User Interface of Unknown Provenance (UOUP)

**Approvals:**

|  |  |  |  |
| --- | --- | --- | --- |
| **Function** | **Name** | **Signature** | **Date** |
| **Lifecycle Design Engineer** | Gracie Brooks | see e-Sig in EpiCenter | see e-Sig in EpiCenter |
| **Lifecycle Quality Engineer** | Scot Harris | see e-Sig in EpiCenterl | see e-Sig in EpiCenter |
| **Industrial Design / Human Factors** | Racquel Redwood | see e-Sig in EpiCenter | see e-Sig in EpiCenter |

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| **Project / Product Name** | Mega Power® Electrosurgical Generator |
| **Design Plan / Design Change Number (if applicable)** | ENG-IOM-010 |

# Device/System Identification and Description

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| --- | --- |
| **Device / System Description** | The Megadyne Mega Power® Electrosurgical Generator is for use by qualified medical personnel skilled in the particular techniques and procedures to be performed. Using the appropriate approved accessories, the qualified medical personnel identifies the part of the body and/or tissue for cutting and/or coagulation during the procedure.  The Mega Power is to be used in an operating theatre or a surgical setting only. It is not to be used for home use, in ambulances, during hospital transport or wall mounted. The  Mega Power is not to be used as a permanent implant in a patient. It may be used for use on the general population (with multiple patients) with no patient age limit. |
| **Applicable Product Code(s)** | 1000 |

**REVISION HISTORY**

|  |  |  |
| --- | --- | --- |
| **Revision** | **Date** | **Summary of Change** |
| A | 31 July 2020 | Original Issue |

# Identify Context of Use and User Interface Characteristics Related to Safety

A Use Specification has been created to address context of use and user interface characteristics related to safety for the Mega Power Generator. Reference SCN072058.

# Identify Known or Foreseeable Hazards and Hazardous Situations Related to Use

Post-production information is reviewed in multiple areas of the Quality System: Complaints Reportability Matrix and Risk Management Reports (governed by CP0212), Post Market Surveillance (PMS) (governed by PR-0000385), Product Quality Safety Surveillance (PQSS) Data Review Board (DRB) (governed by 100583575) and Clinical Expert Reports (CER) (governed by WE001460).

**Complaints Reportability Matrix Review**

Analysis Codes (ACs) and definitions identified in the Complaints Reportability Matrix (QA-FRM-150 Rev 005) have been reviewed and assessed to determine which ACs could be potentially use-related. Complaints over the time period (Dec 1, 2017 to April 3, 2019) were pulled including the field ‘potential cause’ which includes all complaints that were potentially related to use or potential use errors. After reviewing these details, the following list of ACs were identified as potentially related to use related issues:

|  |  |
| --- | --- |
| Analysis codes (AC) | ECM definition |
| Gen-User Error | User or clinician mistake(s) that led to the reported event (not intended for user damage). |
| Gen-User Damage | Impairment of a device that is the result of mistreatment beyond the scope of the design. |

The most severe potential harm for each of the ACs listed above are identified in the Complaints Reportability Matrix (QA-FRM-150 Rev 005). The associated standardized hazards associated with each harm are listed in the Risk Management Report (ENG-RMF-018). Risk assessments for each are in the respective documents. Upon review of the risk assessments for each associated harm and hazard for the potential use-related issues, it can be confirmed that all hazards and hazardous situations associated with usability have been identified and documented within the Complaints Reportability Matrix and Risk Management Report.

**PMS Review:**

**For PMS Report RA-REC-013**

Post-production information was also reviewed using the most recent Post Market Surveillance (PMS) report RA-REC-013 RE V 001. The product code included in this review is as follows:

**Mega Power 1000 A Generator: 1000**

A total of 14 alerts came back in the Medicines and Healthcare Products Regulatory Agency (MHRA) Database maintained by the Department of Health of the United Kingdom. The search conducted on January 14, 2019 returned 1 alert for “Megadyne Generator,” related to the Mega Power Electrosurgical Generator for the period of November 2014 to October 2018.

During the total period (Nov 2017 to Oct 2018) covered by this PMS Review, there were 6 CAPAs initiated or Closed in relation to the Mega Power Electrosurgical Generator. There is one CAPA which is use related. CAPA details are as follow:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **CAPA Number** | **CAPA Title** | **CAPA Create Date** | **CAPA Description** | **CAPA Root**  **Cause(s)** | **CAPA Status** |
| CAPA-008296 | Mega Power  Dual Activation  Issue | May 25, 2018 | Sales rep reports burn to patient. Customer reports doing a breast augmentation with cut/coag settings of 40/40. They had a Megadyne pencil in Port A. They were using an additional instrument called Endo-Breast and somehow  plugged that into Port A as well. They had been in serviced about where to plug in instruments and foot control devices. The pencil was placed on the patient and when the second device was activated, it burned the patient on the chest. Burn is reportedly 2nd degree. No holster was used. | The design allows for two devices to be plugged into one channel, the  instructions for use manual provides information to mitigate this risk. The end user did  not follow the instructions for use manual which  clearly states that  only ONE active device may be plugged into each  channel at a time. | Open |

Overall complaints and rates were low in the reporting period. There were no adverse trends or signals that could contribute to the efficacy of the Electrosurgical Generator product Families.

