NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

Medical technology guidance

Assessment report overview

Mega Soft Patient Return Electrode for use during monopolar electrosurgery

This assessment report overview has been prepared by the Medical Technologies Evaluation Programme team to highlight the significant findings of the assessment report. It includes key features of the evidence base and the cost analysis, any additional analysis carried out, and additional information, uncertainties and key issues the Committee may wish to discuss. It should be read along with the sponsor's submission of evidence and with the assessment report. The overview forms part of the information received by the Medical Technologies Advisory Committee when it develops its recommendations on the technology.

This overview also contains:

- Appendix A: Sources of evidence
- Appendix B: Comments from professional bodies
- Appendix C: Comments from patient organisations
- Appendix D: Additional submission information
- Appendix E: Sponsor's factual check of the assessment report and the External Assessment Centre's responses

1 The technology

The Mega Soft Patient Return Electrode (Megadyne Medical Products - manufacturer and Advance Surgical - sponsor) is designed for use during monopolar electrosurgery, specifically to reduce the risk of burns and to provide pressure relief. Mega Soft Patient Return Electrode is CE marked as a medical device.

The Mega Soft Patient Return Electrode conducts high frequency electrical current from the target tissue to an electrosurgical unit, or generator. The electrical circuit includes the electrosurgical unit, the active electrode, and the patient's tissues. Once

the electrical current is applied to the target tissue, it is distributed widely throughout the body and then returns to the electrosurgical unit via a patient return (grounding) electrode.

In current NHS clinical practice, a disposable single use patient return electrode is attached directly to the patient's skin via a 'sticky surface; the Mega Soft Patient Return Electrode is incorporated into a padded layer on which the patient lies during surgery. It is claimed that the Mega Soft Patient Return Electrode also acts as a pressure-relieving device.

The Mega Soft Patient Return Electrode is made of a layer of conductive material between two sheets of urethane and sealed between two asymmetrical layers of a viscoelastic polymer called Akton. The conductive layer is connected to a standard monopolar electrosurgical unit via a proprietary cable ('DetachaCable') that is insulated and attaches deep inside the device in order to prevent burns to the patient or user.

The adult size device extends to at least half the length and the full width of a typical patient torso, with a pad size of approximately 117 x 51 x 1.25 cm. The paediatric size device is approximately 66 x 30.5 x 1.3 cm and is intended for patients weighing between 0.4 kg and 22.7 kg.

The electrical circuit is completed with the patient lying on the device.

2 Proposed use of the technology

2.1 Disease or condition

During 2009/10 there were approximately 9.7 million inpatient surgical procedures in the UK. It has been estimated that 2.81 million (29% of the total) involved general anaesthesia and lasted for more than 30 minutes, and that monopolar electrosurgery is used in a minimum of half of all surgical procedures.

Burns occur during electrosurgery when the return electrode is applied incorrectly and so fails to disperse energy. Return pad burns typically occur when the contact area becomes accidentally reduced during surgery. The issue is sufficiently important clinically for the Medicines and Healthcare products Regulatory Agency (MHRA) to publish alerts for healthcare professionals about the safe use of

electrosurgery, and to encourage them to report adverse incidents. Most (70%) adverse incidents related to electrosurgery reported to the MHRA are related to burns, with approximately 35% of burns being related to the neutral (return) electrodes. Since 2000, there has been an average of 117 electrosurgery incidents a year, with an average of 82 of these related to burns, and 29 related specifically to return electrode burns. There were approximately 104 electrosurgery incidents reported in 2009, with 26 relating to return pad burns. There were approximately 180 electrosurgery incidents reported in 2010, with 44 relating to return pad burns.

In current NHS clinical practice, a disposable single-use patient return electrode is attached directly to the patient's skin via a 'sticky surface'. The skin may need to be shaved, and it can cause skin irritation that may persist during postoperative recovery. Other possible skin complications include hypersensitivity and the removal of dermis when the pad is removed.

2.2 Patient group

The Mega Soft Patient Return Electrode is designed for use in patients having monopolar electrosurgery, specifically to reduce the risk of burns and to provide pressure relief.

If the evidence allows, the following subgroups will be considered in this assessment:

- patients with burns
- patients with skin conditions
- babies and children
- patients with fragile skin. (for example, older patients)
- patients with high or low body mass index (BMI).

2.3 Current management

In current practice a disposable single-use patient return electrode is applied to the skin during monopolar electrosurgery. Standard electrodes comprise a conductive foil covered by a polymer and a sticky surface that allows for skin adherence. The electrode surface must be large enough to minimise the temperature as the electrical energy leaves the patient. There is a rise in skin temperature and a risk of burning if electrical conduction is impeded at the skin-to-pad surface interface. Excessive

impedance may be caused by reduced contact area of the patient return electrode, which can result from body hair, adipose tissue, bony prominences, fluid invasion, failure of the electrode to stick or scar tissue. To prevent this, pads need to be strategically placed to avoid bony prominences and should be placed on hair-free areas of the body. This may mean that the area needs to be shaved before the electrode is applied.

Current management includes a range of disposable single-use patient return electrodes these are:

- disposable single-use patient return electrode non-split (also called solid)
    - with lead wire
    - without lead wire
    - paediatric with lead wire
    - paediatric without lead wire.
- disposable single-use patient return electrodes split
    - with lead wire
    - without lead wire
    - paediatric with lead wire
    - paediatric without lead wire

The most common, according to supply chain is the split adult disposable single-use patient return electrode no lead wire.

2.4 Proposed management with new technology

The Mega Soft Patient Return Electrode is an alternative to a disposable single-use patient return electrode, which reduces the risk of patient burns during monopolar electrosurgery.

The Mega Soft Patient Return Electrode is incorporated into a pad on which the patient lies during surgery. Electrodes do not need to be attached directly to the skin

and shaving is not needed. The Mega Soft Patient Return Electrode is reusable; it can be placed on the operating table before the first patient is prepared and can remain on the operating table for subsequent procedures.

The Mega Soft Patient Return Electrode has pressure-relieving properties, so may remove the need for a pressure-relieving mattress on the operating table. The usual product life is 24 months.

2.5 Equality issues

Cultural sensitivities exist surrounding the shaving of body hair; this may be an issue when using 'sticky surface' disposable single use patient return electrodes but is potentially avoidable through the use of the Mega Soft Patient Return Electrode.

Although the device may have particular advantages for people who do not wish to shave body hair, it is suitable for all skin colours and types.

3 Issues for consideration by the Committee

3.1 Claimed benefits

The benefits to patients claimed by the sponsor are:

- reduction in burns in patients undergoing monopolar electrosurgery
- avoidance of skin shaving
- reduction in skin irritation because the Mega Soft Patient Return Electrode does not need to be attached directly to the patient's skin.
- particular applicability to patients with burns or other skin conditions as well as to paediatric and older patients with fragile skin
- reduction in the risk of pressure-related injury as a result of immobility during surgery.

The benefits to the healthcare system claimed by the sponsor are:

- reduction in staff time because the patient is placed on the Mega Soft Patient Return Electrode and there is no need to attach a disposable single-use patient return electrode, which means the clinician does not actively have to avoid bony prominences, scar tissue and tattoos
- reduction in the need for treatment and litigation costs associated with burns

- cost saving and improved sustainability compared with current practice because the Mega Soft Patient Return Electrode is re-usable and a separate pressure-relieving device may not be needed.

3.2 Main issues

Technical assessment

At the selection and routing stage, the Committee considerations included six technical questions. An additional technical assessment was commissioned, the results of which are summarised in section 4.1 and described in detail in the Technical Assessment Report by the CEDAR External Assessment Centre. The External Assessment Centre studied evidence, largely from the manufacturer's unpublished test data, and carried out independent testing on the device. The External Assessment Centre concluded that there were no significant concerns relating to any of the six questions for adult size pads. Its findings will be used, as appropriate, to support the development of implementation tools.

Clinical evidence

Of the six main studies included by the sponsor, only one provided evidence on the use of the Mega Soft Patient Return Electrode in patients (Sheridan 2003). The study was small, but demonstrated the effectiveness of the product in 17 children with burns. The External Assessment Centre stated that the study had a low risk of confounding or bias and provides limited evidence that the product is safe to use for children with burns undergoing monopolar surgery. However, the study was not comparative so the clinical effectiveness of the Mega Soft Patient Return Electrode could not be determined relative to a disposable single-use patient return electrode.

The External Assessment Centre noted that one study (ECRI 2000) provided independent evidence on the safety, technical performance and practical use of the device and was particularly relevant to the decision problem. The External Assessment Centre stated that it provided an unbiased measure and therefore good quality evidence on the technical and the functionality of the Mega 2000 (an earlier version of the Mega Soft Patient Return Electrode).operational effectiveness

The External Assessment Centre noted that two studies were based in the laboratory and examined the technical efficiency of the Mega Soft Patient Return Electrode.

One was a study by the manufacturer comparing the heat from the Mega Soft Patient Return Electrode with that from a disposable single-use patient return electrode, but few details were presented on how it was conducted. (See section 4.1, independent testing data for further details.) The External Assessment Centre noted that this was the only comparative study but may have been subject to bias because few details were provided on its methods.

The External Assessment Centre noted that the remaining evidence was in the form of testimonials (Megadyne 2011b; Megadyne 2011c); and the evaluation reports (Megadyne 2001c) and that these were low grade evidence. These provided qualitative feedback on the benefits of the device for patients such as time and cost savings. The External Assessment Centre stated that these studies did not provide reliable clinical evidence and had limited value in demonstrating that the product may have potential benefits beyond preventing burns. There were issues of selection bias, methodological weaknesses, outcome bias and results bias. However the External Assessment Centre stated that these studies were retained because they answer questions other than those about clinical safety and burns, and questionnaires are often used to explore organisational issues so they are an appropriate study design. The External Assessment Centre also stated that testimonials have no generalisability beyond their immediate setting, but because of the lack of evidence in this area they were retained for further consideration.

The External Assessment Centre did not identify any additional clinical evidence that was not included in the sponsor's submission, and no ongoing studies were identified.

The External Assessment Centre noted that evidence was not submitted by the sponsor, or available elsewhere, on most of the pre-specified end points including: the incidence of dispersive electrode burns, stray electrosurgical burns and postoperative pressure ulcers; other device-related adverse effect; and staff time to clean the device. Furthermore, no evidence was available on the subgroups defined in the scope, other than from a study in 17 children with burns (Sheridan 2003).

Economic evidence

The sponsor’s base-case analysis compared the adult Mega Soft Patient Return Electrode with an adult split disposable single-use patient return electrode with a

lead wire and the paediatric Mega Soft Patient Return Electrode with a paediatric split disposable single-use patient return electrode with a lead wire. The base-case analysis showed that for adults if the Mega Soft Patient Return Electrode is used instead of the split disposable single-use patient return electrode, there is cost savings of £70.83 per operation; for children if the Mega Soft Patient Return Electrode is used instead of the split disposable single-use patient return electrode, there is a cost saving of £70.31 per operation. Table 1 shows the key assumptions in the sponsor's base-case analysis.

Table 1 the sponsor base-case assumptions

Assumption	Cost/price/usage
The cost of the adult or paediatric Mega Soft Patient Return Electrode (without VAT)	£1900
The usage of Mega Soft Patient Return Electrode based on assumption and estimates	3 times a day, 5 days a week, 52 weeks a year
There are four types of disposable single use patient return electrode used commonly in the NHS. The prices given are based on different electrode manufacturer prices.	Split adult single use patient return electrode with lead wire: £2.44 per electrode
	Non-split (Solid) adult single use patient return electrode with lead wire: £2.60 per electrode
	Split paediatric single use patient return electrode with lead wire: £1.92 per electrode
	Non-split (Solid) paediatric single use patient return electrode with lead wire: £1.74 per electrode
The operating table pressure-relieving mattress price; taken from one manufacturer	£334
The usage of operating table pressure-relieving mattress	3 times a day, 5 days a week for 52 weeks a year
Razor costs to shave patients taken from razor manufacturer quotes	£1.13 mean cost from disposable razor (£0.16) and clipper head (£2.09)
The percentage of patients needing to be shaved when using a disposable single-use patient return electrode	100%
The discount rate of Mega Soft Patient Return Electrode	A 3.5% discount rate applied in year 0
The Mega Soft Patient Return Electrode lifespan	2 years/24 months
The resource costs taken from Personal Social Services Research Unit (PSSRU) based on 'per operation hour'	One surgeon per operation: £347 per hour
	One consultant anaesthetist per operation: £347 per hour
	One nurse anaesthetist per operation: £41 per hour
	Two operating theatre nurses per operation:

Assumption	Cost/price/usage
	£41 per hour
Estimated time needed for site preparation when using a disposable single-use patient return electrode	5 minutes

The sensitivity analyses carried out by the sponsor demonstrated that the results of the model were sensitive to the assumptions for staff time and the cost per hour for surgeons, anaesthetists and nurses. However, the External Assessment Centre noted that no justification was given for the range of values tested.

The External Assessment Centre expressed particular concerns about a number of parameters in the sponsor's model such as:

- the omission of VAT for the price of the Mega Soft Patient Return Electrode
- the type of single-use disposable patient return electrodes that are most commonly used in UK clinical practice and the unit costs for each type
- the usage of operating table pressure-relieving mattresses
- the percentage of patients who need shaving
- clinical staff time costs in terms of cost 'per contract hour' rather than 'per operating hour'
- the estimated time delay for site preparation and the placing of the disposable single-use patient return electrodes on the patient, and therefore clinical staff time saved.

