



The Electrosurgical Authority®

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|---|--|--|
| Megadyne Medical Products Inc. | PRODUCT SPECIFICATION | Document Number: ENG-PS-007 |
| | Smoke Evacuation Pencil and Accessories | Revision: 007 |
| | | Page 1 of 20 |

TABLE OF CONTENTS

| | |
|---|-----------|
| 1. GENERAL..... | 1 |
| 1.1. PURPOSE | 1 |
| 1.2. SCOPE | 1 |
| 1.3. INTENDED USE | 2 |
| 1.4. PROJECT/DEVICE OVERVIEW | 2 |
| 1.5. APPROVALS | 2 |
| 2. ABBREVIATIONS | 2 |
| 3. APPLICABLE DOCUMENTS..... | 3 |
| 3.1. REFERENCE DOCUMENTS` | 3 |
| 3.2. REGULATORY/SAFETY AGENCY DOCUMENTS..... | 3 |
| STANDARD TITLE..... | 3 |
| 4. DEVICE REQUIREMENTS..... | 4 |
| 4.1. INTENDED USE | 5 |
| 4.2. SAFETY AND GENERAL PERFORMANCE | 5 |
| 4.3. ENVIRONMENTAL REQUIREMENTS | 7 |
| 4.4. MECHANICAL REQUIREMENTS | 7 |
| 4.5. ELECTRICAL REQUIREMENTS | 9 |
| 4.6. BIOCOMPATIBILITY | 10 |
| 5. PACKAGING AND LABELING..... | 11 |
| 5.1. UNIT PACKAGING | 11 |
| 5.2. UNIT LABELING | 12 |
| 5.3. CASE PACKAGING | 15 |
| 5.4. CASE LABELING | 16 |
| 5.5. EXPIRATION DATE | 19 |
| 6. REVISION | 20 |

1. GENERAL

1.1. PURPOSE

The purpose of this document is to specify the design requirements for the Megadyne Medical Products Zip-Pen Smoke Evacuation line of Pencils. This document is the primary specification used for design verification activities and proving the intended use of the device. This document describes the safety, environmental, electrical, mechanical and labeling requirements to be met by the device.

1.2. SCOPE

This document applies to the Megadyne Smoke Evacuation Pencil.

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| | | |
|---------------------------------------|--|--|
| Megadyne Medical Products Inc. | PRODUCT SPECIFICATION | Document Number: ENG-PS-007 |
| | Smoke Evacuation Pencil and Accessories | Revision: 007 |
| | | Page 2 of 20 |

1.3. INTENDED USE

Zip-Pen smoke evacuation pencils are an accessory to a general purpose electrosurgical generator and are designed to remove surgical smoke while also conducting radio frequency (RF) current for the cutting and coagulation of targeted tissue during general surgical procedures.

1.4. PROJECT/DEVICE OVERVIEW

The Megadyne Smoke Evacuation Pencil combines an electrosurgical pencil with a smoke evacuation device. Megadyne has sold an OEM smoke evacuation pencil for approximately 10 years. This project creates a unique smoke evacuation pencil designed by Megadyne that will replace and/or augment the OEM version.

1.5. APPROVALS

This product is developed per Megadyne Design Control procedures with the intent of obtaining the following agency approvals. By meeting requirements of this document Megadyne will have sufficient evidence to support registrations in other countries.

| Agency | Approval/Registration |
|-----------------------------|---------------------------------|
| European Union | CE Mark Approval |
| Canadian Ministry of Health | Canadian Medical Device License |
| United States FDA | Premarket 510(k) Approval |

2. ABBREVIATIONS

| Acronym | Definition |
|----------------|--|
| AAMI | Association for the Advancement of Medical Instrumentation |
| ASTM | American Standards and Testing of Materials |
| ANSI | American National Standards Institute |
| EN | European Norm |
| ESU | Electrosurgical Unit |
| FDA | Food and Drug Administration |
| FMEA | Failure Mode Effects and Analysis |
| IEC | International Electrotechnical Commission |
| ISO | International Organization for Standardization |
| PRS | Product Requirements Specification |
| RF | Radio Frequency |

| | | |
|---|--|--|
| Megadyne Medical Products Inc. | PRODUCT SPECIFICATION | Document Number: ENG-PS-007 |
| | Smoke Evacuation Pencil and Accessories | Revision: 007 |
| | | Page 3 of 20 |

3. APPLICABLE DOCUMENTS

The listed documents apply to the extent specified in the detailed requirements of this product specification.

