National Institute for Health and Clinical Excellence

Medical Technologies Evaluation Programme

MT 141 – Mega Soft Patient Return Electrode
Consultation Comments table

MTAC date: 11 May 2012

There were 23 consultation comments from two consultees (1 manufacturer (the topic sponsor) and 1 professional organisation.

Com no.	Consultee number and organisation	Sec. no.	Comments	Response
1	Consultee 1 Megadyne Medical Products Inc (sponsor)	**1.1**	Section 1 – Provisional recommendations 1.1 – "The published clinical evidence on the Mega Soft Patient Return Electrode for use during monopolar electrosurgery is very limited and does not demonstrate a change in the incidence of buns as a result of its use". 1.1 – *"It is technically plausible that the Mega Soft Patient Return Electrode may reduce the risk of burns* **Megadyne response:** The Megadyne Mega Soft return electrode is safer than CQM or REM™ patient return electrode technology. This can be proven by the 45 Million procedures in which the Mega Soft has been used with 0 confirmed pad site burns. Terms like "plausible" and "may reduce risk of burns", greatly diminishes the reality of a 13 year history, 45 Million procedures and 41,000 pads used.	Thank you for your comment. The Committee considered this comment and decided to change sections 1.1 (now section 1.2) 3.10 and 6.2. The test report referred to by the consultee is summarised in section 3.6 of the guidance, and described in detail in the technical assessment report prepared by the CEDAR External Assessment Centre (EAC). Please refer to the responses to comments 13 and 20.

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			Comments: Megadyne has FDA clearance to market the Mega Soft family as "Safer then REM". Test results are shown in submitted test report **1150379-01** (attached). A)The following Regulatory bodies have reported that there are zero incidents of pad site burns with the Mega Soft patient return electrode; MHRA – United Kingdom FDA – United States BfArm – Germany Japanese Ministry of Health – Japan	
2	Consultee 1 Megadyne Medical Products Inc (sponsor)	**1.4**	1.4 – *"Clinicians and managers considering adopting the Mega Soft Patient Return Electrode should therefore, in judging the likely benefits, should take into account current practice in their operating theatres with regard to prevention of alternate site burns and the proportion of inpatient operations for which it would be used."* **Megadyne response:** The same considertions that are made when using the Mega Soft should also be made when using standard disposable patient return electrodes with regards to alternate site burns **Comments:** Same considerations should be made with sticky pads. Alternate site burns are not unique to the Mega Soft, see article from Valleylab, "Ouch, I got shocked". **a. http://www.valleylab.com/education/hotline/pdfs/hotline_9903.pdf**	Thank you for your comment. The Committee considered this comment and decided not to change section 1.4 of the guidance. Medical technologies guidance focuses on the case for adoption of the notified product, in this case,the Mega Soft Patient Return Electrode. Detailed consideration of other technologies is outside the scope of the guidance. In addition, the report cited is a general alert published in 1999 in the US by a manufacturer about the general risks of electrosurgery. It contains no information on the Mega Soft Patient Return Electrode.

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			b. Need to send hard copy as well.	
3	Consultee 1 Megadyne Medical Products Inc (sponsor)	**2.4**	<u>Section 2 – The technology</u> 2.4 – *"A standard disposable single-use patient return electrode forms a resistive circuit and the direct electrical connection relies on good contact with the patient. The Mega Soft Patient Return Electrode does not rely on direct contact with the patient and forms a capacitive circuit. The Mega Soft Patient Return Electrode is much larger than a standard disposable single-use patient return electrode, and lies under the whole of the patient's upper body."* **<u>Megadyne response:</u>** The larger sized Mega Soft Return electrode provides a much lower level of current density when compared to the standard disposable single-use electrode. The standard disposable single-use pad only provides 156 cm2 of surface area to disperse current versus the over 4, 800 cm2 of surface area provided by the adult Mega Soft, that is 30 times more area --- **Comments:** A) The advantages and positive findings of the ECRI report should also be included in the NICE report (not just the questionable findings). Include the following statement from the ECRI report: *"The distribution of charge in the electrode (Mega Soft) remains relatively uniform (Pearce 1986), eliminating the edge effects and heating that normally occur with conductive return electrodes (standard disposable*	Thank you for your comments. The Committee considered these comments and decided to change section 2.4 of the guidance and noted that, current density will also depend on patient positioning and other factors such as whether the patient is lying supine and covering a large area of the pad. --- The Committee considered this comment and decided to change section 3.4 to clarify the differences between the Mega 2000 and the Mega Soft Patent Return Electrode. Please refer to the response to consultee comment

