis.

Mr Hume was invited to be a member of the EAC Advisory Board to give guidance on purchasing matters.[1] NUTH is one of the five largest trusts in England; its purchasing behaviour of diathermy pads was judged to be more representative of the purchasing behaviour of other trusts than a price derived as the arithmetic average of all prices for diathermy pads in the NHS Supply Chain catalogue. The prices per diathermy pad in NUTH are the same as the NHS Supply Chain catalogue. The benefit of using the NUTH Trust data is it provides a measure of the volume of each of the different types of pad purchased in a large trust.

The EAC notes this does not remove all purchasing related uncertainty; the EAC does not claim the purchasing outcomes of the NUTH trust are representative of all trusts, only that it is a better approximation than an average of the list prices from the NHS Supply Chain catalogue.

The EAC also requested data from the NHS Litigation Authority (NHSLA) on the cost of settling claims arising from diathermy pad burns. The NHSLA settles claims of clinical and non-clinical negligence against NHS trusts. Reducing the number of diathermy pad related burns will reduce the claims against NHS trusts and thus the monies paid to settle such claims by this NHS organisation.

[1] Details of the members and functions of the Advisory Board members were provided to NICE as part of the tendering process for the EAC contracts.

The information from NHSLA, together with published costs produced by the Department of Health enabled the EAC to estimate that the cost to treat and settle claims for burns from diathermy pads. The estimated cost per diathermy pad burn was about £33,300 per year, equivalent to some £0.93 million. With 1.29 monopolar surgical procedures each year, the mean cost of treating the burn and paying related claims, was estimated at about 70 pence per procedure.

The technical analysis commissioned by NICE from Cedar should inform the likelihood of these claims being avoided by the NHS adopting the Mega Soft Patient Return Electrode rather than using diathermy pads.

Section 1.5 of this report has identified the some of the differences identified by the EAC on the advice of the NICE experts. The EAC used the sponsor's model to estimate the impact of these changes on the cost of an operation using Mega Soft compared to diathermy pads.

On 16 January 2112, the NHS Supply Chain was asked to provide an analysis of the volume and mean purchase price of adult diathermy pads with lead wires and adult diathermy pads without lead wires to provide an estimate of NHS practice. No response had been received.

Section 2: Background

2.1 OVERVIEW AND CRITIQUE OF SPONSOR'S DESCRIPTION OF CLINICAL CONTEXT

2.1.1 Number of Procedures

The sponsor estimated that monopolar electrosurgery is used in half of all surgical procedures lasting over 30 minutes, some 1.29 million procedures each year in the UK. This value was estimated using data in 'MTG7 Inditherm patient warming mattress for the prevention of inadvertent hypothermia: costing template'. Values in that report are for England only. The population in the UK is 15% higher than in England hence the number of procedures in the UK will be about 15% higher, nearer 1.5 million.

Suggesting that half of all surgical procedures lasting over 30 minutes are monopolar may be an underestimate. Valleylab, a manufacturer of diathermy pads, noted this is the most commonly used electrosurgical modality (Valleylab 2011).

2.1.2 Guidelines: MHRA

The sponsor advised they were unaware of any guidelines applying to this technology. The EAC searched the Medicines and Healthcare products Regulatory Agency (MHRA) website on 17/11/2011 for safety warnings, medical device alerts, field safety notices and one-liners for relevant information and advice on monopolar electrosurgery and patient return electrodes. This identified several relevant documents: a safety poster, an e-learning module, a safety notice, a medical devices alert and several 'one-liners'. Areas of relevance were extracted from each document.

Electrosurgery equipment safety poster

Published in July 1999 by the Medical Devices Agency (MDA), the predecessor of the MHRA, and updated in 2009 by the MHRA, a poster was aimed at all healthcare professional involved with electrosurgery. The poster describes that every year patients and staff are injured during electrosurgical procedures often due to user error and poor work systems and not the equipment itself. The poster states staff must:

- Not use alcohol based skin preparation solutions (MDA SN 2000 17);
- Check the electrosurgery machine and its accessories prior to use; prepare the patient properly; check the return electrode site after plate removal;
- Consider the position of the return electrode in relation to the patient's position, the operating site, scars, metal implants or foreign bodies; active implants such as pacemakers which may need to be checked by a cardiology team pre/post operation; consent to shaving; allergy to return electrode gel.

Electrosurgery e-learning module

This on-line presentation incorporates a test aimed at all operating theatre staff including surgeons, assistants, anaesthetists, and scrub staff and operating department practitioners. The lecturer noted plate burns are 'very rare' and refers to a Medical Devices Agency poster in 2002 that stated user error and poor work systems as the most common causes, not the equipment. One slide states: "ECRI strongly recommends using electrosurgical units with return electrode contact quality monitor (RECQM)".

This effectively means that only split pads are recommended by ECRI, since these must be used in order for RECQM to work. The recommendation was endorsed by the speaker who identified the reasons provided by ECRI for its recommendation. These included the spilt pads detecting and warning if plates become dislodged, if a connection is broken or if increased voltage is detected around the site of the pad. These safety features all reduce risk of site burns.

Safety notice 2000 (17)

This gives guidance on use of spirit-based solutions during surgical procedures requiring the use of electrosurgical equipment. It advises there should be no pooling of preparations.

Medical Devices Alert

In 2003, an alert, MDA/2003/037 on electrosurgery components was issued. This alert required NHS trust staff to inspect, among other items, all electrosurgical cables, to ensure suitability for continued use and to establish a system for determining how long a particular accessory has been in use; its age, frequency of use and number of sterilisation cycles.

One liners

'One liners' issued in January 2000, October 2009 and April 2011 gave relevant information about electrosurgery. The earliest addressed using other medical devices in conjunction with electrosurgery and advised that compatibility of all surgical equipment used in conjunction with diathermy be checked via manufacturer's information prior to use. The October 2009 edition highlighted the e-learning package whilst the most recent addressed tissue burns.

2.1.3 Other Guidelines

A 'Google' search for guidelines for electrosurgery returned three relevant documents. The first was a poster from the National Association of Theatre Nurses (NATM) titled 'Electrosurgery: managing the risk' (2004) which noted the source of an accidental burn was often linked to the return electrode, adding:

> '*This problem has largely been eliminated due to the development of Contact Quality Monitors (CQMs) and Return Electrode Monitor (REM) plates'*.

The European Society of Gastrointestinal Endoscopy (ESGE) guideline: 'The use of electrosurgical units' (Rey J F. et al.) made seven recommendations on use of the neutral electrode:

- Only patient neutral electrodes (plates or grounding pads) recommended by the electrosurgical unit (ESU) manufacturer should be used;
- Check expiration date (if expired patient plates are used, the adhesive may fail to maintain contact with the patient's skin and burns may result);
- Check the patient plate for any damage/modification or sharp edges;
- The neutral electrode should not be attached over some structures, including bony protuberances, metal implants or prosthesis, skin folds, scar tissue, hairy areas, any form of skin discoloration/injury, limbs with a restricted blood supply, adjacent to ECG electrodes or onto pressure areas/points;
- The neutral electrode should be attached over well perfused muscle tissue; the skin must be clean, dry, and free of hair to avoid loss of contact between plate and skin. The electrode should not be completely wrapped around a limb. Overlapping must be avoided. Ensure the neutral electrode has full patient-skin contact;
- The patient plate should be of appropriate size for patient weight and should never be cut to size;
- Patient plates that have once been removed from the patient skin have to be replaced by new ones.

The third concerned guidelines produced by the International Federation of Perioperative Nurse; 'The IFPN Guideline for Electrosurgery Safety' which recommended:

1. The patient return electrode should be used in a manner promoting patient safety and reducing potential for patient injury;
2. The patient's skin integrity should be evaluated prior to placement of the patient return electrode and when the patient return electrode is removed;
3. The patient return electrode should be placed as close to the operative site as possible on a large muscle mass. It should not be placed over scar tissue, hairy areas, near metal implants, bony prominences, in areas of vascular insufficiency or where it may be invaded by fluid;
4. Excessive hair should be removed before applying the patient return electrode;
5. The patient return electrode should uniformly contact the patient's body;
6. The patient return electrode should be removed carefully while supporting the patient's tissue. The return electrode site should be inspected to assure no injury has occurred.

Searches were also conducted of the Association of periOperative Registered Nurses website and Association for Perioperative Practice (AfPP). The former had no accessible relevant information; the focus of electrosurgery burns was laparoscopic surgery.

The AfPP site housed a poster 'The Electrosurgery Team' that noted the need to ensure accessories were compatible with ESU generator. It also provided advice about diathermy for patients wearing an electronic monitoring device and had the NATN poster referred to earlier.

2.1.4 International Electrotechnical Commission Standard

International Electrotechnical Commission (IEC) is a worldwide organization for standardization in the electrical and electronic fields. Recently it drafted a technical report on High Frequency Surgical Equipment – Operation and Maintenance'. It is hoped this will be published in the UK by BSI as a BS Published Document. It is in addition to the safety Standard for HF Surgery Equipment and Accessories, published in the UK as BS EN 60601-2-2:2009.

The draft Technical Report is not available for distribution to the MTAC. However, the EAC has had privileged access and can advise the draft addresses of the need for:

- Adequate site preparation;
- Checking patient positioning;
- Careful placement of neutral electrodes;
- Ensuring active accessories and neutral electrodes are compatible with the high frequency (HF) surgical equipment and its operational modes;
- Requirement for operators to confirm compatibility of different pieces of HF surgical equipment with all manufacturers involved;
- Ensuring adequate contact area of a neutral electrode;
- Inappropriate application;
- Compliance with manufacturer recommendations.

2.1.5 Sponsor's Evidence Base and Guidelines and Technical Reports

Evidence from guidelines and technical notices is consistent with the sponsor's statements that there are certain sites of the body that the comparator, diathermy pads with and without RECQM, should not be placed upon and that site preparation to ensure the skin is clean, dry and shaven is essential. The rationale for such careful placement includes avoiding possible skin problems including hypersensitivity and denuding of dermis at pad removal.

2.1.6 Clinical Pathway of Care

The sponsor correctly describes the clinical pathway of care being monopolar surgery. In this form of surgery, the active electrode is in the surgical site. The patient return electrode is elsewhere on the patient's body. Current passes through the patient as it completes the circuit between electrodes. The patient return electrode's function is the safe removal of electrical charge from the patient.

