EP141 Technical Testing of Mega Soft Patient Return electrode

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Declared interests of the authors

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Rider on responsibility for report

The views expressed in this report are those of the authors and not necessarily those of the National Centre for Health and Clinical Excellence. Any errors are the responsibility of the authors.

[1] http://www.nice.org.uk/niceMedia/pdf/Guidanceondeclarationsofinterest.pdf

Summary

There are risks present in all electrosurgery. This report considers if there is evidence that there are any new risks, or increased risks due to using a large capacitive return electrode rather than a conventional sticky conductive electrode. Evidence is largely from unpublished test data and testing carried out by Cedar.

There are approximately 5,500 Mega Soft pads in use globally, with the majority in the USA, and the pads have been in use since 2003. Searches of incident databases in the USA and UK found only a small number of reports.

The risk of return site burns is very low due to the current reducing when a poor capacitive connection is present.

The risk of alternate site burns is higher with capacitive pads than with resistive pads, although it is present in all electrosurgery. The risk is greatly reduced by following normal good theatre practice of using as low a power setting as possible and avoiding alternate current pathways (eg contact with metal objects that are referred to earth).

It is unlikely that any issues of electromagnetic interference are altered by the use of a capacitive return pad.

Accidental puncturing or cutting of the pad does not appear to present a hazard to the patient.

In both the UK and the USA, the Mega Soft pad is used with a variety of different electrosurgery generators. Megadyne can provide a certificate stating that the Mega Soft is compatible with a particular generator.

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Abbreviations and Glossary

CE	CE Marking, compulsory for medical devices sold within the EU.
CHUS	Centre hospitalier universitaire de Sherbrooke
CQM, Contact quality monitoring	The generator monitors a split return electrode, and stops function if there is not good contact between the return electrode and the patient.
EAC	External assessment centre (for NICE) eg Cedar
ESU	Electro Surgery Unit, or generator
FDA	Food and Drug Administration, USA
Grounded	An electrosurgery generator that is earth referenced, the circuit can be completed by any other earthed object that comes into contact with it.
hf	High Frequency, frequency of alternating electrical current used (approx 200 kHz to 2 MHz) which do not cause muscle or nerve stimulation i.e. electric shock
Isolated	The electrosurgery generator is not referenced to earth
MAUDE	Manufacturer and User Facility Device Evaluation, USA FDA Adverse Incident database
MHRA	Medicines and Healthcare Regulatory Agency, UK Competent Authority
Monopolar	The current flows from the active electrode, through the patient and back through the return electrode.
NE, neutral electrode	Neutral electrode, return electrode or dispersive electrode
Notified body	An organisation notified to the EC by one of the EU nations as being competent to carry out assessments of medical devices in accordance with the Medical Devices Directive
RECQM	Return Electrode Contact Quality Monitoring (see CQM)
REM	Return electrode monitoring (See CQM)
UL	Underwriters Laboratory (US notified body)

1 Electrosurgery background information

The information in this section is to assist understanding of the remainder of the document for readers without detailed technical knowledge of electrosurgery. It is by necessity brief and orientated towards the remainder of the report with some simplifications. It should not be considered as a full explanation of electrosurgery.

Electrosurgery uses high frequency (hf) current to achieve surgical effects such as cutting and coagulation. The majority of surgical procedures will use some electrosurgery.

Monopolar electrosurgery relies on the patient forming part of the electrical circuit. Current passes from the tool used by the surgeon (the active electrode), through the patient to a return electrode, and then returns to the electrosurgery generator, figure 1. The active electrode is effective because it has a small area, resulting in a high current density. The return electrode has a relatively large area and the current density is low, therefore there is almost no heating effect at this point. For this reason it is also known as a dispersive electrode. It may also be called a neutral electrode, and this is the name used in the relevant standards.

1.1 Types of return electrode

A standard return electrode is stuck onto the patient's skin forming a direct electrical connection, as shown in figure 1.

A capacitive electrode does not rely on a direct contact between the patient and the pad, figure 2. The patient and the pad can be represented as two parallel metal plates, a charge builds up on one plate, causing an opposite charge on the second plate. As the high frequency current changes direction, the charges build up and discharge, completing the electric circuit. The term *capacitance* describes how effectively this works, and depends on factors such as plate area, gap between plates, frequency and the properties of materials (dielectric constant) between the plates. A higher capacitance means that the circuit is completed more readily.

Simple circuit diagrams representing a basic resistive and capacitive circuit are shown in figures 3 and 4.

Figure 1. Electrosurgery using conventional, conductive return electrode

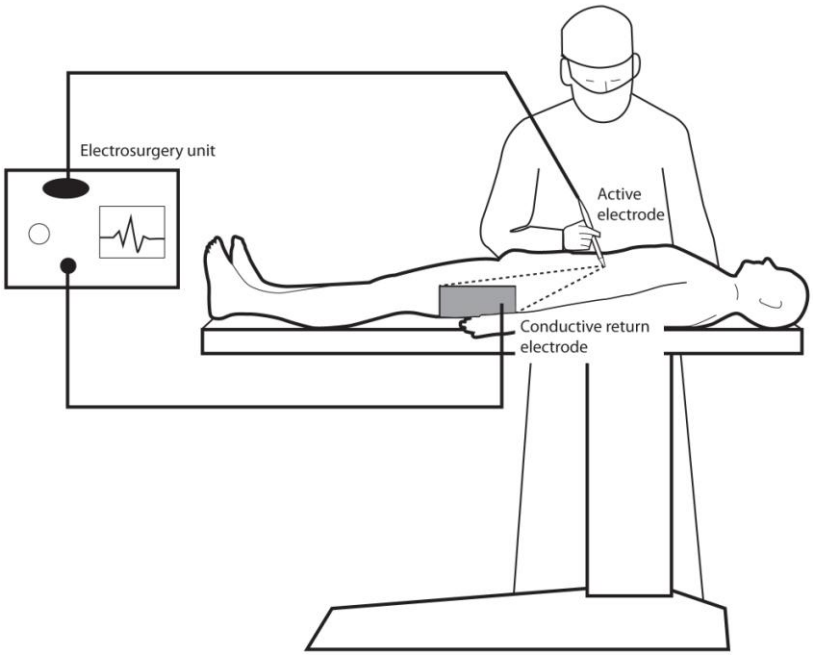


Figure 3. A simple circuit showing a resistor

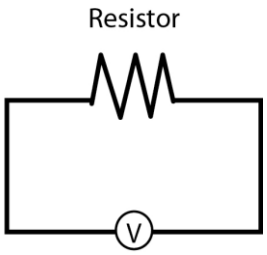


Figure 2. Electrosurgery using large capacitive return electrode

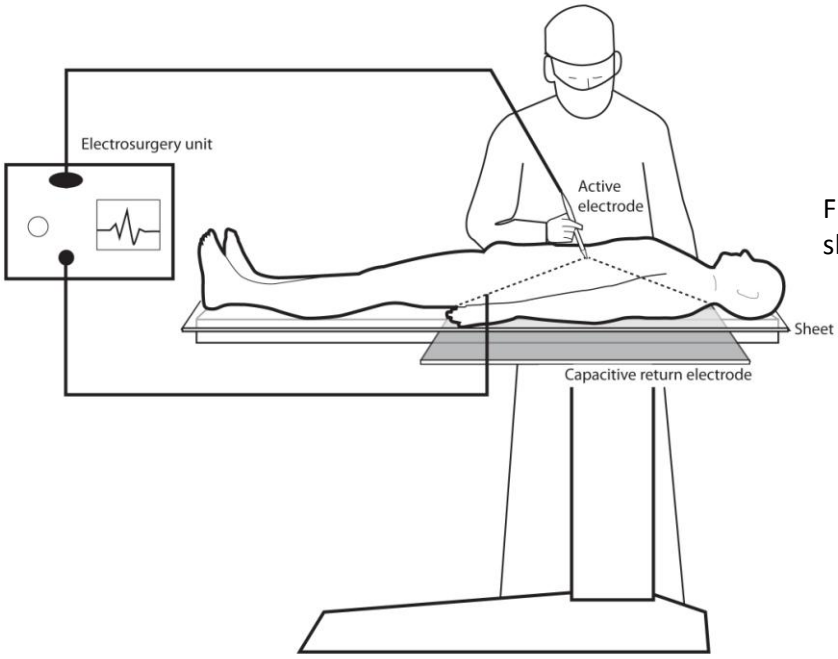
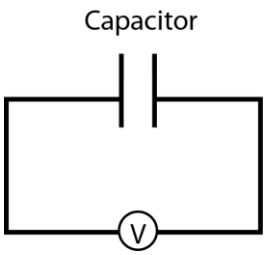


Figure 4. A simple circuit showing a capacitor



Capacitance *increases* if:

- Area of the plates *increases*
- Distance between the plates *decreases*

The Mega Soft return electrode is a capacitive electrode that is built into a pressure relieving mattress. It is much larger than conventional return electrodes, lying under the whole of the patient's upper body. The area in close proximity to the patient will depend on the position required for surgery and the patient physiology.

1.2 Grounded and isolated generators

The high frequency (hf) circuits in early electrosurgery generators were deliberately referenced to earth, or grounded. This means that the circuit could be completed unintentionally via another earthed item, such as a metal drip stand. Some generators in use may still be earth referenced, but the vast majority are isolated; the hf circuit is not referenced to earth directly, and an earthed object could not accidentally form part of the circuit. But, whenever high frequency currents are used, there is some leakage. This means that some of the current does not follow the main circuit route, but finds an alternative path. Even in an isolated circuit there will be some stray capacitive current leakage to earth. If the main circuit becomes harder to complete (eg reduced patient contact with the return electrode), there is an increased possibility of alternate current pathways that can result in alternate site burns to the patient. The risk is greater with earth referenced electrosurgery generators than with isolated ones.

1.3 Contact quality monitoring

Conventional return electrodes rely on good contact with the patient and a large enough area to disperse the current. If the electrode starts to peel off during surgery the contact area is reduced, and the current density increased. If the area is sufficiently small, the current density can cause burning, known as return electrode burns. Most electrodes used now are split-pads, which enable contact quality monitoring (CQM), also called by some manufacturers return electrode monitoring (REM). Split pads have two conductive areas, side by side on a single pad, separated by a small non-conductive gap. If the electrosurgery generator (ESU) has contact quality monitoring then it will monitor the flow of current between these two conductive areas, via the patient. If the pad

starts to peel off, then the current path through the patient is reduced. This is detected and the ESU will stop functioning and an alarm sounds.