3.1. REFERENCE DOCUMENTS`

- 3.1.1. MKT-CMR-029 Megadyne Smoke Evacuation Product Line CMR
- 3.1.2. ENG-DMR-012 Device Master Record, Smoke Evacuation Pencils
- 3.1.3. ENG-RMF-044 Smoke Evacuation Electrosurgical Pencils and Accessories Hazard Assessment Summary
- 3.1.4. ENG-RMF-043 Zip Project Risk Management Plan
- 3.1.5. MKT-SOP-001 Labeling Development, Approval and Bar Code and Control
- 3.1.6. MKT-US-002 Smoke Evacuation Pencils, Extension Nozzles and Universal ULPA Filter Usability Requirements Specification

3.2. REGULATORY/SAFETY AGENCY DOCUMENTS

3.2.1. Applicable Particular Requirements

| STANDARD NUMBER | STANDARD TITLE |
|--------------------|--|
| ISO 13485 | ISO 13485 Quality Systems - Medical Devices - System Requirements For Regulatory Purposes |
| US 21 CFR Part 820 | Current Good Manufacturing Practice for Medical Devices (USA FDA) |
| ISO 11137 | Sterilization of health care products - Requirements for validation and routine control - Radiation sterilization |
| EN 60601-1 | Medical Electrical Equipment Part 1: General Requirements for Basic Safety and Essential Performance |
| EN 60601-2-2 | Medical electrical equipment, Part 2: Particular requirements for the safety of high frequency surgical equipment |
| EN 62366 | Medical devices – Application of usability engineering to medical devices |
| ISO 14971 | Medical devices - Risk management - Part 1: Application of risk analysis |
| EN 1041 | Terminology, symbols and information provided with medical devices - Information supplied by the manufacturer with medical devices |

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| | | |
|---------------------------------------|--|--|
| Megadyne Medical Products Inc. | PRODUCT SPECIFICATION | Document Number: ENG-PS-007 |
| | Smoke Evacuation Pencil and Accessories | Revision: 007 |
| | | Page 4 of 20 |

| STANDARD NUMBER | STANDARD TITLE |
|-----------------|---|
| ISO 15223-1 | Medical Devices - Symbols to be used with medical device labels, labeling and information to be supplied |
| ISO 11607-1 | Packaging for terminally sterilized medical devices – Part 1: Requirements for Materials, Sterile Barrier Systems and Packaging Systems |
| ISO 11607-2 | Packaging for terminally sterilized medical devices – Part 2: Validation Requirements for Forming, Sealing and Assembly Processes |
| ISO 10993-1 | Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing |
| ISO 80369 | Small Bore connectors for Liquids and Gasses in Healthcare Applications - Part 1: General Requirements |
| EN 556-1 | Sterilization of Medical Devices – Requirements for terminally sterilized devices to be labeled “Sterile” |
| ISO 11737-1 | Sterilization of Medical Devices – Microbiological methods – Part 1: Determination of a population of microorganisms on products |
| MEDDEV 2.7.1 | Guidelines on Medical Devices – Clinical Evaluation: A guide for Manufacturers and Notified Bodies |
| ASTM D4169-05 | Standard Practice for Performance Testing of Shipping containers and Systems |

3.2.2. Order of preference

In case of conflict between agency requirements, the following preference shall be used to resolve the conflict: FDA, IEC/ISO/EN and AAMI/ANSI.

4. DEVICE REQUIREMENTS

The requirements for the following devices are listed in this product specification.

| Catalog No. | Description |
|-------------|--|
| 2525-10 | Zip-Pen Smoke Evacuation Pencil with E-Z Clean Electrode and 10 feet of tubing with Holster |
| 2525-10EC | Zip-Pen Smoke Evacuation Pencil EC, with E-Z Clean Electrode and 10 feet of tubing with Holster |
| 2525-10BN | Zip-Pen Smoke Evacuation Pencil EC with E-Z Clean Electrode and 10 feet of tubing with Holster, Bulk Non-Sterile |
| 2525-10ECBN | Zip-Pen Smoke Evacuation Pencil with E-Z Clean Electrode and 10 feet of tubing with Holster, Bulk Non-Sterile |
| 2525-15 | Zip-Pen Smoke Evacuation Pencil with E-Z Clean Electrode and 15 feet of tubing with Holster |
| 2525-15EC | Zip-Pen Smoke Evacuation Pencil EC, with E-Z Clean Electrode and 15 feet of tubing with Holster |