2.1.6.1 Issues relating to current clinical practice, including any uncertainty about best practice

The sponsor estimated use of split diathermy pads with quality monitoring to solid diathermy pads to be about 20:1. This was confirmed by the purchases by the NUTH Trust which showed split pads with RECQM, formed 95% of the purchases.

The sponsor states the most commonly reported complication of electrosurgery is a burn resulting from improper application of the diathermy pad return electrode. No evidence substantiates this statement.

The sponsor infers that two-thirds of all electrosurgical accidents are due to burns resulting from the improper application of the sticky pad return electrode. This was referenced to a study by Brill (2011). This is an incorrect interpretation of the study. The burns reported in the study included those arising during laparoscopic procedures for reasons other than the improper application of the sticky pad.

The submission did not quantify the extent of burns resulting from electrosurgical accidents in clinical practice. The EAC's structured search but did not find any such evidence. To establish whether burns resulting from inappropriate use of split pads with RECQM were a problem for the NHS, 50 medical directors were contacted by the EAC and asked if they were aware of adverse events arising from use of split and solid sticky pads as return electrodes. The letter asked if any patient had received burns from these pads and if so whether that led to litigation. A nil response was received.

Similar questions were also asked of the NICE Experts, with a nil response received. The EAC was able to obtain information from MHRA and NHS Litigation Authority on the number and cost of electrode burns.

2.1.6.2 MHRA data on return electrode burns

Information was provided by MHRA, for the period from 2000, on the estimated number of reported electrosurgery incidents. The MHRA stated that approximately 70% of these incidents were related to burns, with approximately 35% of the burn events related to the neutral (return) electrodes.

Causes of the return electrode burns included device problem, poor site positioning, failure to ensure the neutral electrode adheres to the skin properly, poor patient skin preparation and failure to monitor alarms correctly. The MHRA estimate of 70% of electrosurgery incidents being related to burns is consistent with the estimate of 66% in Brill, 2011. Table 2.1 presents the estimated number of incidents related to return electrode burns using the MHRA assumptions. These suggest that over the last eleven years the mean number of burns attributable to return electrodes was 29; the largest number 44, was reported in 2010. Prior to this the trend had been flat around the mid-20's. No analyses by pad type were available.

Table 2.1: MHRA Estimated Total Number of Electrosurgery Incidents

Year	MHRA Total electrosurgery incidents	EAC Estimated incidents related to burns (70%)	EAC Estimated incidents related to return electrode burns (35%)
2000	100	70	25
2001	145	102	36
2002	145	102	36
2003	120	84	29
2004	110	77	27
2005	75	53	19
2006	90	63	22
2007	110	77	27
2008	107	75	26
2009	104	73	26
2010	180	126	44
Total	**1,286**	**902**	**317**
Average	117	82	29

2.1.6.3 NHS Litigation Authority and other costs to the NHS

The NHS Litigation Authority (NHSLA) handles negligence claims against the NHS. The EAC requested information on claims relating to diathermy burns. The NHSLA provided the information, noting that the database from which the data were taken was designed primarily as a claims management tool rather than for risk management purposes. The NHSLA therefore cannot guarantee that the coding used is accurate or consistent; moreover the detail available is often very limited and should not be relied upon as a basis for research.

Table 2.2 provides the information from NHSLA on claims reported to it since January 2005. The EAC estimate of the number of claims per year of 28 is very similar to the number of incidents reported to the MHRA. The mean payment per claim was almost £29,000.

Table 2.2: Claims reported to NHSLA since January 2005 and per year

	Since January 2005	Estimate per year (EAC)
Number of claims brought	276	39
Closed with no damages	34	4.9
Closed with damages	195	27.9
Total paid (damages and costs)	**£5,651,312**	**£807,330**
Open	47	Not available

In addition the NHS is likely to incur additional treatment costs. There is no information on the nature of the burn from diathermy pads. However, the mean cost of all burns treated in the NHS in year to 31 March 2011 was £4,310, ranging from £24,416 for burns requiring major grafting and with complications to under £2,000 for other burns, with no complications or other procedures.

Summing a mean cost of £4,310 per burn and the £29,000 claim payment, then each successful diathermy pad burn claim against the NHS could cost it about £33,300. The annual cost to the NHS of claims for diathermy pad burns is estimated by the EAC to be about £0.93 million, assuming 27.9 burns per year. With 1.29 million monopolar surgical operations per year, the mean cost of diathermy pads burns is estimated at about 72 pence per procedure.

2.1.6.4 Adverse events reported in the USA

The US Food and Drug Administration runs an adverse reporting system for medical devices, Manufacturer and User Facility Device Experience (MAUDE). This database was interrogated for all electrosurgical patient return electrode notifications in the most recent year 30/11/2010 to 30/11/2011. Five incidents were reported and none related to burn; all concerned condition of the pad when the package was opened. In the year to 30/11/2010, 31 incidents were reported of which 16 were burns, two cases required plastic surgery and/or skin graft; the others were managed by ointment or no care. It was not possible to differentiate burns between those from split or solid diathermy pads. No insights are available for the smaller rate of burns reported in the USA compared to the UK.

The MAUDE site was also searched for reports on Mega 2000 or Mega Soft from 1/1/2001 to 31/10/2011. Six notifications were found and are described in Table 2.3. Two burn-related adverse event reports have been submitted about the Mega Soft Patient Return Electrode but it was impossible to establish cause of the burn. Two burn related reports were found for Mega 2000.

Table 2.3: MAUDE reported events with Mega Soft and Mega 2000

Date	Event description	Result of investigation
Mega 2000		
18/06/2010	System did not work until the electrosurgical patient return electrode pad was replaced.	Not reported.
24/06/2002	Two white lesions, quarter-size, on bilateral buttocks at 9:15.	Reporter concluded: it was less safe to use an ESU system if no return electrode continuous quality monitoring; and it was unlikely the burns were from the Mega 2000 pad.
27/10/2000	A skin breakdown between skin folds on back. The surgeon felt source of breakdown was contributed by the grounding pad.	Not reported.
Mega Soft		
12/08/2011	On testing found that the ESU could be keyed and the hand piece energized, even though there was no connection to the pad.	Megadyne noted this was not a malfunction and would not happen if staff were trained adequately.
19/07/2005	Two minor reddened burn areas, 2 cm in diameter over right and left scapula of a child.	Not reported.
18/01/2005	Secondary degree burn to left buttocks.	Not reported.

2.1.6.5 New pathway of care incorporating the new technology

The sponsor noted the main change to the pathway with the Mega Soft Patient Return Electrode was the absence of burns caused by other patient return electrodes which seems reasonable - albeit there are very few each year, 29 out of 1.5 million (0.002%).

A secondary change was to enable the Mega Soft Patient Return Electrode to be used for people already having frail skin or extensive injuries such as burns, with the inference being these patients are denied surgery under current practice. No evidence to substantiate this view has been found.

The EAC concurs that no major changes in service configuration, tests or investigations or facilities would be required but notes the very weak evidence on time savings (see Section 3). Testimonials from two hospitals in the USA stated that nurse time was saved by eliminating many of the pre- and post-operative steps required when using disposable sticky pads, with surgical staff time saved by eliminating interruptions and delays whilst nursing staff placed disposable grounding pads and re-draped the patient.

2.2 OVERVIEW OF SPONSOR'S DESCRIPTION OF ONGOING STUDIES

The sponsor stated no relevant studies are underway and EAC has found no evidence to the contrary.

2.3 CRITIQUE OF SPONSOR'S DEFINITION OF THE DECISION PROBLEM

2.3.1 Population

Only one of the six pieces of clinical evidence directly included patients (children with large burns) and these were a small sub-group of the population in the Final Scope, being monopolar electrosurgery patients. Technical studies evaluated the devices for use with such patients whilst the qualitative evidence was informed by use of the Mega Soft Patient Return Electrode on monopolar electrosurgery patients.

2.3.2 Intervention

Only clinical evidence on the adult Mega Soft Patient Return Electrode is described in the sponsor's submission. The Final Scope included the paediatric size. This is not a material deviation.

The Mega Soft Patient Return Electrode is a reusable, capacitively coupled return electrode enclosed in a polymer pad. The product is placed on the operating table with the patient lying on top of that, often with a sheet intervening. No separate pressure pad is required, although some pressure relieving devices may be required at body parts which are not on the pad.

The sponsor has submitted an ISO certificate. Mega Soft Patient Return Electrode is a CE-marked medical device. The CE-marking means that the product has met the Essential Requirements of the EU Medical Device Directive.

2.3.3 Comparator(s)

The two comparators were conductive return electrode with RECQM and solid pads with no control monitoring. These are referred to as diathermy pads throughout this report. None of the submitted studies were comparative; virtually no clinical evidence has been provided on either form of pad.

Safety data from MHRA and MAUDE do not distinguish between forms of pad although recommendations and current use clearly favour the split pads with the quality control mechanism to reduce the risk of adverse events (see Section 2.1.1.6).

2.3.4 Outcomes

The sponsor provided evidence on the incidence of burns with Mega Soft Patient Return Electrode but not its comparators. Other outcomes addressed in the submission were:

- Sustainability and cost impact due to the re-usable nature of the pad;
- Other device-related adverse events;
- Resource utilisation and staff time.

Outcomes in the Final Scope not addressed in the sponsor's submission were:

- Incidence of stray electrosurgical burns;
- Incidence of post-operative pressure ulcers;
- Cleaning time.

2.3.5 Cost Analysis

The economic evaluation submitted by the sponsor compared the Mega Soft Patient Return Electrode to split and solid diathermy pads as required in the Final Scope. It adopted a two year time horizon and adopted a NHS and personal social services perspective. The economic model was accompanied by sensitivity analyses to address uncertainties. The Final Scope stated the analysis should address whether or not there will be a requirement to buy new diathermy equipment that is compatible with the Mega Soft Patient Return Electrode but this was not provided.

2.3.6 Subgroups

Other sub-groups mentioned in the Final Scope but not included in the sponsor's submission were:

- Patients with skin conditions;
- Babies and children;
- Patients with fragile skin. (e.g. older patients);
- Patients with high or low BMI.

No specific evidence was provided for these groups.