The External Assessment Centre carried out additional analyses to examine the impact of changing these parameters (summary in table 2 on page 26 and detailed analysis in section 4.3).

Overall these changes resulted in a cost saving of £0.19 saved per operation compared with current practice for adult pads and £0.33 per operation for paediatric pads. The Committee may wish to consider which of the assumptions used in the model are most plausible.

4 The evidence

4.1 Summary of technical evidence

Six specific technical issues were raised at both the selection and scoping stage:

- The sponsor states that the Mega Soft Patient Return Electrode is a self-contained current-limiting device, which is safe to use if the patient is in contact with only a small portion of the pad. Clarification is needed on the minimum contact area between the patient and the pad below which safety is compromised.
- Concern was raised about whether alcohol-based products spilt on the pad would collect in pools and lead to a higher risk of burns.
- Clarification is needed on whether the product can be used with all other equipment in the operating theatre.
- Clarification is needed about safety implications if the outer skin of the Mega Soft Patient Return Electrode is punctured.
- Clarification is needed about what thickness of intervening material between the Mega Soft Patient Return Electrode would lead to conduction being compromised.
- The disposable single use patient return electrodes used as comparators are resistive coupling electrodes; the Mega Soft Patient Return Electrode is a capacitive coupling electrode. Clarification is needed about whether the Mega Soft Patient Return Electrode can be used with all electrosurgical units because these are likely to have been tested for use with resistive coupling electrodes rather than capacitive coupling electrodes.

Please refer to the technical assessment report for details. The External Assessment Centre considered seven areas of evidence: two databases with details of adverse events; data on independent testing from a total of three published and unpublished sources; manufacturer (different to sponsor) testing; and its own independent testing. The sponsor stated there are approximately 5500 Mega Soft Patient Return Electrodes in use globally, with the majority in the USA, and these have been in use since 2003.

Adverse effect reporting databases

The MHRA database has no reports of adverse effects related to Mega Soft Patient Return Electrodes.

The External Assessment Centre examined the USA-based MAUDE database, which contained 11 reports of 10 separate incidents relating to Mega Soft devices. Six incidents were identified using Mega Soft Patient Return Electrode (none in the UK) and four using the earlier version of the device, Mega 2000. Although there was no full investigation of the incidents, the External Assessment Centre judged that alternate site burns were likely to have been involved.. These occur where the current takes an alternative route to earth, rather than through the generator. These burns can occur where the patient is in direct contact with metal equipment that may form a connection to earth and these could have been avoided by careful theatre procedures. With any electrosurgery there will always remain some stray capacitive coupling to earth that makes alternate site burns possible. The risk of alternate site burns is generally higher with capacitive pads than with resistive pads.

Independent testing data

The ECRI report (2000) was based on tests on an earlier version of the Mega Soft Patient Return Electrode (the main difference between the current and earlier versions is the covering material). Testing included: performance; heating different areas of the pad; pinholes in pad; alternate current pathways; activation of the connectivity alarm; ease of use and quality of construction. The report indicated technical success with the Mega 2000, but did not recommend it for use with thick gel pads, paediatric patients and certain settings on ERBE electrosurgical units, the last two of which are in the manufacturer's instructions for use. The results were not reported in full; only unexpected or unfavourable results were noted. However, all the tests were rated as good except the test of alternate current pathways which was rated as fair.

The UL is an identified notified body. It reported on the testing or justification of non-testing to assess compliance with IEC 60601-2-2-2006. Detailed results were not available but Mega Soft Patient Return Electrode was deemed to be compliant.

Independent testing was carried out by the Centre Hospitalier Universitaire de Sherbrooke (CHUS) in Canada (draft, unpublished 2012). This included testing with the pad folded; pad compressed widthways to wrinkle up; pad with undried bleach on it; pad soaked in saline; pad placed upside down; a split sticky neutral electrode with poor contact to pork belly; pad positioned as if seated; pad positioned as if it had slid down giving poor contact area; poor contact with pad; different numbers of sheets

between pad and pork belly; and with a cushion between pad and pork belly. The External Assessment Centre noted that this report was unpublished, with the final results due in early 2012. The CHUS looked at temperature rise in the pork belly, and considered that a temperature change of 6°C would indicate when harm would occur to a patient. This is derived from an international standard, but with different test conditions, so may not be applicable. The External Assessment Centre examined the preliminary results, using the assumption that a rise in temperature of 6°C indicated harm to a patient. One test (the poor contact test) resulted in a heating rise of 6.3°C; however, the power settings used were unusually high and would be exceptional for normal surgery. Overall the CHUS concluded that the Mega Soft Patient Return Electrode is safe and reliable.

Manufacturer's testing

The manufacturer provided full details of the tests completed before the product came to market. These included: capacitance of adult and paediatric pad with one size plate; heating of the adult and paediatric Mega Soft Patient Return Electrode and conventional disposable single-use patient return electrode under extreme conditions and investigating alternate site paths. The tests met all the required standards. Capacitance levels for the adult Mega Soft Patient Return Electrode were all above the required minimum of 4 nF with a range between 7.2 nF and 10.2 nF. Capacitance levels for the paediatric Mega Soft Patient Return Electrode ranged from 4 nF to 5.1 nF. The skin temperature changes seen after ESU activations were between 1°C and 1.4°C, which were within the requirement of less than 6°C.

External Assessment Centre testing

The External Assessment Centre investigated how small the contact area between the patient and the Mega Soft Patient Return Electrode would need to be before safety is compromised. The External Assessment Centre's independent testing demonstrated that if less than 55% of the pad is covered capacitance is below 4 nF, which does not comply with IEC 60601-2-2:2009 recommendations. The value is based on historical precedent rather than clinical or scientific evidence. The External Assessment Centre were advised by Megadyne and expert advisors who agreed that lower power settings would typically be used in paediatric surgery than adult surgery. Use of lower power settings would reduce the risk of alternate site burns..

The External Assessment Centre examined the spillage and pooling of alcohol-based products on the Mega Soft Patient Return Electrode pad and the risk of burns. There was no evidence to suggest that any change to capacitance of the system resulting from fluid pooling would cause harm.

The External Assessment Centre stated that it was unlikely that any electromagnetic interference would be caused by the use of a capacitive return pad, therefore it would be safe to use with other devices in the operating theatre.

The External Assessment Centre investigated the effect of punctures to the outer skin of the Mega Soft Patient Return Electrode. Testing demonstrated that accidental puncturing or cutting of the pad does not expose the electrode and therefore it is unlikely that it would present a hazard to the patient.

The External Assessment Centre examined the thickness of the intervening material between the Mega Soft Patient Return Electrode and the patient before function is compromised. Testing demonstrated that an increased number of layers does decrease the capacitance. Standard clinical practice in the UK is to use a sheet under a patient, a heated sheet or incontinence pad may also be used. The expert advisers stated they have not experienced problems in these situations. The External Assessment Centre reports that Megadyne recommends that no more than two sheets should be used between the patient and Mega Soft Patient Return Electrode.

The External Assessment Centre investigated whether Mega Soft Patient Electrode can be used with all electrosurgical units. The manufacturer states that in both the UK and the USA, the Mega Soft Patient Return Electrode is used with a variety of different electrosurgery generators. There is a list of approved generators available on the manufacturer’s website and by request and the sponsor is happy to provide certificates stating that the Mega Soft Patient Return Electrode is compatible with generators, should an NHS trust require them. This information would be based on historical clinical use, the specification of the electrosurgical unit or functional testing if the electrosurgical unit is available for testing.

4.2 Summary of evidence of clinical benefit

The sponsor identified two published studies and four unpublished documents relevant to the scope. The published studies were one technical evaluation (ECRI 2000) and one observational study (Sheridan 2003). Both studies evaluated the earlier version of the Mega Soft Patient Return Electrode, the Mega 2000. The unpublished evidence was two testimonials from two USA hospitals examining the Mega 2000 and the Mega Soft Patient Return Electrode, and one technical evaluation and one amalgamated London-based hospital questionnaire on the Mega Soft Patient Return Electrode.

The External Assessment Centre did not identify any further studies.

Published studies

ECRI (2000) was a laboratory-based study that examined the safety, efficacy and cost-effectiveness of Mega 2000 compared with disposable single-use patient return electrodes, to relevant American and international technical standards using existing protocols. One adult volunteer was used in the tests and a piece of meat was used to assess burns. No statistical tests were reported. Mega 2000 was rated 'acceptable (with conditions)'. All the test results were rated as good except the test of alternate current pathways, which was rated as fair. Advantages included: relatively uniform distribution of charge eliminating the edge effects and heating that normally occur with conductive return electrodes; skin preparation unnecessary; and the ability to use it with patients with frail skin or extensive injuries that would make the use of adhesive electrodes difficult or impossible. Concerns included use with: bulky materials; one specified unit in the High Cut or Endo Cut mode: and gel pads or other thick pads. See section 4.1 'Summary of technical evidence' (independent testing).

Sheridan (2003) reported an observational study of 17 children with extensive burns in a tertiary hospital in the USA. It monitored the use of Mega 2000 in children with extensive burns who had only a few areas on the body suitable to ground the current and therefore place an electrode. No statistical tests were reported. The results showed that Mega 2000 did not cause any burns, was convenient to use, and enabled effective patient grounding despite the limited availability resulting from the extensive burns.

Unpublished submitted evidence

Megadyne (2011a) was a laboratory-based and comparative technical study of split disposable single-use patient return electrode compared with Mega Soft Patient Return Electrode. It has not been peer-reviewed. The tests were carried out on meat. No statistical tests were reported; the main outcome was whether or not pad site burn was observed (that is, yes or no). The split pad experienced a rise in temperature of 9.7°C, compared with 1.2°C with the Mega Soft Patient Return Electrode. The IEC 60601-2-2 and ANSI/AAMI HF18 standards for electrosurgery allow a maximum temperature increase of 6°C to minimise the risk of pad site burns under limited test conditions. See also section 4.1, 'Summary of technical evidence' (manufacturer's testing).

The manufacturer provided two testimonial reports from Christus St Joseph's Hospital, USA in 2011. These were not clinical studies and no statistical tests were reported. There were no pre-defined outcomes and no patients were recruited. These hospitals initially used Mega 2000 and then switched to using Mega 2000 Soft (the US name for the Mega Soft Patient Return Electrode) when it came on to the market. In both reports Mega 2000/Mega 2000 Soft was compared indirectly with disposable single-use patient return electrodes for patient comfort and cost savings. Both hospitals issued statements saying that the device improved patient comfort and provided cost savings. The External Assessment Centre noted the weaknesses of these studies but decided to retain them because they demonstrated that certain users, at one point in time, valued the benefits from Mega Soft Patient Return Electrode. There is no assumption that these benefits generalise to other sites. These benefits are additional to those rated by the Emergency Care Research Institute which were of the safety, technical and organisational aspects of the product.

An evaluation report was provided based on the use of the device at three London hospitals. Patients at each hospital were asked by theatre nurses to complete a questionnaire after surgery to rate use of the Mega Soft Patient Return Electrode over a period of 2 weeks. No analysis was provided about the completeness of responses and the data were incomplete. Questionnaire data were available from 18 paediatric patients at one hospital and from 12 and 24 adult patients respectively at the other two. Mean scores were provided, together with raw data submitted for each

question. Scores were from 0–5, with a higher score indicating a better outcome, and were averaged. Overall a rating of 4.7 was recorded for the device. The highest scores were for skin irritation and power settings (4.9) and the lowest score was for positioning (4.2).

4.3 Summary of economic evidence

No published economic evidence on the Mega Soft Patient Return Electrode was identified by the sponsor. Testimonials from two hospitals in the USA were provided but did not quantify benefits.

The External Assessment Centre found one study, ECRI (2000) that undertook a cost consequences analysis of the Mega 2000 in the USA. This study was not submitted by the sponsor for the economic evaluation. The External Assessment Centre noted that ECRI reported that the frequency of use and cost differential meant that with greater use of the Mega 2000, the technology became more economical; however, the values used in the study were not considered relevant to the decision problem. .

The External Assessment Centre stated that no clinical evidence was presented on which to base the incidence of skin burns from disposable single-use patient return electrode and their associated costs in the sponsor's model. Evidence was not included on the cost to procure, store and dispose of disposable single-use patient return electrodes. There was no independent evidence supplied on the time saved in theatre from using Mega Soft Patient Return Electrodes rather than disposable single-use patient return electrodes.

De novo cost analysis

The sponsor submitted a de novo economic model that estimated the cost per operation for the Mega Soft Patient Return Electrode compared with a split disposable single-use patient return electrode and a solid disposable single-use patient return electrode in adult and paediatric patients undergoing monopolar electrosurgery. The analysis was from the NHS and personal social services perspective.

The model used linear formulae that described the relationships between the resource and cost variables. The model did not use any health states. The External

Assessment Centre noted that this structure was appropriate to quantify the main cost differences between the technologies given the level of clinical evidence available.

