NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

Medical Technologies Evaluation Programme

Sponsor submission of evidence:

Evaluation title: Mega Soft Patient Return Electrode for use during monopolar electrosurgery

Sponsor: Advance Surgical Ltd

Date sections A and B submitted: 11th November 2011

Date section C submitted: 9th December 2011

August 2011

Contents

Instructions for sponsors

This is the template for submission of evidence to the National Institute for Health and Clinical Excellence (NICE) as part of the Medical Technologies Evaluation Programme process for developing NICE medical technologies guidance. Use of the submission template is mandatory.

The purpose of the submission is for the sponsor to collate, analyse and present all relevant evidence that supports the case for adoption of the technology into the NHS in England, within the scope defined by NICE. Failure to comply with the submission template and instructions could mean that the NICE cannot issue recommendations on use of the technology.

The submission should be completed after reading the 'Medical Technologies Evaluation Programme Methods guide' and the 'Medical Technologies Evaluation Programme Process guide' available at www.nice.org.uk/mt. After submission to, and acceptance by, NICE, the submission will be critically appraised by an External Assessment Centre appointed by NICE.

Under exceptional circumstances, unpublished evidence is accepted under agreement of confidentiality. Such evidence includes 'commercial in confidence' information and data that are awaiting publication ('academic in confidence'). When data are 'commercial in confidence' or 'academic in confidence', it is the sponsor's responsibility to highlight such data clearly. For further information on disclosure of information, submitting cost models and equality issues, users should see section 11 of this document 'Related procedures for evidence submission'.

The submission should be concise and informative. The main body of the submission should not exceed 100 pages (excluding the pages covered by the template and appendices). The submission should be sent to NICE electronically in Word or a compatible format, not as a PDF file.

The submission must be a stand-alone document. Additional appendices may only be used for supplementary explanatory information that exceeds the level

of detail requested, but that is considered to be relevant to the case for adoption. Appendices will not normally be presented to the Medical Technologies Advisory Committee when developing its recommendations. Any additional appendices should be clearly referenced in the body of the submission. Appendices should not be used for core information that has been requested in the specification. For example, it is not acceptable to attach a key study as an appendix and to complete the economic evidence section with 'see appendix X'.

All studies and data included in the submission must be referenced. Identify studies by the first author or trial ID, rather than by relying on numerical referencing alone (for example, 'Trial 123/Jones et al.[126], rather than 'one trial[126]').Please use a recognised referencing style, such as Harvard or Vancouver.

The sponsor should provide a PDF copy of all studies included in the submission. For unpublished studies for which a manuscript is not available, provide a structured abstract about future journal publication. If a structured abstract is not available, the sponsor must provide a statement from the authors to verify the data provided.

If a submission is based on preliminary regulatory recommendations, the sponsor must advise NICE immediately of any variation between the preliminary and final approval.

Document key

Boxed text with a grey background provides specific and/or important guidance for that section. This should not be removed.

Information in highlighted black italic is to help the user complete the submission and may be deleted.

The user should enter text at the point marked 'Response' or in the tables as appropriate. 'Response' text may be deleted.

List of tables and figures

Glossary of terms

If a glossary of terms is required to inform the submission of evidence include in the table. Delete if not required.

Term	Definition

Section A – Decision problem

Section A describes the decision problem, the technology and its clinical context. There is also information about ongoing studies, regulatory information and equality issues.

Sponsors should submit section A before the full submission (for details on timelines, see the NICE document 'Guide to the Medical Technologies Evaluation Programme process', available from www.nice.org.uk/mt

1 Statement of the decision problem

The decision problem is specified in the final scope issued by NICE. The decision problem states the key parameters that should be addressed by the information in the evidence submission. All statements should be evidence based and directly relevant to the decision problem.

Table A1 Statement of the decision problem

	Scope issued by NICE	Variation from scope	Rationale for variation
Population	Monopolar electrosurgery patients	None	
Intervention	Mega Soft Patient Return Electrode – adult and paediatric sizes	None	
Comparator(s)	Return electrode monitoring single use sticky pads (non-split pad) Return electrode contact quality monitoring single use sticky pads (split pad).	None	
Outcomes	Incidence of dispersive electrode burns. Incidence of stray electrosurgical burns. Incidence of post-operative pressure ulcers Other device-related adverse events. Sustainability and cost impact due to the re-usable nature of the pad Resource utilisation and staff time; to include cleaning time	None	
Cost analysis	Intervention: Mega Soft Patient Return Electrode Comparator(s): Return electrode monitoring single use sticky pads (non-split pad) Return electrode contact quality monitoring single use sticky pads (split pad). Costs will be considered from an NHS and personal social services perspective. The time horizon for the cost analysis will be sufficiently long to reflect any differences in costs and consequences between the technologies being compared. Sensitivity analysis will be	None	

	undertaken to address uncertainties in the model parameters, including an analysis of whether or not there will be a requirement to buy new diathermy equipment that is compatible with the Mega Soft Patient Return Electrode.		
Subgroups to be considered	Patients with burns. Patients with skin conditions. Babies and children. Patients with fragile skin. (e.g. older patients) Patients with high or low BMI	None	
Special considerations, including issues related to equality	Cultural sensitivities exist surrounding the shaving of body hair; this may be an issue when using 'sticky pad' electrodes but is potentially avoidable through the use of the Mega Soft pad.	None	

If the sponsor considers that additional parameters should be included in the submission, which are not stated in the decision problem, this variation from the scope and the rationale for it must be clearly described in the relevant columns in table A1.

2 Description of technology under assessment

2.1 Give the brand name, approved name and details of any different versions of the same device.

The technology is the Mega Soft Patient Return Electrode. 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 1.25cm. The paediatric size device is approximately 66 x 30.5 x 1.3cm and is intended for patients weighing between 0.4kg and 22.7kg.

The Mega 2000 was the predecessor to the Mega Soft Patient Return Electrode.

All different versions/prototypes of the technology listed here must be CE marked or have equivalent UK regulatory approval.

2.2 What is the principal mechanism of action of the technology?

The Mega Soft Patient Return Electrode is intended for use during monopolar electrosurgery, specifically to reduce the risk of skin burns and to provide pressure relief.

During monopolar electrosurgery, the Mega Soft Patient Return Electrode conducts high frequency electrical current from the patient target tissue back 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 grounding electrode.

In current NHS clinical practice, a patient return electrode is attached directly to the patient’s body using a sticky pad. By contrast, the Mega Soft Patient Return Electrode is incorporated into a pad on which the patient lies during surgery. Safe contact is made when the patient lies directly on the pad, but more typically the pad is covered by up to two layers of linen, one of which is

often a warming blanket. The Mega Soft works satisfactorily in both scenarios. The pad also acts as a pressure relieving device for the patient.

The Mega Soft Patient Return Electrode is made of a layer of conductive material which is strain-relieved with 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 dual conducting cable ('DetachaCable') which is insulated and strain-relieved and attaches deep inside the device in order to prevent patient or user burns.

Complete electrical contact is achieved with the patient lying on the device. Mega Soft is a self-contained current limiting device which allows the patient to be in contact with only a small portion of the pad. The patient is safe even if he/she is in contact with only a small portion of the pad because the pad is a self-contained current limiting device.

3 Clinical context

3.1 Provide a brief overview of the disease or condition for which the technology is being considered in the scope issued by NICE.

It is estimated that, in 2009/10, 2.58 million inpatient surgical procedures (29% of the total) lasted for longer than 30 minutes (Medical Technology Guidance 7: Inditherm patient warming mattress for the prevention of inadvertent hypothermia: HES data and guidance http://guidance.nice.org.uk/MTG7). Assuming that monopolar electrosurgery is used in half of all surgical procedures, the Mega Soft Patient Return Electrode could be used in up to 1.29 million procedures each year in the UK.

The disease or condition for which the technology is being considered in the scope must include an estimate of prevalence and/or incidence for the benefitting population. All estimates must be referenced.

3.2 Give details of any relevant NICE or other national guidance or expert guidelines for the condition for which the technology is being used. Specify whether the guidance identifies specific subgroups and make any recommendations for their treatment. If available, these should be UK based guidelines.

We are not aware of any relevant guidance.

3.3 Describe the clinical pathway of care that includes the proposed use of the technology.

The technology is used in monopolar electrosurgery, which itself is used in a wide range of surgery: e.g. dermatological, gynaecological, cardiac, plastic, ocular, spine, ENT, maxillofacial, orthopaedic, urological, neuro- and general surgical procedures.

If a relevant NICE clinical guideline has been published, the clinical pathway of care should be consistent with the NICE guideline and described. If relevant, this should include comparator technologies.

3.4 Describe any issues relating to current clinical practice, including any uncertainty about best practice.

Current practice during monopolar electrosurgery involves the application to the skin of a single use “sticky pad” return electrode. The most commonly reported complication of electrosurgery is a burn resulting from the improper application of the sticky pad return electrode. Such burns, e.g.(2005b, 2005c) occur when there is a failure of energy dispersion through the return electrode, for example if the electrode peels away from the skin(2000), reducing the area of contact. Such burns account for two-thirds of all electrosurgical accidents(Brill, 2011). A rise in skin temperature and a risk of burning occurs if there is impedance to electrical conduction at the skin to pad interface. Such impedance may be caused by excessive body hair, adipose tissue, bony prominences, fluid invasion, adhesive failure and scar tissue(Ziprin and Darzi, 2002). To prevent this occurring, pads need to be strategically placed to avoid bony prominences and metal prosthesis, and

should be placed on hair free areas of the body. This may require a preliminary skin shaving. The chances of burns increases when higher current is applied for longer periods of time(2005a).

Internal electrosurgical burns may also occur in non-target tissue during laparoscopic surgery. This is the adverse event that carries the highest clinical risk associated with monopolar electrosurgery. A thermal burn involving the bowel may lead to bowel perforation with the leakage of intestinal contents into the peritoneal cavity and peritonitis. Bowel injury and the sequelae account for many of the fatalities associated with laparoscopic procedures. Additional complications include organ damage and vessel haemorrhage. Note that there is no evidence that the Mega Soft Patient Return Electrode reduces the risk of internal electrosurgical burns.

In current NHS clinical practice, a patient return electrode is attached directly to the patient's skin using an adhesive pad. This may require the shaving of skin and can cause skin irritation that may persist(1995), including during post-operative recovery. Other possible skin problems include hypersensitivity and the denuding of dermis at the time of pad removal.

If the clinical pathway of care described in response to question 3.3 is not consistent with the relevant NICE clinical guideline, this should be explained in response to question 3.4.

3.5 Describe the new pathway of care incorporating the new technology that would exist if the technology was adopted by the NHS in England.

Care pathways would be largely unchanged, except that monopolar electrosurgery would not result in skin burns, thus avoiding the need for subsequent surgery to treat burns from the comparator technology, the "sticky pads". The new technology would allow use for people who already have frail skin burns or extensive injuries such as burns (2000).

3.6 Describe any changes to the way current services are organised or delivered as a result of introducing the technology.

No major changes, however, time in operating theatre would be reduced given that preparation of skin for sticky pads, application of pads, and disposal of pads would no longer be required.

3.7 Describe any additional tests or investigations needed for selecting or monitoring patients, or particular administration requirements, associated with using this technology that are over and above usual clinical practice.

None.

3.8 Describe any additional facilities, technologies or infrastructure that need to be used alongside the technology under evaluation for the claimed benefits to be realised.

None.

3.9 Describe any tests, investigations, interventions, facilities or technologies that would no longer be needed with using this technology.

Pressure pads to support patients would no longer be required. Treatment for skin burns which occur with the comparator technology, the “sticky pads”, would no longer be required. Preparation of skin for sticky pads, application of sticky pads, and disposal of sticky pads would no longer be required.

3.10 Describe how the NHS in England can disinvest from tests, investigations, interventions, facilities or technologies described in section 3.9 that would no longer be needed with using this technology.

Disinvestment would be realised for each of the reasons in 3.9.

4 Regulatory information

4.1 Provide PDF copies of the following documents:

- instructions for use
- CE mark certificate or equivalent UK regulatory approval such as EC declaration of conformity
- quality systems (ISO 13485) certificate (if required).

PDF copies of these documents should be submitted at the same time as section A.

4.2 Does the technology have CE mark for the indication(s) specified in the scope issued by NICE? If so, give the date that authorisation was received. If not, state current UK regulatory status, with relevant dates (for example, date of application and/or expected approval dates).

The Mega Soft Patient Return Electrode received a CE mark in April 2003 with indications to reduce the risk of burns and to provide pressure relief during monopolar electrosurgery.

4.3 Does the technology have regulatory approval outside the UK? If so, please provide details.

The technology has approval from the FDA in the USA: 510(k) Number K080741.

4.4 If the technology has not been launched in the UK provide the anticipated date of availability in the UK.

Technology has been launched in UK

4.5 If the technology has been launched in the UK provide information on the use in England.

Hospitals currently using the Mega Soft in the UK include;

Royal London (since 2003)
St Bartholomew's (since 2003)
London Chest (since 2003)
Great Ormond Street
St Thomas'
Guy's
Evelina Children’s
The Heart Hospital
Royal Free
The Cromwell
Princess Grace
The Cadogan Clinic
BMI Fitzroy
Birmingham Children’s
Heartlands
Good Hope

Solihull
Royal Sussex
James Cook University
Spire Manchester
Spire Southampton
Frenchay

5 Ongoing studies

5.1 Provide details of all completed and ongoing studies on the technology from which additional evidence relevant to the decision problem is likely to be available in the next 12 months.

No relevant studies.

This should include unpublished and ongoing studies, and studies awaiting publication. Also include post-marketing surveillance and register data.

5.2 If the technology is, or is planned to be, subject to any other form of assessment in the UK, please give details of the assessment, organisation and expected timescale.

No other relevant assessments.

6 Equality

NICE is committed to promoting equality of opportunity and eliminating unlawful discrimination on the grounds of age, disability, gender reassignment, race, religion or belief, sex, and sexual orientation, and to comply fully with legal obligations on equality and human rights.

Equality issues require special attention because of NICE's duties to have due regard to the need to eliminate unlawful discrimination, promote equality and foster good relations between people with a characteristic protected by the equalities legislation and others.

Any issues relating to equality that are relevant to the technology under assessment should be described. This section should identify issues described in the scope and also any equality issues not captured in the final scope.

Further details on equality may be found in section 11.3 of this document.

6.1.1 Describe any equality issues relating to the patient population and condition for which the technology is being used.

Cultural sensitivities exist surrounding the shaving of body hair; this may be an issue when using 'sticky pad' electrodes but is potentially avoidable through the use of the Mega Soft pad.

6.1.2 Describe any equality issues relating to the assessment of the technology that may require special attention.

See previous question.

6.1.3 How will the submission address these issues and any equality issues raised in the scope?

Equality would be achieved using the Mega Soft pad because shaving of body hair is potentially avoidable.

Section B – Clinical evidence

7 Published and unpublished clinical evidence

Section B requires sponsors to present published and unpublished clinical evidence for their technology.

Sponsors should read section 6 of the Medical Technologies Evaluation Programme methods guide on published and unpublished evidence, available from www.nice.org.uk/mt

All statements should be evidence-based and directly relevant to the scope. Reasons for deviating from the scope should be clearly stated and explained in table A1.

Sponsors are required to submit section B in advance of the full submission (for details on timelines, see the NICE document 'Guide to the Medical Technologies Evaluation Programme process', available from www.nice.org.uk/mt

7.1 Identification of studies

Please note: sections 7.1 and 7.2 of the submission are divided into published and unpublished data. Responses must be split accordingly.

The sponsor's review of the clinical evidence should be systematic and transparent, and a suitable instrument for reporting such as the PRISMA statement (http://www.prisma-statement.org/statement.htm) should be used and CRD should be referred to (www.york.ac.uk/inst/crd).

The strategies used to retrieve relevant clinical data from the published literature and unpublished sources should be clearly described. The methods used should be justified with reference to the scope. Sufficient detail should be provided to enable the methods to be reproduced (the External Assessment Centre must be able to reproduce the search), and the rationale for any inclusion and exclusion criteria regarding search terms should be given.

Published studies

7.1.1 Describe the strategies used to retrieve relevant clinical data from the published literature. Exact details of the search strategy used should be provided in section 10, appendix 1.

The purpose of the search was to locate published and unpublished literature on the clinical effectiveness and cost effectiveness of the Mega Soft Patient Return Electrode. The search was systematic and has been recorded to PRISMA standards to be reproducible (Liberati et al., 2009).

The following literature searching strategies have been used to identify published literature:

- Database searching;
- Trials Register searching;
- Grey Literature Searching;
- Conference Abstracts and Proceedings searching;
- Web Searching;
- Forwards Citation Chasing;
- Backwards Citation Chasing;
- Contact with Megadyne; and

A search strategy (syntax) was developed and extensively tested in scoping for the database searching prior to the searching being conducted.

The final strategy used the PICO (Population, Intervention, Comparator(s) and Outcome(s)) structure of the scope as issued by NICE. However, given the anticipated volume of relevant literature, and to improve overall search sensitivity, the search strategy did not reference all aspects of the PICO structure.

The search has not been limited by language (Moher et al., 2000), date or by geographical region (i.e. to OECD countries only) for sensitivity of retrieval. The search has been limited to human only populations (using the Cochrane limit) as per the population identified by NICE for this assessment.

Database Search Structure

Population

The population has not been specified at the search stage. This allows for a more sensitive search, offering literature that is not limited by a pre-specified population. It allows for the potential to retrieve literature where the intervention is not being used by the population per se, but is being evaluated in its own right, such as in technological trials.

Intervention

The intervention has been specified not only by the various names of the product (e.g. current (mega soft patient return electrode) and past (Mega 2000)) but also by the manufacturer name.

The search strategy also included a cross-check line, using the term 'return electrode*'. This increases the volume to screen, and makes the search less specific to the named intervention and producer, but it increases the sensitivity of the search to draw in any literature where the intervention has been misspelled or has been inconsistently referenced under an unforeseen name. The sensitivity of this search line also helps provide any background literature.

Comparator(s)

This element of the PICO structure has not been used at the search stage. Any alternate intervention, which is being compared to the intervention in question, is drawn in to the search by the intervention cluster.

Outcome(s)

No outcome terms are used on this search. Outcome terms limit the sensitivity of the search to outcomes we anticipate *a priori*. This decreases the specificity of the search but, at the same time, improves the sensitivity.

In addition, methodological clusters have not been used. To retain the sensitivity of the search, we have not, for example, limited the search to randomised (randomized) control trials (for the clinical effectiveness section). This allows for a broad retrieval of various methodology and study types (controlled trials, observational studies, qualitative studies etc) which improves the quality of the submission overall.

Additional Search Notes

Additional search strategies have also been employed. Citation chasing, for example, has been shown to improve the yield of includable studies and confirms the theoretical saturation of the search (Papaioannou et al., 2010).

Search Recording

The exported files from the searching were uploaded and de-duplicated in Endnote X4 (Thompson Reuters). Where an export was not possible, for example from a resource without RIS functionality, the data was exported to a MS Word file. A full description of the search is given in Section 10, Appendix 1.

All published data relevant to the decision problem must be included. A PDF version of all published studies included in the submission must be provided by the sponsor.

Unpublished studies

7.1.2 Describe the strategies used to retrieve relevant clinical data from unpublished sources.

The following literature searching strategies have been used to identify unpublished, grey, or difficult-to-locate, literature:

- Database searching of noted Grey Literature Resources (e.g. HMIC);
- Trials Register searching to identify trials which are in early stages;
- Grey Literature Searching;
- Conference Abstracts and Proceedings searching;
- Searching of Library Catalogues for unpublished reports;

- Web Searching;
- Forwards Citation Chasing of published articles to identify includable, unpublished literature;
- Backwards Citation Chasing to identify includable, unpublished literature;
- Contact with Megadyne for any trials, unpublished studies, unpublished reports and any supporting material.