2 Technical background

Mega Soft is a capacitive return electrode, designed to be placed under the patient's torso. It consists of a layer of conductive material, encased in a viscoelastic polymer, Akton. This layer provides one plate of the capacitive system, and the patient acts as the other plate. The adult pad is approximately 117 x 51 x 1.25cm, the paediatric pad is approximately 66 x 30.5 x 1.3cm and designed for use with patients weighing between 0.4kg and 22.7kg. The Akton polymer provides pressure relief, and is the same material as is used in other pressure relief mattresses commercially available. There are currently approximately 5,500 in use globally [Megadyne, 2011], and it received CE marking in 2003.

2.1 International Standards and CE marking

Neutral, or return electrodes are considered to be a class IIb medical device, and this determines the routes to CE marking available. The route taken by Megadyne is to use a full quality system throughout all their processes, and for this quality system to be fully audited by a notified body. The quality system should encompass provision of full design files, risk analysis, technical testing and reporting and post market surveillance. This system does not explicitly demand that testing to a recognised standard is carried out and accepted by the notified body. Megadyne have provided a copy of the relevant documentation certification to the External Assessment Centre (EAC). Certification is provided by The National Standards Authority of Ireland (NASAI), a Notified Body, and is for the product family "Electrosurgical Diathermy System, electrode, return, reusable (Mega Soft)". It remains valid until 31st March 2012.

Megadyne have additionally had testing completed on the Mega Power generator and accessories by the US notified body, Underwriters Laboratory (UL), to International Standards IEC 60601:1988 and IEC 60601-2-2:2006 (4th edition). Mega Soft was included in this testing and details were provided showing the clauses that were tested specifically for the neutral electrode. These standards are still valid, but have now been updated. The testing carried out on Mega Soft would not have been different if the newer standard was used.

The current international standards relevant to return electrodes are:

IEC 60601-1:2005 (third edition): *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*.

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

Previous versions of IEC 60601-2-2 link to the previous version of IEC 60601-1.

IEC 60601-2-2:2009 contains specific sub-clauses that relate to return or neutral electrodes (NE). These are:

201.15.101.1 – NE cord attachment. The EAC consider that this is met by Mega Soft. The specified conductivity test was completed and passed during UL certification, and also during testing by CHUS [CHUS 2011]. The ESU will not work if the pad is not connected to the cord.

201.15.101.3 NE cord connector, no conductive parts on patient. The EAC consider that this is met by Mega Soft, connections are all protected from the patient. This was not tested by UL, as it was deemed inapplicable since the cord cannot be disconnected at neutral electrode site.

201.15.101.4 NE cord insulation The EAC accept that this was tested by UL during certification and that Mega Soft met the test criteria for high frequency (hf) leakage, hf dielectric strength and mains frequency dielectric strength. These test against current leakage via the cord and breakdown of the cord insulation.

201.15.101.5 NE thermal performance. This has not been tested by the EAC, or by UL during certification. It was not considered in the scope of the UL evaluation. Megadyne have submitted to the EAC detailed protocols and test results from in-house testing, showing compliance with this subclause, and the EAC consider that this clause is met by Mega Soft. Independent testing has been carried out by CHUS, however it does not fully comply with the testing specification of the standard. See section 4 for more detail of all testing.

201.15.101.6 NE contact impedance. This was not tested by UL during certification. UL accepted evidence from Megadyne's risk management file and risk analysis as sufficient. Megadyne have submitted detailed protocols and test results from inhouse testing, showing compliance with this subclause. The EAC have also completed tests based on this subclause and found some differences in values for capacitance, particularly for paediatric pads. These are discussed in sections 4 and 5.

201.15.101.7 NE adhesion. This is not applicable to Mega Soft since its correct function does not require it to adhere to the patient. It was deemed not applicable for UL for certification.

201.15.101.8 NE shelf life. This is specifically for single use items, and therefore not applicable to Mega Soft. It was deemed not applicable for UL for certification.

2.2 Patient risk during electrosurgery

The majority of the electrosurgery incidents reported to the MHRA are related to burns [MHRA 2011, NICE 2011]. There are several ways in which burns may occur during monopolar electrosurgery, when a high current density occurs at a site that is not the intended surgical site. Since the anaesthetised patient will not react to the burn, and the site of the burn may not be visible (since it is not the surgical site), a very severe burn can occur before it is detected by the surgical team.

There are also other possible causes of burns during surgery. Chemicals used during skin preparation can cause burns if left in contact with the skin for a long duration. Pressure trauma to the skin can also have an appearance similar to a burn, but not appearing until some time after surgery [Pearce 1986].

The burn mechanisms described below are applicable to all electrosurgery regardless of return electrode type.

Return pad burns typically occur where the contact area becomes accidentally reduced during surgery. If a non-split, sticky return pad peels off the patient, the current is concentrated in a smaller area of skin and a burn may occur. If a split sticky return pad peels off the patient, an electrosurgery generator with contact quality monitoring will alarm and stop working.

If the contact area of a capacitive electrode is reduced then the current flow through the electrode will also be reduced, and because no power is generated by a current flowing through a capacitor it is unlikely to result in a burn at this site. The generator would not alarm to show reduced contact and would continue to work, but with a reduced surgical effect at that power setting and an increased risk of alternate site burns.

Alternate site burns occur where the current takes an alternative route to earth, rather than through the generator. Typical burns seen many years ago were through ECG electrodes. The use of isolated generators (see section 1.2), and changes in ECG design, makes this type of burn much

less likely now. Burns have also occurred where the patient is in direct contact with metal equipment such as drip stands. There will always remain some stray capacitive coupling to earth that makes alternate site burns possible. Good theatre practice should avoid the patient touching metal items that may form a connection to earth [AfPP 2007].

Where a capacitively coupled return electrode is used, the electrical route back to the ESU will tend to be harder to complete than with a conductive electrode, and this can increase the possibility of alternative current pathways. As the capacitance is decreased (eg by decreasing the area of the pad, or increasing the distance between the pad and patient) then alternate current pathways become more likely. If the power is increased to compensate for the lower capacitance, and there are any alternate pathways available, then a burn to the patient could result.

Other burn mechanisms include

- pedicle or channelling burns, where the current is routed through a narrow section of tissue, resulting in increased current density and therefore heating
- endosurgical burns due to capacitive coupling between parts of the endosurgical system

Sparking during electrosurgery has been known to start fires when there is alcohol pooled around the patient. This is simply prevented by either not using alcohol during preparation, or by ensuring that it is thoroughly dried before theatre commences. This is standard practice recommended by Association for Perioperative Practitioners (AfPP) [AfPP 2007].

Electromagnetic interference can result in problems with monitoring during any electrosurgery. It is unlikely that the use of a capacitive electrode will cause more interference than a standard electrode [Technical experts]. Modern monitoring equipment copes quite well with most electrosurgery, and careful positioning of cables can reduce any problems. Instructions for use, discussion with manufacturers and good theatre practice give good guidance for cable placement.

3 Questions from the MTAC committee

1. The manufacturer states that the Mega Soft Patient Return Electrode is a self-contained current limiting device making it safe to use if the patient is in contact with only a small

portion of the pad. Clarification is required regarding the minimal contact area between the patient and the pad before safety is compromised.

2. Concern was raised about whether the spillage of alcohol based products onto the pad would collect in pools and lead to a higher risk of burns.
3. Clarification is required as to whether the product can be used with all other equipment in the operating theatre environment.
4. Clarification is required about safety implications if the outer skin of the Mega Soft pad is punctured.
5. Clarification is required about the thickness of intervening material between the Mega Soft and the patient before conduction is compromised.
6. The sticky pad patient return electrodes, which are to be used as comparators, are resistive coupling electrodes while the Mega Soft Patient Return Electrode is a capacitive coupling electrode. Clarification is required about whether Mega Soft can be used with all electrosurgical units since these are likely to have been tested for use with resistive coupling electrodes rather than capacitive coupling electrodes.

In order to answer these, Cedar have sought some clarification and also re-grouped the questions in terms of the technical difficulties that they arise from. Therefore the available evidence for Mega Soft's safety is presented in section 4, then in section 5 the technical issues that arise with the use of a capacitive return electrode such as Mega Soft are discussed, and cross referenced to the original question.

4 Evidence considered

The EAC considered the following types of evidence:

- Adverse event reporting
- Independent testing from published and unpublished sources
- Manufacturer testing
- Testing by the EAC where data was not fully available
- Expert opinions

These are summarised in table 1, and described and critiqued in the following sections.

Table 1 Summary of evidence considered

MHRA	UK Competent Authority Adverse Incident database		No alerts concerning Mega Soft
MAUDE	USA FDA Adverse Incident database		10 reports relating to Mega Soft
ECRI	Independent test report	Summary of results	Tests carried out on an earlier version of the device, Mega 2000, were: • Performance • Heating of the pad with different areas • Pinholes in pad • Alternate current pathways • Activation of connectivity alarm • Ease of use • Quality of construction
UL	Independent Notified Body	Summary of results	Testing, or justification of non-testing to give compliance to IEC 60601-2-2:2006
Megadyne	Manufacturers	Full details available	Tests were: • Capacitance of adult and paediatric pad with one size plate • Heating of adult and paediatric pad • Heating of Mega Soft and conventional return pads under extreme conditions • Investigation of alternate site paths
CHUS	Independent testing	Summary of results	Tests were: • Pad folded

			• Pad compressed width ways to wrinkle up • Pad with undried bleach on it • Pad soaked in saline • Pad placed upside down • A split sticky neutral electrode with poor contact to pork belly • Pad positioned as if seated • As above, as if pad had slid down, giving poor contact area • Poor contact with pad • Different numbers of sheets between pad and pork belly • With a cushion between pad and pork belly
Cedar	Independent testing	Full details available	Tests were: • Capacitance of adult and paediatric pad with varying metal plate sizes • Capacitance of adult pads with different numbers of layers of cotton sheets. • Performance of adult pad following damage

4.1 Adverse events reported

Megadyne estimate that there are approximately 5,500 Mega Soft pads in use globally, with 3,500 of those in the USA, and approximately 500 of those in the USA being paediatric. Advance Surgical state that there are 170 Mega Soft pads in use in the UK, and 30 of them are paediatric.

The EAC searched two databases of adverse events:

- MHRA, from the UK
- MAUDE from the USA

The MHRA database does not publish all incidents, but does issue alerts and other warnings if there are a significant number of related incidents, or they feel that it is warranted. The MAUDE database publishes all reported incidents, as submitted. This may result in duplication of incidents and incomplete information being available.

No alerts or warnings were identified on the MHRA database. The MHRA subsequently confirmed that there have been no electrosurgical incidents involving Mega Soft reported to them. There were 104 electrosurgery incidents reported in 2009, with 26 relating to return pad burns. There were 180 electrosurgery incidents reported in 2010, with 44 relating to return pad burns.