The following parameters were presented in the model:

- Technology usage and costs for the Mega Soft Patient Return Electrode, disposable single-use patient return electrode, reusable cables to ESU, theatre mattresses and razors.
- Resource savings; that is, theatre staff time (of a surgeon, anaesthetist, nurse anaesthetist and operating room nurse) saved by avoiding the need to shave the patient and place the disposable single-use patient return electrodes, theatre staffing levels, time to clean and handle the Mega Soft Patient Return Electrode and use of reusable cables.
- Other costs saved; that is, from avoiding the use of both a pressure pad and razors/razor heads.

The sponsor stated that several parameters were not included because a lack of data meant that cost savings were not quantifiable. These included:

- disposal of disposable single-use patient return electrodes
- further surgery to treat skin burns from disposable single-use patient return electrodes
- litigation because of skin burns from disposable single-use patient return electrodes
- treatment of skin irritation from disposable single-use patient return electrodes
- ordering and storing boxes of disposable single-use patient return electrodes.

No clinical outcomes such as burns avoided (to patients or staff) were included. The External Assessment Centre stated that this was consistent with the absence of submitted clinical evidence on adverse effects; however, data from the NHS Litigation Authority (NHSLA) indicated that site burns are a risk with disposable single-use patient return electrodes, so burns would be a valid end point.

The sponsor's base case analysis made several key assumptions, which are shown in table 1.

The sponsor tested several of these assumptions in deterministic two-way sensitivity analyses in which the following parameters were increased and decreased by 50% (with no probabilities attached for the likelihood of these events occurring):

- number of operations per week
- cost of single-use disposable patient return electrode pads
- cost of an operating table mattress
- life of an operating table mattress
- cost of razors for shaving
- staff time and hourly staff costs.

The External Assessment Centre noted that no justification was given for why these were the most plausible range of values. Furthermore, the sensitivity analysis was not adequate to capture the lower prices observed for single-use disposable patient return electrodes in one NHS trust.

The sensitivity analyses demonstrated that the results of the sponsor's model were sensitive to assumptions for staff time and the cost per hour for surgeons, anaesthetists and nurses.

Costs and benefits

The External Assessment Centre expressed particular concerns about a number of parameters in the sponsor's model such as:

- the non-inclusion of VAT on the price of the Mega Soft Patient Return Electrode
- the type of single-use disposable patient return electrodes that are most commonly used in UK clinical practice and the unit costs for each type
- the use of operating table pressure-relieving mattresses
- the percentage of patients who need shaving
- clinical staff time costs in terms of cost 'per contract hour' rather than 'per operating hour'
- the estimated time delay for site preparation and placing the disposable single-use patient return electrodes on the patient and therefore clinical staff time saved.

The External Assessment Centre carried out additional analyses to examine the impact of changing these parameters. For full details refer to table 2.

The External Assessment Centre noted that the sponsor did not include the VAT in the cost of the Mega Soft Patient Return Electrode. By changing the value from £1900 in the base-case analysis to £2280 (as determined by the External Assessment Centre), the cost saving associated with the Mega Soft Patient Return Electrode compared with a disposable single-use patient return electrode decreased by £0.25 per operation.

The External Assessment Centre noted that the comparator technologies defined in the scope were disposable single-use patient return electrode (non-split pad) and contact quality monitoring disposable single-use patient return electrodes (split pad). However, the External Assessment Centre noted that these technologies can be further classified into four different types of non-split disposable single-use patient return electrode and split disposable single-use patient return electrodes:

- with lead wire
- without lead wire
- paediatric with lead wire
- paediatric without lead wire.

The External Assessment Centre stated that the sponsor's base-case analysis used the assumption that NHS trusts purchase disposable single-use patient return electrode with lead wires, and it did not include a scenario assuming that disposable single-use patient return electrode were purchased without lead wires. The External Assessment Centre sought costs for all disposable single-use patient return electrodes used in the Newcastle-upon-Tyne Hospital (NUTH) Trust and from NHS Supply Chain. In the NUTH Trust, the mean cost of adult disposable single-use patient return electrodes purchased with lead wires in 2010/11 was £1.78 (NHS Supply Chain £1.92); the cost of split disposable single-use patient return electrode without lead wires was £0.54 (NHS Supply Chain £0.76); and the cost of solid wireless disposable single-use patient return electrodes was £0.46 (NHS Supply Chain £0.49). In comparison, the sponsor assumed a cost of £2.44 for split pads and £2.60 for non-split pads. The External Assessment Centre stated that the cost difference between disposable single-use patient return electrodes with and without wires was substantial. By changing the value from £2.44 hour in the base-case analysis to £0.87 (£0.54 + £0.22 and £0.11 to take into account the price of the extra cable needed and the healthcare assistants' time) as determined by the External

Assessment Centre, the cost saving of the Mega Soft Patient Return Electrode compared with a disposable single-use patient return electrode decreased to £69.00 per operation. This is a difference of £1.83.

The External Assessment Centre also noted that for disposable single-use patient return electrode pads with no lead wire, a reusable cable is needed to link the electrosurgery unit to the disposable single-use patient return electrode pads. The External Assessment Centre noted that the cable must be sterilised after each operation. The cable must also be fitted before and removed after each operation, usually by a healthcare assistant. The External Assessment Centre's additional analysis assumed that this would take up to 30 seconds. The cost of the non-lead wire disposable single-use patient return electrode in table 2 includes the cost of the cable needed to attach the disposable single-use patient return electrode to the electrosurgical unit (£0.22) and the cost of a healthcare assistant carrying out this task (£0.11). This increases the cost of each non-lead wire disposable single-use patient return electrode by £0.33. This cannot be compared to a base case because it was not include by the sponsor.

The External Assessment Centre noted that the sponsor's base-case analysis assumed that a theatre mattress was used three times a day for 260 days a year (780 days in total). However, the External Assessment Centre stated that this daily use was too low because the mattress can be used for all surgery. The External Assessment Centre stated that a more appropriate assumption was the three operations per day for 4 days per week, for 50 weeks per year (a total of 600 operations per year). By changing the value from 780 to 600 uses, the cost saving associated with the Mega Soft Patient Return Electrode compared with a disposable single-use patient return electrode decreased to £70.73 per operation. This is a difference of £0.10.

The External Assessment Centre noted that the sponsor's base-case analysis also assumed that that all patients needed shaving before fitting the disposable electrodes. However, the expert advisers believed that shaving is needed in only 10–40% of cases. The External Assessment Centre believed that the higher estimate of 40% was more appropriate, and tested a minimum and maximum of 10% and 70% in sensitivity analyses. The External Assessment Centre noted that this would also affect other costs and resource use, such as staff time saved and the cost of the

razor. By changing the proportion of people shaved from 100 to 40%, the cost saving associated with the Mega Soft Patient Return Electrode compared with a disposable single-use patient return electrode decreased to £70.15 per operation. This is a difference of £0.68.

The External Assessment Centre noted that the sponsor's base-case analysis used 'Unit Costs of Health and Social Care 2010' Personal Social Services Research Unit (PSSRU) data to cost each hour of staff time, but that these costs have been updated for 2011. The sponsor costed the surgeon's time 'per operating hour', which was £347 based on the 2010 PSSRU figures. The External Assessment Centre believed that a cost of £136 'per contract hour', which did not include costs of qualifications, should be used as reported in the 2011 PSSRU. The External Assessment Centre stated that allocating the costs of employing a surgeon to operating time would suggest that there is no benefit from other work undertaken by the surgeon such as appointments with patients before and after surgery. The External Assessment Centre also carried out a sensitivity analysis assuming an hourly rate of £403 'per operating hour' in theatre for a surgeon, which also covers the costs of qualifications as reported in the 2011 PSSRU. The External Assessment Centre noted that the same principle applied for all other staff included, such as one consultant anaesthetist, one nurse anaesthetist (same price as a nurse) and two operating theatre nurses. All three scenarios were included in the External Assessment Centre's sensitivity analysis for a surgeon and the base case and the External Assessment Centre's estimates were included for nursing staff.

By changing the value for a surgeon from £347 per hour in the base-case analysis to £136 as determined by the External Assessment Centre, the cost saving associated with the Mega Soft Patient Return Electrode compared with a disposable single-use patient return electrode decreased to £35.66 per operation. This is a difference of £35.17. By changing the value to £403, as determined by NICE, the cost saving associated with the Mega Soft Patient Return Electrode compared with a disposable single-use patient return electrode increased to £80.16 per operation. This is a difference of £9.33.

By changing the value for a nurse from £41 in the base-case analysis to £34 as determined by the External Assessment Centre, the cost saving associated with the

Mega Soft Patient Return Electrode compared with a disposable single-use patient return electrode decreased to £69.08 per operation. This is a difference of £1.75.

The External Assessment Centre stated that the sponsor's base-case analysis assumed that there would be a 5-minute delay for all theatre staff per operation caused by using disposable single-use patient return electrode pads. The expert advisers could not determine an exact alternative delay assumption but stated that generally if staff follow a standard operating procedure delays do not occur, only if procedures are not followed or plans change does a delay occur. The External Assessment Centre therefore examined a range of 0–4 minutes in a sensitivity analysis. By changing the value from 5 minutes to 0 minutes, the cost savings associated with the Mega Soft Patient Return Electrode compared with a disposable single-use patient return electrode decreased to £2.74 per operation. This is a difference of £68.09.

Results

The sponsor's base-case analysis estimated the cost per operation using the Mega Soft Patient Return Electrode compared with a disposable single-use patient return electrode with a lead wire. The results showed savings of £70.83 per operation for adults and £70.31 for children when using the adult or the paediatric Mega Soft Patient Return Electrode respectively. More than 95% of the savings were from improving the efficiency of procedures by 5 minutes per operation and more than 80% of the savings were from surgeon and anaesthetist time saved. In all cases using the Mega Soft Patient Return Electrode was estimated to be cost saving by between £1.05 and £1.34. There were greater savings when comparing the device with split pads because of the higher cost. The largest contribution to the cost saving was from surgeon and anaesthetist time saved (£57.84); with nurse time saved resulting in a further £10.25 per operation.

The sponsor demonstrated that the model results were most sensitive to the assumed time savings and the assumed cost per hour for surgeons, anaesthetists and nurses. Halving the time saving from 5 minutes to 2.5 minutes gave a cost saving of £36.65 per operation, and halving the cost of surgeon and anaesthetist time resulted in a cost saving of £41.78 per operation.

As outlined above, the External Assessment Centre expressed particular concerns about a number of parameters in the sponsor's model. The External Assessment Centre carried out additional work to examine the impact of the parameter changes described above using alternative assumptions. These results are presented in tables 2 and 3 for adult and paediatric Mega Soft Patient Return Electrodes respectively.

Table 2 Comparison of parameter values adopted by sponsor and External Assessment Centre and impact on estimated savings per operation: adult Mega Soft Patient Return Electrode

Sponsor's base case (adult Mega Soft Patient Return Electrode) saving = £70.83					
	Parameter	**Sponsor estimate of saving per operation**	**EAC estimate of saving per operation**	**EAC calculated saving per operation and difference compared with sponsor base case**	**Source and rationale (for EAC estimate)**
1	Cost of Mega Soft Patient Return Electrode	£1900	£2280	£70.58 Difference £0.25	VAT at 20% added
2a	Split adult disposable single-use patient return electrode with lead wire	£2.44	£1.78	£69.91 Difference £0.92	Prices from Newcastle upon Tyne hospital (NUTH)
2b	Solid adult disposable single-use patient return electrode with lead wire	£2.60	£1.98	£70.11 Difference £0.72	NHS Supply Chain price
2c	Split adult disposable single-use patient return electrode no lead wire	not applicable – not supplied by the sponsor	£0.54 + £0.22 + £0.11	£69.00 Difference £1.83	Prices from NUTH + reusable lead + staff to fit
2d	Solid adult disposable single-use patient return electrode no lead wire	not applicable – not supplied by the sponsor	£0.46 + £0.22 + £0.11	£68.92 Difference £1.91	Prices from NUTH + reusable lead + staff to fit
2e	Split adult disposable single-use patient return electrode with lead wire	£2.44	£1.92	£70.05 Difference £0.78	Prices from NHS Supply Chain

Sponsor's base case (adult Mega Soft Patient Return Electrode) saving = £70.83					
	Parameter	**Sponsor estimate of saving per operation**	**EAC estimate of saving per operation**	**EAC calculated saving per operation and difference compared with sponsor base case**	**Source and rationale (for EAC estimate)**
2f	Solid adult disposable single-use patient return electrode with lead wire	£2.60	£1.98	£70.11 Difference £0.72	Prices from NHS Supply Chain
2g	Split adult disposable single-use patient return electrode no lead wire	not applicable – not supplied by the sponsor	£0.76 + £0.22 + £0.11	£69.22 Difference £1.61	Prices from NHS Supply Chain + reusable lead + staff to fit
2h	Solid adult disposable single-use patient return electrode no lead wire	not applicable – not supplied by the sponsor	£0.49 + £0.22+ £0.11	£68.95 Difference £1.88	Prices from NHS Supply Chain + +reusable lead + staff to fit
3	Usage of Mega Soft Patient Return Electrode	3 x 5 x 52 = 780	3 x 4 x 50 = 600	£70.56 Difference £0.27	NICE experts informed assumption
4	Usage of mattress	3 x 5 x 52 = 780	5 x 4 x 50 = 1000	£70.73 Difference (£0.10)	NICE experts informed assumption
5	Razors	Mean cost £1.13	Cost £2.09	£71.79 Difference (£0.96)	No disposable razors
6a	% shaved	100%	40%	£70.15 Difference £0.68	NICE experts
6b	% shaved	100%	10%	£69.82 Difference £1.01	Assumption
6c	% shaved	100%	70%	£70.49 Difference £0.34	Assumption
7a	Surgeon and anaesthetist	£347 per hour	£136 per hour	£35.66 Difference £35.17	Used cost per contract hour
7b	Surgeon and anaesthetist	£347 per hour	£403 per hour	£80.16 Difference (£9.33)	Cost per hour of surgery including qualifications