A full description of these searches is given in Section 10, Appendix 1.

The submission of unpublished evidence relevant to the decision problem is encouraged.

7.2 Study selection

Published studies

7.2.1 Complete table B1 to describe the inclusion and exclusion criteria used to select studies from the published literature. Suggested headings are listed in the table below. Other headings should be used if necessary.

Table B2 Selection criteria used for published studies

Inclusion criteria	
Population	Not specified to maximise sensitivity
Interventions	Specified only by the various names of the product (e.g. current (mega soft patient return electrode) and past (Mega 2000)) but also by the manufacturer name.
Outcomes	Not specified to maximise sensitivity
Study design	Not specified to maximise sensitivity
Language restrictions	None
Search dates	16th October 2011
Exclusion criteria	
Population	Not specified to maximise sensitivity
Interventions	Specified only by the various names of the product (e.g. current (mega soft patient return electrode) and past (Mega 2000)) but also by the manufacturer name.
Outcomes	Not specified to maximise sensitivity
Study design	Not specified to maximise sensitivity
Language restrictions	None
Search dates	16th October 2011

7.2.2 Report the numbers of published studies included and excluded at each stage in an appropriate format.

136 titles and abstracts were screened, of which two published studies were included.

It is recommended that the number of published studies included and excluded at each stage is reported using the PRISMA statement flow diagram (available from *www.prisma-statement.org/statement.htm*)

Unpublished studies

7.2.3 Complete table B2 to describe the inclusion and exclusion criteria used to select studies from the unpublished literature. Suggested headings are listed in the table below. Other headings should be used if necessary.

Table B2 Selection criteria used for unpublished studies

Inclusion criteria	
Population	Not specified to maximise sensitivity
Interventions	Specified only by the various names of the product, e.g. “Mega Soft”, “MegaSoft, "mega 2000".
Outcomes	Not specified to maximise sensitivity
Study design	Not specified to maximise sensitivity
Language restrictions	None.
Search dates	17th October 2011
Exclusion criteria	
Population	Not specified to maximise sensitivity
Interventions	Specified only by the various names of the product, e.g. “Mega Soft”, “MegaSoft, "mega 2000".
Outcomes	Not specified to maximise sensitivity
Study design	Not specified to maximise sensitivity
Language restrictions	None.
Search dates	17th October 2011

7.2.4 Report the numbers of unpublished studies included and excluded at each stage in an appropriate format.

Four unpublished studies were included**.**

It is recommended that the number of unpublished studies included and excluded at each stage is reported using the PRISMA statement flow diagram (available from *www.prisma-statement.org/statement.htm*)

7.3 Complete list of relevant studies

The sponsor should provide a PDF copy of all studies included in the submission. For unpublished studies for which a manuscript is not available, provide a structured abstract about future journal publication. If a structured abstract is not available, the sponsor must provide a statement from the authors to verify the data provided.

7.3.1 Provide details of all published and unpublished studies identified using the selection criteria described in tables B1 and B2.

The details of all published and unpublished studies that compare the technology with other treatments for the relevant group of patients should be presented using tables B3 and B4 respectively. The studies that compare the intervention directly with the appropriate comparator(s) referred to in the decision problem should be clearly highlighted. If there are none, please state this. All types of studies should be considered, including observational studies such as cohort, case series and case-control studies, and single case reports and qualitative studies when relevant to the scope.

The list of relevant studies must be complete and will be validated by independent searches conducted by the External Assessment Centre.

Published studies should be referenced by first author name and year of publication. Unpublished studies should be referenced by first author and date of report. Full details of each reference should be provided in the reference list after section 9. In addition, list any trial short names if useful.

Table B3 List of relevant published studies

Primary study reference	Study name (acronym)	Population	Intervention	Comparator
ECRI (2000)(2000)	n/a	Meat on metal tray	Mega 2000 Patient Return Electrode (forerunner to the Mega Soft pad)	None
Sheridan, Wilson et al. (2003)(Sheridan et al., 2003)	n/a	25 operations on 17 children with large burns and limited availability of traditional contact sites	Mega 2000 Patient Return Electrode (forerunner to the Mega Soft pad)	None

Table B4 List of relevant unpublished studies

Data source	Study name (acronym)	Population	Intervention	Comparator
Megadyne (2011)(Megadyne, 2011a)	n/a	Porcine model	Mega Soft pad	Split sticky pad
Kaleida Health hospital, USA(Megadyne, 2011c)	n/a	Patients at Kaleida Health hospital, USA	Mega Soft pad	Sticky pads
Christus St Joseph's Hospital, USA(Megadyne, 2011b)	n/a	Patients at Christus St Joseph's Hospital, USA	Mega Soft pad	None
Mega Soft Evaluation reports	n/a	Various types of surgery on patients	Mega Soft pad	None

7.3.2 State the rationale behind excluding any of the published studies listed in tables B3 and B4.

The rationale for study exclusion must be provided by the sponsor for transparency. For example, if studies have been identified but there is no access to the level of study data needed, this should be indicated.

Of the 136 papers resulting from the search, only the two included papers reported on clinical studies of the Mega Soft Pad or Mega 2000.

7.4 Summary of methodology of relevant studies

It is expected that all key aspects of the methodology will be in the public domain. If a sponsor wishes to submit aspects of the methodology in confidence, section 11.2 describes how to highlight confidential information.

7.4.1 Describe the study design and methodology for each of the published and unpublished studies using tables B5 and B6 as appropriate. A separate table should be completed for each study.

There are no relevant randomised controlled trials.

Table B5 Summary of methodology for randomised controlled trials

Study name
Objectives
Location
Design
Duration of study
Sample size
Inclusion criteria
Exclusion criteria
Method of randomisation
Method of blinding
Intervention(s) (n =) and comparator(s) (n =)
Baseline differences
Duration of follow-up, lost to follow-up information
Statistical tests
Primary outcomes (including scoring methods and timings of assessments)
Secondary outcomes (including scoring methods and timings of assessments)

Table B6 Summary of methodology for observational studies

Study name	**Megadyne (2011)** (Megadyne, 2011a)
Objective	Investigate the relative safety, in terms of incidence of skin burns, of the Mega Soft pad versus the split sticky pad.
Location	Unknown
Design	For the sticky pad, the electrosurgical generator was set at 50 watts coagulation for 3 minutes. For the Mega Soft pad, much more extreme conditions were applied (300W cut 17 mins, 120W coag 10 mins, activation time 27 mins total in 3 min cycles with 1 min off time).
Duration of study	Unknown
Patient population	Porcine model
Sample size	Not clear, but appears to be a single porcine model

Inclusion criteria	Not clear, but appears to be a single porcine model
Exclusion criteria	Not clear, but appears to be a single porcine model
Intervention(s) (n =) and comparator(s) (n =)	Not clear, but appears to be a single porcine model
Baseline differences	n/a
How were participants followed-up (for example, through pro-active follow-up or passively). Duration of follow-up, participants lost to follow-up	n/a
Statistical tests	None
Primary outcomes (including scoring methods and timings of assessments)	Occurrence of skin burns
Secondary outcomes (including scoring methods and timings of assessments)	None

Study name	**Kaleida Health hospital** (Megadyne, 2011c)
Objective	Mega 2000 pads were used in two of Kaleida Health hospital critical care hospitals to see how they would perform for patient comfort and cost savings.
Location	Buffalo, NY, USA
Design	Observational
Duration of study	2 years
Patient population	Patients at the hospitals.
Sample size	Unknown
Inclusion criteria	Unknown
Exclusion criteria	Unknown
Intervention(s) (n =) and comparator(s) (n =)	Unknown
Baseline differences	Unknown
How were participants followed-up (for example, through pro-active follow-up or passively). Duration of follow-up, participants lost to follow-up	During and immediately after surgery
Statistical tests	None

Primary outcomes (including scoring methods and timings of assessments)	Patient comfort and cost.
Secondary outcomes (including scoring methods and timings of assessments)	None

Study name	**Christus St Joseph's Hospital** (Megadyne, 2011b)
Objective	Mega Soft pads were used in Christus St Joseph's Hospital to see how they would perform for patient comfort and cost savings.
Location	Houston, Texas, USA
Design	Observational
Duration of study	Unknown
Patient population	Patients at the hospitals.
Sample size	Number of patients unknown, but Mega Soft used in 16 operating room suites.
Inclusion criteria	Unknown
Exclusion criteria	Unknown
Intervention(s) (n =) and comparator(s) (n =)	Unknown
Baseline differences	Unknown
How were participants followed-up (for example, through pro-active follow-up or passively). Duration of follow-up, participants lost to follow-up	During and immediately after surgery
Statistical tests	None
Primary outcomes (including scoring methods and timings of assessments)	Patient comfort and cost.
Secondary outcomes (including scoring methods and timings of assessments)	None

Study name	**Sheridan, Wilson et al. (2003)**(Sheridan et al., 2003)

Objective	Observe incidence of skin burns with Mega 2000 Patient Return Electrode (the forerunner to the Mega Soft pad)
Location	Massachusetts General Hospital and Harvard Medical School, Boston, Massachusetts, USA.
Design	Observational
Duration of study	Unknown
Patient population	Children with large burns and limited availability of traditional contact sites. This is relevant because grounding patients with large burns to facilitate the use of electrosurgery is often difficult because of the lack of grounding sites.
Sample size	25 operations on 17 children
Inclusion criteria	Children with large burns and limited availability of traditional contact sites
Exclusion criteria	Unknown
Intervention(s) (n =) and comparator(s) (n =)	25 operations on 17 children all using Mega 2000 system.
Baseline differences	n/a
How were participants followed-up (for example, through pro-active follow-up or passively). Duration of follow-up, participants lost to follow-up	Unknown
Statistical tests	None
Primary outcomes (including scoring methods and timings of assessments)	Occurrence of skin burns.
Secondary outcomes (including scoring methods and timings of assessments)	None

Study name	**ECRI (2000)**(2000)
Objective	Investigate the effect of Mega 2000 on performance of electrosurgical unit (ESU), Investigate the safety in terms of incidence of burns, Investigate the current flow through alternate paths, Investigate the ease of use of device, Investigate the quality of construction
Location	Unknown
Design	Performance measured by applying the Mega 2000 to meat on metal tray and operate a variety of generators

	and inspection for burns. Safety measured on adult volunteer. To test safety of Mega 2000 when punctured, holes were put in the device and meat was placed on punctured area. To test alternate current pathways, connected Mega 2000 to adult volunteer. Tested the ease to which the Mega 2000 could be applied to patient, and ease of cleaning.
Duration of study	Unknown
Patient population	See Design above.
Sample size	Appears to be sample of 1 for each test.
Inclusion criteria	Unknown
Exclusion criteria	Unknown
Intervention(s) (n =) and comparator(s) (n =)	Unknown
Baseline differences	n/a
How were participants followed-up (for example, through pro-active follow-up or passively). Duration of follow-up, participants lost to follow-up	Unknown
Statistical tests	None
Primary outcomes (including scoring methods and timings of assessments)	See Design above.
Secondary outcomes (including scoring methods and timings of assessments)	See Design above.

Study name	**Mega Soft Evaluation reports**
Objective	Measure the ease of use and degree of skin irritation of Mega Soft
Location	3 locations: Guy's Hospital, London, Evelina Children's Hospital, St Thomas' Hospital, London and Great Ormond St Hospital, London.
Design	Theatre nurse completed a survey after each operation using the Mega Soft pad. Patients were in a range of surgical positions (mostly supine), and a range of generators were used.
Duration of study	2 weeks, October 2011
Patient population	A range of operations, e.g. nephrectomy, mastectomy, head & neck, hip replacement, ankle surgery, foot

	surgery on adult patients at Guy's Hospital, London. A range of operations on children, e.g. cochlear implants, ENT, nephrectomy at Evelina Children's Hospital, St Thomas' Hospital, London and at Great Ormond St Hospital, London.
Sample size	25 operations at Guy's Hospital, 18 operations at St Thomas' Hospital, and 12 operations at Great Ormond St Hospital.
Inclusion criteria	Unknown
Exclusion criteria	Unknown
Intervention(s) (n =) and comparator(s) (n =)	Number of Mega Soft devices unknown.
Baseline differences	n/a
How were participants followed-up (for example, through pro-active follow-up or passively). Duration of follow-up, participants lost to follow-up	During and Immediately after surgery.
Statistical tests	None
Primary outcomes (including scoring methods and timings of assessments)	Ease of setting up system, Ease of cord attachment, Ease of positioning, Degree of skin irritation, Power settings, Overall rating.
Secondary outcomes (including scoring methods and timings of assessments)	See above.

7.4.2 Provide details on data from any single study that have been drawn from more than one source (for example a poster and unpublished report) and/or when trials are linked this should be made clear (for example, an open-label extension to randomised controlled trial).

None.

7.4.3 Highlight any differences between patient populations and methodology in all included studies.

The patient populations vary greatly between studies, from porcine model (Megadyne **(**2011) (Megadyne, 2011a)) and meat model (e.g. ECRI (2000)(2000) for performance criterion) to human populations (Kaleida Health hospital (Megadyne, 2011c), Christus St Joseph's Hospital (Megadyne, 2011b), Sheridan, Wilson et al. (2003)(Sheridan et al., 2003), Mega Soft Evaluation reports).

Some studies were experimental, e.g. Megadyne **(**2011) (Megadyne, 2011a), Sheridan, Wilson et al. (2003)(Sheridan et al., 2003), ECRI (2000)(2000), whereas other were observational, e.g. Kaleida Health hospital (Megadyne, 2011c), Christus St Joseph's Hospital (Megadyne, 2011b), Mega Soft Evaluation reports.

Differences between study groups to consider include, but are not limited to, baseline patient characteristics, delivery of intervention and care setting.

7.4.4 Provide details of any subgroup analyses that were undertaken in the studies included in section 7.4.1. Specify the rationale and state whether these analyses were pre-planned or post-hoc.

Amongst the studies on human patients, Sheridan, Wilson et al. (2003)(Sheridan et al., 2003) considered only children with large burns and limited availability of traditional contact sites. The Mega Soft Evaluation reports considered adults and children separately. The range of subgroups in the Kaleida Health hospital (Megadyne, 2011c) and Christus St Joseph's Hospital (Megadyne, 2011b) studies is not clear.

7.4.5 If applicable, provide details of the numbers of patients who were eligible to enter the study(s), randomised, and allocated to each treatment in an appropriate format.

n/a.

It is recommended that details of the numbers of patients that were eligible to enter the study(s), randomised and allocated to each treatment are presented as CONSORT flow charts if possible (see www.consort-statement.org/consort-statement/).

7.4.6 If applicable provide details of and the rationale for, patients that were lost to follow-up or withdrew from the studies.

Unknown.

7.5 Critical appraisal of relevant studies

The validity of the results of an individual study will depend on the robustness of its overall design and execution, and its relevance to the scope. Each study that meets the criteria for inclusion should therefore be critically appraised. Whenever possible, the criteria for assessing published studies should also be used to assess the validity of unpublished and part-published studies.

For the quality assessments use an appropriate and validated quality assessment instrument. Key aspects of quality to be considered can be found in 'Systematic reviews: CRD's guidance for undertaking reviews in health care' (www.york.ac.uk/inst/crd).

The critical appraisal will be validated by the External Assessment Centre.

7.5.1 Complete a separate quality assessment table for each study. A suggested format for the quality assessment results is shown in tables B7 and B8.

There are no relevant randomised controlled trials.

Table B7 Critical appraisal of randomised control trials

Study name		
Study question	**Response (yes/no/not clear/N/A)**	**How is the question addressed in the study?**
Was randomisation carried out appropriately?		
Was the concealment of treatment allocation adequate?		
Were the groups similar at the outset of the study in terms of prognostic factors, for example, severity of disease?		
Were the care providers, participants and outcome assessors blind to treatment allocation? If any of these people were not blinded, what might be the likely impact on the risk of bias (for each outcome)?		
Were there any unexpected imbalances in drop-outs between groups? If so, were they explained or adjusted for?		
Is there any evidence to suggest that the authors measured more outcomes than they reported?		
Did the analysis include an intention-to-treat analysis? If so, was this appropriate and were appropriate methods used to account for missing		

data?		
Adapted from Centre for Reviews and Dissemination (2008) Systematic reviews. CRD's guidance for undertaking reviews in health care. York: Centre for Reviews and Dissemination		

Table B8 Critical appraisal of observational studies

Study name Kaleida Health hospital (Megadyne, 2011c)		
Study question	**Response yes/no/not clear/N/A)**	**How is the question addressed in the study?**
Was the cohort recruited in an acceptable way?	Yes	Patients at Kaleida Health hospital.
Was the exposure accurately measured to minimise bias?	n/a	
Was the outcome accurately measured to minimise bias?	No	No formal assessment of outcome.
Have the authors identified all important confounding factors?	n/a	
Have the authors taken account of the confounding factors in the design and/or analysis?	No	
Was the follow-up of patients complete?	Unknown	
How precise (for example, in terms of confidence interval and p values) are the results?	n/a	
Adapted from Critical Appraisal Skills Programme (CASP): Making sense of evidence 12 questions to help you make sense of a cohort study		

Study name Christus St Joseph's Hospital (Megadyne, 2011b)		
Study question	**Response yes/no/not clear/N/A)**	**How is the question addressed in the study?**
Was the cohort	Yes	Patients at Christus St Joseph's Hospital.

recruited in an acceptable way?		
Was the exposure accurately measured to minimise bias?	n/a	
Was the outcome accurately measured to minimise bias?	No	No formal assessment of outcome.
Have the authors identified all important confounding factors?	n/a	
Have the authors taken account of the confounding factors in the design and/or analysis?	No	
Was the follow-up of patients complete?	Unknown	
How precise (for example, in terms of confidence interval and p values) are the results?	n/a	
Adapted from Critical Appraisal Skills Programme (CASP): Making sense of evidence 12 questions to help you make sense of a cohort study		

Study name Sheridan, Wilson et al. (2003)(Sheridan et al., 2003)		
Study question	**Response yes/no/not clear/N/A)**	**How is the question addressed in the study?**
Was the cohort recruited in an acceptable way?	Unknown	
Was the exposure accurately measured to minimise bias?	n/a	
Was the outcome accurately measured to minimise bias?	Unknown	
Have the authors identified all important confounding	n/a	

factors?		
Have the authors taken account of the confounding factors in the design and/or analysis?	No.	
Was the follow-up of patients complete?	Unknown	
How precise (for example, in terms of confidence interval and p values) are the results?	n/a	
Adapted from Critical Appraisal Skills Programme (CASP): Making sense of evidence 12 questions to help you make sense of a cohort study		

Study name Mega Soft Evaluation Reports		
Study question	**Response yes/no/not clear/N/A)**	**How is the question addressed in the study?**
Was the cohort recruited in an acceptable way?	Unknown.	
Was the exposure accurately measured to minimise bias?	n/a	
Was the outcome accurately measured to minimise bias?	Yes, measured by scoring system.	
Have the authors identified all important confounding factors?	n/a	
Have the authors taken account of the confounding factors in the design and/or analysis?	n/a	
Was the follow-up of patients complete?	n/a	
How precise (for example, in terms of confidence interval and p values) are the results?	Single deterministic score for each criterion.	

The Megadyne **(**2011) (Megadyne, 2011a) study concerned a single porcine model and therefore none of the questions in Table B8 are relevant. Similarly, the ECRI (2000)(2000) study concerned either a single meat model or adult model and therefore none of the questions in Table B8 are relevant.