2.3.7 Special Considerations, Including Issues Related to Equality

Cultural sensitivities arising from the need to be shaved were raised in the Final Scope; the sponsor noted the Mega Soft Patient Return Electrode avoided this issue.

Section 3: Clinical Evidence

3.1 CRITIQUE OF THE SPONSOR'S SEARCH STRATEGY

3.1.1 Description of the Sponsor's Search Strategy

The sponsor's final search strategy used the PICO (Population, Intervention, Comparator(s) and Outcome(s)) framework, with the intervention defining the search terms. These included:

- Mega Soft patient return electrode$.mp;
- (Mega Soft or Megasoft or Mega-soft).mp;
- Mega 2000.mp;
- Megadyne.mp;
- (Return electrode$ or diathermy plate$).mp.

The searches were limited to human only populations; no other limits (e.g. date, language or methodological) were used.

Twenty-five databases were searched including:

- Medline;
- Embase;
- Medline (R) In-Process;
- The Cochrane Library;
- DARE, NHS EED & HTA (CRD);
- Conference Proceedings Citation Index- Science (CPCI-S).

In addition, the sponsor employed the following search strategies:

- Trials Register Searching;
- Backwards Citation Chasing (manually) on Included Articles;
- Forwards Citation Chasing on Included Articles (results below);
- Contact with Megadyne.

Full results from each strategy were provided. The exported files from the searching were uploaded and de-duplicated in Endnote X4 (Thompson Reuters).

3.1.2 Unpublished / Grey Literature

Strategies used to search for unpublished/grey literature/difficult-to-locate searching, included:

- Database searching of noted Grey Literature Resources (e.g. HMIC);
- Trials Register searching to identify trials which are in early stages;
- Grey Literature Searching;
- Conference Abstracts and Proceedings searching;
- Searching of Library Catalogues for unpublished reports;
- Web Searching;
- Forwards Citation Chasing of published articles to identify includable, unpublished literature;
- Backwards Citation Chasing to identify includable, unpublished literature;
- Contact with Megadyne for any trials, unpublished studies, unpublished reports and any supporting material.

Full results from applying these strategies were provided.

3.1.3 Review of the Sponsor's Search Strategy

The search strategy submitted by the sponsor was robust. It was clearly reported, well conducted, systematic and extensive. A detailed rationale was given for all decisions made during the development of the search strategy and the purpose of the search strategy was clearly stated: "The purpose of the search was to locate published and unpublished literature on the clinical effectiveness and cost effectiveness of the Mega Soft Patient Return Electrode Patient Return Electrode".

A clear explanation was given for the structure of the search strategy: why it included only intervention search terms and included no search limits (by date, language, geographical region or methodological search filter). Using only intervention search terms enhanced the sensitivity of the search strategy, and not using a methodological filter ensured no study design was excluded from the results. This meant that trials, adverse event data and economic studies were retrieved. As well as searching the suggested core databases, a further 20 databases and resources were searched, covering bibliographic databases, trials registers, conference proceedings, library catalogues, grey literature and citation searching. Searching of the grey literature was extensive, and included selected relevant national and organizational websites (including government, regulatory, medical device, nursing and surgical websites). In addition, searches of a meta-search engine (Dogpile) and Google advanced were undertaken. This approach was appropriate for the review question, and meant the EAC did not need to run separate modified searches.

The EAC re-ran all of the searches, except for Ovid Nursing Database, due to access issues and BIOSIS Previews, which was run from 1969 to 2008 only, again due to access issues. The following searches were run using different service providers to those used by the sponsor: BNI search in ProQuest rather than Ovid; EconLit in Ovid rather than EBSCO; and INSPEC in Ovid rather than ISI Web of Knowledge.

There were some minor issues with the search strategy, although these did not impact on the search results. All database searches included the first line 'Mega Soft Patient Return Electrode patient return electrode$'; this was made redundant by the inclusion of the search line 'Mega Soft Patient Return Electrode or Megasoft or Mega-soft'. Seven database strategies had the following search line '(Mega Soft Patient Return Electrode or Megasoft or Mega-soft) and (electrode$ or diathermy)', which would appear to have been incorrect, and should probably have been two separate search lines. It is possible the search line for 'return electrode' could have included more synonyms, but as this line was included as a "cross check line" in the first instance, in order to make the search less specific to the named intervention, it is unlikely this would have led to the retrieval of any further Mega Soft Patient Return Electrode studies.

The limit to remove animal studies was designed for use in MEDLINE (PubMed), and it is not clear how well it works in other databases. For some grey literature searches only the term 'Megadyne' was searched; it may have been worth searching for 'Mega Soft Patient Return Electrode' and/or 'return electrode' as well. It might also have been worth including two organizations mentioned in the NICE MTEP Final Scope in the grey literature searches: Association of Laparoscopic Surgeons of Great Britain and Ireland, and Institute of Physics and Engineering. To reiterate, none of these issues would have had an impact on the final results, and the search strategy was excellent.

3.2 CRITIQUE OF THE SPONSOR'S STUDY SELECTION

The sponsor only applied one inclusion criterion, being the intervention search terms, including Mega Soft Patient Return Electrode, Mega 2000 (the precursor to Mega Soft Patient Return Electrode) and a Megadyne product. This enhanced sensitivity of the study selection and was appropriate. Reference to a Megadyne product was essential because there are other products described as 'Megasoft'.

No information was provided on the number of researchers who conducted the selection, and whether or not selection of the papers was masked to conceal the publication, authors and institution. This is unlikely to have introduced bias given the reproducibility of the search and selection criteria. The EAC was able to repeat the study selection with ease.

3.3 INCLUDED AND EXCLUDED STUDIES

3.3.1 Published Literature

The sponsor's search strategy identified 136 titles and abstracts which were screened, using the selection criteria. Two studies met the inclusion criteria. The EAC repeated the selection using its database of abstracts (133 titles and abstracts) and found the same two studies. These were:

- ECRI, MegaDyne Mega 2000 return electrode. Health Devices 2000;29(12):445-60. ("ECRI (2000)");
- Sheridan RL, Wilson NC, O'Connell MF, Fabri JA. Noncontact electrosurgical grounding is useful in burn surgery. Journal of Burn Care & Rehabilitation 2003;24(6):400-1. ("Sheridan (2003)").

No list of excluded studies was provided; this does not introduce potential bias because the strategy could be replicated.

3.3.2 Unpublished Studies

The sponsor submitted four unpublished studies being:

- Mega Soft Patient Return Electrode Evaluation reports (Excel® worksheets) from three London hospital sites. ("Evaluation reports (2011)");
- Megadyne, How is Megadyne Mega Soft Patient Return Electrode safer than contact quality monitoring return electrodes? ("Megadyne (2011a)");
- Megadyne, The Mega Soft Patient Return Electrode™—Providing the Best Outcome for the Patient at Christus St. Joseph's ("Megadyne (2011b)");
- Megadyne, The Mega Soft Patient Return Electrode™—Standard Operating Procedure for Comfort and Cost Savings at Kaleida Health. ("Megadyne (2011c)").

No other unpublished literature was found by the sponsor or the EAC from the literature search. However, the EAC found relevant information from the MHRA website (four documents referred to in Section 3.1.2). The EAC also reviewed references used by ECRI and those referenced by the sponsor in Section 3 of their submission.

3.4 OVERVIEW OF METHODOLOGIES OF ALL INCLUDED STUDIES

The methodologies used in the included studies, the statistical approaches and outcome selection for each study, are shown in Table 3.1.

Table 3.1: Summary of studies submitted by sponsor as evidence

Study name	Setting and population	Objective and methodology	Outcome and statistical approach
ECRI (2000)	Laboratory setting, using one adult volunteer and also a piece of meat to assess burns.	Examined the safety, efficacy, and cost-effectiveness of Mega 2000 device compared to conductive return electrodes, to relevant American and International technical standards, using existing protocols.	No statistical tests reported. ECRI rated the Mega 2000 "Acceptable (with Conditions)". Advantages included: relatively uniform distribution of charge eliminating the edge effects and heating that normally occur with conductive return electrodes; skin preparation unnecessary; and can be used with patients with frail skin or extensive injuries that would make the use of adhesive electrodes difficult or impossible. Concerns include use with bulky materials; with one specified unit in the High Cut or Endo Cut mode, or with gel pads or other thick pads.
Megadyne, (2011a)	Laboratory setting and comparative technical study of split pad vs. Mega Soft Patient Return Electrode. Not peer-reviewed. Test on meat.	Test of Mega Soft Patient Return Electrode device and a split style sticky pad applied to a porcine model; both attached to an electrosurgical generator set at 50 watts coagulation for 3 minutes.	No statistical tests reported; the main outcome was whether or not pad site burn was observed (i.e. yes or no). The split pad experienced a rise in temperature of 9.7ºC, compared to 1.2ºC with Mega Soft Patient Return Electrode device. The IEC 60601-2-2 and ANSI/AAMI HF18 standards for electrosurgery allow a maximum temperature increase of 6°C in order to minimize the risk of pad site burns under limited test conditions.
Sheridan (2003)	Observational study of 17 children with extensive burns in tertiary hospital USA.	Monitor use of Mega 2000 in children with extensive burns and thence few areas suitable to use to ground the current.	No statistical tests reported. Mega 2000 did not cause any burns, was convenient for use, and did not require any other equipment to be displaced.
Christus St Joseph's Hospital (Megadyne, 2011b)	Christus St Joseph's Hospital, USA.	Testimony not a clinical study. Mega 2000 compared indirectly to sticky pads for patient comfort and cost savings.	No statistical tests reported. Administrative director of surgical services stated Mega Soft Patient Return Electrode improved patient comfort and delivered significant cost savings.
Kaleida Health Hospital (Megadyne, 2011c)	Kaleida Health Hospital, USA.	Testimony not a clinical study Mega 2000 compared indirectly to sticky pads for patient comfort and cost savings.	No statistical tests reported. Kaleida Health's director of value analysis stated Mega Soft Patient Return Electrode and Mega 2000 provided cost savings and patient comfort compared to sticky pads.
Evaluation reports (2011)	Paediatrics St Thomas' (n=18); Gt Ormond St (n=12). Guys (n=24).	Questionnaire used by theatre nurses after surgery to rate use of Mega Soft Patient Return Electrode. Conducted for 2 weeks in October 2011. No analysis completeness of responses and data not entirely complete.	Mean scores provided, together with raw data submitted for each question. Scores (from 0-5 with a higher score indicating a better outcome) were averaged. Overall rating 4.7; highest score on skin irritation and power settings (4.9); lowest for positioning (4.2).

