User Interface of Unknown Provenance (UOUP)

**Approvals:**

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| --- | --- | --- | --- |
| **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 EpiCenter | 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** | Smoke Evacuators and Accessories |
| **Design Plan / Design Change Number (if applicable)** | ENG-IOM-004 (ME7251C, ME7251E, ME725M1C, ME725M1E)  ENG-IOM-012 (2540, 2560, 2540J, 2560J, 252510, 2525-10, 252510BN, 252510ECBN, 2525-10BN, 2525-10ECBN, 252510EC)  ENG-IOM-018 (251010EC, 251010ECBN, 251015EC, 251015ECBN) |

# Device/System Identification and Description

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| **Device / System Description** | **Smoke Evacuation Pencils** *(252510, ME7251C, ME725M1C, 2525-15, 252515, 252510EC,*  *252510BN, 252510ECBN, 2525-10BN, 2525-10ECBN, ME7251E, ME725M1E, 2525-15EC and 252515EC)*  The Zip Pen Smoke Evacuation Electrosurgical Pencil is a hand-held electrosurgical pencil and smoke evacuation handpiece. It is a monopolar device designed for general  electrosurgical applications including cutting and coagulation and for removing smoke generated by electrosurgery when used in conjunction with an effective smoke evacuation system.  Zip Pen Smoke Evacuation Pencil with E-Z Clean Electrode, 10 or 15 feet of tubing and Holster  The internal mechanism of the Zip Pen device consists of a printed circuit board,  flexible electrical cable, dome switches, button switch mechanisms, and sealing materials. The circuit board and electrical cable provide the means for powering the device. The dome switches operate the Cut and Coag functions.  These components are enclosed within an upper housing and lower molded carriage and nozzle which snap together. The buttons sit on top of the dome switches and extend through the upper housing and facilitate activation of the device. The button proximal to the electrode is yellow and controls the cut function of the device. The button distal to the electrode is blue and controls the coag function of the device. Within the nozzle, there is a metal collet that holds the electrode in place. The housing and other components are designed and assembled to prevent liquid from entering the electrical connections (preventing an electrical short). This is accomplished by over molding the circuit board with nonconductive materials.  **Accessories** *(2540, 2540J 2560, 2560J, 2211J, 2211, 2220J, 2220)*  The Zip Pen Nozzle Extensions are accessories for use in electrosurgery procedures where an electrode longer than the one provided with the Zip Pen is required. The nozzle extensions are used in conjunction with the longer electrodes to extend the Zip Pen smoke capture nozzle to the surgical site.  The ULPA filter, catalog number 2211 and 2211J, utilizes a fluid trap to help prevent fluid from contacting the ULPA filter media.  The Charcoal filter, catalog number 2220 and 2220J, contains carbon to remove odors from the electrical smoke.  2250J-RF sensor, used with MegaVac.  **MiniVac™ Smoke Evacuator** *(ECVV120, ECVV220)*  MEGADYNE® MiniVac™ Smoke Evacuation Systems are intended to evacuate and filter surgical smoke plume and aerosols created by the interface surgical tools with tissue, examples being lasers, electrosurgery systems, and ultrasonic devices.  The MiniVac™ Smoke Evacuation Systems have been designed with a high suction, high flow rate vacuum motor. The ultra-quiet motor is used to draw the surgical smoke from the surgical site through the vacuum tubing and into the MicroSafe™ filter where the surgical smoke is processed  by a series of filters.  The electronic controls on the face panel of the MiniVac™ Smoke Evacuation System has been designed “user friendly” and facilitate unit set up and operation. |
| **Applicable Product Code(s)** | 252510, 252510EC, 2525-15, 252515, 252515EC, 2525-15EC, 252510BN, 252510ECBN, 2525-10BN, 2525-10ECBN, 2540, 2560, 2540J, 2560J, 2211, 2211J, 2220, 2220J, 251010EC, 251010ECBN, 251015EC, 251015ECBN, 2250R, 2250J ACE12BN5, ACE12MBN5, ME7251C, ME7251E, ME725M1C, ME725M1E, ECVV120, ECVV220, |

**REVISION HISTORY**

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| --- | --- | --- |
| **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 Smoke Evacuation and Accessories. Reference SCN072062.