7.6 Results of the relevant studies

All outcomes pertinent to the scope and the measures used to assess those outcomes should be presented.

7.6.1 Complete a results table for each study with all relevant outcome measures pertinent to the decision problem. A suggested format is given in table B9.

A separate table for each study must be completed. State N/A or unknown if appropriate. Any outcomes not tested statistically can be included in the comments section.

For each outcome for each included study, provide the following information:

- *The primary hypothesis under consideration and the statistical analysis used for testing hypotheses. Provide details of the power of the study and a description of sample size calculation, including rationale and assumptions.*
- *The outcome name and unit of measurement. Indicate the outcomes that were specified in the study protocol as primary or secondary, and whether they are relevant with reference to the decision problem.*
- *The size of the effect. For dichotomous outcomes, the results ideally should be expressed as both relative risks (or odds ratios) and risk (or rate) differences. For time-to-event analysis, the hazard ratio is an equivalent statistic. Both absolute and relative measures should be presented.*
- *A 95% confidence interval.*

- *The number of participants in each group included in each analysis and whether the analysis was by 'intention to treat'. State the results in absolute numbers if feasible.*
- *Details of how the analysis took account of patients who withdrew and if patients were excluded from the analysis, give the rationale for this.*
- *Data from pre-specified outcomes rather than post-hoc analysis. If appropriate, provide evidence of reliability or validity, and current status of the measure (such as use in current clinical practice).*
- *Clear statements of when interim study data are quoted, along with the point at which data were taken and the time remaining until completion of that study. Analytical adjustments should be described to cater for the interim nature of the data.*
- *Other relevant data that may assist in interpretation of the results, such as adherence to medication and/or study protocol.*
- *Discussion and justification of definitions of any clinically important differences.*
- *Reports of any other analyses performed, including subgroup analysis and adjusted analyses, indicating whether they are pre-specified or exploratory.*
- *Graphs or figures to supplement text and tabulated data if available.*

Table B9 Outcomes from published and unpublished studies

Study name		**Megadyne (2011)** (Megadyne, 2011a)
Size of study groups	**Treatment**	Appears that both Mega Soft pad and split sticky pad applied to same porcine model
	Control	
Study duration	**Time unit**	Unknown
Type of analysis	**Intention-to-treat/per protocol**	n/a
Outcome	**Name**	Occurrence of skin burns
	Unit	
Effect size	**Value**	The IEC 60601-2-2 and ANSI/AAMI HF18 standards for electrosurgery allow a maximum temperature increase of 6° C in order to minimize the risk of pad site burns under limited test conditions. However, the split style sticky pad applied to the porcine model which satisfies the CQM alarm parameters produces heating under the pad of 9.7 º C, exceeding the 6º C temperature range, and there was a pad site burn. Conversely, thermal analysis of all testing performed with the Mega Soft pad revealed no pad site burns under any test conditions. The largest skin surface temperature rise measured was 1.2° C, under much more extreme conditions than those that produced the pad site burn (300W cut 17 mins, 120W coag 10 mins, activation time 27 mins total in 3 min cycles with 1 min off time). The testing also demonstrates that no pad site burns occur when either the Paediatric or Adult Mega Soft pad was used.
	95% CI	n/a
Statistical test	**Type**	None
	p value	n/a
Other outcome	**Name**	None
	Unit	n/a
Effect size	**Value**	None
	95% CI	n/a
Statistical test	**Type**	None
	p value	n/a
Comments		

Study name		**Kaleida Health hospital** (Megadyne, 2011c)
Size of study groups	**Treatment**	Unknown
	Control	None
Study duration	**Time unit**	2 years
Type of analysis	**Intention-to-treat/per protocol**	n/a
Outcome	**Name**	Patient comfort
	Unit	Qualitative.
Effect size	**Value**	"Nothing comes close to this product," said Patricia Wopperer RN, MS, CNOR, RNFA, Kaleida Health's director of value analysis, describing the time savings, the reduced cost and enhanced patient experience the MEGADYNE® MEGA Soft Patient Return Electrode delivers to Kaleida Health. "We were very pleased with the original MEGA 2000 technology for the comfort it consistently delivered to our patients. So when MEGADYNE introduced the MEGA Soft, which incorporates the pressure reduction pad, we saw it as a great opportunity to reinforce our commitment to patient comfort and immediately transitioned to the new product" "Our surgical teams consistently report that skin redness or "pressure points" that often occurred in surgeries prior to using the MEGA Soft have virtually disappeared. We don't see the number of incident reports we did in the past using the sticky pads," said Wopperer. "In addition, the surgical teams have commented that patients are saying that the MEGA Soft makes them very comfortable. A more comfortable operating table combined with the reduction of pressure points can help patients to recover faster following their procedures."
	95% CI	n/a
Statistical test	**Type**	n/a
	p value	n/a
Other outcome	**Name**	n/a
	Unit	n/a
Effect size	**Value**	n/a
	95% CI	n/a
Statistical test	**Type**	n/a
	p value	n/a
Comments		

Study name		**Christus St Joseph's Hospital** (Megadyne, 2011b)
Size of study groups	**Treatment**	Unknown
	Control	None
Study duration	**Time unit**	Unknown
Type of analysis	**Intention-to-treat/per protocol**	n/a
Outcome	**Name**	Patient comfort
	Unit	Qualitative
Effect size	**Value**	"CHRISTUS St. Joseph's Hospital uses the Mega Soft™ because it is the best thing for the patient," states Etta Hodge, administrative director of surgical services.
	95% CI	n/a
Statistical test	**Type**	n/a
	p value	n/a
Other outcome	**Name**	n/a
	Unit	n/a
Effect size	**Value**	n/a
	95% CI	n/a
Statistical test	**Type**	n/a
	p value	n/a
Comments		

Study name		**Sheridan, Wilson et al. (2003)**(Sheridan et al., 2003)
Size of study groups	**Treatment**	25 operations on 17 children
	Control	None
Study duration	**Time unit**	Unknown
Type of analysis	**Intention-to-treat/per protocol**	n/a
Outcome	**Name**	Occurrence of skin burns
	Unit	Proportion with burns.
Effect size	**Value**	No skins burns were observed.
	95% CI	n/a
Statistical test	**Type**	n/a
	p value	n/a
Other outcome	**Name**	n/a
	Unit	n/a
Effect size	**Value**	n/a
	95% CI	n/a
Statistical test	**Type**	n/a
	p value	n/a
Comments		

Study name		**ECRI (2000)**(2000)
Size of study groups	**Treatment**	Appears to be sample of 1 for each test.
	Control	Appears to be sample of 1 for each test.
Study duration	**Time unit**	Unknown
Type of analysis	**Intention-to-treat/per protocol**	n/a
Outcome	**Name**	Performance measured by applying the Mega 2000 to meat on metal tray and operate a variety of generators and inspection for burns. Safety measured on adult volunteer. To test safety of Mega 2000 when punctured, holes were put in the device and meat was placed on punctured area. To test alternate current pathways, connected Mega 2000 to adult volunteer. Tested the ease to which the Mega 2000 could be applied to patient, and ease of cleaning.
	Unit	
Effect size	**Value**	Overall, ECRI rated the Mega 2000 “Acceptable (with Conditions)”. They found it generally safe and effective, and can make ESU (electrosurgical unit) use much easier on patients with damaged or frail skin. But ECRI considered the Mega 2000 acceptable only if it is not used with ERBE ESUs in the High Cut or Endo Cut mode, or with gel pads or other thick pads. However, although the Mega Soft pad, the successor to the Mega 2000, is still contraindicated in the High Cut or Endo Cut modes with ERBE generators, these modes are used in less than 0.1% of operations. Also, thick gel pads need not be used with the Mega Soft pad, as this is itself a pressure relieving device. ECRI rated the performance of the Mega 2000 “good”. ECRI rated the safety of the Mega 2000 good overall, with one exception: When a 1.3 cm (0.50 in) gel body cushion was placed between the patient and the Mega 2000 during the Alternate Current Pathway test, current through an alternate pathway rose by 33% — from 115 mA to 153 mA — thus increasing the likelihood of alternate-site burns. However, this does not apply to the Mega Soft pad, the successor to the Mega 2000, because being a pressure-relieving device itself, the Mega Soft pad does not require the use of a separate

		cushion under the patient. ECRI rated the product good for all tests concerning ease of use. Unlike conductive electrodes, the Mega 2000 does not require preparation of the patient before use. In addition, the Mega 2000 can be used with patients who have frail skin or extensive injuries (such as burns) that would make the use of adhesive electrodes difficult or impossible.
	95% CI	
Statistical test	**Type**	n/a
	p value	n/a
Other outcome	**Name**	n/a
	Unit	n/a
Effect size	**Value**	n/a
	95% CI	n/a
Statistical test	**Type**	n/a
	p value	n/a
Comments		

Study name		**Mega Soft Evaluation reports**
Size of study groups	**Treatment**	25 operations at Guy's Hospital, London, 18 operations at St Thomas' Hospital, London, and 12 operations at Great Ormond St Hospital, London.
	Control	None
Study duration	**Time unit**	2 weeks
Type of analysis	**Intention-to-treat/per protocol**	n/a
Outcome	**Name**	Ease of setting up system, Ease of cord attachment, Ease of positioning, Rating for skin irritation, Power settings, Overall rating.
	Unit	Scored from 1 = poor to 5 = excellent
Effect size	**Value**	**25 operations on adults at Guy's Hospital, London** Ease of setting up system mean score = 4.5, Ease of cord attachment mean score = 4.6, Ease of positioning mean score = 3.9, Rating for skin irritation mean score = 4.9, Power settings mean score = 4.8, Overall rating mean = 4.6 **18 operations on children at St Thomas' Hospital, London** Ease of setting up system mean score = 4.7, Ease of cord attachment mean score = 4.7, Ease of positioning mean score = 4.6, Rating for skin irritation mean score = 4.6, Power settings mean score = 4.6, Overall rating mean = 4.7. **12 operations on children at Great Ormond St Hospital, London** Ease of setting up system mean score = 4.7, Ease of cord attachment mean score = 4.8, Ease of positioning mean score = 4.8, Rating for skin irritation mean score = 4.8, Power settings mean score = 4.9, Overall rating mean = 4.9.

	95% CI	n/a
Statistical test	**Type**	n/a
	p value	n/a
Other outcome	**Name**	n/a
	Unit	n/a
Effect size	**Value**	n/a
	95% CI	n/a
Statistical test	**Type**	n/a
	p value	n/a
Comments		

7.6.2 Justify the inclusion of outcomes in table B9 from any analyses other than intention-to-treat.

n/a

7.7 Adverse events

In section 7.7 the sponsor is required to provide information on the adverse events experienced with the technology being evaluated in relation to the scope.

For example, post-marketing surveillance data may demonstrate that the technology shows a relative lack of adverse events commonly associated with the comparator.

7.7.1 Using the previous instructions in sections 7.1 to 7.6, provide details of the identification of studies on adverse events, study selection, study methodologies, critical apprasial and results.

For studies that have already been identified as relevant and appraised in sections 7.1 to 7.6 of the submission that were designed primarily to assess safety outcomes (for example, they are powered to detect significant differences between treatments with respect to the incidence of an adverse event), should be presented as a list of studies with the relevant study reference used in the submission.

Examples of search strategies for specific adverse effects and/or generic adverse-effect terms and key aspects of quality criteria for adverse-effects data can found in 'Systematic reviews: CRD's guidance for undertaking reviews in health care' (available from www.york.ac.uk/inst/crd).

Exact details of the search strategy used should be provided in section 10 appendix 2.

The sponsor's search strategy will be replicated by the External Assessment Centre.

The search for the incidence of adverse events was a subset of the search described in Section 7.1. The only adverse event for which study data was available was the incidence of skin burns. Please see Sections 7.1 to 7.6 for discussion of the incidence of skin burns.

7.7.2 Provide details of all important adverse events reported for each study. A suggested format is shown in table B10.

See 7.7.1.

When providing details of important adverse events reported for each study, for each group, give the number of people with the adverse event, the total number of people in the group and the percentage with the event. Present the

relative risk and risk difference and associated 95% confidence intervals for each adverse event.

Table B10 Adverse events across patient groups

	Time period 1			***Time period 2 etc.***		
	Intervention **% of patients (n = *x*)**	***Comparator*** **% of patients (n = *x*)**	**Relative risk (95% CI)**	***Intervention*** **% of patients (n = *x*)**	***Comparator*** **% of patients (n = *x*)**	**Relative risk (95% CI)**
Class 1 (for example, nervous system disorders)						
Adverse event 1						
Adverse event 2						
Class 2 (for example, vascular disorders)						
Adverse event 3						
Adverse event 4						

CI, confidence interval
Adapted from European Public Assessment Reports published by the European Medicines Agency

7.7.3 Describe all adverse events and outcomes associated with the technology in national regulatory databases such as those maintained by the MHRA and FDA (Maude).

None.

7.7.4 Provide a brief overview of the safety of the technology in relation to the scope.

There were no reports of adverse events, including skin burns, in any of the studies above, except by ECRI (2000)(2000) who rated the safety of the Mega 2000 good overall, with one exception: when a 1.3 cm (0.50 in) gel body cushion was placed between the patient and the Mega 2000 during the Alternate Current Pathway test, current through an alternate pathway rose by 33% — from 115 mA to 153 mA — thus increasing the likelihood of alternate-site burns. However, as stated in Table B9, this does not apply to the Mega Soft pad, the successor to the Mega 2000, because being a pressure-relieving device itself, the Mega Soft pad does not require the use of a separate cushion under the patient.

In addition, The Mega Soft family of patient return electrodes has been used since 1999, and no pad site burns have been recorded from 35,000,000 procedures worldwide(Megadyne, 2011a).

7.8 Evidence synthesis and meta-analysis

When more than one study is available and the methodology is comparable, a meta-analysis should be considered.

Section 7.8 should be read in conjunction with the 'Medical Technologies Evaluation Programme Methods Guide', available from www.nice.org.uk/mt

When direct comparative evidence about two key treatments is not available, indirect treatment comparison methods can be used to derive comparative estimates of the effectiveness of these two treatments. For example, if there is evidence comparing A with B, and B with C, indirect treatment comparison techniques could be used to help compare A with C. This option should be considered even though it may be less suitable for the evaluation of many new medical technologies, either because of lack of multiple comparators in the evidence base, or limitations in the evidence base/study designs.

7.8.1 Describe the technique used for evidence synthesis and/or meta-analysis. Include a rationale for the studies selected, details of the methodology used and the results of the analysis.

No quantitative evidence synthesis is performed.

Details should include the selection and quality assessment of the studies, the methodology used for combining the outcomes from the studies, including any tests for heterogeneity, and the results of the analysis including an assessment of the uncertainty associated with these results.

7.8.2 If evidence synthesis is not considered appropriate, give a rationale and provide a qualitative review. The review should summarise the

overall results of the individual studies with reference to their critical appraisal.

No quantitative evidence synthesis is performed due to the lack of high-quality studies with quantitative outcomes.

There were no reports of adverse events, including skin burns, in any of the studies above, except by ECRI (2000)(2000) who rated the safety of the Mega 2000 good overall, with one exception: When a 1.3 cm (0.50 in) gel body cushion was placed between the patient and the Mega 2000 during the Alternate Current Pathway test, current through an alternate pathway rose by 33% — from 115 mA to 153 mA — thus increasing the likelihood of alternate-site burns. However, as stated above, this does not apply to the Mega Soft pad, the successor to the Mega 2000.

In addition, the Mega Soft family of patient return electrodes has been used since 1999, and no pad site burns have been recorded from 35,000,000 procedures worldwide(Megadyne, 2011a).

The Mega Soft family were found to be comfortable for patients and easy to use by nursing staff in the studies by Kaleida Health hospital (Megadyne, 2011c) and in Guy's Hospital, St Thomas' Hospital, and Great Ormond St Hospital, London (Mega Soft Evaluation reports). In particular, the mean scores for ease of use and comfort were close to the maximum possible value using the paediatric and adult versions of the Mega Soft pad in the three London hospitals.

Of the 6 studies, only 2, Megadyne (2011) (Megadyne, 2011a) and Kaleida Health hospital (Megadyne, 2011c) considered either of the two comparator technologies in the Scope, the split sticky pad and the non-split sticky pad. The Megadyne (2011) (Megadyne, 2011a) study considered only the split sticky pad and it is not stated whether the Kaleida Health hospital (Megadyne, 2011c) study referred to the split sticky pad or the non-split sticky pad.

None of the studies distinguished between patients with high or low BMI.

7.9 Interpretation of clinical evidence

7.9.1 Provide a statement of principal findings from the clinical evidence highlighting the clinical benefit and any risks relating to adverse events from the technology.

There is no randomised controlled study of the clinical effectiveness of the Mega Soft pad. However, the Mega Soft family of patient return electrodes has been used since 1999, and no pad site burns have been recorded from 35,000,000 procedures worldwide(Megadyne, 2011a).

Clinical opinion strongly supports the use of the adult and paediatric versions of the Mega Soft pad, specifically concerning skin burns, comfort and ease of use, see Kaleida Health hospital, USA (Megadyne, 2011c), Christus St Joseph's Hospital, USA (Megadyne, 2011b), Mega Soft Evaluation reports from Guy's Hospital, St Thomas' Hospital, and Great Ormond St Hospital, London.

Specific benefits of the Mega Soft pad over sticky pads, include;

- Complete avoidance of skin burns.
- Avoidance of skin shaving for the device to be effective,
- A reduction in skin irritation due to the fact that the Mega Soft does not need to be attached directly to the patient's skin.
- It is particularly difficult to find a suitable site to apply the sticky pads to babies, the elderly and it can be almost impossible for patients with burns. Therefore, monopolar electrosurgery may be an option for these patients only when using the Mega Soft pad, as opposed to sticky pads.
- A reduction in the risk of pressure related injury due to immobility during surgery.

- A reduction in the need for further surgery for skin burns associated with burns from sticky pads.

7.9.2 Provide a summary of the strengths and limitations of the clinical-evidence base of the technology.

A major strength of the evidence base is that no pad site burns have been recorded from 35,000,000 procedures worldwide(Megadyne, 2011a).

A major weakness in the evidence base is the lack of a randomised trial for the use of the Mega Soft pad vs. sticky pad.

Weaknesses of the studies described in Tables B6 are either that the study was performed on porcine or meat models (Megadyne **(**2011) (Megadyne, 2011a), ECRI (2000)(2000)), or that the observational study was of small sample size (Sheridan, Wilson et al. (2003)(Sheridan et al., 2003), Mega Soft Evaluation reports), or that the outcomes were not quantified (Kaleida Health hospital (Megadyne, 2011c), Christus St Joseph's Hospital (Megadyne, 2011b)).

7.9.3 Provide a brief statement on the relevance of the evidence base to the scope. This should focus on the claimed patient- and system-benefits described in the scope.

There is evidence to accept the claim in the Scope that the risk of burns may be reduced using the Mega Soft pad (Megadyne, 2011a).

There is also evidence to accept the claim in the Scope that the Mega Soft pad may be of particular value in patients with extensive skin burns or skin conditions (Sheridan et al., 2003).

There is evidence to accept the claim in the Scope that the Mega Soft pad acts as a pressure relieving device (Kaleida Health hospital (Megadyne, 2011c)).

There is evidence to accept the claim in the Scope that the Mega Soft pad reduces skin irritation (Mega Soft Evaluation reports).

7.9.4 Identify any factors that may influence the external validity of study results to patients in routine clinical practice.

Clearly, the two studies that used non-human subjects (Megadyne **(**2011) (Megadyne, 2011a), and part of ECRI (2000)(2000)) are of limited relevance. The remaining studies consider the use of the Mega Soft pad or the Mega 2000 pad in routine clinical practice.