The six studies comprised two technical evaluations, ECRI (2000) and Megadyne (2011a), one observational study in a specific patient group, Sheridan (2003), two testimonials (Megadyne 2011b and c) and three questionnaires to provide feedback on operating characteristics of the device, Evaluation reports (2011).

None reported any statistical analysis of the results. This was a consequence of study design and outcomes; the studies did not have a number of patients with a range of outcomes. The one study with 17 patients reported a dichotomous outcome (burn/no burn) and no burns were reported.

3.5 OVERVIEW AND CRITIQUE OF SPONSOR'S CRITICAL APPRAISAL FOR EACH STUDY

The sponsor presented summary tables (Tables B.3 and B.4) describing the population, intervention and comparator used in each of the six studies. Separate study design and methodology tables were provided for each of the published and unpublished studies (Table B.6). A critical appraisal of each observational study was provided using a checklist comprising seven questions addressing recruitment, measurement and outcome bias, confounding factors, follow-up and precision of results (Table B.8). Separate outcome tables were provided for each of the four observation studies (excluding the technical evaluations) with comments for outcome, effect size statistical tests.

In the EAC's judgement, tabulations as completed are a valid representation of the studies. However, many methodological and critical appraisal questions could not be answered, or were not applicable, because of the nature of the studies. The absence of answers to these questions highlights the main limitations of the included publications. Only one was an observational study and thus fitted the analytical framework (Sheridan 2003); two were technical evaluations ECRI (2000) and Megadyne (2011a) and the others were qualitative assessments, one structured using a questionnaire, the other two drew on quotes provided as testimonials.

The authors did not state how many reviewers were involved in the validity assessment. If only one reviewer was involved in the process, reviewer bias may have been introduced.

3.6 RESULTS

The results, together with the patient numbers and outcomes are now summarised. Only one study included patients within a clinical setting, being 17 children included in Sheridan (2003). This study reported no cutaneous burns were observed after using the Mega 2000. The authors noted the Mega 2000 enabled effective patient grounding despite the limited availability of traditional grounding sites because of the extensive nature of the burns. No other outcomes or details were reported. These results are assumed to generalise to the Mega Soft Patient Return Electrode.

The main evidence on clinical effectiveness was provided by ECRI (2000), with tests conducted on the Mega 2000. The ECRI Institute, a non- profit health research agency, has been an Evidence-based Practice Centre with the U.S. Agency for Healthcare Research and Quality since 1997. It is also designated as a federal patient safety organization under the Patient Safety and Quality Improvement Act of 2005. It has a good reputation for producing high quality, independent advice on devices, evaluating their technical performance, safety and organisational aspects.

The ECRI study provided evidence that the device has been tested on five commonly used ESUs, to relevant American and International Standards and consistent with protocols adopted for earlier work on return electrode contact quality monitors and return electrodes. The results are fully disclosed and ratings were based on a validated approach adopted by ECRI. The device was rated overall as good; with safety, prevention of electrode burns, activation of a continuity monitor, ease of use and quality of construction all having that rating. The alternate current pathway was rated as fair. Use of the Mega 2000 was rated as poor when used with a specific manufacturer's (ERBE) ESUs in the high cut mode. The device was already contraindicated for these ESUs. No patient outcomes or statistical tests were reported. These results are assumed to apply to the Mega Soft Patient Return Electrode.

Megadyne (2011) reported temperature changes; the diathermy pads with RECQM (split sticky pad) experienced a rise in temperature of 9.7ºC, compared to 1.2ºC with the Mega Soft Patient Return Electrode device, when operated under test conditions designed to represent surgical settings. The diathermy pad was associated with a pad site burn; Mega Soft Patient Return Electrode was not. No patients were included and this is appropriate given the nature of the test.

The two testimonies (Megadyne 2011b and c) had no pre-defined outcomes and did not recruit any patients.

The Evaluation reports (2011) did not recruit any patients. The outcomes were: ease of setting up system, ease of cord attachment, ease of position, degree of skin irritation, power settings, and overall rating. The overall rating was 4.7; the highest scores were on skin irritation and power settings (4.9) and lowest for positioning (4.2)[2]. Guy's hospital staff also added some comments, mainly very positive but four noted the mattress position became disrupted upon patient movement. The only comment from St Thomas's was 'power setting needs to be higher'.

[2] Scores from 0-5 with a higher score indicating a better outcome were averaged.

3.7 DOES EACH RELEVANT STUDY INCLUDE THE PATIENT POPULATION(S), INTERVENTION(S), COMPARATOR(S) AND OUTCOMES AS DEFINED IN THE FINAL SCOPE?

The ECRI study tested the safety and clinical effectiveness of the Mega 2000 for the relevant patient group, being those undergoing monopolar electrosurgery. The main outcome was dispersive burns, one of the specified outcomes. It also considered sustainability and cost impact of the pad given its re-usable nature. It did not address the other outcomes in the Final Scope, being incidence of stray electrosurgical burns, the incidence of post-operative pressure ulcers, other device-related adverse events, resource use and staff and cleaning time.

The Megadyne (2011a) study and Sheridan (2003) also had dispersive burns as their main endpoint. However, it is not known if the definition of 'burn' used in the Megadyne study had any clinical significance. It is suspected not, given the very low level of burns reported from using such pads.

Sheridan (2003) was the only study to enrol relevant patients, being a sub-group of children with burns.

Only Megadyne (2011a) provided a head to head comparison with conductive return electrodes with RECQM (split diathermy pad).

The testimonies (Megadyne 2011b and c) addressed the issues of patient comfort, staff time and cost; factors included in the Final Scope. The outcomes from the Evaluation reports (2011), being the questionnaire completed by three theatre sisters, collected outcomes related mainly to use of the product; these were not specified in the Final Scope. The exception was the question on skin irritation, a potential adverse event with diathermy pads. The responses indicted the theatre nurses were very satisfied with the Mega Soft Patient Return Electrode from that aspect.

In summary, no study evaluated the effectiveness of Mega Soft Patient Return Electrode pad compared to current practice for all specified outcomes. However, the ECRI report did provide evidence on the use of Mega 2000 and the primary outcome of burns but it lacked any comparative evidence against diathermy pads.

3.8 DESCRIPTION OF THE ADVERSE EVENTS REPORTED BY THE SPONSOR

The sponsor did not separately report the incidence of adverse events because the only adverse event for which study data were available was the incidence of skin burns. These were discussed in earlier sections.

The sponsor noted that the only safety concern raised by ECRI was when testing the Mega 2000 with a gel body cushion placed between patient and device. This risk was removed with the introduction of the Mega Soft Patient Return Electrode pad, because it requires no separate cushion under the patient. Experience worldwide also supported its safety with no pad site burns recorded (Megadyne, 2011a).

3.9 DESCRIPTION AND CRITIQUE OF EVIDENCE SYNTHESIS AND META-ANALYSIS CARRIED OUT BY THE SPONSOR

The sponsor has correctly identified available evidence from the literature, including grey literature and supplemented that with some recent analyses. The submission has adequately described the methodology, patient populations, outcomes and results for each of the six studies. The critical appraisal methodology used an adapted checklist from the Centre for Reviews and Dissemination and this was applied correctly. However, interpreting the findings was weak; the submission did not discuss the strong risk of bias and lack of external validity in some studies.

None of the studies, other than Sheridan (2003), conformed to study types typically used to inform evidence based practice in areas such as pharmaceuticals. The sponsor found answering many of the questions was not possible; the questions did not apply to the study forms. The diversity of end points and methodologies precluded any statistical synthesis of the studies.

3.10 ADDITIONAL WORK CARRIED OUT BY THE EXTERNAL ASSESSMENT CENTRE IN RELATION TO CLINICAL EVIDENCE

The EAC has undertaken five pieces of additional work in relation to the clinical evidence.

3.10.1 Literature Search

A second literature search was undertaken to find evidence on the incidence of burns from electrosurgery return electrodes, with the intent of then analysing findings between conductive return electrode (split sticky pad) with RECQM and solid diathermy pads. Three studies were found.

Demir (2006) reviewed 19 patients with intraoperative burn accidents, 15 had superficial and 4 presented with deep dermal or full-thickness burns. Technical analysis demonstrated one malfunctioning electrosurgical device, one incorrect positioned neutral electrode, three incidents occurred after moisture under the negative electrode, eight burns occurred during surgery while fluid or blood created alternate current pathways, five accidents were chemical burns after skin preparation with alcohol solution, and in one case, the cause was not clear. This was retrospective case study review and low grade evidence.

Huang (2001) measured the incidence rate of diathermy injuries, following the introduction of preventive procedures which reduced from 0.053% to 0.021%. This study concluded that preventive procedures can effectively decrease the occurrence of skin injuries in the use of diathermy. This was a prospective case study and low grade evidence.

Lucas (2009) identified the incidence of burns sustained in an English operating theatre. The investigators reviewed the five patients who sustained burns during surgical procedures in 2008. The injuries were caused either by diathermy alone (2) or a combination of diathermy and alcohol based skin prep (3). This was retrospective case study review and low grade evidence.

None of the studies analysed burns by type of diathermy pad (split with RECQM or solid).

3.10.2 Meeting with Sponsor and Subsequent Questions to Sponsor

NICE facilitated a meeting between the EAC and the sponsor who was able to answer thirteen questions on the product. The questions and responses are detailed at Appendix 2 of the Additional Information form and included the following answers.

The pad should not need repair and has been shown to last for 2 years even in very busy theatres. The physical life is consistent with the indemnified life of the Mega Soft Patient Return Electrode being 24 months. The pad is indemnified to a limit of $10M irrespective of generator use as long as the Instructions for Use are followed.

The main reason for hospitals to cease using the Mega Soft was absence of capital monies. The pad has benefits for all patients, with additional benefits for those patients with frail skin or burns or existing prostheses. Secondary pressure devices may be needed, for example, at the heels.

In future all pads will be sold at £1,900 plus VAT. The Mega Power generator system is £7,900. All prices are exclusive of VAT.