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			single-use patient return electrode).” Ref. Health Devices, December 2000, Volume 29, Number 12, page 450.2.5 – *“Return electrode burns can occur when the contact area is reduced (for example, the pad can partially peel during surgery) and the current density increases.”* --- **<u>Megadyne Response</u>**: It is not only reduced contact of a standard sticky pad that can cause a burn. Pad site burns can occur during long activations because of heat build up at the pad site or pad site placement (bony prominences, hairy areas, adipose tissue, tattoos, piercing, metal implnats). **Comments:** A) Pad site burns can occur during long activations of the electrosurgical pencil. See sticky pad IFU, i.e. Valleylab. ***a.*** **http://www.valleylab.com/education/hotline/pdfs/hotline_0806.pdf** b. High current, long duration activation can occur during many procedures, increasing the risk of a pad site burn under a traditional sticky pad. In addition, duty cycles are recommended as no more than a 10 second activation, followed by 30 seconds off. (Found on page 2 on the above listed Covidien Hotline News Article)	7. --- The Committee considered this comment (and comment 6) and decided to change section 2.9 of the guidance to further clarify the risk of return electrode site burns. Please refer to the response to consultee comment 6.
4	Consultee 1 Megadyne Medical	**2.5**	2.5 – *“The risk of alternate site burns is generally recognized to be higher with capacitive pads (such as Mega Soft Patient Return Electrode) than with resistive pads (such as standard disposable single-use patient*	Thank you for your comment. The Committee considered this comment and decided to change section 2.5.

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	Products Inc (sponsor)		*return electrodes).”* **Megadyne Response:** Where is a reference to a scientific study by a 3rd party to support the statement “generally recognized”? If the Mega Soft product is to be judged by the lack of published studies by 3rd parties then statements like this cannot be allowed without support. **Comments:** A) For this to be true it requires two user errors to occur simultaneously. First, the patient must be positioned on the Mega Soft in a manner that is contraindicated by the IFU (too little contact or too much material between the pad and patient). Second, the power setting on the ESU must be increased to a level that is outside the normally expected operating range for a given surgical procedure, this is also contraindicated by the IFU. Only when both of these conditions are met can it be stated that the risk of alternate site burns in higher for a capacitive pad when compared to sticky pad. B) Alternate site burns are not unique to the Mega Soft, see article from Valleylab, “Ouch, I got shocked” **a.** **http://www.valleylab.com/education/hotline/pdfs/hotline_9903.pdf**	The report to which the consultee refers is a generalised alert by an manufacturer of other electrosurgery equipment and does not contain information about the Megasoft Patient Return Electrode.
5	Consultee 1 Megadyne Medical	**2.7**	2.7 – *“The Mega Soft Patient Return Electrode can be used with all other electrosurgery generators, with the exception of the ERBE generator when that device is*	Thank you for your comment. The Committee considered this comment and decided to change section 2.7 to further clarify the

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	Products Inc (sponsor)		*used on certain settings."* **Megadyne Response:** The settings referred to on the Erbe electrosurgical generator are High Cut and Endo Cut modes. These settings are not typically used in standard O.R.T.	precaution on use of the Mega Soft Patient Return Electrode with the ERBE generator.
6	Consultee 1 Megadyne Medical Products Inc (sponsor)	**2.9**	2.9 – *"If electrical conduction is impeded at the skin-to-pad surface interface there is a rise in skin temperature and risk of burning. Impedance of the current may occur when the contact area of the standard disposable single-use patient return electrode is reduced by body hair, adipose tissue, bony prominences, fluid invasion, failure of the electrode to adhere to the patient, or scar tissue."* **Megadyne response:** This is not technically correct. The increase in impedance at the skin-to-pad surface interface does NOT cause a rise in the skin temperature; rather, the increase in impedance causes the current to flow to an area where the skin-to-pad impedance is lower. This then causes an increase in current density in the areas of lower impedance, the increase in current density (amount of current per unit area) is what causes the skin temperature to rise and cause burns. When the impedance at the skin-to-pad interface increases due to body hair, adipose tissue, bony prominences, scar tissue, etc. the available area to conduct current in the disposable single-use electrode has effectively been reduced, causing higher current density and an increase in skin temperature	Thank you for your comment. The Committee considered this comment (and comment 3) and decided to change section 2.9 in the guidance to clarify the risk of electrode site burns. Please refer to the response to comment 3.