7.9.5 Based on external validity factors identified in 7.9.4 describe any criteria that would be used in clinical practice to select patients for whom the technology would be suitable.

None.

Section C – Economic evidence

Section C requires sponsors to present economic evidence for their technology.

All statements should be evidence-based and directly relevant to the decision problem.

The approach to the de novo cost analysis expected to be appropriate for most technologies is cost-consequence analysis. Sponsors should read section 7 of the Medical Technologies Evaluation Programme Methods guide on cost-consequences analysis, available from www.nice.org.uk/mt

Sponsors are requested to submit section C with the full submission. For details on timelines, see the NICE document 'Guide to the Medical Technologies Evaluation Programme process', available from www.nice.org.uk/mt

8 Existing economic evaluations

8.1 Identification of studies

The review of the economic evidence should be systematic and transparent and a suitable instrument for reporting such as the PRISMA statement (www.prisma-statement.org/statement.htm).

A PDF copy of all included studies should be provided by the sponsor.

8.1.1 Describe the strategies used to retrieve relevant health economics studies from the published literature and to identify all unpublished data. The search strategy used should be provided as in section 10, appendix 3.

Searching for economic evaluations and associated literature was performed within the search for clinical studies (see Section 7.1.1 and Section 10, Appendix 1). As the search used only an intervention cluster (i.e. terms relating explicitly to the intervention under assessment) and did not use outcome or methodological filters, we were able to screen the literature as one. Cost or economic studies suitable for inclusion in this section of the assessment were therefore screened simultaneously with the clinical studies.

Health economics studies should include all types of economic evaluation and cost studies, including cost analyses and cost-effectiveness and budget-impact analyses. The methods used should be justified with reference to the decision problem.

Sufficient detail should be provided to enable the methods to be reproduced (the External Assessment Centre must be able to reproduce the search), and the rationale for any inclusion and exclusion criteria regarding search terms should be used.

8.1.2 Describe the inclusion and exclusion criteria used to select studies from the published and unpublished literature. Suggested headings are listed in the table below. Other headings should be used if necessary.

Table C1 Selection criteria used for health economic studies

Inclusion criteria	
Population	Not specified to maximise sensitivity
Interventions	Specified only by the various names of the product (e.g. current (mega soft patient return electrode) and past (Mega 2000)) but also by the manufacturer name.
Outcomes	Not specified to maximise sensitivity
Study design	Not specified to maximise sensitivity
Language restrictions	None
Search dates	16th October 2011
Exclusion criteria	
Population	Not specified to maximise sensitivity
Interventions	Specified only by the various names of the product (e.g. current (mega soft patient return electrode) and past (Mega 2000)) but also by the manufacturer name.
Outcomes	Not specified to maximise sensitivity
Study design	Not specified to maximise sensitivity
Language restrictions	None
Search dates	16th October 2011

8.1.3 Report the numbers of published studies included and excluded at each stage in an appropriate format.

The 136 titles and abstracts of the global search were screened, which revealed no published formal cost-effectiveness studies. However, two studies are included which are in the form of quotes from two hospitals in USA that have used either the Mega 2000 or Mega Soft.

It is recommended that the number of published studies included and excluded at each stage is reported using the PRISMA statement flow diagram (available from *www.prisma-statement.org/statement.htm*)

8.2 Description of identified studies

8.2.1 Provide a brief review of each study, stating the methods, results and relevance to the scope. A suggested format is provided in table C2.

Outcome measures should be included if applicable. Patient outcomes could include gains in life expectancy, improved quality of life, longer time to recurrence, and comparative costs.

Table C2 Summary list of all evaluations involving costs

Study name (year)	**Location of study**	**Summary of model and comparators**	**Patient population *(key characteristics, average age)***	**Costs *(intervention and comparator)***	***Patient outcomes (clinical outcomes, utilities, life expectancy, time to recurrence for intervention and comparator)***	***Results (annual cost savings, annual savings per patient, incremental cost per QALY)***
Kaleida Health hospital (Megadyne, 2011c)	Kaleida Health hospital, Buffalo, NY, USA	No model, but three-year projective cost comparison between sticky pad vs. Mega 2000 pad (predecessor to Mega Soft)	Unknown	Not quantified	Patient comfort and reduction of pressure points, see Table B9 for details.	The Mega 2000 gave “tremendous cost savings” over the cost of sticky electrodes and their disposal according to Patricia Wopperer RN, MS, CNOR, RNFA, Kaleida Health's director of value analysis.
Christus St Joseph’s Hospital	Christus St Joseph’s Hospital,	No model available. Comparison	Unknown	Not quantified	"CHRISTUS St. Joseph's Hospital uses the Mega Soft because it is the best thing for	Quote from Etta Hodge, administrative director of surgical services. “Using the Mega Soft has also helped to save nurses time by eliminating many of the pre- and post-

(Megadyne, 2011b)	USA	between sticky pad vs. Mega Soft pad			the patient," states Etta Hodge, administrative director of surgical services.	operative steps required when using disposable sticky pads. During surgeries, the Mega Soft also helps to save time for the surgical staff and improve efficiency in the OR. Interruptions and delays from having to wait while the nursing staff places disposable grounding pads and re-drapes the patient are eliminated. Because patients have already been placed onto the Mega Soft during pre-op, if electrosurgery is needed during a procedure, all the circulating nurse needs to do is plug in the electrode. Since we began using the Mega Soft in our OR suites, we have seen significant savings on purchasing and disposing of grounding pads."

8.2.2 Provide a complete quality assessment for each health economic study identified. A suggested format is shown in table C3.

The two included studies above provide only anecdotal evidence on the cost-effectiveness of the technology. Given that they do not represent formal assessments of cost-effectiveness, Table C3 below is not appropriate.

Table C3 Quality assessment of health economic studies

Study name		
Study design		
Study question	**Response (yes/no/not clear/N/A)**	**Comments**
1. Was the research question stated?		
2. Was the economic importance of the research question stated?		
3. Was/were the viewpoint(s) of the analysis clearly stated and justified?		
4. Was a rationale reported for the choice of the alternative programmes or interventions compared?		
5. Were the alternatives being compared clearly described?		
6. Was the form of economic evaluation stated?		
7. Was the choice of form of economic evaluation justified in relation to the questions addressed?		
8. Was/were the source(s) of effectiveness estimates used stated?		
9. Were details of the design and results of the effectiveness study given (if based on a single study)?		
10. Were details of the methods of synthesis or meta-analysis of estimates given (if based on an overview of a number of effectiveness studies)?		
11. Were the primary outcome measure(s) for the economic evaluation clearly stated?		
12. Were the methods used to value health states and other benefits stated?		
13. Were the details of the subjects from whom valuations were obtained given?		

14. Were productivity changes (if included) reported separately?		
15. Was the relevance of productivity changes to the study question discussed?		
16. Were quantities of resources reported separately from their unit cost?		
17. Were the methods for the estimation of quantities and unit costs described?		
18. Were currency and price data recorded?		
19. Were details of price adjustments for inflation or currency conversion given?		
20. Were details of any model used given?		
21. Was there a justification for the choice of model used and the key parameters on which it was based?		
22. Was the time horizon of cost and benefits stated?		
23. Was the discount rate stated?		
24. Was the choice of rate justified?		
25. Was an explanation given if cost or benefits were not discounted?		
26. Were the details of statistical test(s) and confidence intervals given for stochastic data?		
27. Was the approach to sensitivity analysis described?		
28. Was the choice of variables for sensitivity analysis justified?		
29. Were the ranges over which the parameters were varied stated?		
30. Were relevant alternatives compared? (That is, were appropriate comparisons made when conducting the incremental analysis?)		

31. Was an incremental analysis reported?		
32. Were major outcomes presented in a disaggregated as well as aggregated form?		
33. Was the answer to the study question given?		
34. Did conclusions follow from the data reported?		
35. Were conclusions accompanied by the appropriate caveats?		
36. Were generalisability issues addressed?		
Adapted from Drummond MF, Jefferson TO (1996) Guidelines for authors and peer reviewers of economic submissions to the BMJ. The BMJ Economic Evaluation Working Party. British Medical Journal 313 (7052): 275–83. Cited in Centre for Reviews and Dissemination (2008) Systematic reviews. CRD's guidance for undertaking reviews in health care. York: Centre for Reviews and Dissemination		

9 De novo cost analysis

Section 9 requires the sponsor to provide information on the de novo cost analysis.

The de novo cost analysis developed should be relevant to the scope.

All costs resulting from or associated with the use of the technology should be estimated using processes relevant to the NHS and personal social services.

Note that NICE cites the price of the product used in the model in the Medical Technology guidance.

9.1 Description of the de novo cost analysis

9.1.1 Provide the rationale for undertaking further cost analysis in relation to the scope.

We present an analysis of the relative cost per operation of treatment using a Mega Soft pad vs. a sticky pad, given that we have identified no relevant cost analyses in the literature.

Patients

9.1.2 What patient group(s) is (are) included in the cost analysis?

Adults and children/babies are considered separately.

The patient group(s) included in the cost analysis must reflect the licensed indication/CE mark/marketing authorisation and be relevant to the scope.

The sponsor should not deviate from the scope.

Technology and comparator

9.1.3 Provide a justification if the comparator used in the cost analysis is different from the scope.

If the choice of comparator used in the cost analysis is different from the scope an explanation must be provided.

As stated in the Scope, two comparators are modelled, the two varieties of sticky pad: split and non-split. We believe that split sticky pads are used far more frequently than non-split sticky pads, by approx. 20:1.

Model structure

9.1.4 Provide a diagram of the model structure you have chosen.

The model structure must be supplied to NICE in a legible format when printed on A4 paper.

Not applicable because disease progression and separate health states are not modelled.

9.1.5 Justify the chosen structure in line with the clinical pathway of care identified in response to question 3.3.

Consider how the model structure captures the main aspects of the condition for patients and the NHS. What was the underlying disease progression implemented in the model? Or what treatment was assumed to reflect underlying disease progression? Cross-reference to section 3.3.

See previous response.

9.1.6 Provide a list of all assumptions in the cost model and a justification for each assumption.

The relative cost of using the Mega Soft pad vs. sticky pad is assessed on a per operation basis. There is no need to model care pathways or the natural history of the multitude of conditions for which patients receive operations given that these do not depend on whether the Mega Soft pad or sticky pad is used in an operation.

Three types of cost are explicitly modelled.

(1) The cost per operation associated with the technologies themselves, the Mega Soft pad vs. the sticky pad.

(2) The cost per operation associated with the two technologies which are used in conjunction with sticky pads (but not with the Mega Soft pad). These are the pressure-relieving gel mattress and the razor which is used to shave the patient to allow the sticky pad to stick to the patient's skin.

(3) The cost per operation corresponding to the cost of the time equivalent for all theatre staff for the time taken by the theatre nurse to prepare the patient's skin for sticky pads, application of sticky pads, and disposal of pads.

The following additional cost savings are associated with the use of the Mega Soft vs. sticky pads. Due to lack of data, these are not quantified;

- Disposal of sticky pads,
- Further surgery to treat skin burns from sticky pads,
- Litigation due to skin burns from sticky pads,
- Treatment of skin irritation from sticky pads,
- Ordering and storing boxes of sticky pads.

9.1.7 Define what the model's health states are intended to capture.

Not applicable because disease progression and separate health states are not modelled.

9.1.8 Describe any key features of the cost model not previously reported. A suggested format is presented below.

Table C4 Key features of model not previously reported

Factor	Chosen values	Justification	Reference
Time horizon of model	n/a	Disease progression not modelled	n/a
Discount of 3.5% for costs	3.5% for costs	NICE reference case	(NICE, 2008)
Perspective (NHS/PSS)	NHS and PSS	NICE reference case	(NICE, 2008)
Cycle length	n/a	Disease progression not modelled	n/a
NHS, National Health Service; PSS, Personal Social Services			

9.2 Clinical parameters and variables

When relevant, answers to the following questions should be derived from, and be consistent with, the clinical evidence section of the submission (section 7). Cross-references should be provided. If alternative sources of evidence have been used, the method of identification, selection and synthesis should be provided as well as a justification for the approach.

9.2.1 Describe how the data from the clinical evidence were used in the cost analysis.

In addition, if transition probabilities have been used in the model, explain how they were calculated from the clinical data. If appropriate, provide the transition matrix, details of the transformation of clinical outcomes or other details here. If the (transition) probabilities vary over time for the condition or disease, state how this has this been included in the evaluation and if it has not been included, provide an explanation of why it has been excluded. If transition probabilities have not been used, explain how the results of the clinical evidence were incorporated into the model.

There is little quantitative data in the Clinical Effectiveness section. The following studies all support the cost analysis assumption that the incidence of skin burns with the Mega Soft pad is zero: Megadyne (2011) (Megadyne, 2011a), Sheridan, Wilson et al. (2003)(Sheridan et al., 2003), ECRI (2000)(2000). However, the cost savings related to the higher incidence of burns with sticky pads is not quantified in the model, as explained in Section 9.1.6.

9.2.2 Are costs and clinical outcomes extrapolated beyond the study follow-up period(s)? If so, what are the assumptions that underpin this extrapolation and how are they justified?

In particular, consider what assumption was used regarding the longer term difference in effectiveness between the technology and its comparator.

Were any assumptions and/or techniques used for the extrapolation of longer term differences in clinical outcomes between the technology and its comparator?

Only costs associated with operations are modelled (although the costs per operation associated with the capital expenditures for the Mega Soft pad and pressure-relieving mattress are amortised over time, see Section 9.3.7). Therefore this section is not relevant.

9.2.3 Were intermediate outcome measures linked to final outcomes (for example, was a change in a surrogate outcome linked to a final clinical outcome)? If so, how was this relationship estimated, what sources of evidence were used and what other evidence is there to support it?

Not relevant as surrogate outcomes not modelled.

9.2.4 Were adverse events such as those described in section 7.7 included in the cost analysis? If appropriate, provide a rationale for the calculation of the risk of each adverse event.

As discussed in Section 7.7, the only adverse event for which study data was available was the incidence of skin burns. As stated in Section 9.1.6, we do not quantify the cost savings associated with the elimination of skin burns associated with the Mega Soft pad vs. the sticky pad.

9.2.5 Provide details of the process used when the sponsor's clinical advisers assessed the applicability of available or estimated clinical model parameter and inputs used in the analysis.

This is a critical step and the names and professional titles of the clinical advisers should be included along with the following[1]:

- *the criteria for selecting the experts*
- *the number of experts approached*
- *the number of experts who participated*
- *declaration of potential conflict(s) of interest from each expert or medical speciality whose opinion was sought*
- *the background information provided and its consistency with the totality of the evidence provided in the submission*
- *the method(s) used to collect and collate the opinions*
- *the medium used to collect opinions (for example, was information gathered by direct interview, telephone interview or self-administered questionnaire?)*
- *the questions asked*
- *whether iteration was used in the collation of opinions and if so, how it was used*
- *the uncertainly around these values should be addressed in the sensitivity analysis.*

[1] Adapted from Pharmaceutical Benefits Advisory Committee (2008) Guidelines for preparing submissions to the Pharmaceutical Benefits Advisory Committee (Version 4.3). Canberra: Pharmaceutical Benefits Advisory Committee.

No model parameters were informed by clinical advisers.

9.2.6 Summarise all the variables included in the cost analysis. Provide cross-references to other parts of the submission. A suggested format is provided in table C5 below.

All parameters used to estimate cost should be presented clearly and include details of data sources. For continuous variables, mean values should be presented and used in the analyses. For all variables, measures of precision should be detailed.

Details should also include the values used, range (and distribution) and source.

Table C5 Summary of variables applied in the cost model

Variable	Value	Range or 95% CI (distribution)	Source
Undiscounted cost of adult Mega Soft pad	£2,100	No uncertainty	Advance Surgical
Undiscounted cost of paediatric Mega Soft pad	£2,950	No uncertainty	Advance Surgical
Discounted cost of adult or paediatric Mega Soft pad (used in sensitivity analysis only)	£1,900	No uncertainty	Advance Surgical
Life span of Mega Soft pad (adult or paediatric)	2 years	No uncertainty	Megadyne guarantee period
Number of operations using a single Mega Soft pad per unit time	15 per week	Rather uncertain	Experience of Advance Surgical
Cost per spit sticky pad for adults	£2.44	Little uncertainty	See ¥ below
Cost per spit sticky pad for children/babies	£1.92	Little uncertainty	Lang Skintact Cool Contact FDJ106 Paediatric REM 110 x 110mm butterfly shape £96.08 for box of 50 (NHS, April 2010)
Cost per non-spit sticky pad for adults (used in sensitivity analysis only)	£2.60	Little uncertainty	3M FDJ045 Universal 120x132mm with safety ring for a more uniform dispersion of current £103.98 for Box of 40 (NHS, April 2010)
Cost per non-spit sticky pad for children/babies (used in sensitivity analysis only)	£1.74	Little uncertainty	Lang Skintact Cool Contact FDJ059 Paediatric 110 x 107mm to suit child 2.7-11.4kg £87.15 for Box of 50(NHS, April 2010)
Cost of pressure-relieving gel mattress	£334	Some uncertainty, depending on manufacturer	Central Medical Supplies Action overlay quote over telephone(Action®ProductsInc, 2011)

Life span of pressure-relieving gel mattress	1 year	Some uncertainty	Experience of Advance Surgical.
Cost of use of razor per operation	£1.13	Some uncertainty	Assume half of operations use disposal razor cost £0.18 and half of operations use disposable razor clipper head, at £2.09. ¶ The latter is preferable because the former can cause skin cuts.
Mean reduction in operation time using Mega Soft pad vs. sticky pad	5 minutes	Some uncertainty	Experience of Advance Surgical.
Mean number surgeons per operation	1	Little uncertainty	Experience of Advance Surgical
Cost per hour of surgeon time	£347	Some uncertainty	PSSRU Consultant: surgical. Cost whilst operating, excluding costs of qualifications(Curtis, 2010)
Mean number anaesthetists per operation	1	Little uncertainty	Experience of Advance Surgical
Cost per hour of anaesthetist time	£347	Some uncertainty	Estimated same as cost per hour of surgeon given similar basic salary as surgeon
Mean number nurse anaesthetists per operation	1	Little uncertainty	Experience of Advance Surgical
Cost per hour nurse anaesthetist time	£41	Some uncertainty	PSSRU Nurse, day ward (includes staff nurse, registered nurse, registered)(Curtis, 2010)
Mean number operating room nurses per operation	2	Some uncertainty	Experience of Advance Surgical
Cost per hour operating room nurse time	£41	Some uncertainty	PSSRU Nurse, day ward (includes staff nurse, registered nurse, registered)(Curtis, 2010)
CI, confidence interval ¥ 3M FDJ046 Universal 120x132mm with safety ring for a more uniform dispersion of current Box of 40 £113.24, ConMed FDJ083 Universal 152x127mm dual foil Box of 25 £51.43			

(NHS, April 2010). £2.44 is calculated as the average per pad cost of these two makes.

¶ Average of disposal razor (Universal razor code UN2000 £0.18 each, Wilkinson Sword razor 182H £0.15 each from NHS Supplies Catalogue.(NHS, April 2010)) and disposable razor clipper head at £2.09 (3M code 9660 £104.50 per 50 - price quoted from 3M telesales).

9.3 Resource identification, measurement and valuation

NHS costs

9.3.1 Describe how the clinical management of the condition is currently costed in the NHS in terms of reference costs and the payment by results (PbR) tariff.

Provide Healthcare Resource Groups (HRG) and PbR codes and justify their selection.