Eleven reports were identified from MAUDE that related to Mega Soft, or Mega 2000, and these appear to relate to ten separate incidents, six of the incidents occurred using Mega Soft, and the remainder using Mega 2000. These are listed in appendix 1. A search for “electrosurgical patient return electrode” AND “injury” over the same time period gave 102 results. The EAC have not established how many involved non-split pads (some did), the severity of the incidents, or how many reports related to the same incident.

Some of the incidents were probably alternate site burns which could have been avoided by careful theatre procedures. Most of the incidents do not have a full investigation reported, therefore, although the EAC can confirm that Mega Soft was in use, and reported as the relevant device, we cannot confirm that its use definitely contributed to the incident, or if there were other contributing factors.

It is also possible that some incidents such as alternate site burns or electromagnetic interference may not be attributed to the return pad, and therefore not be identifiable in the database as such. There is not normally information on the return pad type within the report, unless it is initially suspected of causing the problem.

4.2 Report from ECRI

This report was based on testing on the Mega 2000 pad, the predecessor to the Mega Soft [ECRI 2000]. Therefore the results cannot be directly applied to the Mega Soft, however the background explanation, discussion and considerations are useful. It provides a useful background explanation of electrosurgery, its risks and the principles of conductive and capacitive neutral electrodes. ECRI are a well established independent evaluation organisation. The tests are not based on the

standard tests described in IEC601-2-2, but consider some of the same issues using an alternative approach. ECRI generally reported favourably on the Mega 2000, with some conditions. These were that it was not recommended for use with:

- Thick gel pads
- Paediatric patients
- Certain settings on ERBE ESUs

The last two of these were already in the Megadyne instructions for use. The results for the tests were not reported in full, with only unexpected, or unsatisfactory results being noted. All test results were rated as good, except alternate current pathways which was rated as fair.

Tests carried out were;

Performance

Meat samples were used with conductive and capacitive neutral electrodes with user surveys to determine if there was any difference in the user experience or effectiveness.

Heating at the Megadyne 2000 site

The ESU active side was connected to a volunteer via a conductive electrode (to prevent burns) and the volunteer was placed on a Mega 2000 which was connected to the ESU. Using high voltage settings, the area of contact with the Mega 2000 was decreased until the volunteer reported feeling heating. None was reported until a very small area of 100cm^2 was reached.

Pinholes in the Megadyne 2000

Pin holes and a 1cm slit were placed in the Mega 2000, meat placed over the area and energised for 30 seconds with an active electrode. The meat was inspected for any blanching, and the test repeated with saline in and around the hole. No safety concerns were reported.

Alternate current pathways

A volunteer was connected with the active electrode applied via a piece of fruit to protect the patient, and an additional conductive electrode placed on the volunteer and connected to ground. The current passing through this alternate pathway was measured both with just the Mega 2000, at 115mA and also with a 1.3cm gel pad between the patient and the Mega 2000, at 153mA. This

increase in current increases the likelihood of an alternate site burn and therefore ECRI recommended that the Mega 2000 should not be used with thick pads.

Activation of a continuity monitor if the electrode cable is broken or disconnected

Ease of use

Quality of construction.

The test methods used were described in the report, and were reasonable methods for the investigations.

4.3 Testing by CHUS

Independent testing has been carried out on the Mega Soft pad by the Centre Hospitalier Universitaire de Sherbrooke in Quebec, Canada. This report has kindly been shared as a draft version, the final version is expected to be published in early 2012, first in French and then English. The technology evaluation unit at this hospital regularly publishes evaluations of devices and technologies which are available on its website.

Methods: The testing was based on the protocol for testing heating of a neutral electrode in IEC 60601-2-2:2009, subclause 201.15.101.5, although as the authors point out it does not attempt to comply with this protocol fully. The standard requires that there is a rise in temperature of no more than 6°C when tested as stated.

The authors list differences as including:

- Use of pork belly rather than human subject or thermally equivalent surrogate
- No repeat tests on different electrodes
- Temperature of test media not within limits required (23°C ± 2 C)
- Application of 700mA for 60 seconds

While these differences are clearly noted, the approach means that it is difficult to apply the rule of a rise in temperature of less than 6°C being safe for use, since the standard test conditions were not applied. Additionally, the correlation between the location of the reference and second temperature scans is not reported, and may not meet the criteria of the standard. For all the tests the power setting was recorded, but the current was not measured or recorded. The power

setting used of 300W cutting, 120W coagulation is very high for normal use, and the period of electrosurgery of 2-3 minutes is also long compared to 60 seconds in the standard. It is likely that the power setting would be very much lower in clinical practice. The actual current that passes through the circuit at a given power setting will depend on the whole circuit and will not be the same for all the scenarios even where a standard power setting is used. The current density is what causes the heating effect, and therefore a standardised current is desirable in these tests.

The use of pork belly means that there is no circulation of blood in the sample, and heat will not be distributed in the same way as in a human patient. This would be expected to result in more localised heat accumulation in a sample of meat than in a live patient.

The tests take a very different approach from those carried out by Cedar. They are all looking at the heating effect on the pork belly at the site of the neutral electrode under a variety of different conditions. CHUS investigate if the patient may receive a return pad burn from a wide variety of different misuses, or less than optimum uses, of the Mega Soft. None of the investigations consider if these would increase the risk of an alternate site burn. Testing scenarios were:

- Pad folded: a corner was folded over
- Pad compressed width ways to wrinkle up
- Pad with poorly dried bleach on it
- Pad soaked in saline
- Pad placed upside down
- A conventional split sticky neutral electrode with poor contact to pork belly, but without causing the CQM to alarm
- Pad positioned as if seated
- As above, as if pad had slid down, giving poor contact area
- Poor contact with pad
- Different numbers of sheets between pad and pork belly (up to 8)
- With a 5cm thick cushion between pad and pork belly

The test for the numbers of sheets referenced the test by ECRI for alternate site burn risk, however the tests looked at the heating effect at the return electrode, rather than any alternate pathways that could develop.

Results and discussion: The results are reported by normal and thermal photography of the skin after heating, and with some reporting of the range of skin temperatures reached and changes in temperature. The variation in applied current, and the lack of standardisation in test protocol means that it is hard to clearly interpret the results. CHUS have used a temperature change of 6°C as an indication of when harm would occur to a patient; this is derived from IEC60601-2-2:2009, but with different test conditions.

Rises of temperature of between 5 and 6°C occurred in:

- Compressed pad, coagulation setting
- Poorly dried bleach, coagulation setting
- Possibly saline soaked pad (incomplete results reported)
- Poor sticking of a self-adhesive electrode (complying with CQM)

Rises of temperature over 6°C occurred in:

- Poor contact test resulted in heating of 6.3°C. This test reduced the contact area to 100cm^2 by suspending the pork belly, meaning that there is reduced weight as well as a reduced area. No reduction in surgical effect was seen, however the power settings used were extremely high.

The rise in temperature was difficult to ascertain during testing with sheets, since the initial temperature of the sample was not regained in between tests.

These temperature changes should be seen as indicative of what conditions may cause heating, rather than as a definitive ruling on where burns would occur. As the authors intended, the settings used were extreme for normal surgery and not the same as those required by the standard.

Additional results were that there was a marked reduction in surgical effect when a 5cm cushion was placed between the pad and the pork belly, despite the high power setting. This is not

surprising as it significantly increases the distance between the “patient” and the pad, and is not within the recommended uses of Mega Soft.

CHUS conclude that the Mega Soft technology is safe and reliable.

4.4 Testing by notified body

UL certification – this is independent testing by a long established laboratory who are also Notified in the EU for the Medical Devices Directive (MDD). The EAC do not have access to detailed results, but have had copies of the final certificate accompanied by relevant pages identifying the tests carried out on the Mega Soft pad, together with a pass or fail. These are detailed in section 2.

4.5 Information from Megadyne

Megadyne provided detailed information about testing that they had carried out, and this is summarised and critiqued below. They also provided certification relevant to CE marking and copies of information available to consumers, which is included in appendices 3-4.

- Advice on avoiding interference when using electrosurgery
- List of generators that are compatible with Mega Soft

4.5.1 Megadyne Test Protocol 1150130-10 AC Coupled Electrode and Third Party Material Capacitance Testing, together with test reports; 1150130-02 Paediatric Mega Soft Capacitance Testing, and 1150130-03 Adult Mega Soft Capacitance Testing

Method: Megadyne made available a detailed protocol and test report, with methods based on IEC 60601-2-2:2009, sub-clause 201.15.101.6 NE contact impedance. The standard requires that there is a capacitance of at least 4nF when tested as stated. An adequate capacitance ensures that a good circuit has been made, minimising risk from heating at the return pad site and also from alternate site burns.

The equipment used was listed, and was appropriate and in calibration.

Variations from the standard are that only three frequencies are used (300 KHz, 400 KHz and 666 KHz), compared to the range of 200 KHz, 500 kHz, 1 MHz, 2 MHz and 5 MHz stated in the standard. It is not easy, as Cedar discovered, to test to the full range of frequencies at the current of 200mA required. Since impedance decreases at higher frequencies the lower range is more likely to have a problem and these have been tested. The instructions for use for Mega Soft state a frequency range of 300-600 KHz.

IEC 60601-2-2:2006 specifies that the metal plate used should be 20cm by 30cm, however the current standard IEC 60601-2-2:2009 does not specify the size of plate. There was some confusion in the protocol over the size of plate used, however communication with Megadyne established that the adult pad was tested with a 600 inch^2 stainless steel plate, and the paediatric pad was tested using a 198inch^2 stainless steel plate. Both of these are approximately 80% of the electrical mesh area of the pad. Smaller areas would be expected to give lower capacitances.

The adult pad was tested with three different samples, one new, one at one year, and one after two years use. There was no correlation with capacitance and age in the reported results.

Results and discussion: The adult pad capacitances ranged from 7.2 to 10.2 nF, which are all comfortably above the level of 4nF required by the standard.

It was reported in the results that previous test results had been 6.3nF at 400kHz, compared to 7.4nF at 400kHz for this test. This was explained by Megadyne as differences in the ESU used and power settings. Cedar did not find that different power settings gave different capacitances, however we did use different equipment and find different capacitance results from those reported by Megadyne.

The paediatric pad was tested using ten different samples. The plate size of 198inch^2 was achieved by placing a slightly larger plate overlapping on the internal mesh, to give an overlap of 198 inch^2.

The results for the paediatric pad ranged from 4.0 nF to 5.1 nF, just over the 4nF required by the standard.

4.5.2 Megadyne Test Protocol 1150331-10 Temperature Rise Testing of Paediatric Reusable Return Electrode, together with test report; 1150331-01 Paediatric Return Pad Temperature Rise Testing

Method: Megadyne made available a detailed protocol and test report, with methods based on IEC 60601-2-2:2009, sub-clause 201.15.101.5 NE thermal performance. The standard requires that there is a rise in temperature of no more than 6°C when tested as stated.

