National Institute for Health and Clinical Excellence

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Additional Submission Information

EP141 Technical Testing of Mega Soft Patient Return electrode

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

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

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

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Section 2.2	Telephone conversation to discuss the question: 1. Clarification is required as to whether the product can be used with all other equipment in the operating theatre environment. Particularly with the emphaisis on electromagnetic compatibility. Experts were also asked if there were any other issues that they felt may occur.	**Technical experts 1 &2 (summary of phone conversation)::** The current density is high at the active tip, but low at the return electrode. The main problems in terms of emc will be at the tip rather than the plate. If the area of contact with Mega Soft is small, then the current will reduce, but the voltage on the patient will be high. This could mean the patient body acts as an antennae. Measurements could be made to investigate this, using a patient or substitute. High electromagnetic fields are often present during electrosurgery (in general), however patient monitoring systems tend to cope well with this most of the time. If there are no reported issues, and it has been in use for some time, it is unlikely that there will be any greater emc issues with a large capacitive electrode than a standard return electrode. There is one type of ESU that monitors high frequency voltage on the patient body to warn against potential alternate site burns. A capacitive plate system would not trigger the alarm. One expert has not had to investigate an electrosurgery burn in their trust for about 20 years, and not in any other trust for about 15 years.	**Summary of the telephone conversation was used for part of the report text.**

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Section 2.2, **Section 5.1.1**	An important factor for this device is the occurrence of adverse events. Both Cedar and York have looked at MHRA and Maude listings, and York have obtained a breakdown from the MHRA of the number of electrosurgery incidents annually between 2000 and 2010, showing the number related to burns, and to return electrode burns. It would be very useful to know if • the return electrode burns include alternate site burns • what number of these were using split or non-split pads • were any of these incidents involving Mega Soft	**MHRA information:** • The return electrode burns did not include alternate site burns; • We do not know the numbers of split or non-split pads; • None of these incidents involved Mega Soft.	**This information was incorporated into the report text.**
General informatioin	• Do you use of alcohol in preparation for surgery? • What is placed between the patient and Mega Soft in normal practice, and if it varies, could you please give more details?	**Clinical Expert 1 (summary of phone conversation)::** Mega Soft has been used in all the theatres for the past 5-6 years, and there have been no problems with its use. When ablation (high power) procedures are carried out the Mega Soft is not used, and multiple return electrodes are used. **Relating to the use of alcohol based fluid for patient preparation:**	**General information, no action required**

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		Alcohol is used during patient preparation, and care is taken to avoid pooling. There would be no difference with any other mattress used that would have some pressure relief. **Material placed between Mega Soft and patient:** Sometimes draw sheets are used, so there may be 2 or 3 layers of cotton between the Mega Soft and the patient. It has never been an issue. Have seen in some other hospitals Mega Soft used with slide sheets containing Nylon. Where underbody warmers are used they are placed under the patient, and over the sheet and the Mega Soft. The warmer is compressed where the patient is lying on it, and so there is not a large air gap between the patient and the Mega Soft.	
General Information	• Do you use of alcohol in preparation for surgery? • What is placed between the patient and Mega Soft in normal practice, and if it varies, could you please give more details?	**Clinical Expert 2 (summary of phone conversation):** **Relating to the use of alcohol based fluid for patient preparation:** The fluid is dried before surgery. Pooling of alcohol should not be a problem, and would be similar for any other mattress used now, since all will have some pressure relief. They have not experienced any problems relating to the use of alcohol. **Material placed between Mega Soft and patient:** There is always a sheet between the Mega Soft and the patient. Quite often an underbody patient warmer will be used, and this	**General information, no action required.**