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			Comments: A) The Mega Soft electrode does not have this issue with body hair, adipose tissue, bony prominences, scar tissue and fluid invasion. These conditions do not increase the impedance in a capacitively coupled system (Mega Soft). B) Please see attached Megadyne Technical Bulletin: "**Safer than CQM 3000150-01"**	
7	Consultee 1 Megadyne Medical Products Inc (sponsor)	**3.4**	<u>Section 3 – Clinical evidence</u> 3.4 – *Whole paragraph.* **Megadyne response:** The testing ECRI conducted was on the Mega 2000 and not the Mega Soft pad. As the conductive mesh is embedded towards the upper region of the pad, the same test results would not occur when compared to a full gel pad overlay being placed over the Mega 2000. It is clinically unlikely that someone would place another gel overlay over an existing gel overlay such as is found in the Mega Soft.	Thank you for your comment. The Committee considered this comment and decided to change section 3.4 to further clarify the differences between the Mega 2000 and the Mega Soft Patent Return Electrode. Please refer to the response to comment 3
8	Consultee 1 Megadyne Medical Products Inc (sponsor)	**3.6**	3.6 – *"The tests were carried out on meat."* **Megadyne response:** Test report **1150331-01** section 2 states that the testing was done on live swine test subjects. The IEC standard allows for use of a surrogate media for this testing, reference IEC 60601-2-2 Edition 5 Subclause 201.15.101.5 – NE thermal performance. **Comments:** A) The use of swine tissue as a surrogate for human	Thank you for your comment. The Committee considered this comment and decided to change section 3.6 of the guidance to clarify the test design.Test report 1150331-01 is considered in detail in the Cedar External Assessment Report (p23).

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			tissues is widely accepted. The following are just a few of the studies that support this: a. William Richard Douglas. *Of Pigs and Men and Research: A review of applications and Analogies of the Pig, sus scrofa, in Human Medical Research.* Oct. 4, 1971. b. Biana Godin, Elka Touitou. *Transdermal skin delivery: Predictions for humans from in vivo, ex vivo and animal models*. May 10, 2007.	
9	Consultee 1 Megadyne Medical Products Inc (sponsor)	**3.7**	3.7 – *"Both hospitals issued statements saying that the Mega Soft Patient Return Electrode improved patient comfort and provided cost savings. It was not clear from the testimonial reports whether these benefits are generalisable."* **Megadyne response:** When compared to our U.S. reference list of satisfied customers, the number of pads that have been placed globally, and the number of pad re-orders over the last decade, these reports of product benefits are easily generalizable. As previously supplied to CEDAR, attached is the current Mega Soft reference list. **Comments:** . **See "Mega Soft Reference List – Nov 2011.pdf**	Thank you for your comment. The Committee considered this comment and decided to change section 3.7 to provide further clarity on the report .
10	Consultee 1 Megadyne Medical Products Inc (sponsor)	**3.8**	*"The data were incomplete and no analysis was provided about the completeness of responses."* **Megadyne response:** This sentence seems to discredit the rest of the information provided in this paragraph.	Thank you your comment. The Committee considered this comment and decided to change section 3.7 to further clarify the completeness of the analysis.

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			The numbers presented in this paragraph constitute the analysis.	
11	Consultee 1 Megadyne Medical Products Inc (sponsor)	**3.9**	3.9 – *"good operating theatre practice"* **Megadyne response**: The use of "good operating theatre practice" is used in a positive manner in this section with respect to the use of disposable sticky pads. Why can't the use of "good operating theatre practice" be used in a positive manner in 3.10 & 3.11 when referencing the Mega Soft product?	Thank you for your comment. The Committee considered this comment and decided to change sections 3.10 and 3.11. Please refer to the response to comment 14
12	Consultee 1 Megadyne Medical Products Inc (sponsor)	**3.9**	3.9 – *"In addition, the Expert Advisers stated that patient return electrode burns are very uncommon indeed. They said that when these burns occur, they are usually not severe and are treated by a topical cream. The Committee was advised that all types of burn can usually be avoided by good operating theatre practice."* **Megadyne response:** This is not scientific data, "they said" is subjective and not supported by anything other than personal history. Please see Valleylab's warning on sticky pads. Please refer to the following article of warnings againt disposable patient return electrodes. **a**.**http://www.valleylab.com/education/hotline/pdfs/hotline_0806.pdf** Comments: b.Please reference data base for pad site injuries such as the MAUDE (FDA's site on patient injuries and	Thank you for your comment. The Committee considered this comment and decided to change section 3.9 to further clarify the input of Expert Advisers. Expert advice is a key component of the published process and methods for developing Medical Technologies Guidance. The Committee considered the MAUDE database statistics (which were assessed in the Cedar Exeternal Assessment Centre Report (Appendix 2, p36) but decided not to change section 3.9 because it was uncertain about their relevance to UK practice.