The equipment used was listed, and was appropriate and in calibration.

Variations from testing detailed in the standard were that live anaesthetised pigs were used rather than adult human subjects. The standard allows for the use of a surrogate medium, but states that there should be documentation to show that the surrogate would give lower temperature

changes. There appear to be slight differences between the American and British versions of the standard, applying to the current used at different subject weights, however the current values used by Megadyne will be at least as high as required by either version.

Ten pigs were used of varying sizes reflecting the weight range appropriate for the paediatric pad.

Results and discussion: The skin temperature changes seen after ESU activations at 500 or 700mA for 60 seconds were between 1 °C and 1.4°C, which easily satisfies the standard requirement of less than 6 °C.

4.5.3 Megadyne Test Results 115066-02 Puncture Resistance of Paediatric Mega Soft return electrode

This test is based on the methods reported by ECRI when testing the Mega 2000. It is not a required test for IEC 60601-2-2:2009.

Chicken breast was placed on the paediatric pad and the ESU activated across it. This was repeated with combinations of a ½ inch slit in the pad and linen over the slit, both with dry and saline soaked conditions.

The chicken breast was examined for evidence of burning, but no burns were reported. Megadyne report that this may be partly due to the self-healing properties of the Akton gel used in the pad.

4.5.4 Megadyne memo January 2010: Investigate possibility of causing an electrical burn under an ECG pad when using a Mega Soft return electrode

Method: This reports testing undertaken in response to a possible incident where a burn was reported under an ECG pad after using electrosurgery with a paediatric Mega Soft pad.

Megadyne used the IEC60601-2-2:2009 guidance of 100mA/cm2 being allowable before skin damage from heating will occur to calculate a limit of 388mA through a typical ECG electrode before burns would occur.

They tested a number of possible set ups using a pig leg on the pad and measured the current flowing through the ECG lead.

Results and discussion: The highest result found was 4.41mA when the ECG lead was wrapped around the active electrode, and a setting of 40 watts, coagulation was used. Megadyne also tested a conventional conductive return electrode, and found slightly lower currents in all the

situations. This is as expected; a slightly higher current through alternative pathways is seen with capacitive electrodes compared to resistive electrodes.

A current of 18.37mA was achieved when the ECG leads were removed, and standard cables put in place. This is explained by Megadyne as being due to removing the 10,000 ohm resistance in the ECG cables that makes it hard for alternate current routes to be established through them.

4.5.5 Megadyne test protocol 1150379-10 Safer than CQMS, together with Test report 1150379-01 Safer than CQMS

Method: The methods for this testing are based on the NE thermal performance protocol described earlier, however the currents and duration of exposure are much higher than specified in the standard. The standard requires that there is a rise in temperature of no more than 6°C when tested as stated.

Megadyne tested a variety of conventional sticky pads as well as the adult and paediatric Mega Soft pads at 1A for 60 seconds. In some cases they could not achieve 1A with the ESU and neutral electrode, so they opted to use a current of 500mA and a duration of 180 seconds.

14 different pigs of varying sizes were used, together with four ESUs, four disposable conductive return electrodes (including one Megadyne) and an adult and paediatric Mega Soft pad. Pure and Coagulation settings were used on the ESUs. The use of 1A test current gave consistent current application, but inevitably results in variable power settings on the ESUs.

Due to the number of variables, the results are complex and and it is hard, in the time available to examine in adequate detail any confounding issues such as testing orders, differences in ESU settings, different combinations of options etc.

Results and discussion: Megadyne reported that there were no tests using either Mega Soft pad where the skin temperature rise exceeded 6°C , or where skin showed a burn. They also reported that 69% of the tests using disposable sticky pads saw a rise of over 6°C, and 57% caused visible damage (2nd degree burn). It should be remembered that these are quite extreme test conditions, and that all the pads used are assumed to pass the testing required by international standards.

4.6 Testing by Cedar (EAC)

Where there were gaps in the evidence available, Cedar undertook bench testing of one adult and one paediatric pad. Where possible protocols were closely based on tests described in IEC 60101-

2-2:2009. A more complete description of the test protocol and results is found in appendix 2. Megadyne had already measured capacitance with one size of plate. Most of the other tests on Mega Soft looked exclusively at the heating effect at the return pad site, and did not look at the risk of alternate site burns.

Methods: Testing was based on IEC 60601-2-2:2009, sub-clause 201.15.101.6 NE contact impedance. The standard requires that there is a capacitance of at least 4nF when tested as stated. All equipment was calibrated (as detailed in appendix 2)

The basic test method was as IEC 60601-2-2:2009 with the following variations:

- An oscilloscope with true r.m.s. measuring capabilities was used for measurement rather than a true r.m.s. a.c. ammeter or voltmeter
- Only one frequency was tested (approx 400 kHz) available from the generator used
- Only one adult and one paediatric pad was tested

This was adapted to give the following tests;

- Variations in the size of the metal plate used to represent the patient
- Insertion of between one and three layers of sheets between the plate and the pad
- Creation of slits through the gel pad to the conductive mesh

Results and discussion: The capacitance measured by Cedar was only 70 and 80% of the Megadyne values for paediatric and adult pads respectively, using an equivalent size plate. Some of the difference will be due to the lower weight used by Cedar (the value is not defined in the standard) and also due to different generators and Mega Soft pads being used. Neither the EAC or Megadyne have been able to explain the full extent of the difference. It was noted that Megadyne reported a lower measurement (85%) for the adult pad in previous tests.

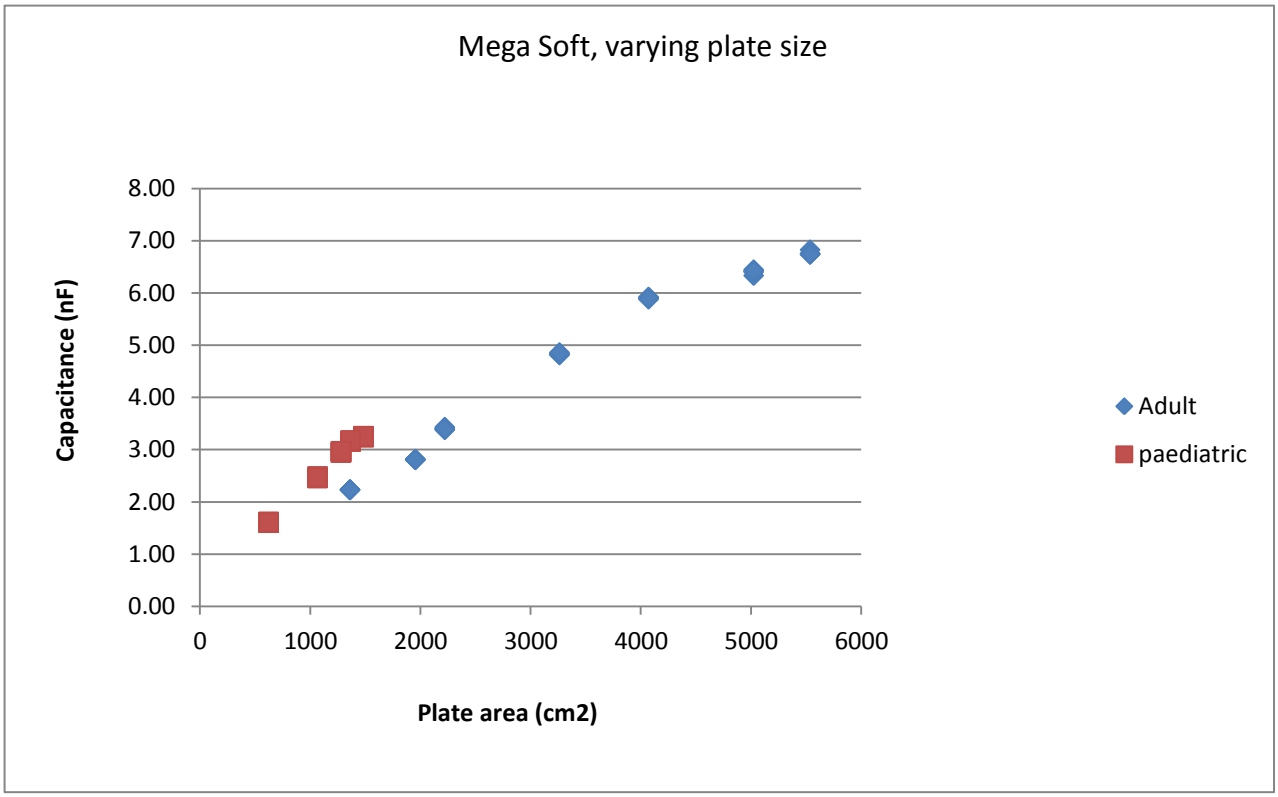
The adult pad had a capacitance of greater than 4 nF for plates that were over approximately 55% of the pads' surface area (by interpolating between experimental points). Cedar did not measure a capacitance of greater than 4nF for any plate size with the paediatric pad, including 100% coverage. Figure 5 shows that the thinner gel pad of the paediatric plate gives a higher capacitance than the adult plate for any given area, but this does not completely compensate for the smaller area of the pad.

The limit of 4nF is based on historical precedent rather than clinical or scientific evidence of what is required. The guidance in Annex AA of IEC60601-2-2:2009 states:

"…..A value of 4nF was specified as the minimum acceptable capacitance because it is consistent with the characteristics of the majority of capacitive NEs which have been commercially available for many years and found to be clinically acceptable."