Sponsor's base case (adult Mega Soft Patient Return Electrode) saving = £70.83					
	Parameter	**Sponsor estimate of saving per operation**	**EAC estimate of saving per operation**	**EAC calculated saving per operation and difference compared with sponsor base case**	**Source and rationale (for EAC estimate)**
8	Nurse	£41 per hour	£34 per hour	£69.08 Difference £1.75	Used cost per contract hour
9a	Delay for site preparation for disposable single use patient return electrode	5 minutes	4 minutes	£57.21 Difference £13.62	NICE experts
9b	Delay for site preparation for disposable single use patient return electrode	5 minutes	0 minutes	£2.74 Difference £68.09	NICE experts

Table 3 Comparison of parameter values adopted by sponsor and External Assessment Centre and impact on estimated savings per operation: paediatric Mega Soft Patient Return Electrode

Sponsor base case paediatric Mega Soft Patient Return Electrode saving = £70.30					
Parameter		**Sponsor estimate of saving per operation**	**EAC estimate of saving per operation**	**EAC calculated saving per operation and difference compared with sponsor base case**	**Source and rationale (for EAC estimate)**
10 a	Split paediatric disposable single-use patient return electrode with lead wire	£1.92	£2.14	£70.52 Difference (£0.22)	Prices from NHS Supply
10 b	Split paediatric disposable single-use patient return electrode with no lead wire	£1.92	£0.68+ £0.22 +£0.11	£69.39 Difference £0.91	Prices from NHS Supply + reusable lead + staff to fit

The External Assessment Centre provided two scenarios, for the adult and paediatric disposable single-use patient return electrodes, that included their preferred

assumptions. The External Assessment Centre's analyses demonstrated a cost saving of £0.19 per operation when using an adult Mega Soft Patient Return Electrode compared with a single-use patient return electrode when the following assumptions were applied:

- inclusion of VAT on the price of the Mega Soft Patient Return Electrode
- the comparator electrodes is a split adult disposable single-use patient return electrode with no lead wire
- the use of the Mega Soft Patient Return Electrode three times per day, 4 days per week for 50 weeks per year
- a razor cost of £2.09
- the need for 40% of patients to be shaved
- staff costs of £136 per hour for a surgeon and an anaesthetist, and £34 per for a nurse
- no theatre wide delay for site preparation when using a disposable single-use patient return electrode.

When applying the same assumptions but comparing the paediatric Mega Soft Patient Return Electrode with the split paediatric disposable single-use patient return electrode with no lead wire, the External Assessment Centre's additional analyses demonstrated a cost saving of £0.33 per operation.

These scenarios are shown in table 4

Table 4 Plausible scenarios for adult and child Mega Soft Patient Return Electrode

Plausible scenarios	Parameter prices/value of staff time	External Assessment Centre 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 £2280 disposable single-use patient return electrode £0.54 + £0.22+ £0.11 Razors £2.09 Surgeon and anaesthetist £136 per hour Nurse £34 per hour Time saved = 0	£0.19 Difference £70.64

Sponsor base case for child plus 1, 3, 4, 5, 6a, 7a, 8, 9, 10a £70.30	Mega Soft Patient £2,280 disposable single-use patient return electrode £0.68 + £0.22 + £0.11 Razors £2.09 Surgeon and anaesthetist £136 per hour Nurse £34 per hour Time saved = 0	£0.33 Difference £70.50

The External Assessment Centre stated that the savings increase for paediatric Mega Soft Patient Return Electrodes is because the cost of the comparator, the paediatric disposable single-use patient return electrode, is slightly higher (£0.68 compared with £0.54).

The results suggest that in settings where the work plan has been optimised so that there are no delays in theatre while staff apply disposable single-use patient return electrodes; the cost of the electrodes per operation for an adult patient is £2.16. The annual cost of using the Mega Soft Patient Return Electrode per adult operation is estimated at £1.97 (cost of £2280 and assuming 600 operations a year for 2 years). This is a £0.19 saving.

The External Assessment Centre stated that if the potential savings from claims avoided by using the Mega Soft Patient Return Electrode were considered, which are approximately £0.70 per procedure, then accepting the Mega Soft Patient Return Electrode for use in the NHS would be cost saving for each monopolar electrosurgery procedure.

5 Ongoing research

The manufacturer and the External Assessment Centre are not aware of any ongoing research on the Mega Soft Patient Return Electrode.

6 Authors

Jo Burnett, Technical Analyst
Fay McCracken, Technical Adviser

NICE Medical Technologies Evaluation Programme

February 2012

Appendix A: Sources of evidence considered in the preparation of the overview

A Details of assessment reports:

Technical Testing Assessment report – Cedar EAC

- Dale M, McCarthy JP. EP141 Technical Testing of Mega Soft Patient Return electrode, January 2012.

Clinical and Economic Assessment report – NUTH and YHEC EAC

- Craig J, YHEC. Reay C, NUTH. Willits I, NUTH. et al. External Assessment report for Mega Soft Patient Return Electrode for use during Monopolar Electrosurgery, January 2012.

B Submissions from the following sponsor:

- Advance Surgical (Sponsor/UK Distributor) and Megadyne (USA Manufacturer)

C Related NICE guidance

- Suction diathermy adenoidectomy. NICE interventional procedure guidance 328 (2009). Available from www.nice.org.uk/guidance/IPG328
- Electrosurgery (diathermy and coblation) for tonsillectomy. NICE interventional procedure guidance 150 (2005). Available from www.nice.org.uk/guidance/IPG150

D References

Association for Perioperative Practice (2007). Standards and Recommendations for Safe Perioperative Practice. Yorkshire

Audit Commission (2002) Operating theatres: A bulletin for health bodies [online]. Available from www.audit-commission.gov.uk/nationalstudies/health/other/Pages/operatingtheatres.aspx

Brill A, Electrosurgery: principles and practice. APGO Educational Series on Women's Health Issues [online]. Available from www.apgo.org/electrosurgery/monograph.html

Busse R, Ovain J, Velasco M et al. (2002) Best Practice in Undertaking and Reporting Health Technology Assessments. International Journal of Technology Assessment in Health Care 18: 2

Demir E, O'Dey DM, Pallua N (2006) Accidental burns during surgery. Journal of Burn Care and Research 27: 895–900

Department of Health (2011) 2010/11 reference costs [online]. Available from www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_131140

Emergency Care Research Institute (2000) MegaDyne Mega 2000 Return Electrode. Health Devices 29: 445–60

Huang WS, Chen SG, Chen SL et al. (2001). Prevention of accidental burns in the use of diathermy. Asian Journal of Surgery 24: 16-20

International Electrotechnical Commission (1988) IEC 60601-1:1988 (second edition): Medical electrical equipment – part 1: general requirements for basic safety and essential performance

International Electrotechnical Commission (2005). IEC 60601-1:2005 (third edition): Medical electrical equipment – part 1: general requirements for basic safety and essential performance

International Electrotechnical Commission (2006). IEC 60601-2-2:2006 (fourth edition) Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories

International Electrotechnical Commission (2009). IEC 60601-2-2:2009 (fifth edition) Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories.

International Federation of Perioperative Nurses. The IFPN guideline for electrosurgery safety [online]. Available from www.ifpn.org.uk/guidelines/1008_Electrosurgical_Units.phtml

Information Services Division (2011) Theatre costs 2011. Costs R140 Theatre services [onine]. Available from www.isdscotland.org/Health-Topics/Finance/Costs/File-Listings-2011.asp

Lucas NJ, Das M, Hanafiah Z (2009) An audit of burns sustained in the operating theatre. In: Proceedings of European Burns Association Congress, 2–5 September 2009, Lausanne Switzerland.35: S37.

Manufacturer and User Facility Device Experience (MAUDE) [online]. Available fromwww.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm

Medicines and Healthcare Regulatory Agency, Electrosurgery e-learning module. [online]. Available from www.mhra.gov.uk/ConferencesLearningCentre/LearningCentre/Deviceslearningmodules/Electrosurgery/index.htm. [accessed December 2011]

Megadyne(a) (2011) Mega Soft Patient Return Electrode Evaluation reports (Excel worksheets) from three London hospital sites.

Megadyne (2011) How is Megadyne Mega Soft Patient Return Electrode safer than contact quality monitoring return electrodes? [online]. Available from www.megadyne.com/

Megadyne (2011) The Mega Soft Patient Return Electrode – providing the best outcome for the patient at Christus St. Joseph's. [online]. Available from www.megadyne.com/case_study2.php

Megadyne (20110 The Mega Soft Patient Return Electrode – standard operating procedure for comfort and cost savings at Kaleida Health. [online]. Available from www.megadyne.com/case_study1.php

MHRA, Electrosurgery equipment safety poster. July 1999 [online]. Available from www.mhra.gov.uk/

MHRA. Electrosurgery e-learning module [online]. Available from www.mhra.gov.uk/

MHRA (2000) Safety notice 17 [online]. Available from www.mhra.gov.uk/

MHRA (2000) One liners issue 7 [online]. Available from www.mhra.gov.uk/

National Association of Theatre Nurses (2004) Electrosurgery: managing the risk Yorkshire: AfPP

Ogier, Rugman, Spicer (2004) The real cost of capital. Financial Times and Prentice

Hall Pearce J. (1986) Electrosurgery. Chapman and Hall Medical, London

Personal Social Services Research Unit University of Kent (2011) Unit Costs of Health and Social Care 2010 and 2011 [online]. Available from www.pssru.ac.uk/pdf/uc/uc2011/uc-order-form-2011.pdf

Rey JF, Beilenhoff U, Neumann CS et al. (2010) European Society of Gastrointestinal Endoscopy: the use of electrosurgical units. Endoscopy 42: 764–72. Available from http://dx.doi.org/10.1055/s-0030-1255594

Sheridan RL, Wilson NC, O'Connell MF et al. (2003) Noncontact electrosurgical grounding is useful in burn surgery. Journal of Burn Care and Rehabilitation 24: 400–1

Covidien, Valleylab (2011) Monopolar Electrosurgery [online]. Available from www.valleylab.com/education/poes/poes_06.html

Appendix B: Comments from professional bodies

Expert advice was sought from experts who have been nominated or ratified by their Specialist Society, Royal College or Professional Body. The advice received is their individual opinion and does not represent the view of the society.

Dr Ian Armstrong Consultant Anaesthetist, British Association of Day Surgery

Dr Liam Horgan Consultant Surgeon, British Association of Day Surgery

Josef Crutchley Acting resource and equipment manager, HPC

Maureen Theakston Deputy Cardiothoracic Theatre manager, NMC

Jilly Hale Head of Nursing Theatres, Association for Perioperative Practice

Kim Wall Senior Sister, ENT, College of Operating Department Practitioners

- Six expert advisors have used the Mega Soft Patient Return Electrode.
- Three expert advisors considered the technology to be a significant modification of of an existing technology with real potential for different outcomes and impact. Two experts considered the technology to be thoroughly novel and different in concept and/or design to any existing technology.
- All six expert advisors considered operating theatre environments which require the use of monopolar diathermy to be the most appropriate use for this technology. One expert advisor also believes that this technology has a higher patient safety ratio so is safer for all clinical scenarios that require a return electrode.
- Three experts considered the likely additional benefits to patients include reduction in patient diathermy burns. Three experts stated the benefits included the reduction in the associated risk of skin damage when using adhesive alternatives. Two experts state the benefits include not having to shave patients. One expert stated that it was reusable and quicker to use if it can be left on the operating table between uses.
- The expert advisers considered likely additional benefits for the healthcare system to include patient safety due to the absence of diathermy burns and adhesive skin irritation, cost savings due to better care for patients and the reusability of the technology and environmental impact savings due to less disposable waste.

- Four experts stated that particular infrastructure was not required to use this technology. One believed that it would need to be compatible with existing equipment and one expert advisor stated that good after sales service and regular teaching and education would be required.
- Three experts believed training was required to use this technology. One expert advisor considered that staff would have to be aware of the need for adequate skin contact particularly in patient positions other than supine and when repositioning the patient or where limbs are not in contact with the operating table.

Appendix C: Comments from patient organisations

The following patient organisations were contacted and no response was received.

- CritPaL – Patient Liaison Committee of the Intensive Care Society
- ICU Steps
- Royal College of Anaesthetists Patient Liaison Group
- Royal College of Surgeons Patient Liaison Group
- The Patients Association

Appendix D: Additional submission information

Technical testing assessment report additional information – Cedar EAC

National Institute for Health and Clinical Excellence

Additional Submission Information

EP141 Technical Testing of Mega Soft Patient Return electrode

The purpose of this table is to show where the External Assessment Centre relied in their assessment of the topic on information or evidence not included in the original manufacturer submission. This is normally where the External Assessment Centre:

a) become aware of additional relevant evidence not submitted by the manufacturer
b) need to check "real world" assumptions with NICE's Expert Advisers, or
c) need to ask the manufacturer for additional information or data not included in the original submission

These events are recorded in the table to ensure that all information relevant to the assessment of the topic is made available to MTAC. The table is presented to MTAC in the Assessment Report Summary, and is made available at public consultation.