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| | | |
|---------------------------------------|--|--|
| Megadyne Medical Products Inc. | PRODUCT SPECIFICATION | Document Number: ENG-PS-007 |
| | Smoke Evacuation Pencil and Accessories | Revision: 007 |
| | | Page 5 of 20 |

| Catalog No. | Description |
|-------------|---|
| ME7251C | Megadyne ACE Blade™ 700, 2.5" Blade, Zip Pen Smoke Evacuation Pencil, C connector |
| ME7251E | Megadyne ACE Blade™ 700, 2.5" Blade, Zip Pen Smoke Evacuation Pencil, E connector |
| ME725M1C | Megadyne ACE Blade™ 700, 2.5" Blade, Modified, Zip Pen Smoke Evacuation Pencil, C connector |
| ME725M1E | Megadyne ACE Blade™ 700, 2.5" Blade, Modified, Zip Pen Smoke Evacuation Pencil, E connector |
| 2540 | Zip-Pen Nozzle Extension 4" |
| 2560 | Zip-Pen Nozzle Extension 6.5" |
| 2211 | ULPA Filter |
| 2220 | Charcoal Filter |

4.1. Intended Use

- 4.1.1. PRS 1001: Zip-Pen smoke evacuation electrosurgical pencil is a monopolar device designed for electrosurgical applications including cutting and coagulation and for removing smoke generated by electrosurgery when used in conjunction with an effective smoke evacuation system. This device conducts an electrosurgical current from an electrosurgical generator and delivers it to the target tissue to achieve the desired surgical effect.

4.2. Safety and General Performance

4.2.1. Smoke Evacuation Pencil, Zip-Pen

- 4.2.1.1. PRS 1101: The device meets all essential design inputs after sterilization by Gamma Irradiation (50kGy Maximum), excluding ME725M1C and ME725M1E.
- 4.2.1.2. PRS 1101.5: The device meets all essential design inputs after sterilization by EO exposure, applying only to ME725M1C and ME725M1E.

| | | |
|---|--|--|
| Megadyne Medical Products Inc. | PRODUCT SPECIFICATION | Document Number: ENG-PS-007 |
| | Smoke Evacuation Pencil and Accessories | Revision: 007 |
| | | Page 6 of 20 |

- 4.2.1.3. PRS 1102: The device in conjunction with its packaging is free from damage during normal shipping, storage, and handling.
- 4.2.1.4. PRS 1103: The pencil handle is gray Pantone 427 with inlayed TPR that is Green Pantone 356.
- 4.2.1.5. PRS 1104: The “Megadyne” name is molded on the handle.
- 4.2.1.6. PRS 1105: The Cut and Coag buttons will be approximately the same size as the Megadyne disposable pencil buttons (e.g. 0035).
- 4.2.1.7. PRS 1106: The Yellow Cut button is nearer to the active electrode and the coag button is farthest from the active electrode.
- 4.2.1.8. PRS 1107: The electrode is not able to be incorrectly inserted such that it is held in place without making electrical contact.
- 4.2.1.9. PRS 1108: The nozzle is clear in the area of the electrode.
- 4.2.1.10. PRS 1109: The product is sold with a holster that is large enough to hold the standard length pencil. The holster color is Pantone 427.
- 4.2.1.11. PRS 1110: The pencil cord is inside of the tubing for the first 64 inches of tubing and then exits the tubing.

4.2.2. Extension Nozzles

- 4.2.2.1. PRS 1111: The devices meet all essential design inputs after sterilization by Gamma Irradiation (50kGy Maximum).
- 4.2.2.2. PRS 1112: The device in conjunction with its packaging is free from damage during normal shipping, storage, and handling.
- 4.2.2.3. PRS 1113: The nozzles are clear.

4.2.3. ULPA Filter and Charcoal Filter

| | | |
|---|--|--|
| Megadyne Medical Products Inc. | PRODUCT SPECIFICATION | Document Number: ENG-PS-007 |
| | Smoke Evacuation Pencil and Accessories | Revision: 007 |
| | | Page 7 of 20 |

- 4.2.3.1. PRS 1114: These devices in conjunction with their packaging are free from damage during normal shipping, storage, and handling.