The sponsor advised the marginal cost of cleaning the Mega Soft pad between patients, compared to no Mega Soft Patient product, was nil because any surface would need to be wiped down between patients. At night the Mega Soft was often left on the table or possibly rolled up and placed at end of the table taking at most 30 seconds.

Other responses are included in the economics section; the information on lead wires has already been referred to Section 1.5.

3.10.3 NHS Trusts: Medical Directors

Fifty medical directors were contacted and asked to respond if they were aware of burns caused by return electrode monitoring diathermy pads and if so whether litigation was pursued. A nil response rate was achieved.

3.10.4 NICE Experts

The NICE experts were asked 11 questions grouped into:

- Existing use of return electrode monitoring diathermy pads;
- Purchase of diathermy pads and electrosurgical units;
- Theatre utilisation.

One expert responded to all questions. A shorter list of questions was sent out with a reminder and responses were received from two experts.

Separately Cedar established, on behalf of the EAC, from one expert the use of theatre table linen and the use of pads with the Mega Soft pad.

None of the experts who responded were aware of burns from split or from solid diathermy pads within their trusts. One advised that about 15 % of surgical patients may have burns or trauma, including extensive skin and tissue damage, or are elderly with frail skin and hence more prone to experience skin tears when an adhesive electrode is removed.

One doctor estimated red skin and minor abrasions were reasonably common (30+ %) with diathermy pad but these were not sufficiently serious to record on the centralised incident reporting system.

Further details of responses are provided at Section 4 because they informed the economic evaluation.

3.10.5 Information Gathering Meeting

A meeting was held with three theatre sisters) to enable the EAC team to gain background information on the clinical setting and current practice. The sisters explained how diathermy pads were used in their theatres and showed the team a typical diathermy pad.

3.11 CONCLUSIONS ON THE CLINICAL EVIDENCE

Of the six studies only one provided evidence of the use of the Mega Soft Patient Return Electrode on patients. This small study by Sheridan (2003) demonstrated the effectiveness of the product for 17 children with burns. This study had a low risk of confounding or bias and provides limited evidence that the product is effective in this patient group. There was no comparative arm so relative effect cannot be determined

Two studies were based in the laboratory and concerned with the technical efficiency of the product. A manufacturer-led study (Megadyne (2011a), compared the heat from the Mega Soft Patient Return Electrode with that from a diathermy pad, with few details on how it was conducted. This was the only comparative study and subject to potential bias because of its conduct and lack of transparency.

An independent study by ECRI (2000) provided an unbiased measure, and hence good grade of evidence, of the technical and operational effectiveness of the Mega 2000 patient return electrode.

The remaining studies were expert opinion and very low grade evidence. They provide qualitative feedback that named users found the device of benefit to patients, offered time and cost savings. Methodologies used are not described. These studies provide no reliable clinical evidence but have some limited value in demonstrating the product may have potential benefits beyond prevention of burns. All raise issues of selectivity in outcomes selected, reliability, validity and generalisability of data. They did however show consistency of scores.

In conclusion, the six studies forming the sponsor's clinical evidence included the only studies identified by the EAC. The EAC has not excluded any studies although the three qualitative studies (Megadyne, 2011b, Megadyne, 2011c and the Evaluation Reports) have identified flaws likely to bias the results (selection bias, methodological weaknesses, outcome bias and results bias), are low quality studies and hence offer a very low level of evidence . Their findings have limited internal or external validity. The reasons for retaining them were twofold:

- The studies are seeking to answer different questions to that of clinical safety and burns. This aspect was efficiently addressed in the ECRI study. Questionnaires are often used to explore organisational issues and are therefore an appropriate study design (Busse 2002). However, the absence of any information on how they were conducted, sites selected etcetera limits their reliability;
- Testimonials have no generalisability beyond the immediate setting. However, given the paucity of evidence the harm in rejecting these is judged greater than the risk of including them, as long as they are supported by strong statements indicating their limited validity beyond their immediate setting.

The Sheridan (2003) and ECRI (2000) studies provide evidence that the Mega Soft Patient Return Electrode is safe to use with children with burns undergoing monopolar surgery. These studies are directly relevant to the target population. No evidence of its clinical effectiveness relative to diathermy pads with RECQM (split diathermy pads) or diathermy pads without RECQM pads (solid pad) has been provided.

The outcomes studied have been limited to burns, the only adverse event considered, and the sustainability of using the pad; there was no evidence submitted on the incidence of post-operative pressure ulcers.

Section 4: Economic Evidence

4.1 CRITIQUE OF THE SPONSOR'S SEARCH STRATEGY

The sponsor used one search for clinical studies and economic evaluations (see Section 3.1). No outcome or methodological filters were used to limit the search. This search was supported by a robust search of grey literature.

The search strategy is judged likely to have a high sensitivity, i.e. to find all studies including economic evaluations related to Mega Soft Patient Return Electrode or Mega 2000. This approach was appropriate for the Mega Soft Patient Return Electrode.

4.2 CRITIQUE OF THE SPONSOR'S STUDY SELECTION

The sponsor used the same study selection process for clinical and economic studies. This was critiqued in Section 3.2 and judged adequate.

4.2.1 Included and Excluded Studies

The sponsor found no economic evaluations from the literature review. Two testimonials (Megadyne 2011b and c) were submitted as economic evidence.

One study, ECRI (2000) undertook a cost consequences analysis of the Mega 2000 in the Year 2000, in US dollars, but was not submitted by the sponsor for the economic evaluation. This was valid given prices and exchange rates have changed markedly over the intervening years. Moreover, that product was only warranted for 18 months but the Mega Soft Patient Return Electrode is warranted for two years. However, the overall conclusion does have validity for the English setting in that potential users should trial the product in the busiest operating theatres because the more the Mega 2000 is used in a given operating room, the more economical it is. The main drivers were cost differential between diathermy pads and the Mega 2000 and use of the latter. ECRI also noted that purchasing a large number of these electrodes may require a large initial investment.

4.2.2 Overview of Methodologies of all Included Economic Studies

No methodology was provided for these testimonials.

4.2.3 Overview and Critique of the Sponsor's Critical Appraisal for Each Study

A robust checklist was provided for use in quality assuring economic evaluation but it was not completed for the testimonials. These do not provide evidence to use within a formal economic evaluation.

4.2.4 Does the Sponsor's Review of Economic Evidence Draw Conclusions from the Data Available?

No explicit conclusions were drawn but absence of completed quality assurance checklists suggests the sponsor was aware of the deficiencies in published evidence.

4.3 DE NOVO COST ANALYSIS

The sponsor submitted an Excel® model analysing relative cost per operation of treatment using a Mega Soft Patient Return Electrode compared to a conductive return electrode (diathermy pad) with RECQM.

4.3.1 Patients

The model provides results for adult and paediatric patients undergoing monopolar electrosurgery.

4.3.2 Technology and Comparators

The model compared the Mega Soft Patient Return Electrode to conductive return electrode (diathermy pad) with RECQM and conductive return electrode with no RECQM (solid diathermy pad). The sponsor noted the split diathermy pads are current practice, having a twenty times higher market share than solid diathermy pads.

4.3.3 Model Structure

The Excel® model consisted of five linked worksheets and a title page. This explained which cells were user defined and able to be changed such that modelled results would be updated for the change. The results worksheet summarised the difference in cost per operation for each parameter. The parameters were contained in three other worksheets; technology costs, time saving costs and other costs. Sensitivity analyses, displayed using a tornado diagram were reported in the final worksheet.

The structure was non stochastic and linear; it was appropriate to quantify the main cost difference between the technologies. These were grouped as:

- Cost of Mega Soft Patient Return Electrode compared to diathermy pads;
- Savings from avoided pressure pad and razors/razor heads;
- Surgeon, anaesthetist, nurse anaesthetist and operating room nurses' time saved by avoiding need to shave patient and place pads.

No health states were included. No clinical benefits such as adverse burns (to patients or staff) avoided were included.

This model structure was appropriate for the decision question and the clinical evidence.

4.3.4 Clinical Parameters and Variables

Table 4.1 details data values and sources for each parameter used in the model and EAC estimates for the same parameter. Costs are divided between technology related usage and costs and resource savings. More detailed discussion of the assumptions follows the Table.

Table 4.1: Parameter values used and source of assumptions

	Cost/price	Source	EAC estimate	Source and rationale
Cost and use of technologies, lives and discount rates				
Cost of adult or paediatric Mega Soft pad	£1,900	Sponsor	£1,900 plus 20% for VAT	Sponsor price excluded VAT
Usage of Mega Soft Pad	3 times a day 5 days a week 52 weeks	Assumption	3 times a day 200 days a year	Mean estimate from NICE experts (range 1.6 to 5); one NICE expert advised 200 days
Split diathermy pad adult	£2.44 per pad	Sponsor: estimate of two diathermy pad products	**No lead wires** Mean cost of £0.46 and £0.54 adult split and solid pads respectively. Purchase price for paediatrics split pads £0.48; no solid paediatric pads purchased. **With lead wires** Cost of split pads £1.78. Costs include VAT. Source NUTH Trust. As sensitivity analysis the arithmetic mean of Supply Chain catalogue prices were used being: No lead wire adult split £0.76; No lead wire adult solid £0.49 With lead wire adult split £1.92 With lead wire adult solid £1.98	
Solid diathermy pad adult	£2.60 per pad	Sponsor: price of one diathermy pad product		
Split diathermy pad child	£1.92 per pad	Sponsor: price of one diathermy pad product		
Solid diathermy pad child	£1.74 per pad	Sponsor: price of one diathermy pad product		
Re-usable lead wire from ESU			£21.86. Use 100 times.	Mean price of four products from NHS Supply Chain catalogue. Estimate of use from sponsor. No marginal cost to sterilise. 30 seconds to affix/remove to/from ESU by health care assistant.
Mattress	£334 and used 3 times a day 5 days a week 52 weeks	Estimate one manufacturer	Price consistent with one year use.	One manufacturer for duration and price could not be verified by NHS Supply Chain without extra work; this not requested by EAC.
Usage of mattress	3 times a day 5 days a week 52 weeks	Assumption	5 times a day, 200 days a year	Mean estimate from NICE experts (range 1.6 to 5); one expert advised 200 days
Razor head	£1.13 mean of disposable razor (£0.16) and clipper head (£2.09)	Manufacturers' quotes and 50/50 use an estimate	£2.09	NICE Experts indicate disposable razors are not used
% patients shaved	100%	Assumption	40%	From 2 NICE experts who advised % shaved less than 50%- 40% used and tested in sensitivity