Table 5 Additional information – Cedar EAC

Submission Document Section/ Sub-section number	**Question / Request to Manufacturer or Expert Adviser** *Please indicate whether Manufacturer or Expert Adviser was contacted. If an Expert Adviser, only include significant correspondence and include clinical area of expertise.*	**Response** *Attach additional documents provided in response as Appendices and reference in relevant cells below.*	**Action / Impact / Other comments**
Section 2.2	Telephone conversation to discuss the question: 1. Clarification is required as to whether the product can be used with all other equipment in the operating theatre environment. Particularly with the emphaisis on electromagnetic	**Technical experts 1 &2 (summary of phone conversation):** The current density is high at the active tip, but low at the return electrode. The main problems in terms of emc will be at the tip rather than the plate. If the area of contact with Mega Soft is small, then the current will reduce, but the voltage on the patient will be high. This could mean the patient body acts as an antennae. Measurements could be made to investigate	Summary of the telephone conversation was used for part of the report text**.**

Submission Document Section/ Sub-section number	Question / Request to Manufacturer or Expert Adviser *Please indicate whether Manufacturer or Expert Adviser was contacted. If an Expert Adviser, only include significant correspondence and include clinical area of expertise.*	Response *Attach additional documents provided in response as Appendices and reference in relevant cells below.*	Action / Impact / Other comments
	compatibility. Experts were also asked if there were any other issues that they felt may occur.	this, using a patient or substitute. High electromagnetic fields are often present during electrosurgery (in general), however patient monitoring systems tend to cope well with this most of the time. If there are no reported issues, and it has been in use for some time, it is unlikely that there will be any greater emc issues with a large capacitive electrode than a standard return electrode. There is one type of ESU that monitors high frequency voltage on the patient body to warn against potential alternate site burns. A capacitive plate system would not trigger the alarm. One expert has not had to investigate an electrosurgery burn in their trust for about 20 years, and not in any other trust for about 15 years.	
Section 2.2, **Section 5.1.1**	An important factor for this device is the occurrence of adverse events. Both Cedar and York have looked at MHRA and Maude listings, and York have obtained a breakdown from the MHRA of the number of electrosurgery incidents annually between 2000 and 2010, showing the number related to burns, and to return electrode burns. It would be very useful to know if • the return electrode burns include alternate site burns • what number of these	**MHRA information:** • The return electrode burns did not include alternate site burns; • We do not know the numbers of split or non-split pads; • None of these incidents involved Mega Soft.	This information was incorporated into the report text.

Submission Document Section/ Sub-section number	Question / Request to Manufacturer or Expert Adviser *Please indicate whether Manufacturer or Expert Adviser was contacted. If an Expert Adviser, only include significant correspondence and include clinical area of expertise.*	Response *Attach additional documents provided in response as Appendices and reference in relevant cells below.*	Action / Impact / Other comments
	were using split or non-split pads • were any of these incidents involving Mega Soft		
General informatioin	• Do you use of alcohol in preparation for surgery? • What is placed between the patient and Mega Soft in normal practice, and if it varies, could you please give more details?	**Clinical Expert 1 (summary of phone conversation)::** Mega Soft has been used in all the theatres for the past 5-6 years, and there have been no problems with its use. When ablation (high power) procedures are carried out the Mega Soft is not used, and multiple return electrodes are used. **Relating to the use of alcohol based fluid for patient preparation:** Alcohol is used during patient preparation, and care is taken to avoid pooling. There would be no difference with any other mattress used that would have some pressure relief. **Material placed between Mega Soft and patient:** Sometimes draw sheets are used, so there may be 2 or 3 layers of cotton between the Mega Soft and the patient. It has never been an issue. Have seen in some other hospitals Mega Soft used with slide sheets containing Nylon. Where underbody warmers are used they are placed under the patient, and over the sheet and the Mega Soft. The warmer is compressed where the patient is lying on it, and so there is not a large air gap between the patient and the Mega Soft.	General information, no action required
General Information	• Do you use of alcohol in preparation for	**Clinical Expert 2 (summary of phone conversation):** **Relating to the use of**	General information, no action

Submission Document Section/ Sub-section number	Question / Request to Manufacturer or Expert Adviser *Please indicate whether Manufacturer or Expert Adviser was contacted. If an Expert Adviser, only include significant correspondence and include clinical area of expertise.*	Response *Attach additional documents provided in response as Appendices and reference in relevant cells below.*	Action / Impact / Other comments
	surgery? • What is placed between the patient and Mega Soft in normal practice, and if it varies, could you please give more details?	**alcohol based fluid for patient preparation:** The fluid is dried before surgery. Pooling of alcohol should not be a problem, and would be similar for any other mattress used now, since all will have some pressure relief. They have not experienced any problems relating to the use of alcohol. **Material placed between Mega Soft and patient:** There is always a sheet between the Mega Soft and the patient. Quite often an underbody patient warmer will be used, and this is placed directly under the patient, above the sheet and Mega Soft. Incontinence pads, if used, are also placed directly under the patient, and above the sheet and Mega Soft. No problems have been experienced using any of these combinations. They have not experienced any difficulties in using Mega Soft.	required.
Section 4.3	Was the temperature reading taken from the side of the pork belly that was in contact with the pad?	The electrosurgery was always performed on one side and the temperature readings were always taken on the side were the pork belly was in direct contact with the pad.	Information used in critiquing CHUS report, no action required.
	• Do you use paediatric and adult Mega Soft pads?, If so how often and for how long (approximately)? • Are the power settings that you use for paediatric	**Clinical Expert 3:** Yes, we use both, and surgery lasts all day if necessary. The power settings for paediatric surgery are usually less (10 - 15) but we do have the occasional adult sized 16 year old so the settings would be a for an adult.	General information, no action required.

Submission Document Section/ Sub-section number	Question / Request to Manufacturer or Expert Adviser *Please indicate whether Manufacturer or Expert Adviser was contacted. If an Expert Adviser, only include significant correspondence and include clinical area of expertise.*	Response *Attach additional documents provided in response as Appendices and reference in relevant cells below.*	Action / Impact / Other comments
	electrosurgery similar to adult electrosurgery? If not, how do they differ?	We have 10 paediatric pads for 10 theatres - although the adult size does the majority of our patients. I cannot remember off the top of my head what the weight limits are but the adult one starts at a fairly low weight. We have had them for nearly 2 years.	
Section 4.1	Could you let me know how many of the Mega Soft pads in use in the UK and in the USA are adult Mega Softs, and how many paediatric?	**Advance Surgical:** Of the 170 Mega Softs in use in GB hospitals 30 are paediatric. The paediatric pads have been in use since October 2009. **Megadyne:** You also asked for the number of pads placed and in use in the U.S. market. On average, we have about 3500 pads in use in the U.S. and about 5500 in use globally. This includes only our Mega Soft line, not our original Mega 2000.	This information was incorporated into the report text.
Section 2	Please could you estimate the number of Mega Soft pads in use in the UK and in the USA?	**Advance Surgical:** We currently have 170 Mega Softs in use in GB hospitals. **Megadyne:** I would quickly estimate that there are 500 pediatric pads in service.	This information was incorporated into the report text.
Section 4.5.1	Please could you clarify the plate sizes used in the capacitive testing reports?	a - Test report 1150130-02 was completed first, it was done for the Pediatric Mega Soft pad, and the 80% rule was used to come up with the test plate size of 198 in^2. The conductive mesh for the Pediatric Mega Soft is ~ 235 in^2 and 80% is 188 in^2. For us, the easiest way to do this was to use an existing test plate and hang some of it over the edge, thus the 198 in^2 size used (see section 5.2). b - Test report 1150130-03	This information was used in comparing test results and incorporated into the report text.

Submission Document Section/ Sub-section number	Question / Request to Manufacturer or Expert Adviser *Please indicate whether Manufacturer or Expert Adviser was contacted. If an Expert Adviser, only include significant correspondence and include clinical area of expertise.*	Response *Attach additional documents provided in response as Appendices and reference in relevant cells below.*	Action / Impact / Other comments
		was done for the Adult Mega Soft, and Section 3 was just copied over from 1150130-02 and updating the test plate size was missed. That testing was actually done using a 600 in^2 test plate that is ~80% of the conductive mesh of the Adult pad (Adult area = 780 in^2, 80% = 624 in^2). This test report will be corrected, sorry for the confusion during our call,	
Section 5.4	Please could you advise relating to compatibility between Megasoft patient return electrodes and other brand generators.	**MHRA expert 2 (summary of phone conversation)::** Provided companies such as Megadyne are able to provide documentation to confirm compatibility with specified goods including generators (ideally indicating relevant model numbers), users are free to utilise appropriate products from any manufacturer. Documentation or certificates of conformity held by a user indicate that they have carried out due diligence, and means that the company which has verified compatibility would be the liable party in the instance of any malfunction provided that all user instructions have been correctly followed. MHRA advise ensure medical devices that you purchase are CE marked and have appropriate documentation to demonstrate compliance with the essential requirements of the Medical Device Directive 93/42/EEC in this instance demonstrating compatibility to the original equipment device being used.	This summary was incorporated into the report text.
Section 5.4	Please could you advise relating to compatibility	**NHS Supply chain, (summary of phone**	The information

Submission Document Section/ Sub-section number	Question / Request to Manufacturer or Expert Adviser *Please indicate whether Manufacturer or Expert Adviser was contacted. If an Expert Adviser, only include significant correspondence and include clinical area of expertise.*	Response *Attach additional documents provided in response as Appendices and reference in relevant cells below.*	Action / Impact / Other comments
	between Megasoft patient return electrodes and other brand generators.	**conversation):** It is the responsibility of the end user to obtain written confirmation of compatibility between items such as generators and related consumables. This ensures that the correct make and model numbers are always being checked to prevent incompatible products being used together due to changes in product specification etc. Confirmation may be obtained by requesting documentation directly from a supplier when purchasing goods.	was included in the report, but was requested that it not be as a statement of the NHS supply chain's position.
Section 4.5	Two telephone meetings with Megadyne and Advance Surgical to discuss what evidence they could provide in order to answer the questions posed by MTAC.	The evidence was provided by Megadyne and Advance Surgical and is included in the technical report. Some background information was also given.	The evidence was discussed and critiqued in the report
Section 5.1.1	MTAC Q1. The manufacturer states that the Mega Soft Patient Return Electrode is a self-contained current limiting device making it safe to use if the patient is in contact with only a small portion of the pad. Clarification is required regarding the minimal contact area between the patient and the pad before safety is compromised. EAC comment: this should address the risk of alternate site burns as well as return pad burns, as a smaller area of patient contact would increase the impedance.	EAC's concern of being able to produce a test condition that would not meet the 4 nF value specified in IEC 60601-2-2 5th Edition section 201.15.101.6 was also discussed during our phone conference in connection to the above items. As you know, the test Standards for Neutral Electrodes (NE) have evolved around the single use disposable sticky NE pad and Clause 59.104.6 of IEC60601-2-2, 4th Edition makes allowances for the "old" style capacitive NE that looked and functioned much like a standard single use disposable sticky NE pad. The Megadyne family of Mega Soft reusable NE pads (0800, 0830 & 0840) have a very different construction and function	Background information for report. No action

Submission Document Section/ Sub-section number	Question / Request to Manufacturer or Expert Adviser *Please indicate whether Manufacturer or Expert Adviser was contacted. If an Expert Adviser, only include significant correspondence and include clinical area of expertise.*	Response *Attach additional documents provided in response as Appendices and reference in relevant cells below.*	Action / Impact / Other comments
		differently from the "old" style capacitive NE. The “old” style of capacitive NE do not function based on the contact area of the patient (as the Mega Soft does) and standard testing to make sure they are designed to meet the 4 nF value will ensure that the “old” style of capacitive NE will always have that level of impedance when used. The “old” style of capacitive NE also do NOT have the built-in current limiting safety feature that the Mega Soft has, therefore the test conditions (size of plate) and results (less than 4 nF) of Clause 59.104.6 do not directly apply to the Megadyne family of Mega Soft reusable NE pads. In the 5th Edition of 60601-2-2 the requirement of a specific plate size was removed (ref. section 201.15.101.6). This allows us to apply a plate of any size on the Mega Soft to test for the 4 nF. The Mega Soft will pass this test as shown in test report # 1150130-02 and 1150130-03. However, this still represents only one set-up condition for the Mega Soft NE. We do, however, believe that the Megadyne family of Mega Soft reusable NE pads is safe and in complete compliance with the intent of Clause 59.104.6 of the 4th Edition (and 201.15.101.6 of the 5th Edition), that is, "..... to prevent a risk of PATIENT burn due to ohmic heating during passage of HF surgical current." The advanced technology that is built into the Megadyne family of Mega Soft reusable NE	