The only non-device related cost is the cost associated with the time of the theatre staff, detailed in the previous section. The cost per time of the theatre staff were taken from the Personal Social Services Research Unit (PSSRU) (Curtis, 2010)

9.3.2 State the Office of Population, Censuses and Surveys Classification of Surgical Operations and Procedures (OPCS) codes for the operations, procedures and interventions relevant to the use of the technology for the clinical management of the condition.

The Mega Soft pad is used for all monopolar diathermy cases including;

Cardiac
Plastic
Laparoscopic
Neuro
Spinal
General
Nephrectomy
Mastectomy and reconstruction
Total knee replacement

Head and neck surgery
Hip replacement
Thoracic surgery
Ankle surgery
Foot surgery
Renal surgery

Resource identification, measurement and valuation studies

9.3.3 Provide a systematic search of relevant resource data for the NHS in England. Include a search strategy and inclusion criteria, and consider published and unpublished studies.

Resource use data was not collected by systematic search. Instead, the following sources were used;

- Personal Social Services Research Unit (PSSRU)(Curtis, 2010) for costs of theatre staff time,
- The manufacturer, Megadyne / Advance Surgical for the cost and guarantee period of the Mega Soft pads,
- The NHS Supplies Catalogue(NHS, April 2010) for the costs of sticky pads and disposable razors,
- Action® Products Inc for the cost of the pressure-relieving gel mattress(Action®ProductsInc, 2011), one of the manufacturers of the mattress, and 3M telesales for the disposable razor clipper head.
- Advance Surgical for the remaining parameters which we could not find in the literature;
    - typical composition of a surgical team,
    - typical life span of a pressure-relieving mattress,
    - typical number of operations using a single Mega Soft pad per unit time,

- typical reduction in operation time using Mega Soft pad vs. sticky pad

9.3.4 Provide details of the process used when clinical advisers assessed the applicability of the resources used in the model[2].

The details of the process should include:

- *the criteria for selecting the experts*
- *the number of experts approached*
- *the number of experts who participated*
- *declaration of potential conflict(s) of interest from each expert or medical speciality whose opinion was sought*
- *the background information provided and its consistency with the totality of the evidence provided in the submission*
- *the method(s) used to collect and collate the opinions*
- *the medium used to collect opinions (for example, was information gathered by direct interview, telephone interview or self-administered questionnaire?)*
- *the questions asked*
- *whether iteration was used in the collation of opinions and if so, how it was used*
- *the uncertainty around these values should be addressed in the sensitivity analysis.*

No model parameters were informed by clinical advisers.

[2] Adapted from Pharmaceutical Benefits Advisory Committee (2008) Guidelines for preparing submissions to the Pharmaceutical Benefits Advisory Committee (Version 4.3). Canberra: Pharmaceutical Benefits Advisory Committee.

Technology and comparators' costs

9.3.5 Provide the list price for the technology.

The undiscounted price of the adult Mega Soft pad is £2,100, and the paediatric Mega Soft pad £2,950. These prices are used in the base case analysis.

9.3.6 If the list price is not used in the de novo cost model, provide the alternative price and a justification.

A rationale must be provided for the choice of values used in the cost model. All prices should be referenced. Any uncertainty around prices should be addressed by sensitivity analysis. All costs must be cross-referenced to other sections of the submission if possible.

The discounted price of both the paediatric and adult size Mega Soft pads is £1,900. This price is used in one sensitivity analysis.

9.3.7 Summarise the annual costs associated with the technology and the comparator technology (if applicable) applied in the cost model. A suggested format is provided in tables C6 and C7. Table C7 should only be completed when the most relevant UK comparator for the cost analysis refers to another technology.

When completing tables C6 and C7 the price of the technology should refer to the list price stated in 9.3.4 unless a justification for using an alternative price has been provided in 9.3.5. If a technology is not for single use and consumables are needed to provide a treatment, these must be itemised and a breakdown of prices presented.

For all costs presented a source of the data must be stated.

As explained above, all costs are calculated per operation.

In order to estimate the price of the Mega Soft pad per operation, it is necessary first to estimate the "equivalent annual cost" of the pad (Drummond

et al., 2005), and then divide by the expected number of operations that the pad will be used for per year.

Assuming a constant force of discounting of costs, at a rate *r*, and an expected lifetime of *N* years, the equivalent annual cost of the pad equals the cost of the pad divided by the annuity factor;

$$= \int_{t=0}^{N} \frac{1}{(1+r)^{t}} dt = \frac{1-(1+r)^{-N}}{\ln(1+r)}$$

Mega Soft pads are guaranteed for two years by the manufacturer and we understand that hospitals routinely replace the pad after two years. Therefore, the lifetime of the Mega Soft pad is estimated as two years.

When *N* = 2 years and *r* = 3.5%, the annuity factor equals 1.93. Therefore, the equivalent annual cost of the adult pad equals £1,087, the paediatric pad £1,526 and the discounted cost of both pads £983.

Next, we assume that the pads will be used for three operations per day from Monday to Friday, with no operations at the weekend. Therefore, we estimate the number of operations per year as 3 x 5 x 52 = 780.

Therefore, we estimate the cost of the adult pad per operation as £1,087 / 780 = £1.39, the paediatric pad £1,526 / 780 = £1.96, and the discounted cost as £983 / 780 = £1.26.

Next, a pressure-relieving gel mattress must be used in conjunction with a sticky pad. Similar to the Mega Soft pad, in order to estimate the price of the mattress per operation, it is necessary first to estimate the “equivalent annual cost” of the pad, and then divide by the expected number of operations that the mattress will be used for per year.

We understand that gel mattresses are typically used for about a year.

We obtained a quote of £334 for the cost of the Action OR overlay(Action®ProductsInc, 2011) pressure-relieving gel mattress. The

company do not provide publicly available written prices. When N = 1 years and r = 3.5%, the annuity factor equals 0.98. Therefore, the equivalent annual cost of the mattress equals £340. Again assuming 780 operations per year, this gives a cost per operation of the mattress of £0.44.

Table C6 Costs per treatment/patient associated with the technology in the cost model

Items	Value	Source
Price of the technology per treatment/patient	Price of adult Mega Soft pad per operation estimated as £1.39, paediatric version £1.96 and discounted price for adult and paediatric £1.26	See text above.
Consumables (if applicable)	None	
Maintenance cost	Punctures of the pad are extremely rare.	Advance Surgical
Training cost	No cost to NHS because Advance Surgical provide training	Advance Surgical
Other costs	None	
Total cost per treatment/patient	See first row of table	

Table C7 Costs per treatment/patient associated with the comparator technology in the cost model

Items	Value	Source
Cost of the comparator per treatment/patient	Estimated cost of single adult split pad = £2.44, paediatric split pad = £1.92, adult non-split pad = £2.60, paediatric non-split pad = £1.74.	NHS Supplies Catalogue April 2010(NHS, April 2010) For details of makes, see Table C5 above. Only the most common makes of sticky pad are considered.
Consumables (if applicable)	Cost per operation of razor = £1.13 Pressure-relieving gel mattress = £0.44 per operation	Assume half of operations use disposal razor, cost £0.18, and half of operations use disposable razor clipper head, at £2.09. See Table C5 for source of costs. See details of calculation above.
Maintenance cost	Zero	

Training cost	Zero	
Other costs	Zero	
Total cost per treatment/patient	Adult split pad = £4.00, paediatric split pad = £3.48, adult non-split pad = £4.16, paediatric non-split pad = £3.30.	

Health-state costs

9.3.8 If the cost model presents health states, the costs related to each health state should be presented in table C8. The health states should refer to the states in section 9.1.7. Provide a rationale for the choice of values used in the cost model.

Health states are not modelled, therefore this section is not applicable.

Table C8 List of health states and associated costs in the economic model

Health states	Items	Value	Reference
Health state 1	**Technology cost**		
	Staff		
	Hospital costs		
	[Other items]		
	Total		
Health state 2			
Health state [X]			

Adverse-event costs

9.3.9 Complete table C9 with details of the costs associated with each adverse event referred to in 9.2.4 included in the cost model. Include all adverse events and complication costs, both during and after longer-term use of the technology.

As discussed in Section 7.7, the only adverse event for which study data was available was the incidence of skin burns. As stated in Section 9.1.6, we do not quantify the cost savings associated with the elimination of skin burns associated with the Mega Soft pad vs. the sticky pad.

Table C9 List of adverse events and summary of costs included in the cost model

Adverse events	Items	Value	Reference
Adverse event 1	**Technology**		
	Staff		
	Hospital costs		
	[Other items]		
	Total		
Adverse event 2	**Technology**		
	Staff		
Adverse event [X]			

Miscellaneous costs

9.3.10 Describe any additional costs and cost savings that have not been covered anywhere else (for example, PSS costs, and patient and carer costs). If none, please state.

We estimate that the duration of a typical operation will be approximately 5 minutes shorter using the Mega Soft pad compared to a sticky pad. This 5 minutes represents the time for a nurse to;

- prepare the patients' skin for sticky pads, e.g. shaving skin,
- locate the correct sticky pad from storage for children, since different sticky pads have different patient weight limitations,
- apply the sticky pads, noting that it can be difficult to find a suitable site for the sticky pads for some patients, avoiding bony prominences, scar tissue and tattoos,
- dispose of the sticky pads.

By contrast, the Mega Soft pad requires none of these activities: there is no skin preparation and the pad can remain on the operating table between patients (with the usual hygiene precautions) and does not require strategic placement.

We estimate that the 5 minute delay will apply to all members of the surgical team, and this is corroborated by the experience at Christus Hospital, USA(Megadyne, 2011b);

"*Using the Mega Soft has also helped to save nurses time by eliminating many of the pre- and post-operative steps required when using disposable sticky pads. During surgeries, the Mega Soft also helps to save time for the surgical staff and improve efficiency in the OR. Interruptions and delays from having to wait while the nursing staff places disposable grounding pads and re-drapes the patient are eliminated. Because patients have already been placed onto the Mega Soft during pre-op, if electrosurgery is needed during a procedure, all the circulating nurse needs to do is plug in the electrode*."

Next, we estimate that a typical surgical team, across a broad range of operations, consists of;

- 1 surgeon,
- 1 anaesthetist,
- 1 nurse anaesthetist,
- 2 operating room nurses

We estimate the costs per hour for these staff as;

- £347 for a surgeon, PSSRU Consultant: surgical. Cost whilst operating, excluding costs of qualifications(Curtis, 2010),
- £347 for an anaesthetist, assumed the same as for a surgeon given assumed similar basic salaries,
- £41 for a nurse anaesthetist, PSSRU Nurse, day ward (includes staff nurse, registered nurse, registered)(Curtis, 2010),
- £41 for an operating room nurse, PSSRU Nurse, day ward (includes staff nurse, registered nurse, registered practitioner). Cost is during patient contact, excluding qualifications(Curtis, 2010)

9.3.11 Are there any other opportunities for resource savings or redirection of resources that it has not been possible to quantify?

Include a justification as to why it has not possible to quantify the resource use and/or costs.

We believe that the following factors will all results in cost savings when using the Mega Soft versus sticky pad;

- Purchasing and disposal of sticky pads. Kaleida Hospital and Christus Hospital cite these additional costs for sticky pads(Megadyne, 2011c, Megadyne, 2011b),
- Cost of further surgery to treat skin burns with sticky pads,
- Litigation for skin burns with sticky pads,
- Cost of treating skin irritation from sticky pads,
- Ordering and storing boxes of sticky pads

We have not quantified these factors due to a lack of data.

9.4 Approach to sensitivity analysis

Section 9.4 requires the sponsor to carry out sensitivity analyses to explore uncertainty around the structural assumptions and parameters used in the analysis. All inputs used in the analysis will be estimated with a degree of imprecision. For technologies whose final price/acquisition cost has not been confirmed, sensitivity analysis should be conducted over a plausible range of prices.

Analysis of a representative range of plausible scenarios should be presented and each alternative analysis should present separate results.

9.4.1 Has the uncertainty around structural assumptions been investigated? State the types of sensitivity analysis that have been carried out in the cost analysis.

Deterministic sensitivity analysis was performed on several of the key model parameters, see Table C10.1 below.

Given that the model is very simple and that we display the cost-savings by source, i.e. technology (Mega Soft pad vs. sticky pad), associated technologies (i.e. pressure mattress, razor), and staff time saved, we believe that no further structural sensitivity analyses are required.

9.4.2 Was a deterministic and/or probabilistic sensitivity analysis undertaken? If not, why not? How were variables varied and what was the rationale for this? If relevant, the distributions and their sources should be clearly stated.

All scenarios and/or ranges of variables must be justified.

We believe that deterministic sensitivity analysis is the most appropriate tool to assess the uncertainty in the net cost of using the Mega Soft pad versus sticky pad. We did not perform probabilistic sensitivity analysis due to the substantial uncertainty in the standard errors of some of the parameters themselves.

In Table C5, we estimate the degree of uncertainty in each of the parameters qualitatively. We have performed sensitivity analyses for each parameter which we believe is highly uncertain. Each of these parameters is separately halved and doubled to capture what we believe is a plausible range of values.

9.4.3 Complete table C10.1, C10.2 and/or C10.3 as appropriate to summarise the variables used in the sensitivity analysis.

Table C10.1 Variables used in one-way scenario-based deterministic sensitivity analysis

Variable	Base-case value	Range of values
Number of operations per week a typical Mega Soft pad is used for	15	7 and 30
Cost per sticky pad for adults	£2.44	£2.60 being the cost per **non**-split sticky pad for adults
Cost per sticky pad for adults	£2.44	£1.22 and £4.88
Cost per sticky pad for children/babies	£1.92	£1.74 being the cost per **non**-split sticky pad for children/babies
Cost per sticky pad for children/babies	£1.92	£0.96 and £3.84
Cost of pressure-relieving gel mattress	£334	£167 and £668
Life span of pressure-relieving gel mattress	1 year	0.5 and 2 years
Cost of razor per operation	£1.13	£0.56 and £2.26.
Mean reduction in operation time using Mega Soft pad vs. sticky pad	5 minutes	2.5 and 10 minutes
Cost per hour of surgeon time and anaesthetist time	£347	£173 and £694
Cost per hour of nurse anaesthetist and nurse time	£41	£20 and £82

Table C10.2 Variables used in multi-way scenario-based sensitivity analysis

Variable	***Parameter 1***	***Parameter 2***	***Parameter 3***
Base case	None		
Scenario 1			
Scenario 2			

Table C10.3 Variable values used in probabilistic sensitivity analysis

Variable	Base-case value	Distribution
n/a		

9.4.4 If any parameters or variables listed in section 9.2.6 were omitted from the sensitivity analysis, provide the rationale.

It is acknowledged that some model parameters may be excluded from sensitivity analysis considerations, for example, because they can be considered 'constant' or because evidence exists about unbiased and accurate measurement.

The cost of a Mega Soft pad is known with certainty.

Life time of Mega Soft pad is set at 2 years, given that this is the guarantee period, and we understand the hospitals routinely replace the pad at 2 years.

The number of surgeons, anaesthetists, nurse anaesthetists and operating room nurses were not explicitly varied. However, varying each of these quantities is equivalent to varying the cost per hour of each staff member.

9.5 Results of de novo cost analysis

Section 9.5 requires the sponsor to report the de novo cost analysis results. These should include the following:

- costs
- disaggregated results such as costs associated with treatment, costs associated with adverse events, and costs associated with follow-up/subsequent treatment
- a tabulation of the mean cost results
- results of the sensitivity analysis.

Base-case analysis

9.5.1 Report the total costs associated with use of the technology and the comparator(s) in the base-case analysis. A suggested format is presented in table C11.

Not applicable, because the cost of operating room staff time is on an incremental basis only.

Table C11 Base-case results

	Total per patient cost (£)

9.5.2 Report the total difference in costs between the technology and comparator(s).

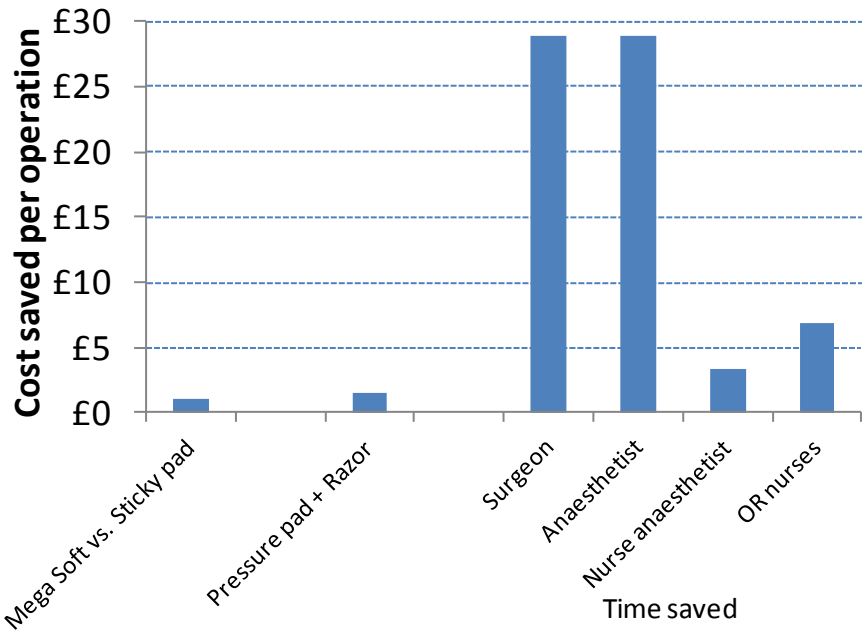
The cost per operation associated with sticky pads for adults is £70.70 greater than associated with the adult version of the Mega Soft pad.

The cost per operation associated with sticky pads for children/babies is £69.61 greater than associated with the paediatric version of the Mega Soft pad.

9.5.3 Provide details of the costs for the technology and its comparator by category of cost. A suggested format is presented in table C12.

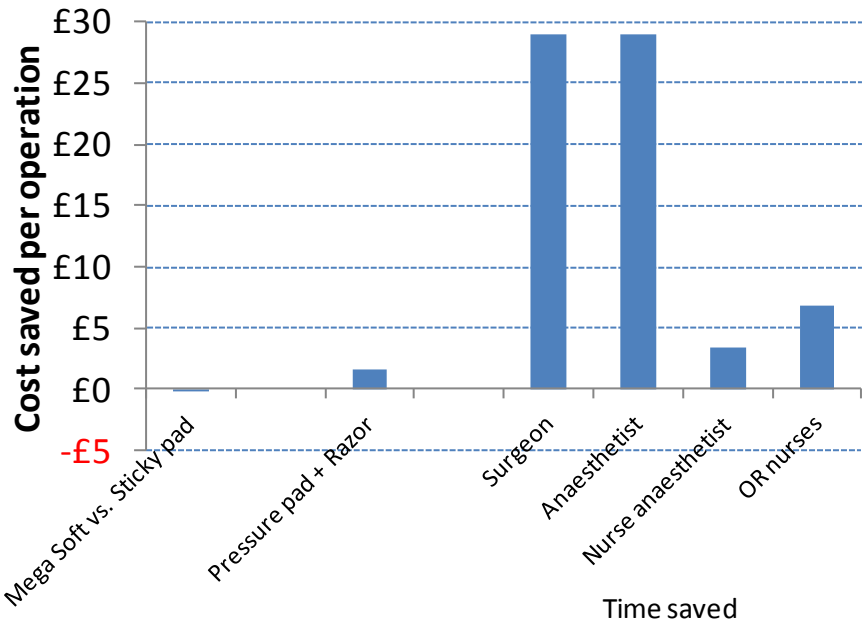
Table C12 Summary of costs by category of cost per patient

Item	Cost Mega Soft pad	Cost Sticky pad	Increment (Cost sticky pad – cost Mega Soft Pad)
ADULT mega Soft pad vs. adult sticky pad	£1.39	£2.44	£1.05
Technologies used with sticky pad (pressure mattress and razor)	zero	£1.56	£1.56
Operating room staff time saved	Not estimated	Not estimated	£68.08
Total	Not estimated	Not estimated	**£70.70**



Item	Cost Mega Soft pad	Cost Sticky pad	Increment (Cost sticky pad – cost Mega Soft Pad)
PAEDIATRIC mega Soft pad vs.	£1.96	£1.92	- £0.04

child sticky pad			
Technologies used with sticky pad (pressure mattress and razor)	zero	£1.56	£1.56
Operating room staff time saved	Not estimated	Not estimated	£68.08
Total	Not estimated	Not estimated	**£69.61**



9.5.4 If appropriate, provide details of the costs for the technology and its comparator by health state. A suggested format is presented in table C13.