	Cost/price	Source	EAC estimate	Source and rationale
				analysis..
Discount rate and life	A 2 year life and 3.5% discount rate applied in year 0	2 year life consistent with warranty and 3.5% consistent with NICE reference case	Values agreed but 3.5% applied to first year	Assumption
Resource savings				
Surgeon and Consultant anaesthetist (1 each per operation)	£347 per hour	PSSRU	£136 per hour	PSSRU (see section 4.3.5)
Surgeon and Consultant anaesthetist (1 each per operation)	£347 per hour	PSSRU	£403 per hour	PSSRU (see section 4.3.5). Full costs including qualifications per hour in theatre and alternative costing approach
Nurse anaesthetist and 2 operating theatre nurses	£41 per hour	PSSRU	£34 per hour	PSSRU (see section 4.3.5)
Delay for site prep	5 mins	Sponsor estimate	0 to 4 minutes	NICE Experts (see section 4.3.5)
Healthcare assistant			30 seconds	£0.11

4.3.4.1 Technology costs and usage

Unit cost: mega soft patient return electrode

The sponsor submitted three prices for the product, a discounted price for adult and paediatric products and an undiscounted price for each. He has asked that only the discounted price of £1,900 be used in the economic evaluation because that will now be the price for all customers. This price was exclusive of VAT which has now been added at 20% to give a price of £2,280.

Unit cost: diathermy pads

The sponsor has supplied costs for diathermy pads based on one or two prices selected from the NHS Supply Chain catalogue. The EAC judges the unit costs submitted by the sponsor for diathermy pads are inappropriate for some NHS settings. These are hospitals which have adopted reusable diathermy cables. As shown in Table 1.1, the cost of diathermy pads varies between those with lead wires and those which are connected to the ESU through a re-usable cable. For example, the mean cost of all adult spilt pads with no lead wire listed in the NHS Supply Chain catalogue is £0.76, compared to £1.92 for split pads with a lead wire.

For sites using diathermy pads with lead wires, the one or two prices selected from the NHS Supply Chain catalogue by the sponsor may not be representative of the purchases of individual trusts. To address this volume uncertainty, the EAC has received a detailed analysis, by product, of all purchases made by NUTH Trust in 2010/11 and 2011/12. The mean cost per pad was £0.59 in each year, with a mean cost for split diathermy pads of £0.61 and £0.46 for solid diathermy pads. The price range was from £0.48 to £2.00 for split pads; only one product line of solid pads was purchased.

The mean price for adult split pads without wires purchased by NUTH Trust was £0.54, for wireless solid pads the mean price was £0.46 and split with lead wires £1.78.

The EAC has access to the purchasing behaviour of the NUTH Trust where split pads formed 85% of all purchases of diathermy pads. The sponsor advised that the most common form of electrode used in some hospital sites was diathermy pads with wires. Given the uncertainty about the purchasing behaviour of other trusts, the EAC has requested this information from NHS Supplies. A response will be provided by 20th February 2012.

In the meantime the central case will assume that split wireless pads are current practice and adopt a price of £0.54 and conduct a sensitivity analysis using split pads with wires at a cost of £1.78.

Table 4.2 summarises the price scenarios, including VAT: these are explored in the sensitivity analysis (see Table 5.2).

Table 4.2: Prices of diathermy pads from sponsor, NHS Supply Chain and NHS NUTH

	Adult split pads		Adult solid pads		Child split pads		Child solid pads	
	With wires	**No wires**	**With wires**	**No wires**	**With wires**	**No wires**	**With wires**	**No wires**
Sponsor	£2.44		£2.60		£1.92		£1.74	
Mean Supply Chain catalogue	£1.92	£0.76	£1.98	£0.49	£2.14	£0.68	£1.88	£0.68
NUTH Trust	£1.78	£0.54	N/A	£0.46	N/A	N/A	N/A	£0.48

Unit cost: reusable cable to ESU

The mean price of a reusable cable to connect the diathermy pad to the ESU was estimated from the price of four reusable leads (excluding the specific Bard/Birtcher Erbe ESU) from the NHS Supply Chain catalogue at £21.86, (details in appendix 1). The sponsor estimated these could be re-used for 100 times, giving a cost off-set per operation of £0.22. The cable must also be sterilised on the tray of instrument after each operation. This has no marginal cost. The time and cost to remove and re-fit the cable is considered in Section 4.3.5.

Unit cost: theatre mattresses

A second manufacturer advised that theatre mattresses costing under £350 are available but have a limited life of one year and limited pressure reliving properties. NHS Supply Chain did not have the price of a similar mattress in its catalogue and hence had to request a price from a manufacturer. The quote received for two operating table gel pads was £363 each before VAT. These prices are consistent with the price adopted in the sponsor's submission. If anything the sponsor's price may be a slight underestimate.

Unit cost: razors

The NICE experts advised electric razors are used for shaving with disposable heads for all patients who require to be shaved. The sponsor advised these cost £2.09 each and this is consistent with indicative prices from the NHS Supply Chain online product catalogue https://my.supplychain.nhs.uk/catalogue.

Usage

The assumed usage rate of three times a day for the Mega Soft Patient Return Electrode was consistent with the majority opinion of the NICE experts but one NICE expert advised theatres would only operate 200 days a year (4 days, 50 weeks), not 260 (5 days, 52 weeks) assumed by the sponsor.

No recent evidence was found by the EAC on mean utilisation of theatres for monopolar or bipolar surgery per week or annually. A 2002 Audit Commission report on 'Operating theatres' estimated theatres were used for an average of 24.3 hours a week, with many having low utilisation on Fridays and at weekends. This is consistent with evidence from Information Services Division (ISD) Scotland which showed that theatres were used on average for 27 hours a week in 2010/11. In addition, the Audit Commission found that 10% of all operations were cancelled. Taking these factors together suggest a base case of 3 operations a day for 200 days a year may be a reasonable estimate of usage for the Mega Soft Patient Return Electrode.

The sponsor also assumed usage of the mattress at 3 times a day for 260 days a year (780 total). Given the evidence from the Audit Commission and ISD the assumed number of days used is judged to be too high. However, the daily utilisation of three is judged too low given the mattress can be used for all surgery. The EAC will adopt, as a base case, utilisation for five operations a day for 4 days a week for 50 weeks a year (1,000 operations a year).

The sponsor assumed all patients were shaved but the NICE experts advised less than 50% required shaving. A base case of 40% was used, with sensitivity analyses assuming 10% and 70% will be conducted.

Time horizon

The sponsor has used a two year time horizon consistent with the warranty on the Mega Soft Patient Return Electrode. A discount rate of 3.5% has been applied to the first year and 3.5%[2] to the second year. It would be more usual not to discount the first year costs (Ogier, 2004).

Clinical outcomes

No clinical outcome measures were applied and this is consistent with the absence of submitted clinical evidence on adverse events from the Mega Soft Patient Return Electrode or more particularly its comparators. However, NHSLA data do indicate site burns are a risk with diathermy pads and hence burns would be a valid endpoint.

4.3.5 Resource Identification, Measurement and Valuation

Theatre time saved

The main claimed resource saving was reduced theatre time as nurses no longer had to get the pads, shave the patient, put on and dispose of the pads. Estimated saving was five minutes; this assumption by the sponsor is based on one of the citations from the US hospitals (Megadyne 2011b).

The sponsor explained that the five minutes was per patient and comprised the following activities: pick up diathermy pad from store, possibly in an anteroom; check plate and size; read instructions on where not to apply pad and find appropriate area of patient; shave patient if required, apply and dispose of the pad. The sponsor advised that these activities are conducted in theatre because the ESU is sited there. He noted that if the diathermy pad was applied in the preparation room with the diathermy pad with lead wires, then the patient would be wheeled into theatre with the loose wire attached. This is consistent with the advice from one NICE expert who suggested this activity may take place in the preparation room, not theatre. If this is common practice then time to put on pads would be included in the scheduling of patient flows between the anaesthetic room and theatre and cause no delays to other members of the surgical team.

The NICE experts advised that the sponsor's estimate of a five minute delay per operation over-stated the delay caused by using diathermy pads. Two NICE experts advised that 40% and 10% respectively of patients were shaved; the higher estimate was used in the base case with a sensitivity analysis based on 10%.

There is no evidence that other theatre staff are not occupied on their own set up duties during the period when the pad is attached. One NICE expert advised that issues such as:

> '*Finding a plate, forgetting to put it on in the anaesthetic room or the surgeon changing their minds and then having to rummage around under the drapes are much more common causes of delay'*.

This suggests that if staff follow a standard operating procedure delays do not occur; but delays can happen when procedures are not followed or plans change.

No alternative delay assumption expressed in minutes was provided by the NICE experts. The sponsor's concern about loose wires does not apply to diathermy pads fitted to the ESU with re-usable cables. Hence applying the diathermy pads in the preparation room to avoid delaying theatre staff would be an option for hospitals using these pads. Given the qualitative comments a range of 0 to 4 minutes was used in the EAC analysis.

Theatre staffing levels

The sponsor assumed a theatre staffing level of five: A surgeon, an anaesthetist and three nurses. These were all assumed to incur the 5 minutes delay.

NICE experts were asked to advise on the minimum number and mix of staff for such surgery. One NICE expert advised a minimum of six. These included a surgeon, an anaesthetist and two nurses, with an anaesthetic practitioner deployed rather than a nurse anaesthetist plus a health care assistant.

A second NICE expert advised the minimum would be one surgeon, one anaesthetist, one nurse, one support worker and one operating department assistant (technician), five in total; with seven a more common configuration and rising above that level for major cases. The base case has assumed five staff per theatre.

Additional time to clean and handle mega soft patient return electrode

The NICE experts have advised that using Mega Soft Patient Return Electrode does not add to cleaning or handing time compared to theatres using diathermy pads. In such theatres staff must also wipe down a mattress between patients and store it overnight

Use of reusable cables

Using renewable cables requires a healthcare assistant to remove the cable at the end of a procedure, place it on the sterilising tray and attach a sterile cable before the next procedure. This was assumed to take 30 seconds of a healthcare assistant's time.