Submission Document Section/ Sub-section number	Question / Request to Manufacturer or Expert Adviser *Please indicate whether Manufacturer or Expert Adviser was contacted. If an Expert Adviser, only include significant correspondence and include clinical area of expertise.*	Response *Attach additional documents provided in response as Appendices and reference in relevant cells below.*	Action / Impact / Other comments
		pads prevents any risk of patient burns due to ohmic heating during the passage of HF current as demonstrated by the testing we have done per Clause 59.104.5 of IEC60601-2-2, 4th Edition, “An NE shall not subject a PATIENT to a risk of thermal injury at the NE application site under conditions of NORMAL USE and when applied in accordance with the instructions for use.” Reference the following Megadyne test reports for evidence of such testing: 1150331-01 and 1150379-01. IEC60601-1, 2nd Edition Clause 3.4 states, "EQUIPMENT or parts thereof, using materials or having forms of construction different from those detailed in this Standard, shall be accepted if it can be demonstrated that an equivalent degree of safety is obtained." Megadyne has done the Risk Analysis and we believe that we have "demonstrated that an equivalent degree of safety (if not higher degree of safety) is obtained" when you consider the history of over 35 Million procedures performed over the past 10 years with zero pad-site burns combined with the extensive testing that has been done on the Megadyne family of Mega Soft reusable NE pads. Your concerns about alternate site burns when the Mega Soft is used contra the Instructions for Use are valid, but these concerns are NOT unique to the Mega Soft return pad and are also present with the	

Submission Document Section/ Sub-section number	Question / Request to Manufacturer or Expert Adviser *Please indicate whether Manufacturer or Expert Adviser was contacted. If an Expert Adviser, only include significant correspondence and include clinical area of expertise.*	Response *Attach additional documents provided in response as Appendices and reference in relevant cells below.*	Action / Impact / Other comments
		traditional disposable sticky pads.	
Section 5.1.3	MTAC Q2: Concern was raised about whether the spillage of alcohol based products onto the pad would collect in pools and lead to a higher risk of burns. EAC comment: There are two aspects to address: Sparking due to alcohol products (note that AfPP does not recommend that alcohol is not used in prep for electrosurgery, but that it is thoroughly dry before surgery commences) The dielectric properties of any liquid in contact with the patient and mattress, and what effect this may have on the electrical system and subsequent safety implications.	Using the advanced technology that is built into the Megadyne family of Mega Soft reusable NE pads prevents any sparking between the patient and the pad. Unlike the condition that can exist between the patient and a poorly placed disposable sticky return pad. Testing was done by CHUS where pools of conductive liquids were left on the Mega Soft. They found no issues, see test report from CHUS. Also see Megadyne test report # 1150066-02.	Background information for report. No action
Section 5.1.2	MTAC Q3: Clarification is required as to whether the product can be used with all other equipment in the operating theatre environment. EAC comment: again two aspects: • Electromagnetic compatibility ie interference with other devices • The risk of alternate site burns eg ECG electrodes	See technical documentation from Megadyne. Monitor Interference TB	Supplied evidence was critiqued in report.
Section 5.3	MTAC Q4: Clarification is required about safety implications if the outer skin of the Mega Soft pad is punctured. EAC comment: We are aware of the testing on the Mega 2000 by ECRI, has	See test report # 1150066-02.	Supplied evidence was critiqued in report.

Submission Document Section/ Sub-section number	Question / Request to Manufacturer or Expert Adviser *Please indicate whether Manufacturer or Expert Adviser was contacted. If an Expert Adviser, only include significant correspondence and include clinical area of expertise.*	Response *Attach additional documents provided in response as Appendices and reference in relevant cells below.*	Action / Impact / Other comments
	any similar test been carried out on the Mega Soft?		
Section 5.1.2	MTAC Q5: Clarification is required about the thickness of intervening material between the Mega Soft and the patient before conduction is compromised. EAC comment: We are aware that this will vary for different patients and positions, however are there any bench tests that indicate the effect that different materials have?	Megadyne recommends that our Instructions for Use be followed for best results. How many layers of any given type of the many available materials that might cause a reduction in surgical effect is a very complicated scenario. It depends on the type of ESU, power settings, surgical site impedance, patient body size and type, contact area with the pad and separation distance between the patient and pad. To try and isolate just one of these variables and set conditions on it is NOT clinically relevant. When the Mega Soft is used as instructed most surgeons notice no difference.	Background information for report. No action
Section 5.4	MTAC Q6: The sticky pad patient return electrodes, which are to be used as comparators, are resistive coupling electrodes while the Mega Soft Patient Return Electrode is a capacitive coupling electrode. Clarification is required about whether Mega Soft can be used with all electrosurgical units since these are likely to have been tested for use with resistive coupling electrodes rather than capacitive coupling electrodes. EAC comment: We realise that Mega Soft is in practice used with other ESUs both in the UK and USA, however do you have any test evidence looking at Mega Soft with	See Megadyne ESU compatibility list for the Mega Soft family. Generator Compatibility Chart. If an ESU is not on this list a request can be made to Megadyne to research and determine compatibility based on testing or technical review. Also see testing done by UL.	This information was included in the report.

Submission Document Section/ Sub-section number	Question / Request to Manufacturer or Expert Adviser *Please indicate whether Manufacturer or Expert Adviser was contacted. If an Expert Adviser, only include significant correspondence and include clinical area of expertise.*	Response *Attach additional documents provided in response as Appendices and reference in relevant cells below.*	Action / Impact / Other comments
	electrosurgical units from other manufacturers?		

Clinical and Economic Assessment report – NUTH and YHEC EAC

National Institute for Health and Clinical Excellence

Additional Submission Information

Mega Soft Patient Return Electrode for use during Monopolar Electrosurgery

The purpose of this table is to show where the External Assessment Centre relied in their assessment of the topic on information or evidence not included in the original manufacturer submission. This is normally where the External Assessment Centre:

d) become aware of additional relevant evidence not submitted by the manufacturer
e) need to check "real world" assumptions with NICE's Expert Advisers, or
f) need to ask the manufacturer for additional information or data not included in the original submission

These events are recorded in the table to ensure that all information relevant to the assessment of the topic is made available to MTAC. The table is presented to MTAC in the Assessment Report Overview, and is made available at public consultation.

Table 6 Additional information – NUTH and YHEC EAC

Submission Document Section/Sub-section number	**Question / Request to Manufacturer or Expert Adviser** *Please indicate whether Manufacturer or Expert Adviser was contacted. If an Expert Adviser, only include significant correspondence and include clinical area of expertise.*	**Response** *Attach additional documents provided in response as Appendices and reference in relevant cells below.*	**Action / Impact / Other comments**
Section 2.1.6 and subsequent	Cost to NUTH of diathermy pads: and NHS Supply Chain prices for diathermy pads and reusable cables	See Tables 9 to 10 following this table	Cost used as base case and price as sensitivity analysis
Section 3.10.1 and subsequent	A set of questions were sent to the sponsor during the course of the assessment. The questions presented below:	Responses to the questions from the sponsor are presented below	Impacted on clinical and economic evaluation
	What is the frequency of pad repair? Please describe robustness of pad.	The pad shouldn't need repair. If it is cut accidentally we have a bespoke patch kit which can be used. The pad is very robust and lasts for 2 years even in very busy theatres such as St Barts.	Informed economic evaluation
	What is the mean operational life and range, rather than the regulatory life of 18 months warranty?	The indemnified life of the Mega Soft Patient Return Electrode is 24 months. Its	Informed economic evaluation

Submission Document Section/Sub-section number	Question / Request to Manufacturer or Expert Adviser *Please indicate whether Manufacturer or Expert Adviser was contacted. If an Expert Adviser, only include significant correspondence and include clinical area of expertise.*	Response *Attach additional documents provided in response as Appendices and reference in relevant cells below.*	Action / Impact / Other comments
		predecessor, the Mega2000, was indemnified for 18 months.	
	Please describe the warranted use of Mega Soft Patient Return Electrode with other generators' equipment, particularly with the market leaders Valleylab and Covidien. Please explain the level of indemnity cover provided through the statement '*We provide a warranty and hold-harmless for each pad*."	The pad is indemnified to a limit of $10M irrespective of generator used as long as the Instructions for Use are followed.	Informed economic evaluation
	Please provide names of a contact at five sites using the device and at five sites which have trialled Mega Soft Patient Return Electrode and have stopped using it.	5 names were provided. 5 hospitals that have used the Mega Soft Patient Return Electrode pad and no longer do (mainly down to unavailability of capital monies) • Solihull; • BMI Sandringham; • Frenchay; • Southmead; • Leicester Nuffield.	Not taken forward
	Please summarise Megadyne's experience in placing devices in hospitals for trials (adults and paediatrics) in Europe and USA.	Acceptance of the product and acceptance of the advantages versus using sticky plates is almost universal. The second stage is always securing capital monies and this is often the biggest challenge. Megadyne supply product direct and via a dealer network in the USA. In the rest of the world they supply via dealer partners such as ourselves. The product is used widely throughout the	Informed economic evaluation

Submission Document Section/Sub-section number	Question / Request to Manufacturer or Expert Adviser *Please indicate whether Manufacturer or Expert Adviser was contacted. If an Expert Adviser, only include significant correspondence and include clinical area of expertise.*	Response *Attach additional documents provided in response as Appendices and reference in relevant cells below.*	Action / Impact / Other comments
		world.	
	Please describe the product's main use in USA surgical theatres, for example short day cases or long theatre cases >4 hrs.	The pad is used extensively in short and long cases. There is no real distinction. The pad has advantages over sticky plates in both scenarios.	Informed economic evaluation
	Is use focussed on surgical patients (adults and paediatric) with burns or trauma, including extensive skin and tissue damage, or who are elderly with frail skin and who may experience skin tears when an adhesive electrode is removed?	The pad has benefits for all patients and provides the safest patient grounding solution available. It is not limited to any sub sect. Additional benefits apply for patients with frail skin or burns or existing prostheses etc.	Informed economic evaluation
	Please provide the cost of various Megadyne products (pre and post discount assuming a large volume order) being: **Sticky Pads:** • Adult, disposable dual plate, with 3m (10') pre-attached cord; • Adult, disposable single plate, with 3m (10') pre-attached cord; • Paediatric dual plate, with 3m (10') pre-attached cord; • Paediatric single plate, with 3m (10') pre-attached cord. **Mega Soft Patient Return Electrode:** • Mega Soft Patient Return Electrode Paediatric Patient Return Electrode; • Mega Soft Patient Return Electrode Patient Return Electrode. **Power Generator:** • Mega power generator.	We only supply one sticky pad (code 0855C). The price is £120 per box of 50. The adult Mega Soft Patient Return Electrode is £2,100 (£1,900 discounted) and the paediatric pad is £2,950 (£1,900 discounted). The Mega Power generator system is £7,900	Informed economic evaluation
	Is there a hard plastic moulding over a corner of the electrode that may cause pressure necrosis if a patient is placed on it for long time?	There is a hard moulding in the top corner of the product but there is no need for the patient to contact this area.	Technical consideration

Submission Document Section/Sub-section number	**Question / Request to Manufacturer or Expert Adviser** *Please indicate whether Manufacturer or Expert Adviser was contacted. If an Expert Adviser, only include significant correspondence and include clinical area of expertise.*	**Response** *Attach additional documents provided in response as Appendices and reference in relevant cells below.*	**Action / Impact / Other comments**
	Explain Guy's and paediatric evaluation St Thomas's scoring please (issue is some scores exceed 5).	Not sure on this one - maybe we can discuss at our meeting when our Health Economist is present.	Informed economic evaluation
	It is stated on page 1 of the scope issued by NICE that a proprietary cable called a 'DetachaCable' is connected 'deep inside' the Mega Soft Patient Return Electrode. • If the DetachaCable is proprietary how does it connect to other manufacturers generators? • Are all generator connectors manufacturer specific? • Are all disposable pad connectors manufacturer specific? • If the connectors are not the same, do adaptor cables or connectors need to be purchased separately? [NB this might affect economics] • Is the area where the DetachaCable connects to the Mega Soft Patient Return Electrode (known as the 'rigid corner' in the Mega Soft Patient Return Electrode instructions for use) padded to prevent pressure injuries?	*(Response provided verbally at a meeting).* DetachaCable is proprietary.	Technical consideration
	On page 2 of the scope, the Mega Soft Patient Return Electrode is specified as measuring 117 cm x 51 cm. For pressure relief, this is not a large enough area to accommodate a full size adult e.g. depending on position, the patients legs, head, or arms etc. will not be resting on the Mega Soft Patient Return Electrode (assume most adults are >117 cm tall). • If the Mega Soft Patient Return Electrode is to be used as a pressure relieving device, what relieves the pressure on the shoulder, head, arms, elbows, legs, feet, heels etc. (depending on the position of the patient)?	*(Response provided verbally at a meeting)*. Secondary pressure devices may be needed for example at the heels.	Informed economic evaluation

Submission Document Section/Sub-section number	**Question / Request to Manufacturer or Expert Adviser** *Please indicate whether Manufacturer or Expert Adviser was contacted. If an Expert Adviser, only include significant correspondence and include clinical area of expertise.*	**Response** *Attach additional documents provided in response as Appendices and reference in relevant cells below.*	**Action / Impact / Other comments**
	• Will a pressure relieving mattress/operating table top cover still be required? [NB this may affect economics] • The paediatric Mega Soft Patient Return Electrode may also have the same issue - it measures 66 cm x 30.5 cm.		
	If for some reason the patient does not contact the Mega Soft Patient Return Electrode for the minimum required area and the patient cannot be repositioned, how can electrosurgery still be performed? • How often does this happen? • If this is the case the manufacturer instructs in their FAQ to use a disposable adhesive electrode (pad) - this may be something to consider in the economic analysis.	*(Response provided verbally at a meeting)*. Sufficient patient contact can always be maintained without the use of additional sticky pads.	Informed economic evaluation
	Are technology costs (Mega Soft Patient Return Electrode, mattress and pads) inclusive or exclusive of VAT?	Costs are exclusive of VAT	Informed economic evaluation
	The PSSRU cost (2010/11) for a surgeon contract hour is £136 excluding qualifications. Can you please explain additional assumptions to get to £347 per hour per submission?	The last row of the table on p219 of "CURTIS, L. 2010. Unit costs of health and social care. Personal Social Services Research Unit (PSSRU)." reads; "£110 (£127) per contract hour; £347 (£403) per hour operating; £148 (£171) per patient-related hour (includes A to F). I have selected the £347 per hour as it relates to the cost of the surgeon's time whilst he/she is operating. I believe this appropriate because we assume that use of the Mega Soft pad reduces the time of	Informed economic evaluation