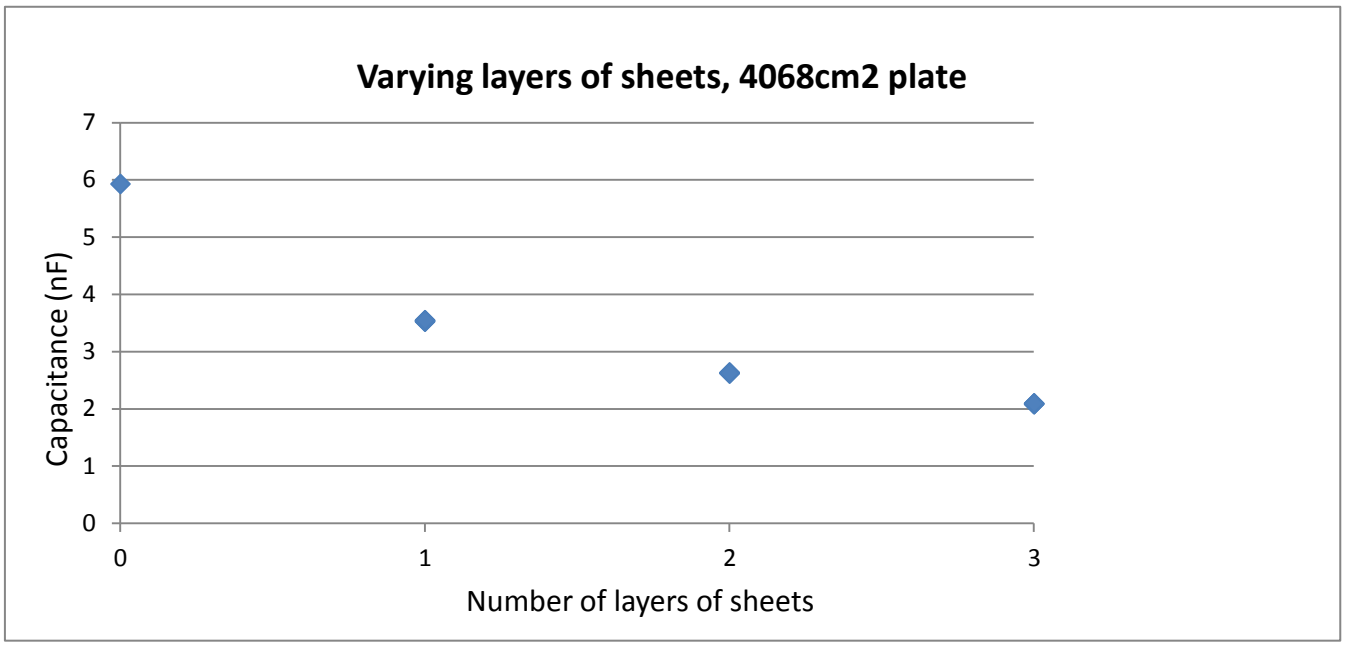
Therefore although Mega Soft paediatric would not pass the test required of the IEC60601-2-2:2009 based on Cedar's testing, this does not necessarily mean that it is unsafe. The lower capacitance does mean that there will be an increased risk of alternate current pathways, however this risk may be reduced by the lower power settings used in paediatric surgery.

Figure 5 Mega Soft adult and paediatric pads tested with varying metal plate sizes



As was expected, the capacitance diminishes with increasing layers of sheets between the adult pad and the plate (figure 6).

Figure 6. Variation in capacitance with 1-3 layers of sheets for an adult Mega Soft.



The final test by Cedar was to create 12mm slits in the mat and retest. On cutting the mat it was evident that the gel properties made it very hard for an electrical connection to be made to the mesh, even in the presence of saline or other liquids. The gel immediately bonded back together after cutting, and we found we had to re-cut it to repeat tests. There was no difference seen in the phase angle, which would have been expected to change if there was a resistive connection made (ie if the connection was direct to the conductive mesh, rather than being capacitive through the gel). There did appear to be a slight difference in the calculated capacitance before and after the damage, although it could have been due to normal variation. It is also possible that the break in the skin of the pad at the cut and the very slightly thinner gel layer where there is damage to the pad give a slightly higher capacitance. Given that there is no change in the phase angle, Cedar do not believe that this shows any resistive connection.

4.7 NICE advisors

Clinical advisors – background information was sought from clinical advisors, concerning the typical uses of the Mega Soft, materials used between the pad and the patient and clinical experiences of its use. Also information on the power settings used for paediatric surgery. Information was sought on incident reports from Barts and The London NHS Trust, but this was not available in the time available.

Technical advisors – Technical advisors were consulted about electromagnetic interference from electrosurgery units, as well as general background considerations.

4.8 Literature search

A very brief literature search for background information was carried out by the EAC. No additional papers were found that were directly relevant of Mega Soft. Some background papers were identified, however many were not available in English and were not obtained given the time constraints present and the value of the paper as judged by the abstract.

5 Technical issues and responses to MTAC questions

5.1 Capacitance between patient and Mega Soft

The capacitance is proportional to the area of "contact" and inversely proportional to the distance. It is also related to the material between the plates. If you reduce the area, increase the distance, or place items between the patient and Mega Soft, then the capacitance will be reduced. In either of these cases, surgeons may notice a reduction in effect and increase the power setting. As the capacitance decreases, it is harder for the circuit to be completed via the Mega Soft pad. There will be an increased tendency for stray current to return to ground via alternate pathways, and this could result in alternate site burns if there are alternate routes and the power is increased.

The risk of alternate site burns for all electrosurgery is greatly reduced by good theatre practice:

- Avoid the patient touching any conductive items such as clamps, stands etc. [AfPP 2007]
- Use the lowest power setting possible [MHRA e-learning]
- If the effectiveness decreases do not increase the power setting without checking that the equipment is still correctly set up

IEC 60601-2-2:2009 requires there to be at least 4nF capacitance between the pad and a metal plate under defined test conditions, to minimise risk from both return pad burns and alternate site pad burns. This figure is based on historical precedent, being a typical capacitive value for previous versions of capacitive return electrodes that were smaller and applied directly to the patient. The impedance that is actually seen during a surgical procedure will depend on the entire circuit including the patient build, positioning, surgical site, ESU type and settings.

5.1.1 Area of overlap (Q1)

The amount of the pad in good contact with the patient may vary with positioning for different procedures, the contours of the patient body, or for paediatric patients, due to the total size of the patient. It may be possible that the patient is moved during a procedure and the total area in contact changes.

Megadyne submitted evidence to show that during testing to IEC 60601-2-2:2009, the capacitance was measured at greater than 4nF for both paediatric and adult pads. The metal plate used for testing was approximately 85% of the area of the pad in both cases. There may be occasions when less than 85% of the pad is in contact with the patient, and a very small baby could not cover 85% of the pad.

Cedar also repeated these tests for adult and paediatric pads at a variety of sizes. We confirmed that increased area of overlap gave increased capacitance. A small area of contact (less than approximately 55%) of the adult pad gave less than 4nF. In Cedar's testing no plate size resulted in a capacitance of greater than 4nF for paediatric pads.

Megadyne advise [Megadyne 2011] that this limit is not appropriate, and that for paediatric patients a much lower power setting would be used than for adults, and it would therefore be safe. Discussion with clinical experts has confirmed that a lower power setting is normally used for paediatric patients, [ref additional info] and this would reduce the tendency for creation of alternate current pathways.

Both adult and paediatric pads have been used in the UK and the USA for a number of years, and there have been very few incidents reported that result from their use (none in the UK [MHRA 2011]). This is strong evidence for their safety.

5.1.2 Insertion of materials (Q5)

The insertion of any sheets, drapes, or other materials between the patient and the Mega Soft will decrease the capacitance. Advice from clinical experts in the UK is that a sheet is normally used under a patient, and on occasions other items such as an underbody warmer or incontinence pads may also be used. This has been standard practice in some locations for many years without reported problems. [Clinical Experts]

Cedar's test evidence confirmed the relationship with the number of layers between the device and patient and the decrease in capacitance. When two sheets are in use, with 80% of the pad covered, the capacitance was reduced from 5.93nF to 2.62nF.

CHUS tested up to eight layers of sheets but did not draw conclusive results regarding heating of the skin. They also tested a thicker layer using a cushion and found that although there was no temperature rise, the electrosurgery was not effective even at very high settings.

In normal use, complying with Megadyne's recommendations that no more than two sheets be used for adult pads, the lack of incidents is strong grounds for supporting the use of Mega Soft. However the user should always be aware of that as more items come between the patient and the Mega Soft, the capacitance decreases, the power setting may be increased, and the risk of alternate site burns also then increases.

5.1.3 Pooling of fluids (Q2)

Cedar's testing showed that the presence of saline improved the capacitance when a metal plate was used. We suggest that this is because in dry conditions, small wrinkles in the mat's surface mean there is a partial layer of air between the plate and the mat. When saline was added these gaps were filled by the saline, improving the dielectric properties between the plate and the mat, increasing capacitance. The same may be seen with a patient, but it may be that a patient would be in better contact with the mat due to having a softer surface and perspiration from the skin.

The evidence from the CHUS report is not clear and no conclusions can be drawn for this situation.

Cedar believe that there is little reason to think that any changes to capacitance of the system due to fluid pooling is likely to cause harm. The capacitance value may be slightly altered in that area, but the capacitive effect will still be spread over the whole area of patient in proximity to the pad. There are however good reasons why fluid pooling should be avoided in good theatre practice, for instance to avoid chemical burns, reduce fire risk and to reduce damage to skin.

5.2 Electro magnetic interference (Q3)

None of the evidence from tests identified by Cedar considered electromagnetic interference. Cedar therefore consulted two technical experts in the fields of electromagnetic interference and electrosurgery. Their opinion was that in general during any electrosurgery there are high

electromagnetic fields, but that modern patient monitoring systems tend to cope well with this most of the time.

The question is then, is it likely that a large capacitive return electrode will increase any problems? The expert's opinion was that since the current density is high at the active tip, but low at the return electrode then the main problems would be at the tip rather than the plate. It is possible that if there was a small area of contact between the patient and the Mega Soft, the patient body could act as an antennae, however, if it has been in use for some time without reported issues then it is unlikely that there will be any greater electromagnetic compatibility issues with a large capacitive electrode than a standard return electrode.

5.3 Puncturing of the pad (Q4)

The concern is that if the pad were punctured there could be a direct conductive connection between the patient and the mesh inside the Mega Soft pad. The safety of a traditional conductive return electrode relies on the current being dispersed over a relatively large area. In the case of a puncture of the Mega Soft, is it possible that the current would conductively return via a very small area eg needle prick, or tear? If this were possible it would be likely to result in severe burns, as the current would be concentrated in a small area.

The manufacturer states that the Akton polymer used for construction is self-healing, and that unless a puncture or tear were held open there could be no contact with the conductive mesh inside the pad. On investigation Cedar found that any cuts made in the pad seemed to close up immediately, even if they were all the way through to the other side of the pad.

Cedar tested a Mega Soft pad with a 12mm scalpel cut through to the conductive mesh. In one test this was done through a pool of saline. We found no evidence to suggest that there was conductive connection through the pad, or that such damage would result in patient harm.

The EAC have found no cases of injury caused by tears or damage to the pad reported in FDA MAUDE or in MHRA databases.

The ECRI report tested this scenario for the Mega 2000 and found that the device was still safe for use after being punctured. The Mega 2000 has quite a different construction, without the pressure relieving gel pad.

5.4 Use of Mega Soft with non-Megadyne ESUs (Q6)

There are a number of suppliers of conventional return electrodes that do not also manufacture ESUs and the use of these return electrodes is widely accepted. The current standard IEC 60601-2-2:2009 includes testing specifically for electrosurgery accessories in the realisation that these are sold separately from ESUs and there should be a possibility of testing them independently from a specified ESU. Mega Soft is a different technology from the conventional return electrodes that are supplied by most manufacturers of ESUs, and they work using a different electrical principle, however the standard does allow for capacitive electrodes, and the tests can be applied to them.