4.3. Environmental Requirements

4.3.1. Smoke Evacuation Pencil, Zip-Pen; Extension Nozzles; Filters

- 4.3.1.1. PRS 1201: The device functions under a variation in temperature and a range of humidity determined by the operating conditions of Megadyne ESU. See current ESU Operator's Manual for specified operating conditions.
- 4.3.1.2. PRS 1202: The device shall be capable of being transported and stored at a temperature range of -40° C to +50° C and a range of humidity of 15% to 95%.

4.4. Mechanical Requirements

4.4.1. Smoke Evacuation Pencil, Zip-Pen

- 4.4.1.1. PRS 1301: The Button peak activation force is between 250 grams to 700 grams
- 4.4.1.2. PRS 1302: The electrode extraction force is in the range of 1.5 to 4.5 lbs.
- 4.4.1.3. PRS 1303: The electrode is securely attached to the pencil and does not fall out, meets requirements of IEC 60601-2-2 clause 201.15.4.1.102.
- 4.4.1.4. PRS 1304: The device withstands a minimum 20 lb. vertical force applied at the distal end of the nozzle with the handle held horizontal.
- 4.4.1.5. PRS 1305: The dimension from the distal end of the electrode to the nozzle opening is between 0.80 and 1.05 inches which is comparable to the Ultra Vac 2110-10.
- 4.4.1.6. PRS 1306: The electrode flexing in the collet is less than or equal to a standard electrosurgical pencil collet (e.g. 0035).

| | | |
|---|--|--|
| Megadyne Medical Products Inc. | PRODUCT SPECIFICATION | Document Number: ENG-PS-007 |
| | Smoke Evacuation Pencil and Accessories | Revision: 007 |
| | | Page 8 of 20 |

- 4.4.1.7. PRS 1307: The cable connection to the pencil withstands a strain relief rotational test per IEC 60601-2-2 clause 201.8.10.4.2.
- 4.4.1.8. PRS 1308: The tubing will remain connected to at all connection points under a tensile force applied parallel to the pencil body equal to 4.0 lbs.
- 4.4.1.9. PRS 1309: The cable connection to the plug withstands a strain relief rotational test per IEC 60601-2-2 clause 201.8.10.4.2.
- 4.4.1.10. PRS 1310: The Device Plug shall be compatible with standard ESU and have minimum 2 lb. plug extraction force.
- 4.4.1.11. PRS 1311: The device removes smoke at a rate practically comparable to or better than the existing Megadyne 2110-10 product under similar conditions (determined by flow rate comparison). The flow rate is measured with the Megadyne Mega Vac set at maximum open flow using new clean filters. Practically comparable is defined as a flow variation of up to 10 lpm, as this value may not be distinguishable to the user at maximum flow rates.
- 4.4.1.12. PRS 1319: The device handle shall meet the requirements of IEC 60601-1 clause 11.1.2.2 Applied Parts not intended to supply heat to the patient. Note that the device handle is not an applied part. However, portions of the handle are likely to come in contact with the patient and therefore shall meet this clause of the standard.
- 4.4.1.13. PRS 1320: The device electrode meets the requirements of IEC 60601-1 clause 11.1.2.1 Applied Parts intended to supply heat to the patient. IEC 60601-2-2 clause 201.11.1.2.1 provides an addition to the requirement that indicates the disclosure of temperatures and clinical effects is not required.

4.4.2. Smoke Evacuation Extension Nozzles, Zip-Pen

- 4.4.2.1. PRS 1312: With the Nozzle attached to the Zip-Pen Pencil, the device removes smoke at a rate comparable to or better than the existing Megadyne 2110-10 product under similar conditions (determined by flow rate comparison). The flow rate is measured with the Megadyne Mega Vac set at maximum flow using new clean filters.

| | | |
|---|--|--|
| Megadyne Medical Products Inc. | PRODUCT SPECIFICATION | Document Number: ENG-PS-007 |
| | Smoke Evacuation Pencil and Accessories | Revision: 007 |
| | | Page 9 of 20 |

4.4.2.2. PRS 1313: The nozzle will remain connected to the Zip-Pen Pencil under a tensile force applied parallel to the pencil body equal to 2.0 lbs.