Submission Document Section/Sub-section number	Question / Request to Manufacturer or Expert Adviser *Please indicate whether Manufacturer or Expert Adviser was contacted. If an Expert Adviser, only include significant correspondence and include clinical area of expertise.*	Response *Attach additional documents provided in response as Appendices and reference in relevant cells below.*	Action / Impact / Other comments
		operations."	
	The PSSRU cost (2010/11) for a nurse day ward (includes staff nurse, registered nurse, registered practitioner) is £34 excluding qualifications. Can you please explain additional assumptions to get to £41 per hour per submission	The last row of the table on p207 reads; "£23 (£26) per hour; £41 (£47) per hour of patient contact." I have selected the £41 per hour as it relates to the cost of the nurse's time whilst he/she has patient contact, which is appropriate during an operation."	Informed economic evaluation
	Please provide further comment of the validity of the sponsor's estimate of the 5 minute delay.	The sponsor advised the estimate of 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 re where not to apply pad and find appropriate area; shave patient if required and apply. The sponsor advised that these activities are conducted in theatre because lead to ESU is there; otherwise if in prep room have to wheel patient with loose wire attached.	Informed economic evaluation
	Can you please advise which customers would get a discounted price and who would pay the full price.	If application to MTAC is successful all sales will be at the discounted price. This should be used for the base case analyses.	Informed economic evaluation
	Can you please advise on the cost of a re-usable lead wire to connect to another lead wire from the ESU for diathermy pads without lead wires? (Cost of a reusable lead is from £20 to £80 £20 to £80 100 times)	The sponsor emailed pages from NHS Supply Chain catalogue showing prices for 3m long re-usable diathermy cables, with jack plug	Informed economic evaluation

Submission Document Section/Sub-section number	**Question / Request to Manufacturer or Expert Adviser** *Please indicate whether Manufacturer or Expert Adviser was contacted. If an Expert Adviser, only include significant correspondence and include clinical area of expertise.*	**Response** *Attach additional documents provided in response as Appendices and reference in relevant cells below.*	**Action / Impact / Other comments**
		for REM machines. These varied by supplier from Lang Skintact at £16.63; Unomedical £19.64, ConMed £27.08, cables for all Valleylab generators £30.85 and for use with Eschmann TD411 - Bard/Birtcher - Concept - Erbe - Neomed short insulation generators £85.13. The sponsor noted the cable, whilst re-usable, had to be sterilised between uses and re-attached by a technician. He also noted these can develop faults. He estimated about 100 uses per cable.	
	Can you please provide an estimate of the additional costs of cleaning, handling, folding and storing the Mega Soft Patient Return Electrode?	The sponsor advised the marginal cost of between patients cleans, compared to no Mega Soft Patient product, was nil because any surface would need to be wiped down between patients. At night he noted the Mega Soft was often left on the table or possible rolled up and placed at end of the table taking at most 30 seconds	Informed economic evaluation
Section 3.10.4	A questionnaire was sent to 5 NICE experts. One was returned completed. The questions are presented below.	Responses to the questionnaire are presented below.	Impacted on economic evaluation

<table>
<tr><th>Submission Document Section/Sub-section number</th><th>Question / Request to Manufacturer or Expert Adviser
Please indicate whether Manufacturer or Expert Adviser was contacted. If an Expert Adviser, only include significant correspondence and include clinical area of expertise.</th><th>Response
Attach additional documents provided in response as Appendices and reference in relevant cells below.</th><th>Action / Impact / Other comments</th></tr>
<tr><td></td><td>Q1. Can you please advise of the severity of burns from patient return electrodes using split sticky pads and non-split sticky pads. The categories to use are set out in Table 1.
<table>
<tr><th rowspan="2">Category</th><th colspan="2">% of Burns from Return Electrodes</th></tr>
<tr><td>Split sticky pads</td><td>Non-split sticky pads</td></tr>
<tr><td>Major burn, third degree or more</td><td>0</td><td>N/A</td></tr>
<tr><td>Other burn with major complications</td><td>0</td><td>N/A</td></tr>
<tr><td>Other burn without major complications</td><td>0</td><td>N/A</td></tr>
<tr><td>Total</td><td>100%</td><td>100 %</td></tr>
</table></td><td>Table was not completed</td><td>Followed up with separate question to experts</td></tr>
<tr><td></td><td>Q2. Are you or your members aware of any litigation involving an NHS organisation associated with use of sticky pads? (Yes or no)</td><td>No</td><td>NHS Litigation asked for information</td></tr>
<tr><td></td><td>Q3. For what percentage of adult patients undergoing surgery and paediatric patients undergoing surgery does placement of a sticky pad on the patient give rise to a serious difficulty for the theatre nurses?</td><td>0</td><td>Informed economic evaluation</td></tr>
<tr><td></td><td>Q4. Are protocols in place and training provided to theatre staff on the use of sticky pads? (Yes or no)</td><td>Yes</td><td>Informed economic evaluation</td></tr>
<tr><td></td><td>Q5. Please advise the mean price paid by the Trust (that is after the deduction of discounts) for:
• Adult split pads:
£
• Adult non-split pads</td><td>No costs were given</td><td>NHS NUTH asked for information</td></tr>
</table>

Submission Document Section/Sub-section number	Question / Request to Manufacturer or Expert Adviser *Please indicate whether Manufacturer or Expert Adviser was contacted. If an Expert Adviser, only include significant correspondence and include clinical area of expertise.*	Response *Attach additional documents provided in response as Appendices and reference in relevant cells below.*	Action / Impact / Other comments
	£ • Paediatric split pads **£** • Paediatric non-split pads **£**		
	Q6. Does the Trust require that theatres purchase sticky pads from the manufacturer of the diathermy (electrosurgical) unit [ESU] to ensure the manufacturer's warranty is not invalidated? *(Yes or no)*	No	Informed economic evaluation
	Q7. Does the Trust receive free ESUs as part of a purchasing agreement for electrodes? *(Yes or no)*	No	Informed economic evaluation
	Q8. What is the mean number of surgical procedures per day, per theatre, using monopolar surgery?	80+ *(unspecified number of theatres)*	Informed economic evaluation
	Q9. How many days a year do theatres operate at that level of mean number of procedures?	200	Informed economic evaluation
	Q10. What percentage of surgical patients (adults and paediatric) have burns or trauma, including extensive skin and tissue damage, or are elderly with frail skin and who may experience skin tears when an adhesive electrode is removed?	Informal enquiry: 15%	Informed economic evaluation
	Q11. Does the response to Question 8 on mean number of surgical procedures a day generalise to the specific patient groups in Question 10?	Yes	Informed economic evaluation
	Q12. Any other comments you may wish to make?	We purchase approx 23000 split pads per year. I am not in a position to give a cost breakdown. We run a centralised incident reporting system (DATIX) and in the last 4 years there are no reports of incidents reported. Red skin and minor abrasions are common (30+ %) on informal questioning, reflecting the reporting system.	Informed economic evaluation
	Further responses were provided by experts on the following:		

Submission Document Section/Sub-section number	**Question / Request to Manufacturer or Expert Adviser** *Please indicate whether Manufacturer or Expert Adviser was contacted. If an Expert Adviser, only include significant correspondence and include clinical area of expertise.*	**Response** *Attach additional documents provided in response as Appendices and reference in relevant cells below.*	**Action / Impact / Other comments**
	Delay in theatre	**Response 1** Hold up is a relatively uncommon problem in my experience. I think the time (5mins) is a bit generous but wouldn't argue and I would put the need at nearer 10% purely for placement of the electrode (maybe we have a less hairy population!). Patient safety now means we have to use electric razors with disposable heads all the time. 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!	Informed economic evaluation
	Staff and practices in theatre	**Response 1** The mean number of operations per week per theatre that require the use of monopolar is 13.5. However as we have been using the Mega soft mattress for a number of years now we do not have to shave any of our patients for placement of a patient return electrode. **Response 2** In addition to 1 surgeon, 1 anaesthetist, 1 nurse anaesthetist and 2 operating room nurses per operation	Informed economic evaluation

Submission Document Section/Sub-section number	Question / Request to Manufacturer or Expert Adviser *Please indicate whether Manufacturer or Expert Adviser was contacted. If an Expert Adviser, only include significant correspondence and include clinical area of expertise.*	Response *Attach additional documents provided in response as Appendices and reference in relevant cells below.*	Action / Impact / Other comments
		we also have a Registrar and a healthcare assistant. **Response 3** Any number of surgeons probably 2, on average 2 anaesthetists, 2 nurses, 1 hca, 1 anaesthetic practitioner 9 could by odp/nurse). We don't have nurse anaesthetists. 6 minimum I would of thought. **Response 4** I would estimate that we use monopolar on 4 operations a day per theatre. We use the megadyne mainly so don't shave but when we do it takes approx 3 minutes, 40% of patients shaved and we use electric disposable shavers **Response 5** We carry out approximately 16 monopolar procedures per day across all 10 theatres. We no longer use sticky pads as we have the Megadyne mattresses so no patients are shaved. **Response 6** This number is actually difficult to give as it depends on specialty - for instance cardiac may do an average of three cases whereas gynae	

Submission Document Section/Sub-section number	Question / Request to Manufacturer or Expert Adviser *Please indicate whether Manufacturer or Expert Adviser was contacted. If an Expert Adviser, only include significant correspondence and include clinical area of expertise.*	Response *Attach additional documents provided in response as Appendices and reference in relevant cells below.*	Action / Impact / Other comments
		may do average of 15. We run 24 theatres broken down by specialty. I could get the usage of plates by specialty but I am not sure if that is any better. The figure you are looking for would be an average of 24 theatres divided into 20,000 cases per year - approx 1000 cases/theatre / year - assume 200 working days = average 5 cases/theatre/day.	
	Time to clean and store Mega Soft product	**Response 1** The time to clean is really minimal (less than a minute). They are cleaned with a disinfectant wipe between patients and at the end of a theatre session. This procedure can be undertaken by any grade of staff. They are kept/stored on the operating table so they are always insitu. **Response 2** Although it's an extra layer on the operating table mattress, prior to its use we would have had a pressure relieving gel in its place so the cleaning time is the same. But I would suggest that the time to clean in between patients is 30 seconds performed usually by a healthcare assistant. The operating table mattress and the megadyne are	Informed economic evaluation

Submission Document Section/Sub-section number	**Question / Request to Manufacturer or Expert Adviser** *Please indicate whether Manufacturer or Expert Adviser was contacted. If an Expert Adviser, only include significant correspondence and include clinical area of expertise.*	**Response** *Attach additional documents provided in response as Appendices and reference in relevant cells below.*	**Action / Impact / Other comments**
		removed from the table at the end of the list and placed on a trolley to dry, the addition of the megadyne would add ~ 1min to this, usually by a healthcare assistant but may be nurse/theatre practitioner. **Response 3** It takes about a minute to wipe over the mega soft patient return pad between cases with a sporacidal wipe and it is left on the table at the end of the day. This is usually carried out by a Theatre support worker. **Response 4** Pure guess work, but 5min cleaning between cases (clean and relay on mattress) and 5 min at the end of the day (assuming remains on the table overnight) would seem reasonable.	
	Pressure pads: *a) In all surgical cases, does mega soft act as a pressure relieving mattress during the procedure such that no additional support is required and team thus avoid having to use any other mattress?* *b) What would be the most common form of mattress used prior to MEGA SOFT?*	**Response 1** a) They need heel supports, and for larger patients protection for arms and elbows. When patient positioned on their side, they use a vacuum bean bag for positioning. b) They wouldn't have used anything in addition to the operating table mattress at that time.	Informed economic evaluation

Submission Document Section/Sub-section number	**Question / Request to Manufacturer or Expert Adviser** *Please indicate whether Manufacturer or Expert Adviser was contacted. If an Expert Adviser, only include significant correspondence and include clinical area of expertise.*	**Response** *Attach additional documents provided in response as Appendices and reference in relevant cells below.*	**Action / Impact / Other comments**
		Response 2 a) Nothing else used in the areas where Mega Soft is in place. Other supports may be needed for areas such as arms. b) Don't know, possibly gel mattress from Central Medical Supplies, such as Action pads. http://www.actionproducts.com/operating_room_products/overlays/ViewCategory/catalog.cfm	
Section 2.1.6	NHS Litigation asked to quantify costs paid as a result of diathermy pads burns	Response from NHSLA: Below is a breakdown of the number of claims made and damages paid based on claims relating to diathermy burn claims identified in the NHSLA database. This includes all relevant claims, i.e. closed and outstanding as at 30/11/11, reported to the NHSLA since January 2005. Number of claims brought 276 Closed with no damages 34 Closed with damages 195 Total paid (damages + costs) £5,651,312 Open 47	Used to inform economic evaluation
Section 2.1.6	Fifty Medical Directors asked to advise on issues with diathermy pads	Nil	NHS Litigation contacted
Table 4.1	Enquiry to mattress manufacturer	Response to internet	Confirmed