There are a large number of different ESUs available globally, and even within the UK the number of different makes and models available is large, particularly if older models still in use are also considered. Each model will have a number of different settings available, and these permutations make comprehensive testing of any accessory with every possible model of ESU in all its available modes an impossible task. For this reason Cedar have not attempted any testing to answer this question, but instead have used evidence from the manufacturers, our own expertise and that of technical experts.

Megadyne advise that the Mega Soft should only be used with isolated generators (which includes the majority of current models). They also state that the use of Mega Soft will mean that the CQM system does not warn of reduced contact area with the return electrode, although current flow will be reduced if the contact area is reduced. If there are any other warning systems on the ESU, for instance measuring the voltage potential on the patient's body to protect against alternate site burns, these may also not work, since these systems are designed for a different type of return electrode. It is important that the user is aware that these alarm systems are not functioning and does not rely on them in the case of unexpected behaviour of the ESU. For example if the surgical effect of the ESU is diminished the team should check that there is a good area of overlap between the patient and the pad before increasing the power setting.

Megadyne provided a list of ESUs or generators that they consider safe for use with Mega Soft (appendix 3). If users have an ESU that is not on this list, Megadyne are willing to provide a certificate to state it is safe for use with that ESU. This may be based on historical clinical use, where they are aware that it has been used safely for some time, or it may be based on specification of the ESU, or functional testing if the ESU is available for testing.

Discussions with the MHRA (personal communication) have confirmed that provided companies such as Megadyne are able to provide documentation to confirm compatibility with specified goods including generators (ideally indicating relevant model numbers), users are free to utilise appropriate products from any manufacturer. Documentation or certificates of conformity held by a user indicate that they have carried out due diligence, and means that the company which has verified compatibility would be the liable party in the instance of any malfunction provided that all user instructions have been correctly followed.

It is the responsibility of the end user to obtain written confirmation of compatibility between items such as generators and related consumables. This ensures that the correct make and model numbers are always being checked to prevent incompatible products being used together due to changes in product specification etc. Confirmation may be obtained by requesting documentation directly from a supplier when purchasing goods.

MHRA advice is to “ensure medical devices that you purchase are CE marked and have appropriate documentation to demonstrate compliance with the essential requirements of the Medical Device Directive 93/42/EEC in this instance demonstrating compatibility to the original equipment device being used”.

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Appendix 1 Summary of MAUDE incident reports

Table 2 Summary of MAUDE incident reports

EAC Incident Number	Date Report Received	Event Description	Manufacturer Investigation	Mega Soft or 2000
1	08/12/2011	ESU could be activated without patient in contact with pad.	Capacitive coupling, not a malfunction	Soft
2	06/18/2010	System not working for procedure, pad replaced and worked.	Not reported	2000
3*	08/29/2008	Burn mark at buttocks where towel clamp had been placed	Probable alternate site burn	2000
4*	05/08/2008	0.3cm burn to neck and pelvic bone At this position pelvic bone was locked with towel clamp forceps.	Probable alternate site burn	2000
5	10/03/2006	Patient complained of tingling in hand against stirrup, changed to std return pad, no injury.	Not reported	Soft
6	08/01/2006	Lateral position used with beanbag for positioning over the pad. 2nd degree burn to heel.	Not reported	Soft
7	07/19/2005	Device used for child. 2cm diameter minor burns on both shoulders. Bed sheet over pad and or towel under child's shoulders. Pad & linens were intact.	Not reported	Soft
8	06/16/2005	Skin lesion on right lateral thigh.	Probable alternate site burn	Soft
9	01/18/2005	2nd degree burn to left buttocks.	Not reported	Soft
10	06/24/2002	Non-split sticky pad and Mega 2000 in use. Two white lesions, quarter size on buttocks.	Not reported	2000
11	05/21/2002	Burn to back. Burn appeared to be in same shape and size as metal hospital gown snap patient was wearing.	Not reported	2000
Details on incidents 3* and 4* very similar - possibly refer to the same incident				

Appendix 2 Report for Cedar testing

Introduction

In initial exploratory testing Cedar found that the function generators available to us were not able to supply the required 200 mA with the desired set up. This meant that we changed our plan of testing at the frequencies stipulated by IEC 60601-2-2:2009 to use an ESU and test only at the one frequency (approximately 400 KHz) that was available to us. It is worth noting that:

- Equipment that provides adequate power at the range of frequencies required is not readily available commercially
- Testing at lower currents (eg 100mA) gave the same capacitance result, and may be easier to achieve with signal generators or similar
- A single sample of each pad type was tested, although several measurements were made in different areas of the pad
- Examining the measured signals it was evident that the current was not constant, but that the amplitude of the sine wave fluctuated in a predictable manner. It was seen that the voltage amplitude fluctuated in the same manner, at a consistent phase angle with the current amplitude. Since capacitance is based on a ratio of these measurements this variation will not affect the resultant value

Methods

Equipment used:

Current transformer: Pearson electronics, 2877. Calibrated 1/12/11 by ETC

Digital oscilloscope: Tektronix TDS 3014B. calibrated 28/11/11 by ETC

Voltage probe: Tektronix P3010. Calibrated 7/12/11 by ETC

Valley lab Force FX -8C

Dale Resistor 300 ohms, uncalibrated.

Metal Plate, Brass, various sizes

Lead shot, in 5 containers, 15.2 Kg total

Adult Mega Soft – serial number 10630003

Paediatric Mega Soft – serial number 1186004

Capacitance with varying size metal plates

The Mega Soft was placed on a non-metallic surface, and a brass plate placed on top, ensuring that it was over the conductive mesh area. Where possible the corner where the cable connects to the pad was avoided, since it may have different dielectric properties than the rest of the mesh. The plate area was measured and then covered with a wooden board and weighted down with a known weight. The plate size and weight were recorded on the data sheet.

An active electrode was connected to the ESU, and the tip connected to a 300 ohm resistor (representing the patient). This was then connected to the metal plate, with a current probe to measure the supplied current.

The Mega Soft cable was connected back to the ESU.

A voltage probe was connected at the metal plate, and referenced to the Mega Soft pad cable returning to the ESU.

Both the current and voltage probe were output to an oscilloscope which was used to read the voltage, current and frequency and phase angle.

The ESU was activated and the power adjusted to give a current output of approximately 200 mA. The oscilloscope was adjusted to give a steady reading and the data recorded.

This was repeated five times for each different set up.

Plate sizes were chosen to give a range of sizes including approximately 100% coverage of the mesh area, 85% coverage of the mesh area and a range of smaller areas.

Capacitance with varying thickness of material between plate and pad

The previous tests were repeated on an adult pad, using a 4068 cm^2 brass plate.

A single, double and triple thickness of a theatre sheet were placed under the metal plate and over the Mega Soft pad. Seams and thicker edges of the sheet were avoided.

Testing for conductivity through punctured pads

The test protocol was adapted for the capacitance measurement for different plate sizes. A brass plate of size 1062 cm^2 was chosen to allow for repeat testing in other areas of the pad if required.

An initial investigation placed a 500 ohm resistor across the pad and plate to simulate a possible resistive connection in parallel with the capacitive connection. A change in current and voltage was seen, as well as a change in the phase angle between the current and voltage. This change in phase angle was expected to be the clearest indication of any resistive connection between the pad and plate.

During testing, saline solution was used to simulate a situation where fluid could penetrate a damaged section of the pad and create a resistive pathway for current. The test protocol was to pour 20ml of saline onto the area where the plate was applied. After the plate was weighted down, any excess saline was dried from around the pad.

Throughout these tests the wooden board was not used for two reasons:

- It was unnecessary since the plate area was small, and could be entirely covered by the weights
- The board was seen to soak up the saline and alter the recorded capacitance over the series of measurements.

The damage to the pad was a 12mm cut with a scalpel. During cutting, a multimeter was connected between the scalpel handle and Mega Soft plate to test for continuity and ensure that the cut had reached the conductive mesh.

Testing was done in the following order:

- Dry and undamaged pad
- Undamaged pad with 20ml of saline
- These measurements were repeated to ensure baseline measurements were repeatable
- Dry pad with 12mm cut
- 20ml of saline on pad with 12mm cut

The position of the plate was marked on the pad to allow accurate replacement of the plate in the same position.

This procedure was repeated on a new, adjacent area of the pad:

- Dry and undamaged pad
- Undamaged pad with 20ml of saline
- Saline poured on pad, and 12mm cut made with saline in place, then plate placed and measurement made

Results and discussion

Capacitance with varying size metal plates

Table 3. Adult Mega Soft, mean values

Area		Capacitance
cm^2	%	nF
5534	111	6.76
5022	100	6.41
4068	81	5.91
3260	65	4.83
2219	44	3.40
1951	39	2.81
1359	27	2.23

Figure 7. Adult Mega Soft. Capacitance with varying plate size, all data points

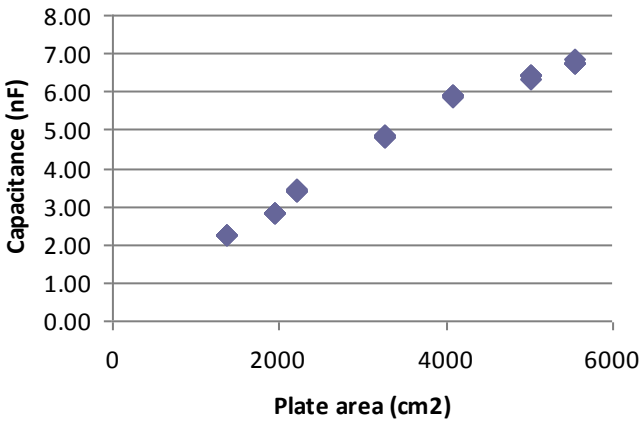
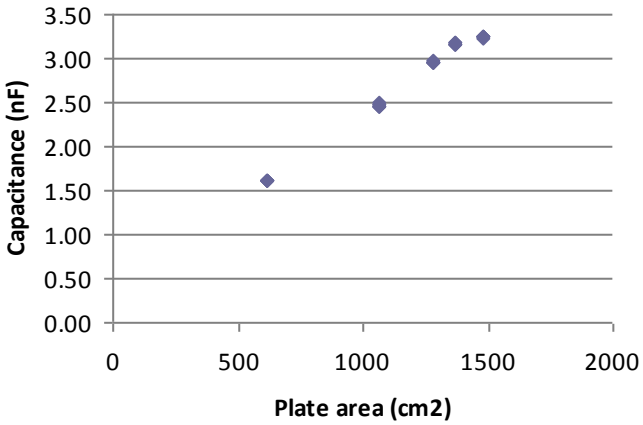


Table 4. Paediatric Mega Soft, mean values

Area		Capacitance
cm^2	%	nF
1482	100	3.25
1364	92	3.17
1277	86	2.96
1065	72	2.47
620	42	1.61

Figure 8. Paediatric Mega Soft. Capacitance with varying plate size, all data points



The tables show averages of all results for each plate size. The graphs show the individual results, but the figures given were very consistent and therefore the five data points cannot be distinguished for each plate size.