Not applicable as separate health states not modelled.

Table C13 Summary of costs by health state per patient

Health state	Cost *intervention (X)*	Cost *comparator (Y)*	Increment	Absolute increment	% absolute increment
Health state 1	*XHS1*	*YHS1*	*XHS1 – YHS1*	*|XHS1 – YHS1|*	*|XHS1 – YHS1|/ (Total absolute increment)*
Health state 2	*XHS2*	*YHS2*	*XHS2 – YHS2*	*|XHS2 – YHS2|*	*|XHS2 – YHS2|/ (Total absolute increment)*
Health state X					
Total	*XTotal*	*YTotal*	*XTotal – YTotal*	*Total absolute increment*	*100%*
Adapted from Pharmaceutical Benefits Advisory Committee (2008) Guidelines for preparing submissions to the Pharmaceutical Benefits Advisory Committee (Version 4.3). Canberra: Pharmaceutical Benefits Advisory Committee					

9.5.5 If appropriate, provide details of the costs for the technology and its comparator by adverse event. A suggested format is provided in table C14.

Not applicable as cost savings from no skin burns with Mega Soft is not quantified.

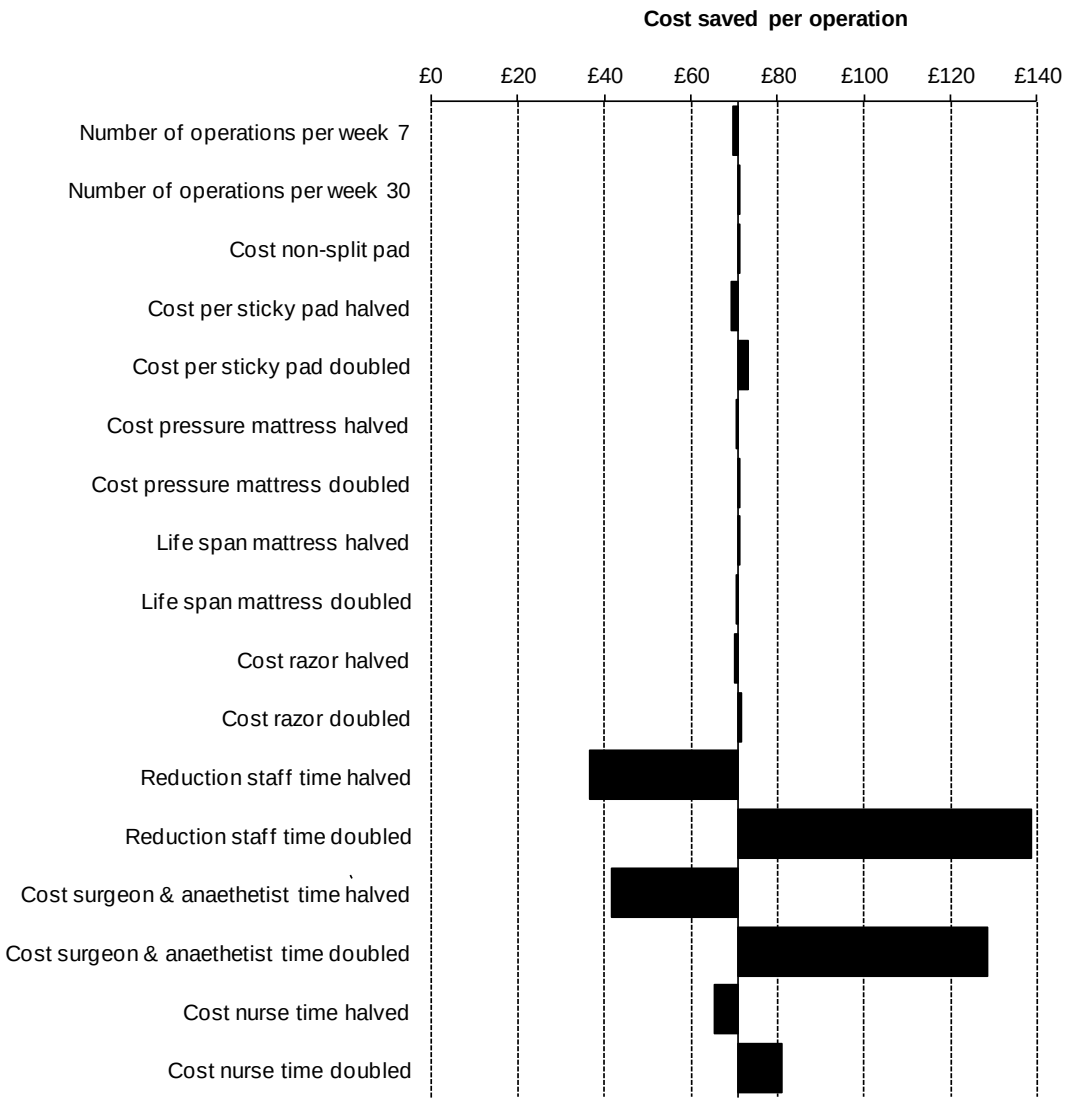
Table C14 Summary of costs by adverse events per patient

Adverse event	Cost *intervention (X)*	Cost *comparator (Y)*	Increment	Absolute increment	% absolute increment
Adverse event 1	*XAE1*	*YAE1*	*XAE1 – YAE1*	*|XAE1 – YAE1|*	*|XAE1 – YAE1|/ (Total absolute increment)*
Adverse event 2	*XAE2*	*YAE2*	*XAE2 – YAE2*	*|XAE2 – YAE2|*	*|XAE2 – YAE2|/ (Total absolute increment)*
Total	*XTotal*	*YTotal*	*XTotal – YTotal*	*Total absolute increment*	*100%*
Adapted from Pharmaceutical Benefits Advisory Committee (2008) Guidelines for preparing submissions to the Pharmaceutical Benefits Advisory Committee (Version 4.3). Canberra: Pharmaceutical Benefits Advisory Committee					

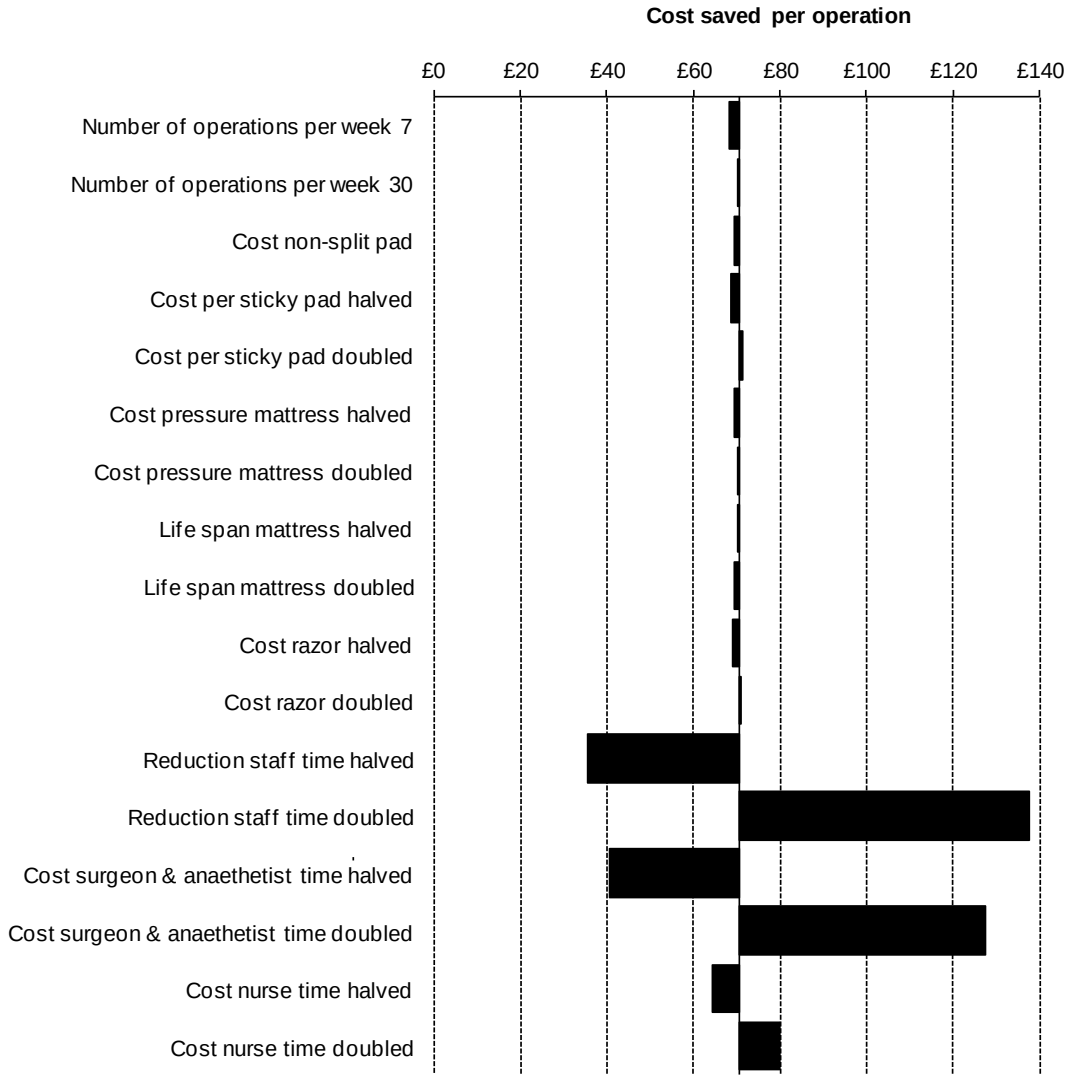
Sensitivity analysis results

9.5.6 Present results of deterministic one-way sensitivity analysis of the variables described in table C10.1.

Results for adults are displayed in the tornado graph below.



Results for children/babies are displayed in the tornado graph below.



9.5.7 Present results of deterministic multi-way scenario sensitivity analysis described in table C10.2.

Not applicable as multi-way sensitivity analysis not performed.

9.5.8 Present results of the probabilistic sensitivity analysis described in table C10.3.

Not applicable as probabilistic sensitivity analysis not performed.

9.5.9 What were the main findings of each of the sensitivity analyses?

The Mega Soft pad is cost saving versus the sticky pad in all sensitivity analyses.

Cost savings are mostly due to the saving in time during operations when the Mega Soft pad is used vs. the sticky pad. The assumptions for the average time saved per operation and the cost per unit time of the surgeon and anaesthetist are important drivers of cost saving.

Cost saving is far less sensitive all parameters unrelated to staff time saved, i.e. frequency of operations, cost of Mega Soft, cost of sticky pad, cost of pressure mattress, cost of razors, life span mattress.

9.5.10 What are the key drivers of the cost results?

See previous answer.

Miscellaneous results

9.5.11 Describe any additional results that have not been specifically requested in this template. If none, please state.

We repeat that the quantified cost savings do not reflect the cost savings identified in Section 9.3.11.

The NICE Methods guide p29, Appendix B asks whether the technology is likely to contribute to the sustainability agenda, for example, less energy usage or less waste generation during production or clinical usage. In answer to this question, the Mega Soft provides the environmental benefit of reducing the need for disposing of a sticky pad from each operation.

9.6 Subgroup analysis

For many technologies, the capacity to benefit from treatment will differ for patients with differing characteristics. Sponsors are required to complete section 9.6 in accordance with the subgroups identified in the scope and for any additional subgroups considered relevant.

Types of subgroups that are not considered relevant are those based solely on the following factors.

- Subgroups based solely on differential treatment costs for individuals according to their social characteristics.
- Subgroups specified in relation to the costs of providing treatment in different geographical locations within the UK (for example, if the costs of facilities available for providing the technology vary according to location).

9.6.1 Specify whether analysis of subgroups was undertaken and how these subgroups were identified. Cross-reference the response to the decision problem in table A1 and sections 3.2 and 7.4.4.

Consider if these subgroups were identified on the basis of a hypothesised expectation of differential clinical benefit or cost because of known, biologically plausible, mechanisms, social characteristics or other clearly justified factors.

We have presented the cost-savings corresponding to surgery with adults separately from cost-savings corresponding to surgery with children/babies.

9.6.2 Define the characteristics of patients in the subgroup(s).

See Section 9.6.1.

9.6.3 Describe how the subgroups were included in the cost analysis.

See Section 9.6.1.

9.6.4 What were the results of the subgroup analysis/analyses, if conducted? The results should be presented in a table similar to that in section 9.5.1 (base-case analysis).

See Section 9.6.1.

9.6.5 Were any subgroups not included in the submission? If so, which ones, and why were they not considered?

The following subgroups are specified in the Scope;

- Patients with burns.

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

For the cost model, we have considered only the subgroup of babies and children. However, we believe that the cost savings for patients with skin conditions, burns and fragile skin are likely to be greater than those presented, because the nurse may take longer to find suitable contact sites for the sticky pads. We see no reason why the cost savings should depend on patient BMI.

9.7 Validation

9.7.1 Describe the methods used to validate and cross-validate (for example with external evidence sources) and quality-assure the model. Provide references to the results produced and cross-reference to evidence identified in the clinical and resources sections.

Given that the model is very simple, there was no need to obtain independent verification of the working of the model.

There are no formal published economic analyses of the sticky pads or Mega Soft pad. Therefore, validation of our analysis against published analyses is not possible. However, our finding that the Mega Soft pad is cost saving vs. sticky pad is consistent with the findings of the Kaleida Health hospital and Christus St Joseph's Hospital, USA.

9.8 Interpretation of economic evidence

9.8.1 Are the results from this cost analysis consistent with the published economic literature? If not, why do the results from this evaluation differ, and why should the results in the submission be given more credence than those in the published literature?

See previous Section.

9.8.2 Is the cost analysis relevant to all groups of patients and NHS settings in England that could potentially use the technology as identified in the scope?

As stated in Section 9.6.5, we have quantified cost savings only for adults and children/babies. However, we believe that the cost savings for patients with skin conditions, burns and fragile skin are likely to be greater than those presented, because the nurse may take longer to find suitable contact sites for the sticky pads. We see no reason why the cost savings should depend on patient BMI.

We see no reason why cost savings should vary substantially across NHS settings in England.

9.8.3 What are the main strengths and weaknesses of the analysis? How might these affect the interpretation of the results?

The main strength of the analysis is that our finding that the Mega Soft pad is cost-saving compared to sticky pads holds regardless of any reasonable changes in individual parameters.

The main weakness of our analysis is that we have not been able to fully quantify the extent of the cost-saving because we are unable to find reliable information on the following parameters;

- Incidence of skin burns from sticky pads,
- Incidence of litigation claims for skin burns from sticky pads (see http://www.gazettelive.co.uk/news/teesside-news/2009/01/14/mum-takes-legal-action-over-burn-claim-84229-22689556/ for example of legal action concerning a skin burn from a sticky pad),
- Cost of disposal of sticky pads,
- Cost of ordering and storing boxes of sticky pads,

Were we to quantify these factors, Mega Soft pads would appear more cost-saving than presented in our base case.

Another weakness of our analysis is that we were unable to obtain a formal evidence-based estimate of the time saved in theatre when using the Mega Soft pad vs. sticky pads.

9.8.4 What further analyses could be undertaken to enhance the robustness/completeness of the results?

The robustness and accuracy of the estimated cost saving per operation would be improved if we were able to perform substantial further research to quantify the unknown variables listed in the previous question, Section 9.8.3.

Further research could be performed to quantify the time saved using the Mega Soft pad, perhaps by surveying theatre nurses.

Further research to quantify the number of operations per week, the typical life span of the pressure-relieving mattress, and the proportion of operations that use the various razors would also be welcome.

10 Appendices

10.1 Appendix 1: Search strategy for clinical evidence (section 7.1.1)

The following information should be provided:

10.1.1 The specific databases searched and the service provider used (for example, Dialog, DataStar, OVID, Silver Platter), including at least:

- Medline
- Embase
- Medline (R) In-Process
- The Cochrane Library.

#	Database	Host
1	Medline	OVID
2	Medline in Process	OVID
3	Embase	OVID
4	PsycINFO	OVID
5	British Nursing Index (BNI)	OVID
6	Health Management Information Consortium (HMIC)	OVID
7	Ovid Nursing Database	OVID
8	Conference Proceedings Citation Index-Science (CPCI-S)	ISI (Thomson Reuters)
9	Conference Proceedings Citation Index-Social Science & Humanities (CPCI-SSH)	ISI (Thomson Reuters)
10	Science Citation Index Expanded (SCI-EXPANDED)	ISI (Thomson Reuters)
11	Social Sciences Citation Index (SSCI)	ISI (Thomson Reuters)
12	BIOSIS Previews	ISI (Thomson Reuters)
13	PROSPERO (CRD)	http://144.32.150.25/PROSPERO/
14	DARE, NHS EED & HTA (CRD)	http://www.crd.york.ac.uk/crdweb/SearchPage.asp
15	The Cochrane Library (Cochrane Reviews, DARE, Central, HTA, Methods & NHS EEDS)	http://www.thecochranelibrary.com/view/0/index.html
16	ECONLIT	EBSCO Host
17	Cumulative Index to Nursing and Allied Health Literature (CINAHL)	EBSCO Host
18	Trip Database	http://www.tripdatabase.com/
19	INSPEC	ISI (Thomson Reuters)
20	ASSIA	CSA
21	BL Direct	http://direct.bl.uk/bld/Home.do
22	British Library Integrated Catalogue	http://tinyurl.com/3zxztyz
23	Library of Congress Catalog	http://catalog.loc.gov/
24	Clinical Trials. Gov	http://clinicaltrials.gov/

10.1.2 The date on which the search was conducted.

All database searching in Section 10.1.1 was conducted on Sunday, October 16th 2011.

10.1.3 The date span of the search.

Each database was searched from database inception. Please see the full search strategy listings (Section 10.1.4) for database specific recording of the various parameters.

10.1.4 The complete search strategies used, including all the search terms: textwords (free text), subject index headings (for example, MeSH) and the relationship between the search terms (for example, Boolean).