4.4.3. ULPA Filter

4.4.3.1. PRS 1314: The ULPA filter will provide filtration of 99.999% efficiency when tested with 0.1 to 0.2 micron particles.

4.4.3.2. PRS 1315: The ULPA Filter will be designed with a fluid trap to help prevent fluid from contacting the ULPA filter media.

4.4.3.3. PRS 1316: The ULPA filter will attach to the Mega Vac and Mega Vac Plus equivalent to the existing Megadyne Cat 2210.

4.4.3.4. PRS 1317: The ULPA Filter will accept smoke evacuation pencils with 10mm threaded connectors, reference the Megadyne 2525-10 Zip Pen proximal threaded connector or equivalent.

4.4.4. Charcoal Filter

4.4.4.1. PRS 1318: The Charcoal filter will contain carbon to remove odors from the electrosurgical smoke.

4.5. Electrical Requirements

4.5.1. Smoke Evacuation Pencil, Zip-Pen

4.5.1.1. PRS 1401: The Device plug meets the requirements for mains frequency dielectric withstand per the requirements of IEC 60601-2-2 clause 201.8.8.3.104. The rated voltage of the device is 5.5 kV peak.

4.5.1.2. PRS 1402: Device continuity for each circuit, CUT and COAG, shall have resistance no greater than 50 ohms with the button depressed.

4.5.1.3. PRS 1403: Device resistance for each circuit, CUT and COAG, shall have resistance greater than 100,000 ohms without buttons depressed.

| | | |
|---|--|--|
| Megadyne Medical Products Inc. | PRODUCT SPECIFICATION | Document Number: ENG-PS-007 |
| | Smoke Evacuation Pencil and Accessories | Revision: 007 |
| | | Page 10 of 20 |

- 4.5.1.4. PRS 1404: The device cable meets the requirements for high frequency leakage per the requirements of IEC 60601-2-2 clause 201.8.8.3.102.
- 4.5.1.5. PRS 1405: The device cable meets the requirements for high frequency dielectric withstand per the requirements of IEC 60601-2-2 clause 201.8.8.3.103. The rated voltage of the device is 5.5 kV peak.
- 4.5.1.6. PRS 1406: The device cable meets the requirements for mains frequency dielectric withstand per the requirements of IEC 60601-2-2 clause 201.8.8.3.104. The rated voltage of the device is 5.5 kV peak.
- 4.5.1.7. PRS 1407: The hand held portion of the device meets the requirements for high frequency dielectric withstand per the requirements of IEC 60601-2-2 clause 201.8.8.3.103. The rated voltage of the device is 5.5 kV peak.
- 4.5.1.8. PRS 1408: The hand held portion of the device meets the requirements for mains frequency dielectric withstand per the requirements of IEC 60601-2-2 clause 201.8.8.3.104. The rated voltage of the device is 5.5 kV peak.
- 4.5.1.9. PRS 1409: The handheld portion of the device meets the requirements for fluid ingress per the requirements of IEC 60601-2-2 clause 201.11.6.5 b).

4.6. Biocompatibility

4.6.1. Smoke Evacuation Pencil, Zip-Pen; Extension Nozzles

- 4.6.1.1. PRS 1501: The patient contact portions of the device meet requirements for cytotoxicity (ISO 10993-1:2009 clause 6.2.2.2).
- 4.6.1.2. PRS 1502: The patient contact portions of the device meets requirement for Delayed-type hypersensitivity (ISO 10993-1:2009 clause 6.2.2.3).
- 4.6.1.3. PRS 1503: The patient contact portions of the device meets requirement for Irritation (ISO 10993-1:2009 clause 6.2.2.4).

| | | |
|---|--|--|
| Megadyne Medical Products Inc. | PRODUCT SPECIFICATION | Document Number: ENG-PS-007 |
| | Smoke Evacuation Pencil and Accessories | Revision: 007 |
| | | Page 11 of 20 |

- 4.6.1.4. PRS 1504: The user contact portions of the device (cable and plug) meet requirements for cytotoxicity (ISO 10993-1:2009 clause 6.2.2.2).