It can be seen that there is a clear correlation between plate area and capacitance. In both the adult and paediatric graphs this seems to tail off at the very high percentages of the mesh covered. Cedar suggest that this is because the metal plate is overlapping the area with the cable connector, and also because there may be rounded corners on the mesh, meaning that some of the metal plate may not be over mesh.

In both cases the number calculated by Cedar is lower than the value calculated by Megadyne. The Cedar values are only 70 and 80% of the Megadyne values for paediatric and adult pads respectively. Some of the difference will be due to the lower weight used by Cedar (the value is not defined in the standard) and also due to different generators and Mega Soft pads being used. Megadyne's use of a metal plate that extended beyond the conductive mesh may also have given them slightly higher results. It was noted that Megadyne reported a lower measurement (85%) for the adult pad in previous tests.

The adult pad had a capacitance of greater than 4 nF for plates that were over approximately 55% of the pads' surface area (by interpolating between experimental points on a line fitting data points less than 100% of mesh area).

Cedar did not measure a capacitance of greater than 4nF for any plate size with the paediatric pad, including 100% coverage. Although the paediatric pad has a thinner gel layer resulting in a higher capacitance.

The limit of 4nF is based on historical precedent rather than clinical or scientific evidence of what is required. Therefore although Mega Soft paediatric would not pass the test required of the IEC60601-2-2:2009 based on Cedar's testing, this does not necessarily mean that it is unsafe. The lower capacitance does mean that there will be an increased risk of alternate current pathways, however this risk may be reduced by the lower power settings used in paediatric surgery [MHRA e-learning module].

Capacitance with varying weight applied to the plate

This was an additional test to investigate possible reasons for variance between Cedar and Megadyne results, it was not intended as a full investigation and testing was limited to the range of weights readily available. It can be seen that increasing the weight increases the capacitance, which is to be expected since the gel will be compressed, and thus the distance between the plates will be decreased. The non-linear relationship could be explained by the fact that the gel can only be compressed or displaced by a limited amount. Cedar tested at a lower weight of 15.2Kg rather than the 50lbs or 22.7 Kg that was used by Megadyne, and this will explain some of the different capacitance values calculated. There are not sufficient data points on the graph to predict what the capacitance would be with a weight of 22.7 Kg.

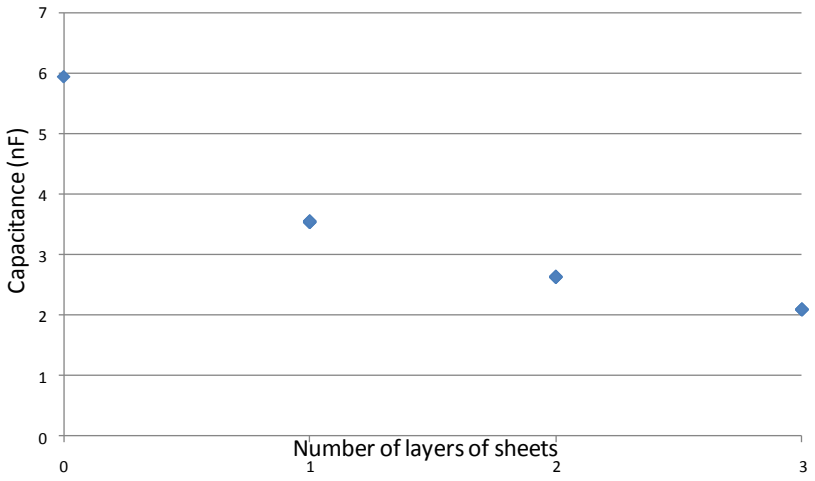
Capacitance with varying thickness of material between plate and pad

These results illustrate how introducing standard theatre sheets can change the capacitance. Any increase in distance between the plates will decrease the capacitance, and a different material will also change the overall dielectric properties. The actual effect in clinical practice will vary according to the patient characteristics, type of surgery, and many other variables.

Table 5 Capacitance with sheets in place, mean values

Number of sheets	Capacitance nF
0	5.93
1	3.53
2	2.62
3	2.09

Figure 9. Capacitance with sheets in place, all data points shown, 4068 cm^2 plate



Capacitance and phase angle when pad damaged, and with saline

There is a notable difference between the capacitance measured when the pad was dry and when it was wet. We suggest that this is because the saline improves the contact between the plate and the pad, since it will fill any air gaps due to the presence of small wrinkles on the surface of the pad.

On cutting the pad it was observed that the gel was very thick and sticky, and indeed, the description self-healing seemed appropriate. After cutting, the gel completely closed up, leaving no access to the conductive layer. Even after cutting the pad all the way through it was very difficult to subsequently push a tool through the pad.

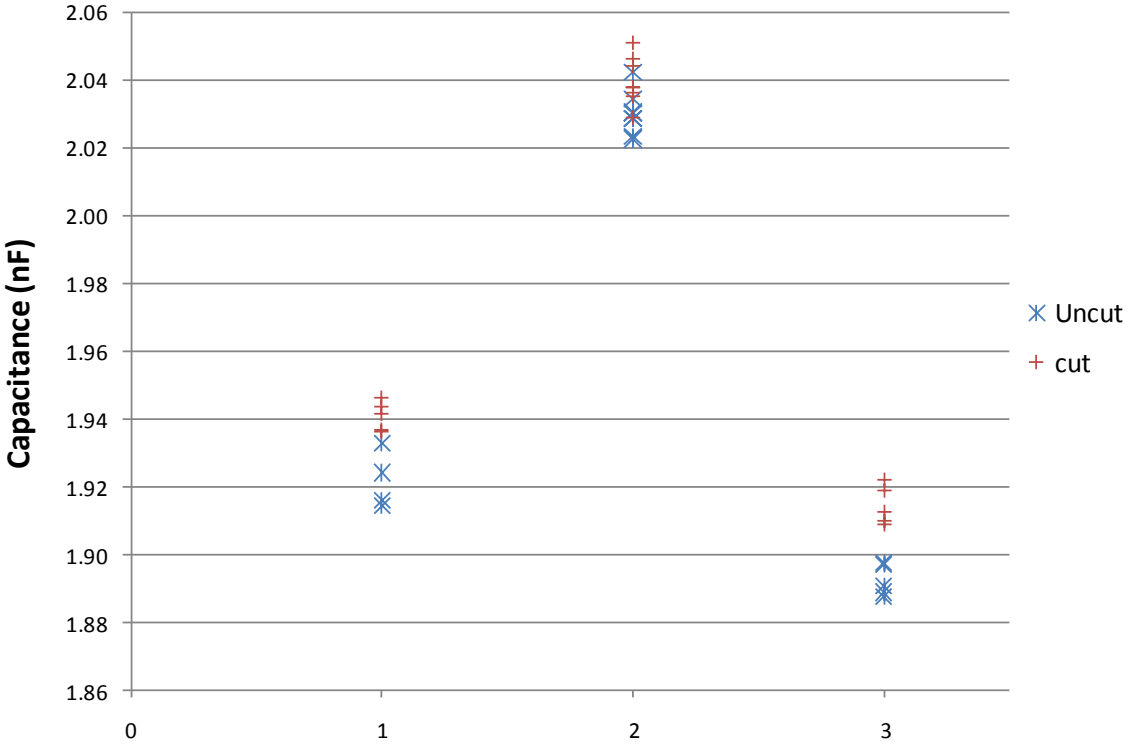
The phase angle was unchanged before and after damage to the pad, even when cutting was carried out through a layer of saline. There was no significant difference (using t test) between dry cut and uncut, or saline cut and uncut. This suggests that there was no conductive connection made due to damage to the pad, meaning that patient safety would not be compromised by accidental damage to the Mega Soft pad.

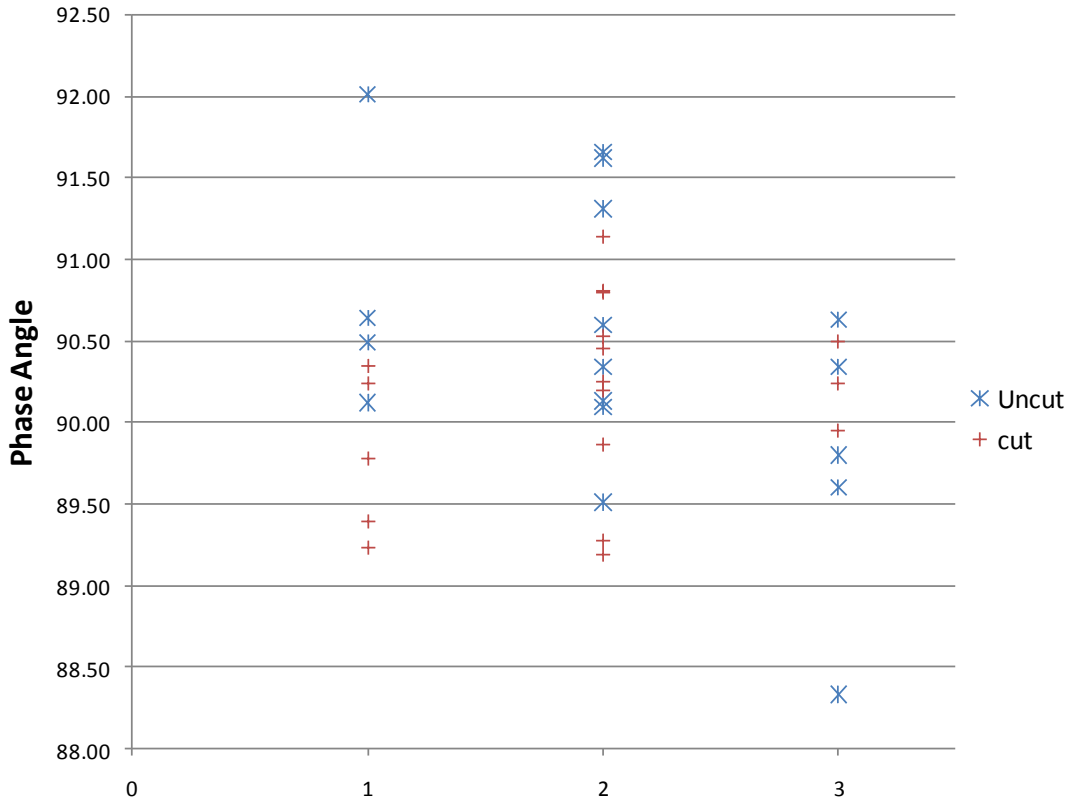
There did appear to be a slight difference in the calculated capacitance before and after the damage. Comparing data using a t-test showed significant differences between saline and saline cut ($p= 0.0003$) and dry and dry cut ($p< 0.0001$). Although the difference is significant, it is very small, and it is probably that the break in the skin of the pad at the cut and the very slightly thinner gel layer where there is damage to the pad give a slightly higher capacitance.