# 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 (See Attachment 1). After reviewing these details, the following list of ACs were identified as potentially related to use related issues:

|  |  |
| --- | --- |
| Analysis codes (AC) | ECM definition |
| Contamination Packaging of Pouch | Foreign material that is on the outside of the packaging or pouch |
| Contamination Particulate | Foreign material that is loose inside the packaging |
| Gen- Contamination: Particulate | Foreign material that is loose inside the packaging |
| GEN - User Damage | Impairment of a device that is the result of mistreatment beyond the scope of the design. |
| User Damage | Impairment of a device that is the result of mistreatment beyond the scope of the design. |
| User Error | User or clinician mistake(s) that led to the reported event (not intended for user damage). |

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-045, ENG-RMF-024). 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-002**

Post-production information was also reviewed using the most recent Post Market Surveillance (PMS) report RA-REC-002 REV 002. The product codes included in this review are as follows:

**Zip Pen Extension Nozzle 2.7in: 2540**

**ZIP Pencil 10ft w/0012 Uconn: 252510**

**ZIP Pencil 10ft w/0012 Uconn BN: 252510BN**

**ZIP Pencil 10ft w/0012 Uconn BN: 2525-10BN**

**ZIP Pencil 10ft w/0012 Econn: 252510EC**

**ZIP Pencil 10ft w/0012 Econn BN: 252510ECBN**

**ZIP Pencil 10ft w/0012 Econn BN: 2525-10ECBN**

**Zip Pen Extension Nozzle 2.7in: 2540J**

**Zip Pen Extension Nozzle 5.2in: 2560**

**Zip Pen Extension Nozzle 5.2in: 2560J**

A total of 2 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 was conducted on September 11, 2019 for “Megadyne”. Neither of the 2 alerts were related to the Megadyne Smoke Evacuation Pencil for the period of July 2014 to June 2019.

During the 5-year total period (Nov 2014 to Jun 2019) covered by this PMS Review, zero CAPAs were initiated and zero CAPAs were closed in relation to Smoke Evacuation Pencil.

Overall complaints and rates were low. Over a 4-year review period there was 12 complaints for a rate of 83.4 CPMO. Of the 12 complaints there was 1 PC for Potential Safety Hazard but no serious injury to the patient occurred. The product family review identified no new harms or hazards and Smoke Evacuation product family is preforming as predicted.

**For PMS Report RA-REC-015**

Post-production information was also reviewed using the most recent Post Market Surveillance (PMS) report RA-REC-015 REV 002. The product codes included in this review are as follows:

**Megadyne ACE Blade™ 700 Soft Tissue Dissector, 2.5” Blade, C, connector: ME7251C**

**Megadyne ACE Blade™ 700 Soft Tissue Dissector, 2.5” Blade, E, connector: ME7251E**

**Megadyne ACE Blade™ 700 Soft Tissue Dissector, 2.5” Blade, Modified, C, connector: ME725M1C**

**Megadyne ACE Blade™ 700 Soft Tissue Dissector, 2.5” Blade, Modified, E, connector: ME725M1E**

During the total period (Dec 2018 to May 2019) covered by this PMS Review, there were no CAPAs initiated or closed in relation to the Smoke Evacuation Accessories.

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 Smoke Evacuation product families.

**For PMS Report RA-REC-019**

Post-production information was also reviewed using the most recent Post Market Surveillance (PMS) report RA-REC-019 REV 001. The product codes included in this review are as follows:

**Ulpa Fltr And Fld Trap Megavac: 2211J, 2211**

**Charcoal Fltr Megavac Smk Evac: 2220J, 2220**

A total of 2 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 was conducted on March 15, 2019 for “Megadyne,”. Nether of the 2 alerts were related to the Megadyne Class 1 Accessories for the period of November 2013 – December 2018.

During the total period (Jan 2018 to Dec 2018) covered by this PMS, there were no CAPAs initiated or closed in relation to the Smoke Evacuation Accessories.

Overall complaints and rates were low in the reporting period. There were no adverse trend or signals that could contribute to the efficacy of the Megadyne Smoke Evacuation 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 | Yes | User Damage | Isolated event-No Assessment  Required |
| 5 | DR007460 | Mar-2019 | Yes | User Damage | Isolated event-No Assessment  Required |
| 6 | DR007562 | Apr-2019 | Yes | User Damage | Isolated event-No Assessment  Required |
| 7 | DR007661 | May-2019 | Yes | User Damage | Isolated event-No Assessment  Required |
| 8 | DR007748 | Jun-2019 | No | N/A | N/A |
| 9 | DR007831 | Jul-2019 | Yes | User Damage | Isolated event-No Assessment  Required |
| User Error | Isolated event-No Assessment  Required |
| 10 | DR007920 | Aug-2019 | No | N/A | N/A |
| 11 | DR008003 | Sep-2019 | Yes | Contamination Particulate | Isolated event-No Assessment Required |
| 12 | DR008125 | Oct-2019 | No | N/A | N/A |

**CER Review:**

**For CER RA-RPT-007 (ME7251C, ME7251E, ME725M1C, ME725M1E, ACE12BN5, ACE12MBN5)**

Within the Clinical Evaluation Report, RA-RPT-007, A total of 5 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 October 26, 2018 returned no alerts for “ACE,” related to the ACE Blade Advance Cutting System for the period of August 2013 to July 2018.