**Product Quality Safety Surveillance (PQSS) Data Review Board (DRB) Review:**

Per the PQSS DRB procedure, all Analysis Codes (ACs) are monitored monthly by rate to detect unusual variation in defects and findings identified after product failure analysis and assessed for product quality, patient safety and customer related implications. Therefore, all ACs (including the specific ACs associated with potential use errors) are monitored monthly during this process.

The signals were assessed from November 1, 2018(when this process went live) through October 31, 2019. No actionable signals or trends potentially associated with use errors have been identified requiring further action for the Analysis Codes (ACs). The statistical signals that were assessed have been listed in the table below:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **S.N.** | **PQSS review** | | **Statistical Signal Present?** | **Use Related Analysis Code** | **Action** |
| **DR #** | **Mon-Year** |
| 1 | DR007006 | Nov-2018 | No | N/A | N/A |
| 2 | DR007158 | Dec-2018 | No | N/A | N/A |
| 3 | DR007245 | Jan-2019 | No | N/A | N/A |
| 4 | DR007329 | Feb-2019 | No | N/A | N/A |
| 5 | DR007460 | Mar-2019 | No | N/A | N/A |
| 6 | DR007562 | Apr-2019 | No | N/A | N/A |
| 7 | DR007661 | May-2019 | No | N/A | N/A |
| 8 | DR007748 | Jun-2019 | No | N/A | N/A |
| 9 | DR007831 | Jul-2019 | Yes | User Damage | Signal is a result of 6 complaints reported from USA.  PC-000430034: Damaged Front panel was replaced.  PC-000432437: Front cover and top cover are broken due to  asset being dropped. Both were replaced to fix.  PC-000433408: Damaged Front panel was replaced.  PC-000439036: Damaged Front panel was replaced.  PC-000450374: Damaged Top Cover and Front Panel were  replaced.  No further action was recommended and need to continue monitoring. |
| 10 | DR007920 | Aug-2019 | No | N/A | N/A |
| 11 | DR008003 | Sep-2019 | Yes | User Damage | Signal is a result of 17 complaints reported from USA. There were no patient consequences reported.  The signal is a result of 16 units that came from DePuy with falling front cover issue and one service request for a unit which was already in service. Issue was discussed in DRA-012226. Front cover was replaced to fix the issue. DRA-012226 was opened to investigate the AC. |
| 12 | DR008125 | Oct-2019 | No | N/A | N/A |

**CER Review:**

Within the Clinical Expert Report, RA-RPT-010, A total of 14 alerts came back in the Medicines and Healthcare Products Regulatory Agency (MHRA) Database maintained by the Department of Health of the United Kingdom. The search conducted on January 14, 2019 returned 1 alerts for “Megadyne Generator,” related to the Mega Power® Electrosurgical Generator for the period of November 2014 to October 2018.

The Mega Power® Electrosurgical Generator has been in clinical use globally for more than 14 years. Given the longevity of the device, there is sufficient data available from clinical use to demonstrate safety and performance of the device. The route of conformity for this clinical evaluation utilized clinical literature as well as post-market surveillance data.

The use of monopolar electrosurgery in open and laparoscopic surgical procedures is wellestablished technology consistent with the State of the Art for this medical field. Comprehensive searches were conducted in accordance with systematic literature review methodology. The body of evidence reviewed is representative of the intended population and intended use of the patient return electrodes. No new, unanticipated, or unacceptable risks were identified in the body of evidence to indicate any new performance or safety issues in the clinical setting that were previously unknown. The risks have been analyzed and assessed individually within the Risk Assessment Summaries for the subject device. Appropriate risk control measures are in place and the overall residual risk is acceptable.

In conclusion, based on the sum-total of existing nonclinical and clinical data, as well as the continual post market surveillance throughout the device’s lifecycle, it has been objectively verified that these data support the safety and performance of the Mega Power® Generator. Based on an objective review of the verification and validation testing and the acute clinical safety and performance data, there are no unanswered questions about safety or diagnostic performance for this device.

# Update Hazards and Hazardous Situations Related to Usability

No new hazards, hazardous situations or harms related to usability were identified based on the review conducted in section 2 above, therefore no update to risk assessments is required.

# Update Risk Controls

No new hazards were identified, therefore no update to risk assessments was required. Additionally, there are no new technologies or designs available to reduce risk for this product family.

Are any design changes required to mitigate the use risks?  No  Yes

Does IFU adequately communicate warnings, precautions, and contraindications based on the overall residual risk?  No  Yes

*Note: Any design changes required to mitigate the use risks are* ***not*** *considered UOUP and are subject to the full Usability Engineering Process (WE01427).*

# Complete Residual Risk Evaluation

The overall Residual Risk and Cumulative Risk Benefit Analysis can be found in the Risk Management Reports ENG-RMF-018.

In conclusion, no new systemic usability risks or residual risks were identified therefore no update to the risk management files are required.

# Reference Documents

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| --- | --- | --- | --- | --- | --- |
| **IFU** | **Complaints Reportability Matrix** | **CER** | **PMS Plan** | **PMS Report** | **Risk Report** |
| 3000158-01 *(1000)* | QA-FRM-150 *(1000)* | RA-RPT-010 *(1000)* | RA-REC-012 *(1000)* | RA-REC-013 *(1000)* | ENG-RMF-018 *(1000)* |

**TEMPLATE FRM003991 REVISION HISTORY.**

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| **REV** | A | **Summary** |
| **ECN** | ECN021673 | Original Issue |