5. PACKAGING AND LABELING

5.1. Unit Packaging

5.1.1. Smoke Evacuation Pencil, Zip-Pen; Extension Nozzles

- 5.1.1.1. PRS 1601: The Zip-Pen device will be packaged individually in a sterile barrier package in a shipping carton of 20 units per carton. See exception for bulk non-sterile version (PRS 1606), and Zip-Pen device with ACE electrode (PRS 1608).
- 5.1.1.2. PRS 1602: The Extension Nozzles will be packaged individually in a sterile barrier package in a shipping carton of 10 units per carton.
- 5.1.1.3. PRS 1603: The complete product packaging will meet the requirements of ISO 11607-1 and will protect the device from damage after transit test per ASTM D4169, distribution cycle DC13 at assurance level II. This cycle requires drop test, stacking, vibration, and drop test. DC13 normally requires a low pressure test; however the product is packaged with Tyvek as one of the barrier materials. Tyvek allows the package to equalize internal air with external pressure change, therefor the package is not susceptible to changes in pressure and this step can be omitted.
- 5.1.1.4. PRS 1604: These device packages will maintain a sterile barrier after transit test per ASTM D4169 described above.
- 5.1.1.5. PRS 1606: The Zip Pen will be sold in a bulk non-sterile configuration. This configuration will be packaged in a case of 30 each. The Zip Pen Bulk Non-Sterile version will be double bagged in a shipping container.
- 5.1.1.6. PRS 1607: The Bulk Non-Sterile Zip Pen will maintain package integrity after transit test per ASTM D4169, distribution cycle DC13 at assurance level II.

| | | |
|---|--|--|
| Megadyne Medical Products Inc. | PRODUCT SPECIFICATION | Document Number: ENG-PS-007 |
| | Smoke Evacuation Pencil and Accessories | Revision: 007 |
| | | Page 12 of 20 |

5.1.1.7. PRS 1608: The Zip-Pen device with ACE electrode will be packaged individually in a sterile barrier package in a shipping carton of 6 units per carton.

5.1.2. ULPA Filter and Charcoal Filter

5.1.2.1. PRS 1605: The ULPA Filter will be packaged individually in poly bags and sold as a case of 10 units. The Charcoal Filter will be packaged individually in poly bags, sold as 1 unit each.

5.2. Unit Labeling

5.2.1. For Sterile Smoke Evacuation Pencil Zip-Pen and Extension Nozzles; the unit label of these devices includes the following as a minimum; refer to ISO 15223 for appropriate symbols.

5.2.1.1. PRS 1701: The label part number

5.2.1.2. PRS 1702: The label revision

5.2.1.3. PRS 1703: A bar code that is unique to the device

5.2.1.4. PRS 1704: The product catalog number preceded by the appropriate symbol

5.2.1.5. PRS 1705: The product trade name

5.2.1.6. PRS 1706: The symbol for “manufacturer” followed by Megadyne (Registered Trade mark), Company name address, city, state, zip code, phone number and fax number.

5.2.1.7. PRS 1707: A graphic representation of the product

5.2.1.8. PRS 1708: The E-Z Clean logo with registered trademark symbol

5.2.1.9. PRS 1709: The product lot number preceded by the appropriate symbol

| | | |
|---|--|--|
| Megadyne Medical Products Inc. | PRODUCT SPECIFICATION | Document Number: ENG-PS-007 |
| | Smoke Evacuation Pencil and Accessories | Revision: 007 |
| | | Page 13 of 20 |

5.2.1.10. PRS 1710: The product expiration date preceded by the appropriate symbol

5.2.1.11. PRS 1711: The CE mark as defined by the MDD

5.2.1.12. PRS 1712: The EC Representative information preceded by the appropriate symbol

5.2.1.13. PRS 1713: The appropriate sterility symbol

5.2.1.14. PRS 1714: The symbol for “do not reuse”

5.2.1.15. PRS 1715: The symbol for “Follow Operating Instructions”

5.2.1.16. PRS 1716: The statement “Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.” This statement may, alternatively, be in Instructions for Use with Rx only symbol used on the device as space permits.