Submission Document Section/Sub-section number	**Question / Request to Manufacturer or Expert Adviser** *Please indicate whether Manufacturer or Expert Adviser was contacted. If an Expert Adviser, only include significant correspondence and include clinical area of expertise.*	**Response** *Attach additional documents provided in response as Appendices and reference in relevant cells below.*	**Action / Impact / Other comments**
	(Charnwood)	enquiry: £330.00 for a basic operating table mattresses, 5cm in depth and consisting of foam with a neoprene covering which would last a year based on consumer feedback. £800.00 for the Liquid Displacement Cell (LDC) mattress- a full pressure relieving operating table mattress complete with gel interior and a good quality pressure relieving foam, covered Permalon anti-static two way stretch fabric for around. There is no clinical evidence that mattresses sold in the market for prices up to £3000.00 are any better in pressure relief.	sponsor estimate of life
Table 4.1	Request for prices from NHS Supply Chain for the following: OPERATING TABLE GEL PAD Operating table gel pad full length (1800x520x10mm) NPC: N0860910 MPC: 8146939 OPERATING TABLE PERINEAL CUT OUT Operating table gel pad 3/4 length with perineal cut-out NPC: N0860912 MPC: 8146954 OPERATING TABLE GEL PAD LIGHTWEIGHT Light weight table gel pad 1150 x 520 x 10mm	Response from NHS Supply Chain re prices NHS Supply chain obtained a quote from Eschmann for the accessories. Operating table gel pad full length (1800x520x10mm) Unit Price: £517.65 Operating table gel pad 3/4 length with perineal cut-out Unit Price: £362.95	Informed economic evaluation

Submission Document Section/Sub-section number	**Question / Request to Manufacturer or Expert Adviser** *Please indicate whether Manufacturer or Expert Adviser was contacted. If an Expert Adviser, only include significant correspondence and include clinical area of expertise.*	**Response** *Attach additional documents provided in response as Appendices and reference in relevant cells below.*	**Action / Impact / Other comments**
	NPC: N0860913 MPC: 8146975	Lightweight table gel pad 1150 x 520 x 10mm Unit Price: £362.95	
Section 2.1.6	MHRA asked for information on reported incidents from diathermy pads	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.	Important to size problem of adverse events from diathermy pads
Section 2.1.2	The EAC extracted information from the MHRA) website for safety warnings, medical device alerts, field safety notices and one-liners for relevant information and advice on monopolar electrosurgery and patient return electrodes.	The findings were sent to MHRA which identified two omissions and this was rectified	Ensure guidance on intervention and device complete.

Table 7 Price paid in year from 1 April 2012 by NUTH for Diathermy Pads (disposable single use patient return electrodes)

Cost and description of diathermy pads	Qty supplied	Total demand (£)	Per unit
Diathermy plate standard (solid) without leadwire Universal 'A' 140 x 106mm soft hydrogel adhesive apple shape with overlapping gel	25	576.25	£0.46
Diathermy plate split without leadwire Universal 'A' REM 140 x 106mm soft hydrogel adhesive apple shape with overlapping gel	28	813.4	£0.58
Diathermy plate split without leadwire Universal 120 x 132mm overlapping gel low profile waterproof woven cloth backing	10	239	£0.48
Diathermy plate split without leadwire Universal 120 x 132mm overlapping gel low profile waterproof woven cloth backing	68	1,613.20	£0.47
Diathermy plate split without leadwire Universal 120 x 132mm overlapping gel low profile waterproof woven cloth backing	15	354.5	£0.47
Diathermy plate split without leadwire Universal 120 x 132mm overlapping gel low profile waterproof woven cloth backing	2	47.8	£0.48
Diathermy plate split without leadwire Universal 120 x 132mm overlapping gel low profile waterproof woven cloth backing	1	23.9	£0.48
Diathermy plate split without leadwire Universal 120 x 132mm overlapping gel low profile waterproof woven cloth backing	60	1,412.40	£0.47
Diathermy plate split without leadwire Universal 120 x 132mm overlapping gel low profile waterproof woven cloth backing	15	354.5	£0.47
Diathermy plate split without leadwire Universal 120 x 132mm overlapping gel low profile waterproof woven cloth backing	2	47.8	£0.48
Diathermy plate split with leadwire Adult 183 x 114mm	6	533.94	£1.78
Diathermy plate split with leadwire Adult 183 x 114mm	2	177.98	£1.78
Diathermy plate split with leadwire Adult 183 x 114mm	1	88.99	£1.78
Diathermy plate split with leadwire Adult 183 x 114mm	3	266.97	£1.78
Diathermy plate split without leadwire Adult 183 x 114mm	7	700.35	£2.00
	245	**7,250.98**	**£0.59**
	Cost per pack inc VAT	**Total cost inc VAT**	
	£23.05	**£576.25**	£0.46
	£30.34	**£6,674.74**	£0.61
	Total	**£7,250.99**	

Table 8 NHS Supply Chain prices for single diathermy pad (inc VAT) (disposable single use patient return electrodes)

			Split				Solid			
Brand	**Unit of issue**	**Price**	**Adult**		**Child**		**Adult**		**Child**	
			No wire	**Cabled**	**No wires**	**Cabled**	**No wires**	**Cabled**	**No wires**	**Cabled**
Covidien	600	589.56	£0.98							
Covidien	12	181.3				£15.11				
Covidien	25	116.86				£4.67				
ConMed	25	49.31						£1.97		
ConMed	25	52.47		£2.10						
ConMed	5	3.18	£0.64							
Lang Skintact	50	95.37				£1.91				
Unomedical Neutralect	50	104.67		£2.09						
3M Health Care Ltd	200	102.71					£0.51			
ConMed	25	52.47								£2.10
Lang Skintact	50	26.56	£0.53							
Lang Skintact Cool Contact	50	33.99			£0.68					
Lang Skintact	50	27.54	£0.55							
Lang Skintact	50	90.38		£1.81						
Lang Skintact	50	22.66					£0.45			
Lang Skintact	50	33.31							£0.67	
Unomedical Neutralect	50	29.05	£0.58							
Unomedical Neutralect	50	21.96					£0.44			
Lang Skintact	50	22.57					£0.45			
Lang Skintact	50	28.44	£0.57							
Lang Skintact	50	83.59						£1.67		
Lang Skintact	50	92.28		£1.85						
Unomedical Neutralect	50	102.91		£2.06						
Unomedical Neutralect	50	104.66		£2.09						
Lang Skintact	50	21.5					£0.43			
Lang Skintact	50	23.4	£0.47							
Lang Skintact	50	85.82						£1.72		
ConMed	10	19.92								£1.99
3M Health Care Ltd	100	67.05					£0.67			
3M Health Care Ltd	100	76.31	£0.76							
ConMed	5	2.45					£0.49			
3M Health Care Ltd	40	105.38						£2.63		

			Split				Solid			
Brand	**Unit of issue**	**Price**	**Adult**		**Child**		**Adult**		**Child**	
			No wire	**Cabled**	**No wires**	**Cabled**	**No wires**	**Cabled**	**No wires**	**Cabled**
Lang Skintact	50	82.64								£1.65
Unomedical Neutralect	50	35.16							£0.70	
Tyco Polyhesive	50	100.05	£2.00							
Tyco Polyhesive	50	88.99		£1.78						
Lang Skintact	100	167.09		£1.67						
Lang Skintact	50	89								£1.78
Lang Skintact	50	96.18						£1.92		
Lang Skintact	50	98.12				£1.96				
Tyco ProRe Universal	50	25.81	£0.52							
Skintact	50	92.28		£1.85						
Mean prices			**£0.76**	**£1.92**	**£0.68**	**£5.91**	**£0.49**	**£1.98**	**£0.68**	**£1.88**

Table 9 Re-usable cables

Brand	**Unit of issue**	**Price**	**No wire**	**Cabled**
Unomedical Neutralect	1	£20.06		£20.06
Unomedical Neutralect	1	£18.91		£18.91
Lang Skintact Cool Contact	1	£16.96		£16.96
Bard/Birtcher Erbe ESU	1	£86.94		£86.94
For Valleylab ESUs	1	£31.51		£31.51
Mean excluding ERBE ESU				**£21.86**

Appendix E: Sponsor's factual check of the assessment report and the External Assessment Centre's responses

Technical Testing Assessment report – Cedar EAC

Issue 1

Description of factual inaccuracy	Description of proposed amendment	Justification for amendment	EAC Action
Regarding the discussion of the testing done by CHUS in section 4.3. The list of differences from the IEC 60601-2-2:2009 is not complete. One important difference is not addressed.	Add: - The spatial correlation between the reference and second temperature scans was not controlled.	As stated in IEC 60601-2-2:2009 section 201.15.101.5: *"The temperature scanning apparatus shall have an accuracy of better than 0,5 °C and a spatial resolution of at least one sample per square cm over the entire* NE *contact area plus the area extending 1 cm beyond the edge of that area. Spatial correlation between the reference and second temperature scans shall be within* □ *1,0 cm."* With this not being controlled the temperature rise values measured by CHUS are not accurate.	Agree, the following text has been added: Additionally, the correlation between the location of the reference and second temperature scans is not reported, and may not meet the criteria of the standard.

Issue 2

Description of factual inaccuracy	Description of proposed amendment	Justification for amendment	EAC Action
Regarding the discussion of Megadyne Test Protocol 1150130-10 in section 4.5.1.	Add: This variation from the standard is noted in the IFU for the Mega Soft device.	As stated in Mega Soft IFU 3000068-01: *"Frequency Rating: 300 to 600 kHz"*	Agree, the following text has been added: The instructions for use for Mega Soft state a

			frequency range of 300-600 KHz.

Clinical and Economic Assessment report – NUTH and YHEC EAC

Issue 1

Description of factual inaccuracy	Description of proposed amendment	Justification for amendment	EAC Action
Comment 1 In our economic model, we, the sponsor, used the acquisition cost of the sticky pads including VAT, whereas Section 5.5.9 of NICE Guide to the Methods of Technology Appraisal (2008) states that VAT should be excluded. We correctly used the price of the Mega Soft pad excluding VAT. The EAC incorrectly included VAT in the acquisition prices of both the sticky pads and the Mega Soft pad.	Both the prices of the sticky pads and the Mega Soft pad should be used in the model excluding VAT	Section 5.5.9 of NICE Guide to the methods of technology appraisal (2008)	The MTEP has adopted cost-consequence analysis as the appropriate method to evaluate technologies. This requires that all the costs and resource consequences resulting from, or associated with, the use of the technology under evaluation and comparator technologies, are included in the cost analysis. Given hospitals pay VAT this includes VAT. In the EAC's analysis VAT has been included for diathermy pads and Mega Soft Patient Return Electrode. The Guide to Technology Appraisals does not apply to this Programme.

Issue 2

Description of factual inaccuracy	Description of proposed amendment	Justification for amendment	EAC Action
Comment 2 In Table 4.3, p41 of the EAC	Value should read £70.98	Presumably a simple typo.	Text amended to £70.98

critique, the cost saving based on the discounted price of the Adult Mega Soft is incorrectly quoted as £79.98			

Issue 3

Description of factual inaccuracy	Description of proposed amendment	Justification for amendment	EAC Action
Comment 3 The last sentence of p46 states; “if the total cost of using each split diathermy pad (pad plus reusable cable plus labour costs) is under £1.06 (£0.54+£0.22+£0.11 +£0.19) then the Mega Soft Patient Return Electrode has the same cost per operation as diathermy pads.”	Should read; “if the total cost of using each split diathermy pad (pad plus reusable cable plus labour costs) equals £0.68 (£0.54+£0.22+£0.1 1-£0.19) then the Mega Soft Patient Return Electrode has the same cost per operation as diathermy pads.”	Logical error.	Text revised to improve clarity using a table.

Issue 4

Description of factual inaccuracy	Description of proposed amendment	Justification for amendment	EAC Action
Comment 4 Section 4 titled "Economic Evidence" states; "The price of split pads without wires will be used as the base case because this is the most common type forming 85% of all purchases".	Should read; "Split pads without wires are the most commonly used style of disposable electrode used in many Trusts". However it should be noted that the adoption of disposable electrodes complete with wire is extremely common and	ConMed Disposable Electrode Code complete with Wire # 410-2000 is the most commonly utilised electrode in all hospitals in Leicester, Peterborough and Doncaster. Eschmann Disposable Electrode complete with Wire Code # 83-	Text re-worded to note the sponsor’s advice that the most common form of electrode used in some hospital sites was diathermy pads with wires. Text added that NHS Supply Chain will advise on this aspect by 20 Feb.

	these products are on average approximately £1 more expensive.	122-33 is the most commonly used electrode at Bradford Royal Infirmary at a unit cost of £1.73 The following disposable electrodes complete with Wire are used at Southampton General Hospital; FDJ106 - £2.00 - Lang E7510-25 - £4.52 – Covidien E7512 - £13.33 – Covidien FDJ154 - £1.90 - Lang	