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		is placed directly under the patient, above the sheet and Mega Soft. Incontinence pads, if used, are also placed directly under the patient, and above the sheet and Mega Soft. No problems have been experienced using any of these combinations. They have not experienced any difficulties in using Mega Soft.	
Section 4.3	Was the temperature reading taken from the side of the pork belly that was in contact with the pad?	The electrosurgery was always performed on one side and the temperature readings were always taken on the side were the pork belly was in direct contact with the pad.	**Information used in critiquing CHUS report, no action required.**
	• Do you use paediatric and adult Mega Soft pads?, If so how often and for how long (approximately)? • Are the power settings that you use for paediatric electrosurgery similar to adult electrosurgery? If not, how do they differ?	**Clinical Expert 3:** Yes, we use both, and surgery lasts all day if necessary. The power settings for paediatric surgery are usually less (10 -15) but we do have the occasional adult sized 16 year old so the settings would be a for an adult. We have 10 paediatric pads for 10 theatres - although the adult size does the majority of our patients. I cannot remember off the top of my head what the weight limits are but the adult one starts at a fairly low weight. We have had them for nearly 2 years.	**General information, no action required.**

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Section 4.1	Could you let me know how many of the Mega Soft pads in use in the UK and in the USA are adult Mega Softs, and how many paediatric?	**Advance Surgical:** Of the 170 Mega Softs in use in GB hospitals 30 are paediatric. The paediatric pads have been in use since October 2009. **Megadyne:** You also asked for the number of pads placed and in use in the U.S. market. On average, we have about 3500 pads in use in the U.S. and about 5500 in use globally. This includes only our Mega Soft line, not our original Mega 2000.	**This information was incorporated into the report text.**
Section 2	Please could you estimate the number of Mega Soft pads in use in the UK and in the USA?	**Advance Surgical:** We currently have 170 Mega Softs in use in GB hospitals. **Megadyne:** I would quickly estimate that there are 500 pediatric pads in service.	**This information was incorporated into the report text.**
Section 4.5.1	Please could you clarify the plate sizes used in the capacitive testing reports?	a - Test report 1150130-02 was completed first, it was done for the Pediatric Mega Soft pad, and the 80% rule was used to come up with the test plate size of 198 in^2. The conductive mesh for the Pediatric Mega Soft is ~ 235 in^2 and 80% is 188 in^2. For us, the easiest way to do this was to use an existing test plate and hang some of it over the edge, thus the 198 in^2 size used (see section 5.2). b - Test report 1150130-03 was done for the Adult Mega Soft,	**This information was used in comparing test results and incorporated into the report text.**

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

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Section 5.4	Please could you advise relating to compatibility between Megasoft patient return electrodes and other brand generators.	**NHS Supply chain, (summary of phone conversation):** It is the responsibility of the end user to obtain written confirmation of compatibility between items such as generators and related consumables. This ensures that the correct make and model numbers are always being checked to prevent incompatible products being used together due to changes in product specification etc. Confirmation may be obtained by requesting documentation directly from a supplier when purchasing goods.	**The information was included in the report, but was requested that it not be as a statement of the NHS supply chain's position.**
Section 4.5	Two telephone meetings with Megadyne and Advance Surgical to discuss what evidence they could provide in order to answer the questions posed by MTAC.	The evidence was provided by Megadyne and Advance Surgical and is included in the technical report. Some background information was also given.	**The evidence was discussed and critiqued in the report**
Section 5.1.1	MTAC Q1. The manufacturer states that the Mega Soft Patient Return Electrode is a self-contained current limiting device making it safe to use if the patient is in contact with only a small portion of the pad. Clarification is required regarding the minimal contact area between the patient and the pad before safety is compromised. EAC comment: this should address the risk of alternate site burns as well as return pad burns, as a smaller area of patient contact would increase the impedance.	EAC's concern of being able to produce a test condition that would not meet the 4 nF value specified in IEC 60601-2-2 5th Edition section 201.15.101.6 was also discussed during our phone conference in connection to the above items. As you know, the test Standards for Neutral Electrodes (NE) have evolved around the single use disposable sticky NE pad and Clause 59.104.6 of IEC60601-2-2, 4th Edition makes allowances for the "old" style capacitive NE that looked and functioned much like a standard single use disposable sticky NE pad. The Megadyne family of Mega Soft reusable NE pads	**Background information for report. No action**