5.2.1.17. PRS 1717: The symbol for “do not use if package is damaged”.

5.2.1.18. PRS 1718: The words “Open Here” located near the tabs used for opening the package.

5.2.1.19. PRS 1719: The statement “Refer to Instructions for Use for Patent Information”.

5.2.1.20. PRS 1720: The labeling must remain clear and legible under normal shipping, handling and storage conditions.

5.2.1.21. PRS 1721: A symbol indicating the maximum and minimum temperature and humidity for shipping conditions

5.2.1.22. PRS 1722: A symbol that specifies the maximum rated voltage for the product (applies to the Zip Pen only and not the Extension Nozzles).

5.2.2. For ULPA Filter and Charcoal Filter; the unit labels of these devices include the following as a minimum; refer to ISO 15223 for appropriate symbols.

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|---|--|--|
| Megadyne Medical Products Inc. | PRODUCT SPECIFICATION | Document Number: ENG-PS-007 |
| | Smoke Evacuation Pencil and Accessories | Revision: 007 |
| | | Page 14 of 20 |

- 5.2.2.1. PRS 1721: The label part number
- 5.2.2.2. PRS 1722: The label revision
- 5.2.2.3. PRS 1723: A bar code that is unique to the device
- 5.2.2.4. PRS 1724: The product catalog number preceded by the appropriate symbol
- 5.2.2.5. PRS 1725: The product trade name (applies to ULPA Filter only and not Charcoal Filter)
- 5.2.2.6. PRS 1726: The symbol for “manufacturer” followed by Megadyne (Registered Trade mark), Company name, address, city, state, zip code, phone number and fax number.
- 5.2.2.7. PRS 1727: A graphic representation of the product
- 5.2.2.8. PRS 1728: The product lot number preceded by the appropriate symbol
- 5.2.2.9. PRS 1729: The CE mark as defined by the MDD
- 5.2.2.10. PRS 1730: The EC Representative information preceded by the appropriate symbol
- 5.2.2.11. PRS 1731: The symbol for “Follow Operating Instructions”
- 5.2.2.12. PRS 1732: The statement “Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.” This statement may, alternatively, be in Instructions for Use with Rx only symbol used on the device as space permits.
- 5.2.2.13. PRS1733: The labeling must remain clear and legible under normal shipping, handling and storage conditions.

- 5.2.3. For Bulk Non-Sterile Smoke Evacuation Pencil Zip-Pen; the unit label on the inner bag of these devices includes the following as a minimum; refer to ISO 15223 for appropriate symbols.

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|---|--|--|
| Megadyne Medical Products Inc. | PRODUCT SPECIFICATION | Document Number: ENG-PS-007 |
| | Smoke Evacuation Pencil and Accessories | Revision: 007 |
| | | Page 15 of 20 |

- 5.2.3.1. PRS 1734: The label part number
- 5.2.3.2. PRS 1735: The label revision
- 5.2.3.3. PRS 1736: A bar code that is unique to the device
- 5.2.3.4. PRS 1737: The product catalog number preceded by the appropriate symbol
- 5.2.3.5. PRS 1738: The product trade name
- 5.2.3.6. PRS 1739: The symbol for “manufacturer” followed by Megadyne (Registered Trade mark), Company name address, city, state, zip code, phone number and fax number.
- 5.2.3.7. PRS 1740: The product lot number preceded by the appropriate symbol
- 5.2.3.8. PRS 1741: The labeling must remain clear and legible under normal shipping, handling and storage conditions.
- 5.2.3.9. PRS 1742: A symbol indicating the maximum and minimum temperature and humidity for shipping and storage conditions.

5.3. Case Packaging

- 5.3.1. Smoke Evacuation Pencil, Zip-Pen; Extension Nozzles; ULPA Filter; Charcoal Filter
 - 5.3.1.1. PRS 1801: The shipping case will be an RSC design, corrugated material, taped closed on top and bottom
 - 5.3.1.2. PRS 1802: One IFU will be included per case. Exceptions, Bulk Non-Sterile Zip Pen will not include an IFU, and ACE Blade 700 (see PRS 1804).
 - 5.3.1.3. PRS 1803: The case must protect the devices from damage during normal shipping, handling and storage after transit test per ASTM D4169 distribution cycle DC13 at assurance level II.