1.
Database: Medline
Host: Ovid
Data Parameters: 1948 to October Week 1 2011
Date Searched: Sunday, October 16th 2011
Hits: 42
Strategy:

#	Searches	Results
1	mega soft patient return electrode$.mp.	0
2	(mega soft or megasoft or mega-soft).mp.	5
3	mega 2000.mp.	2
4	Megadyne.mp.	3
5	(return electrode$ or diathermy plate$).mp.	53
6	or/1-5	59
7	Animals/ not Humans/	3609243
8	6 not 7	42

Limits: Limited to human only populations. No other limits (e.g. date, language or methodological) were used.
Notes: N/A
File Name: Medline n=42.txt

2.
Database: Medline in Process
Host: OVID
Data Parameters: October 14, 2011
Date Searched: Sunday, October 16th 2011
Hits: 5
Strategy:

#	Searches	Results
1	mega soft patient return electrode$.mp.	0
2	(mega soft or megasoft or mega-soft).mp.	0
3	mega 2000.mp.	0
4	Megadyne.mp.	0
5	(return electrode$ or diathermy plate$).mp.	5
6	or/1-5	5
7	Animals/ not Humans/	0
8	6 not 7	5

Limits: Limited to human only populations. No other limits (e.g. date, language or methodological) were used.
Notes: N/A
File Name: Medline in process n=5.txt

3.
Database: Embase
Host: OVID
Data Parameters: 1980 to 2011 Week 41
Date Searched: Sunday, October 16th 2011
Hits: 68
Strategy:

#	Searches	Results
1	mega soft patient return electrode$.mp.	0
2	(mega soft or megasoft or mega-soft).mp.	6
3	mega 2000.mp.	3
4	Megadyne.mp.	5
5	(return electrode$ or diathermy plate$).mp.	59
6	or/1-5	69
7	Animals/ not Humans/	1260672
8	6 not 7	68

Limits: Limited to Human only populations. No other limits (e.g. date, language or methodological) were used.
Notes: N/A
File Name: Embase n=68.txt

4.
Database: PsycINFO

Host: OVID
Data Parameters: 1806 to October Week 2 2011
Date Searched: Sunday, October 16th 2011
Hits: 7
Strategy:

#	Searches	Results
1	mega soft patient return electrode$.mp.	0
2	(mega soft or megasoft or mega-soft).mp.	0
3	mega 2000.mp.	0
4	Megadyne.mp.	0
5	(return electrode$ or diathermy plate$).mp.	7
6	or/1-5	7
7	Animals/ not Humans/	5244
8	6 not 7	7

Limits: Limited to Human only populations. No other limits (e.g. date, language or methodological) were used.
Notes: N/A
File Name: PsycINFO n=7.txt

5.
Database: British Nursing Index
Host: OVID
Data Parameters: 1985 to October 2011
Date Searched: Sunday, October 16th 2011
Hits: 1
Strategy:

#	Searches	Results
1	mega soft patient return electrode$.mp.	0
2	(mega soft or megasoft or mega-soft).mp.	0
3	mega 2000.mp.	0
4	Megadyne.mp.	0
5	(return electrode$ or diathermy plate$).mp.	1
6	or/1-5	1
7	Animals/ not Humans/	0
8	6 not 7	1

Limits: Limited to Human only populations. No other limits (e.g. date, language or methodological) were used.
Notes: N/A
File Name: BNI n=1.txt

6.
Database: Health Management Information Consortium (HMIC)

Host: OVID

Data Parameters: 1979 to September 2011
Date Searched: Sunday, October 16th 2011
Hits: 3
Strategy:

#	Searches	Results
1	mega soft patient return electrode$.mp.	0
2	(mega soft or megasoft or mega-soft).mp.	0
3	mega 2000.mp.	0
4	Megadyne.mp.	0
5	(return electrode$ or diathermy plate$).mp.	3
6	or/1-5	3
7	Animals/ not Humans/	224
8	6 not 7	3

Limits: Limited to Human only populations. No other limits (e.g. date, language or methodological) were used.
Notes: N/A
File Name: HMIC n=3.txt

7.
Database: Ovid Nursing Database
Host: OVID
Data Parameters: 1948 to October Week 1 2011
Date Searched: Sunday, October 16th 2011
Hits: 5
Strategy:

#	Searches	Results
1	mega soft patient return electrode$.mp.	0
2	(mega soft or megasoft or mega-soft).mp.	0
3	mega 2000.mp.	0
4	Megadyne.mp.	0
5	(return electrode$ or diathermy plate$).mp.	5
6	or/1-5	5
7	Animals/ not Humans/	15810
8	6 not 7	5

Limits: Limited to Human only populations. No other limits (e.g. date, language or methodological) were used.
Notes: N/A
File Name: Ovid Nursing n=5.txt

8.
Database: Conference Proceedings Citation Index- Science (CPCI-S)
Host: ISI
Data Parameters: 1990-present
Date Searched: Sunday, October 16th 2011

Hits: 1
Strategy:

#	Searches	Results
1	Topic=("mega soft patient return electrode*")	0
2	Topic=(("mega 2000"))	1
3	Topic =(Megadyne)	1
4	Topic==(((mega soft or megasoft or mega-soft) and (electrode* or diathermy)))	0
5	or/1-4	1

Limits: None Applied.
Notes: Lemmatization=Off
File Name: CPCI n=1.txt

9.
Database: Conference Proceedings Citation Index- Social Science & Humanities (CPCI-SSH)
Host: ISI
Data Parameters: 1990-present
Date Searched: Sunday, October 16th 2011
Hits: 0
Strategy:

#	Searches	Results
1	Topic=("mega soft patient return electrode*")	0
2	Topic=(("mega 2000"))	0
3	Topic =(Megadyne)	0
4	Topic==(((mega soft or megasoft or mega-soft) and (electrode* or diathermy)))	0
5	or/1-4	0

Limits: None Applied.
Notes: Lemmatization=Off
File Name: N/A

10.
Database: Science Citation Index Expanded (SCI-EXPANDED)
Host: ISI
Data Parameters: 1899-present
Date Searched: Sunday, October 16th 2011
Hits: 2
Strategy:

#	Searches	Results
1	Topic=("mega soft patient return electrode*")	0
2	Topic=(("mega 2000"))	1
3	Topic =(Megadyne)	2
4	Topic==(((mega soft or megasoft or mega-soft) and (electrode* or	0

	diathermy)))	
5	or/1-4	2

Limits: None Applied.
Notes: Lemmatization=Off
File Name: SCI-EXPANDED n=2.txt

11.
Database: Social Sciences Citation Index (SSCI)
Host: ISI
Data Parameters: 1956-present
Date Searched: Sunday, October 16th 2011
Hits: 0
Strategy:

#	Searches	Results
1	Topic=("mega soft patient return electrode*")	0
2	Topic=(("mega 2000"))	0
3	Topic =(Megadyne)	0
4	Topic==(((mega soft or megasoft or mega-soft) and (electrode* or diathermy)))	0
5	or/1-4	0

Limits: None Applied.
Notes: Lemmatization=Off
File Name: N/A

12.
Database: BIOSIS Previews
Host: ISI
Data Parameters: 1969-present
Date Searched: Sunday, October 16th 2011
Hits: 0
Strategy:

#	Searches	Results
1	Topic=("mega soft patient return electrode*")	0
2	Topic=(("mega 2000"))	1
3	Topic =(Megadyne)	1
4	Topic==(((mega soft or megasoft or mega-soft) and (electrode* or diathermy)))	0
5	or/1-4	1

Limits: None Applied.
Notes: Lemmatization=Off
File Name: BIOSIS n=1.txt

13.
Database: PROSPERO (CRD)

Host: http://144.32.150.25/PROSPERO/
Data Parameters:
Date Searched: Sunday, October 16th 2011
Hits: 0
Strategy:

1. ("mega soft patient return electrode*")
2. ("mega 2000")
3. (Megadyne)
4. ((mega soft or megasoft or mega-soft) and (electrode* or diathermy))

Limits: None Applied.
Notes: Searching conducted on 'all fields'
File Name: N/A

14.
Database: DARE, NHS EED & HTA (CRD)
Host: http://www.crd.york.ac.uk/crdweb/SearchPage.asp
Data Parameters:
Date Searched: Sunday, October 16th 2011
Hits: 0
Strategy:

1. ("mega soft patient return electrode*")
2. (mega soft or megasoft or mega-soft)
3. ("mega 2000")
4. (Megadyne)
5. ((return electrode* or diathermy plate*))

Limits: None Applied.
Notes: Searching conducted on 'all fields'
File Name: N/A

15.
Database: The Cochrane Library (Cochrane Reviews, DARE, Central, HTA, Methods & NHS EEDS)
Host: http://www.thecochranelibrary.com/view/0/index.html
Data Parameters: Issue 10 of 12, Oct 2011
Date Searched: Sunday, October 16th 2011
Hits: 38
Strategy:

ID	Search	Hits
#1	("mega soft patient return electrode*")	0
#2	("mega 2000")	0
#3	(Megadyne)	0
#4	(mega soft or megasoft or mega-soft):ti,ab,kw	0
#5	(return electrode* or diathermy plate*):ti,ab,kw	38

Show Results in:
Cochrane Reviews [0] | Other Reviews [0] | **Clinical Trials [38]** | Methods Studies [0] | Technology Assessments [0] | Economic Evaluations [0] | Cochrane Groups [0]

Limits: None Applied.
Notes: N/A
File Name: N/A

16.
Database: ECONLIT
Host: EBSCO Host
Data Parameters: 1886-present
Date Searched: Sunday, October 16th 2011
Hits: 0
Strategy:

S1. ("mega soft patient return electrode*")
S2. ("mega 2000")
S3. (Megadyne)
S4. (mega soft or megasoft or mega-soft)
S5. (return electrode* or diathermy plate*)
S1 or S2 or S3 or S4 or S5

Limits: None Applied.
Notes: N/A
File Name: N/A

17.
Database: Cumulative Index to Nursing and Allied Health Literature (CINAHL)
Host: EBSCO Host
Data Parameters:
Date Searched: Sunday, October 16th 2011
Hits: 13
Strategy:

S1. ("mega soft patient return electrode*")
S2. ("mega 2000")
S3. (Megadyne)
S4. (mega soft or megasoft or mega-soft)
S5. (return electrode* or diathermy plate*)
S1 or S2 or S3 or S4 or S5

Limits: None Applied.
Notes: N/A
File Name: Cinahl n=13.txt

18.
Database: Trip Database
Host: http://www.tripdatabase.com/
Data Parameters:
Date Searched: Sunday, October 16th 2011
Hits: 1
Strategy:

1. ("mega soft patient return electrode*")
2. ("mega 2000")
3. (Megadyne)
4. ((mega soft or megasoft or mega-soft) and (return electrode* or diathermy plate*))

Limits: None Applied.
Notes: N/A
File Name: TRIP n=1.txt

19.
Database: INSPEC
Host: ISI
Data Parameters: 1969-present
Date Searched: Sunday, October 16th 2011
Hits: 0
Strategy:

#	Searches	Results
1	Topic=("mega soft patient return electrode*")	0
2	Topic=(("mega 2000"))	0
3	Topic =(Megadyne)	0
4	Topic==(((mega soft or megasoft or mega-soft) and (electrode* or diathermy)))	0
5	or/1-4	0

Limits: None Applied.
Notes: Lemmatization=Off
File Name: N/A

20.
Database: ASSIA
Host: CSA
Data Parameters: Earliest to Current
Date Searched: Sunday, October 16th 2011
Hits: 0
Strategy:

(KW=("mega soft patient return electrode*"))
(KW=("mega 2000"))
(KW=(Megadyne))
(KW=(mega soft) or KW=(megasoft) or KW=("mega-soft"))

(KW=(return electrode*) or KW=(diathermy plate*))

Limits: None Applied.
Notes: N/A
File Name: N/A

21.
Database: BL Direct
Host: http://direct.bl.uk/bld/Home.do
Data Parameters: Last Seven Days
Date Searched: Sunday, October 16th 2011
Hits: 0
Strategy:

(Megadyne)

Limits: None Applied.
Notes: N/A
File Name: N/A

22.
Database: British Library Integrated Catalogue
Host: http://tinyurl.com/3zxztyz
Data Parameters: N/A
Date Searched: Sunday, October 16th 2011
Hits: 0
Strategy:

Megadyne
patient return electrode

Limits: None Applied.
Notes: Filter set 'Word(s) anywhere'
File Name: N/A

23.
Database: Library of Congress Catalog
Host: http://catalog.loc.gov/webvoy.htm
Data Parameters: N/A
Date Searched: Sunday, October 16th 2011
Hits: 0
Strategy:

Megadyne
patient return electrode

Limits: None Applied.
Notes: Search Type '(Keyword(match all words)*
File Name: N/A

24.
Database: Clinical Trials. Gov
Host: http://clinicaltrials.gov/ct2/home
Data Parameters: N/A
Date Searched: Wednesday, October 12th 2011
Hits: 1
Strategy:

1. (mega 2000) n=0
2. (mega soft or megasoft or mega-soft) n=0
3. Megadyne n=1

Limits: None
Notes: 1 hit retrieved on company name. Saved as a MS Word file.
File Name: Clinical Trials. Gov n=1

25.
Database: Current Controlled Trials
Host: http://www.controlled-trials.com/
Data Parameters: N/A
Date Searched: Wednesday, October 12th 2011
Hits: 0
Strategy:

1. (mega 2000) n=0
2. (mega soft or megasoft or mega-soft) n=0
3. Megadyne n=0

Limits: N/A
Notes: The following were selected and searched: ISRCTN Register, NIH ClinicalTrials.gov Register, Action Medical Research (UK), The Wellcome Trust (UK), Medical Research Council (UK), and UK trials (UK).
File Name: N/A

10.1.5 Details of any additional searches, such as searches of company or professional organisation databases (include a description of each database).

The following additional search strategies were employed:

Trials Register Searching;

Backwards Citation Chasing (manually) on Included Articles;

Forwards Citation Chasing on Included Articles (results below);

Contact with Megadyne; and,

Unpublished/Grey Literature/difficult-to-locate searching, including:

- Database searching of high-value grey literature resources (e.g. HMIC);
- Conference Proceedings Abstracts;
- Web-Searching (results below); and
- Searching of Library Catalogues for unpublished literature.

Results from Forwards Citation Chasing

Citation	**Web of Knowledge**	**Google Scholar**	**Medline**	**Number of Unique Items**
"Skin lesions from aggressive adhesive on Valleylab electrosurgical return electrode pads." Health Devices **24**(4): 159-160.	0	0	0	0
"Severe skin burns caused by chemical action with diathermy plates." DHSS Department of Health and Social Security	0	0 (Google was also searched with a view to similar article searching)	0	0
(2005). "Improper return-electrode selection and placement contribute to patient burn with the Smith & Nephew Vulcan ElectroThermal	0	0	0	0

Arthroscopy System (EAS)." Health Devices **34**(8): 284-286.				
(2005). "Return-electrode-site burns associated with Rita Medical Systems Model 1500 and 1500X radio-frequency generators." Health Devices **34**(8): 280-282.	0	0	0	0
(2005). "Higher currents, greater risks: preventing patient burns at the return-electrode site during high-current electrosurgical procedures." Health Devices **34**(8): 273-279.	0	0	0	0
Sheridan, R. L., N. C. Wilson, et al. (2003). "Noncontact Electrosurgical Grounding Is Useful in Burn Surgery." Journal of Burn Care and Rehabilitation **24**(6): 400-401.	2	2	5	5
Ziprin, P. and A. W. Darzi (2002). "Monopolar electrosurgery: Risks and their reduction." Problems in General Surgery **19**(2): 18-23.	0	2	0	2
			Total	**7**

Results from Web-Searching

Web-Searching

Web-searching was carried out on specific web-sites (listed below) and through two web- interfaces. One, meta-search using Dogpile, in addition to a Google-specific search with a specified limit to PDFs.

Specific Websites

Web-Site	URL	Date Searched	Search Terms	Notes	Information found
Megadyne	http://www.megadyne.com/ http://www.megadyne.com/return_reviews.php	Monday, October 17th 2011	N/A	A search of the company web-site for effectiveness, clinical effectiveness and background information	None
NICE	http://www.nice.org.uk/	Monday, October 17th 2011	Megadyne mega 2000 mega soft megasoft	No Results No Results The protocol was located No Results	No Results No Results The NICE protocol but we already have this. No Results
NHS Evidence	www.evidence.nhs.uk/	Monday, October 17th 2011	Megadyne – all fields "mega 2000" – all fields ("mega soft" or "megasoft" or "mega-soft") – all fields	No Results No Results A Result about hand-held PDAs was retrieved by the search	No Results No Results No Result saved as the result located was not relevant
NHS Scotland's	http://www.knowledge.scot.nhs.uk/home.as	Monday, October 17th 2011	Megadyne	2 x Results (1 from Medline and 1 x Embase) of the	No Results retrieved as this was picked up in the database search

Knowledge Network	px		"mega 2000" ("mega soft" or "megasoft" or "mega-soft")	Sloots KL et al (2007) paper were identified 1 copy of the Du P et al (2009) paper was identified No Results	No Results retrieved as this was picked up in the database search No Results
Health in Wales	http://www.wales.nhs.uk/	Monday, October 17th 2011	Megadyne "mega 2000" ("mega soft" or "megasoft" or "mega-soft")	No Results No Results No Results	No Results No Results No Results
Department of Health	http://www.dh.gov.uk/en/index.htm	Monday, October 17th 2011	Megadyne "mega 2000" ("mega soft" or "megasoft" or "mega-soft")	No Results "mega 2000" No Results	No Results "mega 2000" No Results
Association of Surgeons of Great Britain and Ireland	http://www.asgbi.org.uk/	Monday, October 17th 2011	Megadyne mega 2000	No Results 8 items identified but all were not relevant (as were about fellowships) The search would not work if we used speech marks to frame the search therefore not using them meant the 2000 element draw in hits	No Results No Results was retrieved

				1 item identified which linked to ASGBI Link Surgeons Website	
			mega soft	Search interface reported 'invalid search character found' for the hyphen. As other iterations had been searched the search here was ceased.	No Results were identified on either the initial or secondary link
			Megasoft		No Results
			Mega-soft		No Results
British Association of Day Surgery	http://www.bads.co.uk/bads/joomla/	Monday, October 17th 2011	See Notes	The Web-site was read looking for the terms 'Megadyne', Mega 200 or Mega Soft.	No Results were identified
Royal College of Nursing	http://www.rcn.org.uk/	Monday, October 17th 2011	Megadyne	No Results	No Results
			"mega 2000"	No Results	No Results
			"mega soft"	3 x results identified	3 x items retrieved 1) RCN Item 1 4th_Bulletin_16_June_2011.docx 2) RCN item 2

			Megasoft Mega-soft	No Results 3 x Results identified (being the same as above)	5th_Bulletin_30_June_2011.doc 3) RCN Item 3 11th_Bulletin_06_Oct_11.doc No Results Already retrieved the identified results on the search "mega soft"
Royal College of Surgeons	http://www.rcseng.ac.uk/	Monday, October 17th 2011	Megadyne "mega 2000" "mega soft" Megasoft Mega-soft	No Results No Results No Results No Results No Results	No Results No Results No Results No Results No Results
Royal College of Anaesthetists	http://www.rcoa.ac.uk/	Monday, October 17th 2011	Megadyne "mega 2000" "mega soft" Megasoft Mega-soft	No Results No Results No Results No Results No Results	No Results No Results No Results No Results No Results
British Medical Association	http://www.bma.org.uk/	Monday, October 17th 2011	Megadyne "mega 2000" "mega soft"	No Results No Results No Results	No Results No Results No Results

			Megasoft Mega-soft	No Results No Results	No Results No Results
US Food and Drug Administration[3]	http://www.fda.gov/	Monday, October 17th 2011	Mega Soft Patient Return Electrode "mega 2000"	4 items identified 5 items identified	FDA Item 1 510(k) Premarket Notification.doc FDA Item 2 MAUDE Adverse Event Report FDA Item 3 DEC 1 6 2008 FDA Item 4 December 2008 510(k) Clearances.doc FDA Item 5 510(k) Premarket Notification FDA Item 5 510(k) Premarket Notification FDA Item 6 510(k) Premarket Notification.doc FDA Item 7 PDF K031285 FDA Item 8 April 2002 510(k) Clearances FDA Item 9 May 2003 510(k) Clearances

[3] MAUDE was also searched separately as a cross-check. http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm

					See: FDA Item 1 510(k) Premarket Notification.doc FDA Item 10 TPLC - Total Product Life Cycle FDA Item 11 **[PDF]** DEC 1 6 2008 K080741 FDA Item 12 December 2008 510(k) Clearances
			Mega Soft and Electrode – these terms were used in the advanced search function with ‘mega soft’ as the exact phrase and ‘electrode’ in at least one of the words search.		No results
			MegaSoft and Electrode – these terms were used in the advanced search function with ‘mega soft’ as the exact phrase and ‘electrode’ in at least one of the words search.	No results	

MedWatch (via FDA web-site)	http://www.fda.gov/Safety/MedWatch/default.htm	Monday, October 17th 2011	Megadyne Mega Soft MegaSoft "mega 2000"	No Results No Results No Results No Results	No Results No Results No Results No results
DeviceSpace	http://www.devicespace.com/Default.aspx	Monday, October 17th 2011	Megadyne Mega Soft MegaSoft	10 items identified by this search only 1 was relevant to the return electrode No Results No Results No Results	Devicespace item 1 MEGADYNE Introduces the Paediatric Mega Soft(R) Reusable Return Electrode No Results No Results No Results

			"mega 2000"		
CDRH Inspections Database	http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfTPLC/inspect.cfm	Monday, October 17th 2011	Searched on Company Names: Megadyne	No Results	No Results
MAUDE (Manufacturer and User Facility Device Experience)	http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.CFM	Monday, October 17th 2011	Searched Manufacture: Megadyne	10 Results identified of which 2 related to Mega Soft	2 Results saved MAUDE Item one MEGA SOFT DETACHACAB MAUDE Item two MEGA SOFT
MDR (Medical Device Reporting)	http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmdr/search.CFM	Monday, October 17th 2011	This resource was searched even though its updating and resource parameters are out of date for this intervention. This to cross-check any preceding models	No Results	No Results
Premarket Approvals (PMA)	http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm	Monday, October 17th 2011	Megadyne	No Results	No Results
Premarket Notifications (510(k)s)	http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm	Monday, October 17th 2011	Searched on Applicant Names: Megadyne	41 Results returned	14 Items saved 510(k) Premarket Notification Item One mega soft reusable patient return electrode K080741 NB: - the pdf for K080741 (the summary for this record) is saved as: FDA Item 11 [PDF] DEC 1 6

					2008 K080741 510(k) Premarket Notification Item two K031285.doc the pdf for K031285 (the summary for this record) is saved as: FDA Item 7 PDF K031285 510(k) Premarket Notification Item three K021077 510(k) Premarket Notification Item four K021077 summary pdf 510(k) Premarket Notification Item five K982826 510(k) Premarket Notification Item six K982826 summary pdf 510(k) Premarket Notification Item seven K973346.doc 510(k) Premarket Notification Item eight K973346 summary pdf.pdf 510(k) Premarket Notification Item nine K946237

				This was the last item retrieved as the documents	510(k) Premarket Notification Item ten K943055 510(k) Premarket Notification Item eleven K945898 510(k) Premarket Notification Item twelve K942489 510(k) Premarket Notification Item thirteen K932102 510(k) Premarket Notification Item fourteen K912597

				lapsed into being only registrations and stopped including summaries which might have been on use.	
Medical & Radiation Emitting Device Recalls Database	http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm	Monday, October 17th 2011	*"mega 2000"* *Megasoft* *Mega Soft*	No Results No Results No Results	No Results No Results No Results

Generic Web-Searching

After searching specific web-sites (as listed above) two internet searches were conducted. One using the Meta-Search engine, Dogpile, the other using Google with a restriction to PDF document types. A meta-search was appropriate as it federates multiple search engines (in effect being a match alternate to searching various databases) such as Google, Bing and Yahoo. http://www.dogpile.com/info.dogpl.t2.8/support/Metasearch

Dogpile
The search filter for this search was set to none, which is the most sensitive filter.

Search Terms	Web-Site Name & URL	Title	Notes	Items saved
Mega Soft and Electrode	http://www.megadyne.com/pr3.php	MEGADYNE's MEGA 2000 Soft Return Electrode Saves Thousands in Medical Waste Disposal Costs and Helps Protect Our Environment (Press Release)		Dogpile Search Item 1 Mega 2000 press release
Mega Soft	http://www.megadyne.com/r	Patient Return Electrodes		Dogpile Search

and Electrode	eturn_electrodes.php	(Megadyne Website)		Item 2 Megadyne website
Mega Soft and Electrode	http://www.reuters.com/article/2009/03/17/idUS133338+17-Mar-2009+MW20090317	MEGADYNE Introduces the Pediatric Mega Soft(R) Reusable Return Electrode		Dogpile Search Item 3 press release
Mega Soft and Electrode	http://www.megadyne.com/return_compare.php	It's Official: Mega Soft® Return Electrodes are Safer Than ValleyLab REM™ and other CQM "Sticky Pads"		Dogpile Search Item 4 Megadyne web-site
Mega Soft and Electrode	http://www.indiamart.com/unicore-medical/medical-electrodes.html	MEGA SOFT- Reusable Patient Return Electrodes – unicore medical solutions		Dogpile Search Item 5 Unicore
Mega Soft and Electrode	http://www.megadyne.com/safetyreport.pdf	How is Megadyne Mega Soft® Safer than Contact Quality Monitoring Return Electrodes?		Dogpile Search Item 6 Megadyne safety pdf
See Notes (to the right)	http://www.valleylab.com/education/hotline/pdfs/hotline_0806.pdf	Extreme Energy Demands and the Traditional Patient Return Electrode: Updates to Patient Return Electrode Instructions for Use	This item was followed from Dogpile Search Item 6 Megadyne safety pdf	Search Item 7 Covidien pdf

See Notes (to the right)	http://solutions.3m.com.sg/3MContentRetrievalAPI/BlobServlet?locale=en_SG&lmd=1280902208000&assetId=1273661847608&assetType=MMM_Image&blobAttribute=ImageFile	Reducing Grounding Pad Burns During High Current Electrosurgical Procedures	This item was followed from Dogpile Search Item 6 Megadyne safety pdf	Search Item 8 3m briefing
Mega Soft and Electrode	http://www.clin-eng.net/index.php?option=com_content&view=article&id=172:small-patient-big-responsibility&catid=1	Great Ormond Street choose Mega Soft		Dogpile Search Item 9 Great Ormond Street
Mega Soft and Electrode	http://2.imimg.com/data2/CC/HL/MY-3566125/mega-soft-reusable-patient-return-electrodes.pdf	IT'S OFFICIAL: MEGA_SOFT® SAFER THAN "STICKY PADS"		Dogpile Search Item 9 it's official
Mega Soft and Electrode	http://www.dotmed.com/news/story/14637/	Megadyne Named Utah Green Business By Utah Business Magazine		Dogpile Search Item 11 utah

Searching was stopped at the end of page 5. This was because the results were no longer bearing relevance to the search enquiry.

Search Terms	Web-Site Name & URL	Title	Notes	Items saved
"mega 2000"	http://findarticles.com/p/articles/mi_m0BPC/is_7_29/ai_n14735114/	Standard operating procedure for comfort and cost savings at Kaleida Health		Dogpile Search Item 12 kaleida health

Searching was stopped at the end of page 5. This was because the results were no longer bearing relevance to the search enquiry. There was also significant duplication between this search and the search directly above.

Google
The search filter for this search was set to pdf document types using the advanced search function n=32

Search Terms	Web-Site Name & URL	Title	Notes	Items saved
Mega soft and electrode (n=32)	http://www.megadyne.com/pdf/Electrosurgery1.pdf	Megadyne: principles of electrosurgery		Google pdf search item 1
Mega 2000 (n=35)	http://www.valleylab.com/education/hotline/pdfs/hotline_0712.pdf	Hotline news volume 12 issue 2		Google pdf search item 2
	http://www.megadyne.com/pdf/mmp201.pdf	MEGA 2000® Patient Return Electrode System Theory of Operation and Product Description		Google pdf search item 3
	http://bms2.be/doc_upload/06%20Mega%202000%20Product%20Description.pdf	Patient Return Electrode System: Megadyne		Google pdf search item 4
	http://www.rmpd.org.uk/news_and_events/ipem_asm_2002/7_clinical_engineering.pdf	Chapter 7. Clinical Engineering – a conference abstract		Google pdf search item 5
	http://megadyne.com/pdf/mmp202.pdf	A New Approach to _ Return Electrodes for Electrosurgery		Google pdf search item 6

10.1.6 The inclusion and exclusion criteria.

See above.

10.1.7 The data abstraction strategy.

See above.

10.2 Appendix 2: Search strategy for adverse events (section 7.7.1)

The following information should be provided.

10.2.1 The specific databases searched and the service provider used (for example, Dialog, DataStar, OVID, Silver Platter), including at least:

- Medline
- Embase
- Medline (R) In-Process
- The Cochrane Library.

No methodological or study filters were used on the search, and the search was conducted on the intervention alone, so literature on this specific topic area was retrieved through the search recorded at Section 10.1.1.

10.2.2 The date on which the search was conducted.

See Appendix 1.

10.2.3 The date span of the search.

See Appendix 1.

10.2.4 The complete search strategies used, including all the search terms: textwords (free text), subject index headings (for example, MeSH) and the relationship between the search terms (for example, Boolean).

See Appendix 1.

10.2.5 Details of any additional searches (for example, searches of company databases [include a description of each database]).

See Appendix 1.

10.2.6 The inclusion and exclusion criteria.

See Appendix 1.

10.2.7 The data abstraction strategy.

See Appendix 1.

10.3 Appendix 3: Search strategy for economic evidence (section 8.1.1)

The following information should be provided.

10.3.1 The specific databases searched and the service provider used (for example, Dialog, DataStar, OVID, Silver Platter), including at least:

- Medline
- Embase
- Medline (R) In-Process
- EconLIT
- NHS EED.

No methodological or study filters were used on the search, and the search was conducted on the intervention alone, so literature on this specific topic area was retrieved through the search recorded at Section 10.1.1.

10.3.2 The date on which the search was conducted.

See Appendix 1.

10.3.3 The date span of the search.

See Appendix 1.

10.3.4 The complete search strategies used, including all the search terms: textwords (free text), subject index headings (for example, MeSH) and the relationship between the search terms (for example, Boolean).

See Appendix 1.

10.3.5 Details of any additional searches (for example, searches of company databases [include a description of each database]).

See Appendix 1.

10.4 Appendix 4: Resource identification, measurement and valuation (section 9.3.2)

The following information should be provided.

10.4.1 The specific databases searched and the service provider used (for example, Dialog, DataStar, OVID, Silver Platter), including at least:

- Medline
- Embase
- Medline (R) In-Process
- NHS EED
- EconLIT.

No methodological or study filters were used on the search, and the search was conducted on the intervention alone, so literature on this specific topic area was retrieved through the search recorded at Section 10.1.1.

10.4.2 The date on which the search was conducted.

See Appendix 1.

10.4.3 The date span of the search.

See Appendix 1.

10.4.4 The complete search strategies used, including all the search terms: textwords (free text), subject index headings (for example, MeSH) and the relationship between the search terms (for example, Boolean).

See Appendix 1.

10.4.5 Details of any additional searches (for example, searches of company databases [include a description of each database]).

See Appendix 1.

10.4.6 The inclusion and exclusion criteria.

See Appendix 1.

10.4.7 The data abstraction strategy.

See Appendix 1.

11 Related procedures for evidence submission

11.1 Cost models

An electronic executable version of the cost model should be submitted to NICE with the full submission.

NICE accepts executable cost models using standard software – that is, Excel, TreeAge Pro, R or WinBUGs. If you plan to submit a model in a non-standard package, NICE should be informed in advance. NICE, in association with the External Assessment Centre, will investigate whether the requested software is acceptable, and establish if you need to provide NICE and the External Assessment Centre with temporary licences for the non-standard software for the duration of the assessment. NICE reserves the right to reject cost models in non-standard software. A fully executable electronic copy of the model must be submitted to NICE with full access to the programming code. Care should be taken to ensure that the submitted versions of the model programme and the written content of the evidence submission match.

NICE may distribute the executable version of the cost model to a consultee if they request it. If a request is received, NICE will release the model as long as it does not contain information that was designated confidential by the model owner, or the confidential material can be redacted by the model owner without producing severe limitations on the functionality of the model. The consultee will be advised that the model is protected by intellectual property rights, and can be used only for the purposes of commenting on the model's reliability and informing comments on the medical technology consultation document.

Sponsors must ensure that all relevant material pertinent to the decision problem has been disclosed to NICE at the time of submission. NICE may request additional information not submitted in the original submission of evidence. Any other information will be accepted at NICE's discretion.

When making a full submission, sponsors should check that:

- an electronic copy of the submission has been given to NICE with all confidential information highlighted and underlined
- a copy of the instructions for use, regulatory documentation and quality systems certificate have been submitted
- an executable electronic copy of the cost model has been submitted
- the checklist of confidential information provided by NICE has been completed and submitted.

- A PDF version of all studies (or other appropriate format for unpublished data, for example, a structured abstract) included in the submission have been submitted

11.2 Disclosure of information

To ensure that the assessment process is as transparent as possible, NICE considers it highly desirable that evidence pivotal to the Medical Technologies Advisory Committee's decisions should be publicly available at the point of issuing the medical technology consultation document and medical technology guidance.

Under exceptional circumstances, unpublished evidence is accepted under agreement of confidentiality. Such evidence includes 'commercial in confidence' information and data that are awaiting publication ('academic in confidence').

When data are 'commercial in confidence' or 'academic in confidence', it is the sponsor's responsibility to highlight such data clearly, and to provide reasons why they are confidential and the timescale within which they will remain confidential. The checklist of confidential information should be completed: if it is not provided, NICE will assume that there is no confidential information in the submission. It is the responsibility of the manufacturer or sponsor to ensure that the confidential information checklist is kept up to date.

It is the responsibility of the sponsor to ensure that any confidential information in their evidence submission is clearly underlined and highlighted

correctly. NICE is assured that information marked ‘academic in confidence’ can be presented and discussed during the public part of the Medical Technologies Advisory Committee meeting. NICE is confident that such public presentation does not affect the subsequent publication of the information, which is the prerequisite allowing for the marking of information as ‘academic in confidence’.

Please therefore underline all confidential information, and highlight information that is submitted under ‘commercial in confidence’ in blue and information submitted under ‘academic in confidence’ in yellow.

NICE will ask sponsors to reconsider restrictions on the release of data if there appears to be no obvious reason for the restrictions, or if such restrictions would make it difficult or impossible for NICE to show the evidential basis for its guidance. Information that has been put into the public domain, anywhere in the world, cannot be marked as confidential.

Confidential information submitted will be made available for review by the External Assessment Centre and the Medical Technologies Advisory Committee. NICE will at all times seek to protect the confidentiality of the information submitted, but nothing will restrict the disclosure of information by NICE that is required by law (including in particular, but without limitation, the Freedom of Information Act 2000).

The Freedom of Information Act 2000, which came into force on 1 January 2005, enables any person to obtain information from public authorities such as NICE. The Act obliges NICE to respond to requests about the recorded information it holds, and it gives people a right of access to that information. This obligation extends to submissions made to NICE. Information that is designated as ‘commercial in confidence’ may be exempt under the Act. On receipt of a request for information, the NICE secretariat will make every effort to contact the designated company representative to confirm the status of any information previously deemed ‘commercial in confidence’ before making any decision on disclosure.

11.3 Equality

NICE is committed to promoting equality and eliminating unlawful discrimination, including paying particular attention to groups protected by equalities legislation. The scoping process is designed to identify groups who are relevant to the evaluation of the technology, and to reflect the diversity of the population. NICE consults on whether there are any issues relevant to equalities within the scope of the evaluation, or if there is information that could be included in the evidence presented to the Medical Technologies Advisory Committee to enable them to take account of equalities issues when developing guidance.

Evidence submitters are asked to consider whether the chosen decision problem could be impacted by NICE's responsibility in this respect, including when considering subgroups and access to recommendations that use a clinical or biological criterion.

For further information, please see the NICE website (www.nice.org.uk/aboutnice/howwework/NICEEqualityScheme.jsp).

References

1995. Skin lesions from aggressive adhesive on Valleylab electrosurgical return electrode pads. *Health Devices,* 24**,** 159-160.

2000. MegaDyne Mega 2000 return electrode. *Health devices,* 29**,** 445-460.

2005a. Higher currents, greater risks: preventing patient burns at the return-electrode site during high-current electrosurgical procedures. *Health Devices,* 34**,** 273-279.

2005b. Improper return-electrode selection and placement contribute to patient burn with the Smith & Nephew Vulcan ElectroThermal Arthroscopy System (EAS). *Health Devices,* 34**,** 284-286.

2005c. Return-electrode-site burns associated with Rita Medical Systems Model 1500 and 1500X radio-frequency generators. *Health Devices,* 34**,** 280-282.

ACTION®PRODUCTSINC. 2011. *Overlays: Action® O.R. Overlay* [Online]. Available: http://www.actionproducts.com/operating_room_products/overlays/ViewCategory/catalog.cfm.

BRILL, A. 2011. Electrosurgery: Principles & Practice. APGO Educational Series on Women's Health Issues. http://www.apgo.org/electrosurgery/monograph.html.
CURTIS, L. 2010. Unit costs of health and social care. Personal Social Services Research Unit (PSSRU).
DRUMMOND, M. F., O'BRIEN, B., STODDART, G. L. & TORRANCE, G. W. 2005. *Methods for the Economic Evaluation of Health Care Programmes,* Oxford, UK, Oxford University Press.
LIBERATI, A., ALTMAN, D. G., TETZLAFF, J., MULROW, C., GØTZSCHE, P. C., IOANNIDIS, J. P. A., CLARKE, M., DEVEREAUX, P. J., KLEIJNEN, J. & MOHER, D. 2009. The PRISMA Statement for Reporting Systematic Reviews and Meta-Analyses of Studies That Evaluate Health Care Interventions: Explanation and Elaboration. *PLoS Medicine,* 6**,** e1000100-e1000100.
MEGADYNE 2011a. How is Megadyne Mega Soft safer than contact quality monitoring return electrodes ? http://www.megadyne.com/.
MEGADYNE. 2011b. *The Mega Soft™—Providing the Best Outcome for the Patient at CHRISTUS St. Joseph's* [Online]. Available: http://www.megadyne.com/case_study2.php.
MEGADYNE. 2011c. *The MEGA Soft™—Standard Operating Procedure for Comfort and Cost Savings at Kaleida Health* [Online]. Available: http://www.megadyne.com/case_study1.php.
MOHER, D., PHAM, B., KLASSEN, T. P., SCHULZ, K. F., BERLIN, J. A., JADAD, A. R. & LIBERATI, A. 2000. What contributions do languages other than English make on the results of meta-analyses? *Journal of Clinical Epidemiology,* 53**,** 964-72.
NHS April 2010. NHS Supplies Catalogue.
NICE 2008. Guide to the Methods of Technology Appraisal. London, UK.
PAPAIOANNOU, D., SUTTON, A., CARROLL, C., BOOTH, A. & WONG, R. 2010. Literature searching for social science systematic reviews: consideration of a range of search techniques. *Health Information and Libraries Journal,* 27**,** 114-122.
SHERIDAN, R. L., WILSON, N. C., O'CONNELL, M. F. & FABRI, J. A. 2003. Noncontact Electrosurgical Grounding Is Useful in Burn Surgery. *Journal of Burn Care and Rehabilitation,* 24**,** 400-401.
ZIPRIN, P. & DARZI, A. W. 2002. Monopolar electrosurgery: Risks and their reduction. *Problems in General Surgery,* 19**,** 18-23.