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		(0800, 0830 & 0840) have a very different construction and function differently from the "old" style capacitive NE. The “old” style of capacitive NE do not function based on the contact area of the patient (as the Mega Soft does) and standard testing to make sure they are designed to meet the 4 nF value will ensure that the “old” style of capacitive NE will always have that level of impedance when used. The “old” style of capacitive NE also do NOT have the built-in current limiting safety feature that the Mega Soft has, therefore the test conditions (size of plate) and results (less than 4nF) of Clause 59.104.6 do not directly apply to the Megadyne family of Mega Soft reusable NE pads. In the 5th Edition of 60601-2-2 the requirement of a specific plate size was removed (ref. section 201.15.101.6). This allows us to apply a plate of any size on the Mega Soft to test for the 4nF. The Mega Soft will pass this test as shown in test report # 1150130-02 and 1150130-03. However, this still represents only one set-up condition for the Mega Soft NE. We do, however, believe that the Megadyne family of Mega Soft reusable NE pads is safe and in complete compliance with the intent of Clause 59.104.6 of the 4th Edition (and 201.15.101.6 of the 5th Edition), that is, "..... to prevent a risk of PATIENT burn due to ohmic heating during passage of HF surgical current." The advanced technology that is built into the Megadyne family of Mega Soft reusable NE pads prevents any risk of patient burns due to ohmic heating during the	

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		passage of HF current as demonstrated by the testing we have done per Clause 59.104.5 of IEC60601-2-2, 4th Edition, "An NE shall not subject a PATIENT to a risk of thermal injury at the NE application site under conditions of NORMAL USE and when applied in accordance with the instructions for use." Reference the following Megadyne test reports for evidence of such testing: 1150331-01 and 1150379-01. IEC60601-1, 2nd Edition Clause 3.4 states, "EQUIPMENT or parts thereof, using materials or having forms of construction different from those detailed in this Standard, shall be accepted if it can be demonstrated that an equivalent degree of safety is obtained." Megadyne has done the Risk Analysis and we believe that we have "demonstrated that an equivalent degree of safety (if not higher degree of safety) is obtained" when you consider the history of over 35 Million procedures performed over the past 10 years with zero pad-site burns combined with the extensive testing that has been done on the Megadyne family of Mega Soft reusable NE pads. Your concerns about alternate site burns when the Mega Soft is used contra the Instructions for Use are valid, but these concerns are NOT unique to the Mega Soft return pad and are also present with the traditional disposable sticky pads.	
Section 5.1.3	MTAC Q2: Concern was raised about whether the spillage of alcohol based products onto the pad would collect in pools	Using the advanced technology that is built into the Megadyne family of Mega Soft reusable NE pads prevents any sparking between the patient and the pad. Unlike the condition that can	**Background information for**

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	and lead to a higher risk of burns. EAC comment: There are two aspects to address: Sparking due to alcohol products (note that AfPP does not recommend that alcohol is not used in prep for electrosurgery, but that it is thoroughly dry before surgery commences) The dielectric properties of any liquid in contact with the patient and mattress, and what effect this may have on the electrical system and subsequent safety implications.	exist between the patient and a poorly placed disposable sticky return pad. Testing was done by CHUS where pools of conductive liquids were left on the Mega Soft. They found no issues, see test report from CHUS. Also see Megadyne test report # 1150066-02.	**report. No action**
Section 5.1.2	MTAC Q3: Clarification is required as to whether the product can be used with all other equipment in the operating theatre environment. EAC comment: again two aspects: • Electromagnetic compatibility ie interference with other devices • The risk of alternate site burns eg ECG electrodes	See technical documentation from Megadyne. Monitor Interference TB	**Supplied evidence was critiqued in report.**
Section 5.3	MTAC Q4: Clarification is required about safety implications if the outer skin of the Mega Soft pad is punctured. EAC comment: We are aware of the testing on the Mega 2000 by ECRI, has any similar test been carried out on the Mega Soft?	See test report # 1150066-02.	**Supplied evidence was critiqued in report.**

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