Given that there is no change in the phase angle, Cedar do not believe that this shows any resistive connection.

Figures 10 and 11. Phase angle and calculated capacitance for adult pad in dry and saline soaked conditions, with and without damage.

1: Position 1, dry **2: Position 1, saline soaked** **3: Position 2, saline soaked**





Appendix 3 Megadyne information: ESU compatibility

MEGA 2000 and ReCORDable Generator Compatibility and Adapter Requirements

Manufacturer	Model	Isolated - (Most are Compatible w/Mega Soft - see comments)	Adapter Required for Recordable -or- Detachacable Required for MEGA Soft other than M2K-01 if compatible - see comments	Comments
Aesculap	Nelson Deluxe GN 640	Yes	M2K-03, M2K-04 or M2K-05	
Aesculap	GN 300	Yes	M2K-03, M2K-04 or M2K-05	
Alcon	203-0000-501	NA		Ultrasonic Device - does not use a return electrode
Aspen	MF380	Yes	B-205 M2K-03, M2K-04	
Aspen	MF360A	Yes	B-205 M2K-03, M2K-04	
Aspen	MF450	Yes	B-205 M2K-03, M2K-04	
Aspen/Conmed	Sabre 2400	Yes	B-205 M2K-03, M2K-04	
Aspen/Conmed	Sabre180	Yes	B-205 M2K-03, M2K-04	
Aspen/Conmed	Excalibur Plus	Yes	No	
Bard	3000	Yes	B-205 M2K-03, M2K-04	
Berchtold	Elektrotom 400	Yes	M2K-03, M2K-04	
Berchtold	Elektrotom 640	Yes	M2K-03, M2K-04	
Berchtold	Elektrotom 200	Yes	M2K-03, M2K-04	
Berchtold	Elektrotom 200-165	Yes	M2K-03, M2K-05	
Berchtold	Elektrotom 300B	Yes	M2K-03, M2K-04	
Berchtold	Elektrotom 390	Yes	M2K-03, M2K-04	
Berchtold	Elektrotom 621	Yes	M2K-03, M2K-04	
Birtcher	6400	Yes	A-238, M2K-06	Argon Beam Coagulator
Birtcher	4400	Yes	No	
Birtcher	6000	Yes		Argon Beam Coagulator - this model was originally designed for single plate return electrodes and will work with Mega Soft Some units have been retrofitted with PSS (pad sensing system) and do not work with Mega Soft
Birtcher/Bard/EMS/ Davol/NDM	5000	Yes	B-205 M2K-03, M2K-04	
Circon	BC-200	Yes	Yes	
Circon	91-I	Yes	Yes	
Codman	80-1170	NA		Bipolar Only Machine - No Return Electrode Required
Concept	9900	Yes	B-205 M2K-03, M2K-04	
Concept	9700	Yes	B-205 M2K-03,	
Concept	9600	Yes	B-205 M2K-03, M2K-04	
Conmed	6500	Yes	A-238, M2K-06	Argon Beam Coagulator
Conmed	7500	Yes	A-238, M2K-06	Argon Beam Coagulator
ConMed	System 2450	Yes	M2K-01 or M2K-06	
ConMed	System 5000	Yes	M2K-01 or M2K-06	
Cooper	Leep 1000	Yes	B-205 M2K-03, M2K-04	
Cryomedics	91-J	Yes	???	? With MEGA Soft special procedure unit, has not been tested with MEGA Soft
Ellman	Surgitron			No adapters available for this machine

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MEGA 2000 and ReCORDable Generator Compatibility and Adapter Requirements

Manufacturer	Model	Isolated - (Most are Compatible w/Mega Soft - see comments)	Adapter Required for Recordable -or- Detachacable Required for MEGA Soft other than M2K-01 if compatible - see comments	Comments
EP Technologies	EPT-1000	Yes	No	? With MEGA Soft special procedure unit, has not been tested with MEGA Soft
Erbe	ICC350	Yes	M2K-01 or M2K-02	Do not use with the High Cut or Endo Cut Mode. Doing so may result in a greater electrosurgical effect than intended.
Erbe	ICC300	Yes	M2K-01 or M2K-02	Do not use with the High Cut (on the 300). Doing so may result in a greater electrosurgical effect than intended.
Erbe	ICC200	Yes	M2K-01 or M2K-02	Do not use with the Endo Cut Mode (optional on the 200). Doing so may result in a greater electrosurgical effect than intended.
Eschmann	TD 311	Yes	B-205 M2K-03, M2K-04	
Eschmann	TD 302	Yes	B-205 M2K-03, M2K-04	
Eschmann	TD 411	Yes	B-205 M2K-03, M2K-04	
Eschmann	TD 402	Yes	B-205 M2K-03, M2K-04	
Eschmann	TD 411RS	Yes	B-205 M2K-03, M2K-04	
Eschmann	TD411RS2	Yes	B-205 M2K-03, M2K-04	
Eschmann	TD 830	Yes	B-205 M2K-03, M2K-04	
Eschmann	TD 850	Yes	B-205 M2K-03, M2K-04	
Ethicon	G110	NA		Ultrasonic Scalpel - does not use a return electrode
Ethicon (Formerly	Pegasys	Yes	No	
Everest	8750	Yes	No	? With MEGA Soft special procedure unit, has not been tested with MEGA Soft
Martin	ME MB1	Yes	M2K-03, M2K-04	
Martin	ME 200	Yes	M2K-03, M2K-04	
Martin	ME 411	Yes	M2K-03, M2K-04	
Martin	ME-300	Yes	M2K-05	
Martin	ME-400	Yes	M2K-05	
Martin	Maxium	Yes	M2K-01 or M2K-03	Connector depends on country
Maxxim/Bovie	400SR	No	????	Not compat. w/MEGA Soft
Maxxim/Bovie	CSV Bovie	No	B-205	Not compat. w/MEGA Soft
Maxxim/Bovie	URO Bovie	No	B-205	Not compat. w/MEGA Soft
Maxxim/Bovie	Bantam/Bovie	No	E-0504-1L	Not compat. w/MEGA Soft
Maxxim/Bovie	Ritter A	No	E-0504-1L	Not compat. w/MEGA Soft
Maxxim/Bovie	X-10	No	No	Not compat. w/MEGA Soft
Maxxim/Bovie	X-15	Yes	No	
Maxxim/Bovie	X-30	Yes	No	
Maxxim/Bovie	X-40	Yes	No	
Maxxim/Bovie	Specialist	No		Not compat. w/MEGA Soft
Medtronic	601	Yes	???	? With MEGA Soft special procedure unit, has not been tested with MEGA Soft
Medtronic	Cardorhythm	Yes	???	? With MEGA Soft special procedure unit, has not been tested with MEGA Soft
Megadyne	Mega Power	Yes	No	
Microvasive	Endostat	Yes	E-0504-2	? With MEGA Soft special procedure unit, has not been tested with MEGA Soft
NDM	1000 Powerpoint	Yes	B-205 M2K-03, M2K-04	
Neomed	300A	Yes	B-205 M2K-03, M2K-04	Unit was made by Birtcher
Olympus	UES	Yes	Yes	Must obtain from Olympus

MEGA 2000 and ReCORDable Generator Compatibility and Adapter Requirements

Manufacturer	Model	Isolated - (Most are Compatible w/Mega Soft - see comments)	Adapter Required for Recordable -or- Detachacable Required for MEGA Soft other than M2K-01 if compatible - see comments	Comments
Olympus	PSD-20	Yes	Yes	Must obtain from Olympus
Radionics	RFG-3C	Yes	???	? With MEGA Soft special procedure unit, has not been tested with MEGA Soft
Richard Wolf	2083	Yes	???	
Richard Wolf	2093	Yes	???	
Richard Wolf	2094	Yes	???	
Richard Wolf	2353	Yes	???	
Richard Wolf	4083	Yes	???	
Smith and Nephew (formerly Oratech)	Vulcan	Isolated - not compatible with Mega 2000	No	Dedicated to Arthroscopy - functions with monitoring pads only
Smith and Nephew (formerly Oratech)	Ora 50	Yes	Yes, 805019 from Orotec	Dedicated to Arthroscopy - Call Megadyne re: questions
Valleyforge	Symmetry	NA		Bipolar Only Machine - No Return Electrode Required
Valleylab	Surgistat	Yes	E-0504-1L	Adapter required on older units only
Valleylab	SSE2L	Yes	E-0504-1L	
Valleylab	SSE3	No	E-0504-1L	Not compat. w/MEGA Soft
Valleylab	SSE3B	No	E-0504-1L	Not compat. w/MEGA Soft
Valleylab	Force FX	Yes	No	
Valleylab	Force 2	Yes	No	
Valleylab	Force 2 CEM	Yes	No	
Valleylab	Force 1C	Yes	No	
Valleylab	Force 1B	Yes	No	
Valleylab	Force 30	Yes	No	
Valleylab	Force 300	Yes	No	
Valleylab	Force 40	Yes	No	
Valleylab	Force EZ	Yes	No	
Valleylab	Force 4	No	No	Not compat. w/MEGA Soft
Valleylab	Force 4B	No	No	Not compat. w/MEGA Soft
Valleylab	Force Triad	Yes	M2K-08 or M2K-09	Generator will alarm without specialized cable.

Appendix 4 Megadyne information: electromagnetic interference

MEGADYNE®

Electrosurgery and Monitor Interference

Monitor interference can be an artifact of electrosurgery. Steps to minimize interference are as follows:

1. Insure that the ECG electrode is well attached to the patient through proper skin preparation prior to electrode placement.
2. Insure the electrosurgical cables (active and return) do not cross the cables of the affected equipment.
3. Plug the affected equipment into a separate power outlet.
4. Use the lowest possible power setting to achieve the desired effect.
5. Interference is usually greatest in the fulguration mode, it can be reduced by using a lower voltage mode such as desiccate, or cut.
6. Check all connections to the generator, patient return electrode, and accessories.
7. Some manufacturers of ECG electrodes offer RF (radio frequency) choke filters for use in the monitor leads. These filters reduce interference while the generator is activated. RF filters minimize the potential for an electrosurgical burn at the site of the monitor electrode.

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