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			events) c.**http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/Search.cfm**	
13	Consultee 1 Megadyne Medical Products Inc (sponsor)	**3.10**	3.10 – *"The Committee considered that, the published clinical evidence on Mega Soft Patient Return Electrode was very limited and did not provide evidence of whether or not the device prevented patient return electrode burns in practice."* **Megadyne response:** What is the published clinical evidence provided by the competitive sticky pads that are being used today in practice? It is doubtful if there is any. With 13 years of history, 45 million procedures, 0 pad site burns, this is evidence enough verses sticky disposable sticky pads.	Thank you for your comment. The Committee considered this comment and decided to change sections 3.10 (and 1.2 and 6.2). Please refer to the responses to comments 1 and 20
14	Consultee 1 Megadyne Medical Products Inc (sponsor)	**3.11**	3.11 – Whole section (comparison of event alternate site -> pad site burns) **Megadyne response**: Is an alternate current path burn similar (of equal severity) to a pad site burn? We don't need to have the "highest standard" in the theatre to reduce the risk of an alternate site burn; we just need to have the same "good operating theatre practice" that a disposable sticky pad requires. The reason that the operating theatres employ registered nurses is to utilize critical thinking skills and to be the patient advocate. By following the instructions for use, there is no highest level required. It is simply to follow recommended practices and maximize contact with the pad while	Thank you for your comment.The Committee considered this comment and decided to change sections 3.10 and 3.11. Please refer to the response to comment 11.

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			minimizing layers. Megadyne has a large reference list that is attached of satisfied customers that guard patient safety while following standard practices.	
15	Consultee 1 Megadyne Medical Products Inc (sponsor)	**3.12**	3.12 – *"The Committee accepted it was plausible that the Mega Soft Patient Return Electrode may have advantages in selected patient groups, despite the lack of clinical studies to support these claims."* **Megadyne response:** Why the use of the word plausible? We have hundreds of accounts that have years of history using the pad. This is common sense, no clinical study required. Just as the existing sticky pad has history of use and is accepted without clinical studies.	Thank you for your comment. The Committee considered this comment and decided to change section 3.12.
16	Consultee 1 Megadyne Medical Products Inc (sponsor)	**4.3**	Section 4 – NHS considerations 4.3 – *"The Expert Advisers stated that any necessary shaving of patients and placement of standard disposable single-use patient return electrodes are normally done at the same time as other tasks and therefore using the Mega Soft Patient Return Electrode would not save time as claimed."* **Megadyne response:** This comment is not accurate. The Mega Soft patient return electrode has less steps involved in the setup and placement of the pad. The Association of Operating Room Nurse (AORN) Perioperative Standards and Recommended Practices outlines the steps that should be considered when placing a disposable patient return electrode as well as a reusable capacitive coupled patient return electrode	Thank you for your comment. The Committee considered this comment and decided not to update the guidance as no evidence has been presented to prove that using the Mega Soft Patient Return Electrode saves time. The Committee received expert advice that, in current NHS practice, any necessary shaving of patients and placement of standard disposable single-use patient return electrodes are normally done at the same time as other tasks. The Recommended Practices guideline referred to by the consultee is based on US practice which may not be generalisable to current NHS practice. Section 3.12 contains the Committee's considerations of the advantages of the Mega Soft

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			(Mega Soft). When placing a disposable patient return electrode the clinician needs to place the pad on clean, dry skin over a large, well perfused muscle mass on the surgical side as close as possible to the surgical site. Single use electrodes should not be placed over bony prominences, scar tissue, hair, weight bearing surfaces, potential pressure points, or areas distal to tourniquets. The Mega Soft patient return electrode should simply be the appropriate size for the patient and adequate contact with the patient should be ensured. Tissue type, fat, hair, tattoos, bony prominences, and dry skin do not need to be considered with the Mega Soft.	Patient Return Electrode in patient groups where a disposable patient return electrode.
17	Consultee 1 Megadyne Medical Products Inc (sponsor)	**4.6**	4.6 – *"It noted that waste was likely to be reduced because disposable pads and leads would not need to be discarded after each operation but was unable to reach any conclusions on this because of the lack of data."* **Megadyne response:** On average, the Mega Soft pad eliminates the vast majority of electrosurgical waste as only 18 lbs. is generated in the course of two years. I don't think the word "likely" needs to be used.	Thank you for your comment. The Committee considered the new evidence presented during consultation and decided to change section 4.6.
18	Consultee 1 Megadyne Medical Products Inc (sponsor)	**4.7**	4.7 – *"The Committee noted that the Mega Soft Patient Return Electrode is compatible with all electrosurgical units apart from certain settings on one specific unit (see sections 2.6)."* **Megadyne response:** As mentioned earlier, the	Thank you for your comment. The Committee considered this comment and decided to change section 2.7 (rather than 2.6 as referred to the consultee) to further clarify te precautions in using the Mega Soft Patient Return Electrode with the ERBE generator. A sentence