Valuation of time

The sponsor used 'Unit Costs of Health and Social Care 2010' Personal Social Services Research Unit (PSSRU) to cost each hour of staff time. This is a valid source. Updated 2011 costs have recently been published. These no longer report the cost per operating hour for a surgeon (£347), being the indicator used by the sponsor; rather the cost for a surgeon contract hour (£136) only is provided. The cost per hour of £136 has been used in the EAC's analysis because allocating the employment costs of a surgeon to operating time only suggests there is no benefit from other work undertaken such as pre and post appointments with patients. Thus if a surgeon is able to reduce operating time by better triaging of patients such that fewer require surgery then the approach which costs only the hours in theatre would place nil value on the time spent with patients but rather increase the hourly rate for surgery.

NICE has requested that a sensitivity analysis is conducting assuming an hourly rate of £403 per hour in theatre for a surgeon. This value is also provided by PSSRU. It is the unit cost for 2009/2010 for an hour of operating time for a surgeon which also recovers the costs of qualifications.

The 2010 PSSRU cost for a nurse was £41 per patient contact hour, with the cost per contracted hour being £23. The sponsor used the cost per patient contact hour (£41). Equivalent figures in the 2011 PSSRU document are £82 per patient contact hour and £34 per contract hour. The difference in cost per patient contact hour arose because PSSRU used an assumption from a 2009 Department of Health report that hospital nurses spent 41% of their time on patient care; administration, handing over and coordination, discussion with other nurses, and preparing medication accounting for the remaining 59%. The EAC judges that theatre nurses have a higher level of patient contact than others in the hospital setting, having few handovers, no medicine preparation and little discussion time. Moreover,

time spent away from the patient should have equal value to that with the patient; otherwise the hospital can improve efficiency by re-balancing tasks.

The cost of 30 seconds of a healthcare assistant's time was calculated using the mid-point salary for an agenda for change band 3, £17,368 (http://www.nhsemployers.org/SiteCollectionDocuments/AfC_tc_of_service_handbook_fb.pdf). With 25% on-costs for national insurance and superannuation and assuming a 37.5 hour week and 44 weeks a year, the cost per minute is £0.22.

No difference in training costs has been assumed. The Mega Soft product may be easier to train staff to use compared to diathermy pads but there is no evidence to support this. New sites using the Mega Soft pad will incur costs in making changes to standard operating practice. However, once the change is made the practice may be simpler to follow.

4.3.6 Sensitivity Analysis

Deterministic two-way sensitivity analyses were performed by the sponsor on many parameters including the doubling and halving of: Number of operations per week; cost of pads; cost of mattress; life of mattress; cost of razors; staff time savings and hourly staff costs (see Table C.10 1 of submission for actual values). These rates were claimed by the sponsor to be the range of plausible values for each parameter but there is no evidence to support this claim.

The sensitivity analysis was not adequate to capture the lower prices observed for diathermy pads in one Trust. The analysis is also misleading in portraying equal probabilities of the high and low event happening. Again taking pads as an example, the likelihood that the price estimate was too low by 100% is improbable.

The sponsor noted two main groups of cost elements were excluded from the sensitivity analysis due to lack of data:

a) Cost to procure, store and dispose of diathermy pads;
b) Cost of adverse events including burns and skin irritations.

The EAC notes that without data from NHSLA, modelling burns accurately would have been challenging; however, modelling on-costs for pads may have been possible with advice from relevant experts.

4.3.7 Results of Sponsor's Base–Case Cost Analysis

Table 4.3 presents results from the model for the base cases adopted. All scenarios reported the Mega Soft Patient Return Electrode was estimated to save about £70 per operation.

In all cases, the Mega Soft was estimated to be cost saving by between £1.05 and £1.34 compared to diathermy pads, with greater savings against split pads (because of the higher cost of these forms). The largest contribution to the cost saving was from saved surgeon

and anaesthetist time (£57.84), with nurse time saving a further £10.25 per operation. The saving in the mattress was £0.44 and the avoided razor £1.13 were per operation.

Table 4.3: Base case cost analysis

Type of Mega Soft	Price	Comparator pad	Saving per operation
Adult Mega Soft	Non discount price	Split	Cost saving £70.70
	Discounted price	Split	Cost saving £70.83
	Non discount price	Solid	Cost saving £70.85
	Discounted price	Solid	Cost saving £70.98
Child Mega Soft	Non discount price	Split	Cost saving £69.61
	Discounted price	Split	Cost saving £70.31
	Non discount price	Solid	Cost saving £69.43
	Discounted price	Solid	Cost saving £70.13

Note subsequent to the submission of this evidence the sponsor has advised that all Mega Soft Patient Return Electrodes will now be priced at the 'discounted' price of £1,900. The sponsor's base case estimate of savings for a hospital using split pads has increased from £70.70 to £70.83. The revised base case for the child and solid options are in grey.

4.3.8 Results from Sensitivity Analysis

Sensitivity analyses were presented. The sponsor assumed a 50% increase and decrease in parameters, with no probabilities attached to likelihood of the event occurring. The results were sensitive to:

a) Assumed time savings;
b) Assumed cost per hour for the consultants and nurse grades.

If the assumed staff time reduced to 2.5 minutes from the base case of 5 minutes (i.e. a 50% decrease) the savings were estimated to drop to £36.65. If the savings assumed for the surgeon and anaesthetist only reduced to 2.5 minutes the savings fell to £41.78. In all other cases the forecast savings exceeded £65 per procedure. (Note: these have not been altered for the lower price of the Mega Soft Patient Return Electrode).

4.4 SUBGROUP ANALYSIS

Subgroup analyses were limited to reporting results for the paediatric Mega Soft Patient Return Electrode.

4.5 MODEL VALIDATION

No independent internal quality assurance of the model was undertaken; this was justified by the model's simplicity. In terms of external validation, the sponsor noted the results were

consistent with the testimonies of the two US hospitals (Megadyne 2011b and c); no formal economic evaluations were available to compare the results against.

4.6 INTERPRETATION OF ECONOMIC EVIDENCE

4.6.1 Sponsor's Interpretation

The sponsor concluded the Mega Soft Patient Return Electrode adult and paediatric products were cost saving, adding that savings were believed to be an underestimate of potential savings for patients with skin conditions, burns and fragile skin. In these patients nurses were judged to take longer to find suitable contact sites for diathermy pads. These savings were judged available to all NHS sites in England.

The sponsor judged the main strength of the analyses was the consistency of cost savings under all credible ranges of values for each parameter.

The weaknesses included the absence of data on:

- The incidence of skin burns from diathermy pads and their associated costs, including litigation costs;
- The cost to procure, store and dispose of the diathermy pads;
- Absence of independent evidence on the time saved in theatre from using Mega Soft Patient Return Electrode not diathermy pads.

The sponsor noted a survey of theatre nurses could address the last aspect and possibly address the absence of evidence on other parameters including the number of operations per week, the typical life span of the pressure-relieving mattress and the proportion of operations that use the various razors.

4.6.2 EAC Critique of Sponsor's Evaluation

The sponsor's evaluation failed to include a scenario for NHS trusts choosing reusable diathermy wires and wireless diathermy pads. This scenario presents lower costs to the NHS and enables the diathermy pads to be placed in the preparation room. This avoids delaying theatre staff whilst the pad is fitted.

The NICE experts advised that the sponsor's estimate of a five minute delay per operation over-stated the delay caused by using diathermy pads in theatre. Other staff in theatre are assumed to have completed their set-up by the start of this process.

The sponsor's evidence did not identify the potential additional costs to theatre staff of using the Mega Soft Patient Return Electrode, particularly its cleaning, handling and storage. The NICE experts advised there were unlikely to be any additional costs with the Mega Soft compared to using pressure pad mattresses.

The sponsor excluded VAT from the purchase price of the Mega Soft, increasing the price from £1,900 to £2,280.

Other differences in the advice from NICE experts related to percentage of people shaved, cost of the shaver, annual use of the Mega Soft and a pressure mattress and valuation of staff time saved. These have been explained in Section 4.

The EAC would endorse the main weakness as being the absence of robust evidence to support assumptions made. Particularly useful would have been information from members of surgical teams to support these.

4.7 ADDITIONAL WORK UNDERTAKEN BY THE EXTERNAL ASSESSMENT CENTRE IN RELATION TO ECONOMIC EVIDENCE

The EAC asked NICE experts to advise on some parameters used in the sponsor's model and requested information from the NUTH Purchasing Manager on the current price paid for the several different types of diathermy pads purchased by the Trust. The price of a mattress was checked with NHS Supply Chain but staff could not validate it without extra work; however the availability of mattresses at this price and their associated life was validated by a different manufacturer to that used by the sponsor.

The results affect the cost difference between Mega Soft Patient Return Electrode and diathermy pads. The differences and their impact on estimated cost savings are set out in Table 5.1 in the next Section.

4.8 CONCLUSIONS ON THE SUBMITTED ECONOMIC EVIDENCE

The sponsor has undertaken a robust literature search and found no published evidence on the economics of the Mega Soft Patient Return Electrode compared to diathermy pads. The EAC noted the ECRI (2000) study provided information on the main drivers for cost effectiveness being the frequency of use and cost differential; however, the values used in that document were not relevant to the decision problem.

The sponsor has also submitted a non-stochastic, transparent and easy to use economic model that models adequately the main parameters. Comparing the cost of the Mega Soft Patient Return Electrode adult pad for a two year life (£1,900 excluding VAT) with split diathermy pads (cost £2.44 each) and applying the other assumptions from the submission gave a central cost saving of £70.83 per operation. Table 4.4 shows the individual elements which aggregate to that saving.

Table 4.4: Cost savings: mega soft patient return electrode compared to split diathermy pads per operation (sponsor estimate)

Component	Saving
Cost difference Mega Soft and diathermy pads	£1.18
Savings on pressure pad and razors	£1.56
Surgeon and anaesthetist time saved	£57.84
Nurses time saved	£10.25
Total	**£70.83**

The majority of the sponsor's sensitivity analysis indicated this saving was robust to the parameter values assumed plausible. The lowest saving were £37 which occurred if assumed time saving halved from 5 minutes to 2.5 minutes and to about £42 if the value per hour of surgeon and anaesthetist time was halved. In all other cases forecast savings exceeded £65 per procedure

The main weakness with the model was absence of robust evidence to support assumptions made. To address this deficiency the EAC asked the experts appointed by NICE to validate each key assumption. This group was unable to provide information on cost of diathermy pads. To address this weakness the EAC asked the Purchasing and Supplies manager at NUTH for information on the range of prices paid for such pads.