The ACE Blade 700™ Soft Tissue Dissector is a combination of two CE marked devices (the ACE Blade and the Zip Pen Smoke Evacuation Pencil) which have been in clinical use for 10 years. The ACE Blade 700™ consists of an ACE Blade pre-inserted into the Zip Pen device and sold as a single unit. Given the Given that electrocautery is a well-established and accepted technology with very low complaint rates and complications as reported in the literature, there is sufficient data available from clinical use to demonstrate safety and performance of the ACE Blade as the equivalent comparators of the subject NPD device. The route for this clinical evaluation utilized clinical literature as well as post-market surveillance data.

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 ACE Blade 700™ Soft Tissue Dissector.

Therefore, this clinical evaluation has established that the available clinical data are sufficient to establish conformity with all applicable Essential Requirements of the European Council Directive 93/42/EEC (MDD) and confirm the safety and performance of the ACE Blade 700™ Soft Tissue Dissector.

**For CER SCN070740 (2211J, 2211, 2220J, 2220)**

Within the Clinical Expert Report, SCN070740, a total of 2 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 was conducted on March 15, 2019 for “Megadyne,”. Nether of the 2 alerts were related to the Megadyne Class 1 Accessories for the period of November 2013 – December 2018.

Since the Megadyne Class I Accessory Products have been available in the EU for over 20 years, there is sufficient data available from nonclinical use as confirmed with continuous monitoring of data in the Post Market Phase (PMS) to demonstrate safety and performance. The body of evidence used to demonstrate conformity with the Essential Requirements and support the safety and performance of these accessory devices utilized non-clinical data, risk management outputs, and PMS data. Clinical data is neither applicable nor required for these devices. These accessory devices contain no human tissue, blood, or derivatives, animal tissue, or medicinal products. They do not come in contact with the patient and do not contain any computer software.

No new unanticipated, emerging, or unacceptable risks were identified from the PMS data or risk management assessment. These risks have been analyzed within the PMS report and assessed individually. All harms have been defined with their potential causes of failure and associated mitigation activities. Hazards that can lead to these Harms have been shown in the Risk Documentation to be mitigated to as far as possible after risk control measures have been implemented and verified.

In conclusion, it has been shown that there is sufficient objective evidence to establish the safety and performance of Megadyne Class I Accessory Products is maintained in the post market phase when used as intended. The data are adequate to assess the benefits and risks associated with the subject devices, concluding that the benefit-risk profile is acceptable. Megadyne, Inc. has undertaken all necessary steps to ensure that the residual risk factors associated with these accessory devices are mitigated by applying existing State-of-the Art techniques for the design, testing, and manufacturing of these medical devices to ensure safe usage and that the devices will perform as intended.

# 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-045 and ENG-RMF-024.

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** |
| 3000312-01 *(252510, 252510EC)*  3000336-01 *(252510BN, 252510ECBN)*  3000190-01  *(2211, 2211J)*  3000191-01  *(2220, 2220J)*  3000313-01 *(2540, 2560, 2540J, 2560J)*  3000307-01 *(251010EC, 251010ECBN, 251015EC, 251015ECBN)*  3000317-01 & 3000318-01 *(ME7251C, ME7251E, ME725M1C, ME725M1E)* | QA-FRM-150 *(All Codes)* | RA-RPT-007 *(ME7251C, ME7251E, ME725M1C, ME725M1E, ACE12BN5, ACE12MBN5)*  SCN070740 *(2211J, 2211, 2220J, 2220)*  RA-RPT-013  *252510BN, 252510ECBN, 2525-10BN, 2525-10ECBN, 251010ECBN, 251015ECBN, ACE12BN5, ACE12MBN5* | RA-REC-014 *(ME7251C, ME7251E, ME725M1C, ME725M1E)*  RA-REC-018  *(2211J, 2211, 2220J, 2220)*  RA-REC-001 *(2540, 2560, 2540J, 2560J, 252510, 252510BN, 252510ECBN, 2525-10BN, 2525-10ECBN, 252510EC)* | RA-REC-015 *(ME7251C, ME7251E, ME725M1C, ME725M1E)*  RA-REC-019  *(2211J, 2211, 2220J, 2220)*  RA-REC-002 *(2540, 2560, 2540J, 2560J, 252510, 252510BN, 252510ECBN, 2525-10BN, 2525-10ECBN, 252510EC)* | ENG-RMF-045 *(2525-10BN, 2525-10ECBN, 2540, 2560, 0014, 0014A)*  ENG-RMF-024  *(252510, 252510EC, 2525-15, 252515, 252515EC, 2525-15EC, 252510BN, 252510ECBN, 2525-10BN, 2525-10ECBN, 2540, 2560, 2540J, 2560J,*  *2211J, 2211, 2220J, 2220, 2250J, 251010EC, 251010ECBN, 251015EC, 251015ECBN, 2250R, ECVV120, ECVV220)*  ENG-RMF-055  *(ACE12BN5, ACE12MBN5, ME7251C, ME7251E, ME725M1C, ME725M1E)* |

**TEMPLATE FRM003991 REVISION HISTORY.**

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