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			settings referred to are High Cut and Endo Cut modes on the ERBE Erbotom ICC 200, ICC 300H, or ICC350 generator. These settings are not typically used in standard O.R.T.	referring the reader to section 2.7 has been added to section 4.8 (previously 4.7). Please refer to the response to consultation comment 5.
19	Consultee 1 Megadyne Medical Products Inc (sponsor)	**4.8**	4.8 – *"The Committee found no evidence to support the claim that the Mega Soft patient return electrode would reduce the need for a separate pressure-relieving device."* **Megadyne response:** Please see attached studies on viscoelastic polymer supplied by Action Medical, the company that supplies us with the gel overlays. In addition, see attached pressure mapping on the Mega Soft pad and comparisons with existing Action Medical pads.	Thank you for your comment. The Committee considered the six new pieces of evidence presented in support of this comment and and decided to change section 4.8.
20	Consultee 1 Megadyne Medical Products Inc (sponsor)	**6.1**	Section 6 – Conclusions 6.1 – *"The Committee considered that the published clinical evidence on the Mega Soft Patient Return Electrode is very limited and does not demonstrate that burns are reduced as a result of its use."* **Comments:** CEDAR had the opportunity to do temperature rise testing on the disposable sticky pads and the Mega Soft but selected not to do the testing. Megadyne supplied temperature rise testing per the IEC 60601-2-2 standard, we feel that this warrants more than just a	Thank you for your comment. The Committee considered this comment and decided to change section 6.1 (now 6.2) and sections 3.10 and 1.2. Please refer to the responses to consultee comments 1 and 13.

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			"plausible" statement. The safety of the Mega Soft should not be penalized in the report because other 3 party test groups have selected to not do the testing.	
21	Consultee 1 Megadyne Medical Products Inc (sponsor)	**Assessment report overview** **Clinical Evidence**	Page 7 of 68 – In reference to temperature rise testing done by Megadyne *"….few details were presented on how it was conducted."* and *"…but may have been subject to bias because few details were provided on its methods."* **Megadyne response:** No request was made to Megadyne to provide additional information on how this testing was done. A) Test protocol 1150331-10 and report 1150331-01 were provided and includes the statement that testing was done to satisfy ANSI/AAMI HF-18 and IEC 60601-2-2 requirements. The protocol and report provide all the details of how the testing was performed.	Thank you for your comment. Page 7 of f the NICE Assessment Report Overview has been changed to further clarify the study design.
22	Consultee 1 Megadyne Medical Products Inc (sponsor)	**Assessment report overview** **Clinical Evidence**	Page 15 of 68 – *"Megadyne (2011a) was a laboratory-based and comparative technical study of split disposable single-use patient return electrode compared with Mega Soft Patient Return Electrode. It has not been peer-reviewed. The tests were carried out on meat. No statistical tests were reported; the main outcome was whether or not pad site burn was observed (that is, yes or no)."* **Megadyne response:** Test protocol 1150379-10	Thank you for your comment. Page 15 of of the NICE Assessment Report Overview has been changed to further clarify the study report

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			section 9 states that the testing was done on live swine test subjects, not just on meat. More than just a “Yes or No” was reported for this testing. Test report 1150379-01 Tables 2 and 3 contains all the temperature rise data in addition to a determination of whether or not a pad site burn was observed. This data was submitted for FDA review under 510K number K080741 to support the Megadyne claim that the Mega Soft is safer than REM or CQM return electrodes. The claim was cleared Dec. 16, 2008 by the FDA.	
23	Consultee 2 Royal College of Nursing	**General**	As stated in the consultation document there is limited evidence of the use of mega soft patient return electrodes for use during monopolar electrosurgery, and although there may be strong arguments for their use within the UK, further research is probably required. The RCN Perioperative Forum has representation from across the UK, and although the focus of this consultation is the NHS in England, none of the Forum committee members were aware of the product.	Thank you for your comment.

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