The key remaining uncertainty is whether staff in anaesthetic rooms and theatres experience delays whilst some patients are shaved and a pad applied.

The conclusion is the sponsor has over-estimated the savings. Further analyses reported in Section 5 identify that the potential bias for sites using wireless diathermy pads. The bias is of the order of £70, with the Mega Soft Patient Return Electrode having a similar price per operation to trusts using diathermy pads at a cost of £0.54 each. This assumes no staff time saving.

This is before considering the potential gain to NHSLA from fewer claims from adopting the Mega Soft Patient Return Electrode compared to using diathermy pads.

Section 5: Impact on the Cost Difference between the Technology and Comparator of Additional Clinical and Economic Analyses Undertaken by the External Assessment Centre

Table 5.1 sets out the parameters where the estimated values used by the sponsor differ from those adopted by the EAC for the adult Mega Soft Patient Return Electrode. Table 5.2 provides the same information for the child product. Justification for these differences was provided in Section 4.

Table 5.1 Comparison of parameter values adopted by sponsor and EAC and impact on estimated savings per operation: adult Mega Soft Patient Return Electrode

	Parameter	Sponsor estimate of saving per operation	EAC estimate of saving per operation	EAC calculated saving per operation and difference compared to sponsor base case (a)	Source and rationale (For EAC estimate)
Sponsor base case (adult pad)		**£70.83**			
1.	Cost of Mega Soft	£1,900	£2,280	£70.58 Difference £0.25	VAT at 20% added (See 4.3.4.1)
2.a	Split pads adults with wire	£2.44	£1.78	£69.91 Difference £0.92	Prices from NUTH (b)
2.b	Solid adult pads with wire	£2.60	£1.98	£70.11 Difference £0.72	NHS Supply Chain price (b)
2.c	Split pads adults no wire	n.a	£0.54 + £0.22 + £0.11	£69.00 Difference £1.83	Prices from NUTH (b) + reusable lead + staff to fit
2.d	Solid adult pads no wire	n.a	£0.46 + £0.22 + £0.11	£68.92 Difference £1.91	Prices from NUTH (b) + reusable lead + staff to fit

2.e	Split pads adults with wire	£2.44	£1.92	£70.05 Difference £0.78	Prices from NHS Supply (b)
2.f	Solid adult pads with wire	£2.60	£1.98	£70.11 Difference £0.72	Prices from NHS Supply (b)
2.g	Split pads adults no wire	n.a	£0.76 + £0.22 + £0.11	£69.22 Difference £1.61	Prices from NHS Supply (b) + reusable lead + staff to fit
2.h	Solid adult pads no wire	n.a	£0.49 + £0.22+ £0.11	£68.95 Difference £1.88	Prices from NHS Supply+ (b) +reusable lead + staff to fit
3	Usage of Mega Soft	3*5*52 = 780	5*4*50= 1000	£70.56 Difference £0.27	NICE experts informed assumption (See 4.3.4.1)
4	Usage of mattress	3*5*52 = 780	5*4*50 = 1,000	£70.73 Difference (£0.10)	NICE experts informed assumption (see 4.3.4.1)
5	Razors	Mean cost £1.13	Cost £2.09	£71.79 Difference (£0.96)	No disposable razors (see 4.3.4.1)
6.a	% shaved	100%	40%	£70.15 Difference £0.68	NICE experts (see section 4.3.5)
6.b	% shaved	100%	10%	£69.82 Difference £1.01	Assumption
6.c	% shaved	100%	70%	£70.49 Difference £0.34	Assumption
7.a	Surgeon & anaesthetist	£347 per hour	£136 per hour	£35.66 Difference £35.17	Used cost per contract hour (see section 4.3.5)
7.b	Surgeon & anaesthetist	£347 per hour	£403 per hour	£80.16 Difference (£9.33)	Cost per hour of surgery including qualifications
8	Nurse	£41 per hour	£34 per hour	£69.08 Difference £1.75	Used cost per contract hour(see section 4.3.5)
9.a	Delay for site prep for pad	5 mins	4 mins	£57.21 Difference	NICE experts (see section

				£13.62	4.3.5)
9.b	Delay for site prep for pad	5 mins	0 mins	£2.74 Difference £68.09	NICE experts (see section 4.3.5)

Table 5.2 Comparison of parameter values adopted by sponsor and EAC and impact on estimated savings per operation: paediatric Mega Soft Patient Return Electrode

	Parameter	Sponsor estimate of saving per operation	EAC estimate of saving per operation	EAC calculated saving per operation and difference compared to sponsor base case (a)	Source and rationale (For EAC estimate)
Sponsor base case paediatric pad		**£70.30**			
Paediatric split pad with wire		£1.92	£2.14	£70.52 Difference (£0.22)	Prices from NHS Supply
Paediatric split pad with no wire		£1.92	£0.68+ £0.22 +£0.11	£69.39 Difference £0.91	Prices from NHS Supply + reusable lead + staff to fit

Table 5.3 sets out two plausible scenarios for the adult and child Mega Soft product showing the potential savings, with the key values applied being:

- Adults: the NUTH price of split wireless diathermy pads and no staff savings;and
- Child: the NHS Supply Chain price for split wireless diathermy pads and no staff savings.

These are judged to be plausible but also highly challenging combinations of parameter values.

Table 5.3 Plausible scenarios for adult and child Mega Soft Patient Return Electrode

Plausible scenarios	Parameter prices/value of staff time	EAC estimated saving and difference to sponsor
Sponsor base case for adult plus 1, 2c, 3, 4,5, 6a, 7a, 8, 9b £70.83	Mega Soft Patient £2,280 Diathermy pads £0.54 + £0.22+ £0.11 Razors £2.09 Surgeon and anaesthetist £136 per hour Nurse £34 per hour Nil time saved	£0.19 Difference £70.64
Sponsor base case for child plus 1, 3, 4, 5, 6a, 7a, 8, 9, 10.2 £70.30	Mega Soft Patient £2,280 Diathermy pads £0.68 + £0.22 + £0.11 Razors £2.09 Surgeon and anaesthetist £136 per hour Nurse £34per hour Nil time saved	£0.33 Difference £70.50

These findings indicate that under these challenging assumptions, the adult Mega Soft Patient Return Electrode is about 20 pence cheaper per operation compared to using split, wireless diathermy pads on adults. The Mega Soft product for children offers slightly higher potential savings of over 30 pence per operation. The savings increase for paediatric Mega Soft pads because the cost of the comparator, paediatric diathermy pads, is slightly higher (£0.68 compared to £0.54).

The results suggest that in settings where the work plan has been optimised such that there are no delays in theatre whilst staff apply diathermy pads, then the diathermy pad related cost of an operation for an adult patient is about £2.16. The cost items summing to £2.16 are shown in Table 5.3. The costs rise by about 14 pence to £2.30 for an operation on a child (higher cost of diathermy pads is 14 pence being 68p minus 54p adult)

Table 5.3: Estimated cost per procedure of using adult split diathermy pads

Cost items per procedure using split pads	Cost
Diathermy pads	£0.54
Reusable cable	£0.22
Staff to assemble/disassemble cable	£0.11
Razor to shave 40% of patients	£0.84
Gel pad	£0.45
Total	**£2.16**

If the cost of the Mega Soft Patient Return Electrode is less than £2.16 per operation, using that product is cost saving compared to diathermy pads. The annualised cost of using Mega

Soft Patient Return Electrode per adult operation is estimated at £1.97 (cost of £2,280 and assuming 600 operations a year for two years). This is £0.19 less than the cost per operation using diathermy pads (£2.16), offering a potential saving of about 20 pence per operation.

If one also considers the potential savings from claims avoided by using the Mega Soft Patient Return Electrode, about 70 pence per procedure, then accepting the Mega Soft pad for use in the NHS is estimated to be cost saving for each monopolar surgical procedure. The evidence that the Mega Soft Patient Return Electrode can reduce or remove the risk of burns will be informed by the Cedar technical evaluation.

Section 6: Conclusions

The sponsor has undertaken a robust literature search and found no published evidence on the economics of the Mega Soft Patient Return Electrode compared to diathermy pads. The sponsor has also submitted a simple and transparent economic model that models adequately the main parameters. It reported a central cost saving of £70.83 per operation, primarily from saving five minutes for all theatre staff per operation.

Adjusting the parameters to those advised by the NICE experts and assuming no staff in anaesthetic rooms and theatres experienced delays whilst diathermy pads were being applied, resulted in an estimated cost saving of about 20 pence per operation on an adult, and 33 pence for a child, using the Mega Soft rather than diathermy pads.

The NHSLA reported fewer than 30 incidents a year from diathermy pad related burns. This is consistent with the MHRA estimated number of electrosurgery incidents. Cost information from Department of Health on the management of burns and NHSLA on payments for claims indicates that the cost per claim settled, averaged across all monopolar surgical procedures is about 70 pence per procedure. These savings are additional to the 19 pence reported in Table 5.2.

In conclusion, if NHS Trusts adopt the Mega Soft Patient Return Electrode adult pad they may achieve some small cost savings. The more significant savings could accrue to NHSLA from avoided claims arising from burns from diathermy pads. This will be informed by the Cedar technical analysis.

Section 7: Implications for Research

Cedar has been commissioned by NICE to undertake technical testing of Mega Soft to address some of the questions raised by MTAC and others. This will inform on the generalisability of the results to all monopolar electrosurgery procedures. In particular it will inform on the likelihood of return electrode burns with the Mega Soft pad.

The remaining factors influencing the economic evaluation are judged to be site specific, for example, annual use of the Mega Soft pad will depend on theatre utilisation, staff savings by the work planning process adopted and the cost of diathermy pads by the purchasing decisions of each trust. This work has identified the parameters that sites should quantify when seeking to make the business case for the Mega Soft. No further national research is judged necessary.

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