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|---|--|--|
| Megadyne Medical Products Inc. | PRODUCT SPECIFICATION | Document Number: ENG-PS-007 |
| | Smoke Evacuation Pencil and Accessories | Revision: 007 |
| | | Page 16 of 20 |

5.3.1.4. PRS 1804: ACE Blade 700 products will include an ACE IFU in addition to a ZIP IFU in each case.

5.4. Case Labeling

5.4.1. For the Sterile Smoke Evacuation Pencil Zip-Pen and Extension Nozzles, the case label includes the following; refer to SOP MKT-SOP-001 for appropriate symbols

5.4.1.1. PRS 1901: The label part number

5.4.1.2. PRS 1902: The label revision

5.4.1.3. PRS 1903: A bar code that is unique to the device

5.4.1.4. PRS 1904: The product catalog number preceded by the appropriate symbol

5.4.1.5. PRS 1905: The symbol for “manufacturer” followed by Megadyne (Registered Trade mark), Company name, address, city, state, zip code, phone number and fax number.

5.4.1.6. PRS 1906: The product trade name

5.4.1.7. PRS 1907: A graphic representation of the product

5.4.1.8. PRS 1908: The E-Z Clean logo with registered trademark symbol

5.4.1.9. PRS 1909: The CE mark as defined by the MDD

5.4.1.10. PRS 1910: The EC Representative information preceded by the appropriate symbol

5.4.1.11. PRS 1911: The product lot number preceded by the appropriate symbol

5.4.1.12. PRS 1912: The product expiration date preceded by the appropriate symbol

5.4.1.13. PRS 1913: The appropriate sterility symbol

| | | |
|---|--|--|
| Megadyne Medical Products Inc. | PRODUCT SPECIFICATION | Document Number: ENG-PS-007 |
| | Smoke Evacuation Pencil and Accessories | Revision: 007 |
| | | Page 17 of 20 |

5.4.1.14. PRS 1914: The symbol for “do not reuse”

5.4.1.15. PRS 1915: The symbol for “Follow Operating Instructions”

5.4.1.16. PRS 1916: The statement “Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.” (may, alternatively, be on Instructions for Use with Rx only symbol used as space permits).

5.4.1.17. PRS 1917: The symbol for “do not use if package is damaged”

5.4.1.18. PRS 1918: The graphical symbol showing the appropriate transport and storage conditions.

5.4.1.19. PRS 1919: The symbol indicating the number of units in the case.

5.4.1.20. PRS 1920: The labeling must remain clear and legible under normal shipping, handling and storage conditions.

5.4.2. For the ULPA Filter and Charcoal Filter, the case label includes the following; refer to SOP MKT-SOP-001 for appropriate symbols

5.4.2.1. PRS 1921: The label part number

5.4.2.2. PRS 1922: The label revision

5.4.2.3. PRS 1923: A bar code that is unique to the device

5.4.2.4. PRS 1924: The product catalog number preceded by the appropriate symbol

5.4.2.5. PRS 1925: The symbol for “manufacturer” followed by Megadyne (Registered Trade mark), Company name, address, city, state, zip code, phone number and fax number.

5.4.2.6. PRS 1926: Requirement deleted

5.4.2.7. PRS 1927: A graphic representation of the product

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|---|--|--|
| Megadyne Medical Products Inc. | PRODUCT SPECIFICATION | Document Number: ENG-PS-007 |
| | Smoke Evacuation Pencil and Accessories | Revision: 007 |
| | | Page 18 of 20 |

5.4.2.8. PRS 1928: The CE mark as defined by the MDD

5.4.2.9. PRS 1929: The EC Representative information preceded by the appropriate symbol

5.4.2.10. PRS 1930: The product lot number preceded by the appropriate symbol

5.4.2.11. PRS 1931: The symbol for “Follow Operating Instructions”

5.4.2.12. PRS 1932: The statement “Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.” (may, alternatively, be on Instructions for Use with Rx only symbol used as space permits).

5.4.2.13. PRS 1933: The graphical symbol showing the appropriate transport and storage conditions.

5.4.2.14. PRS 1934: The symbol indicating the number of units in the case.

5.4.2.15. PRS 1935: The labeling must remain clear and legible under normal shipping, handling and storage conditions.

5.4.3. Bulk Non-Sterile Smoke Evacuation Pencil Zip-Pen, the case label includes the following; refer to SOP MKT-SOP-001 for appropriate symbols

5.4.3.1. PRS 1936: The label part number

5.4.3.2. PRS 1937: The label revision

5.4.3.3. PRS 1938: A bar code that is unique to the device

5.4.3.4. PRS 1939: The product catalog number preceded by the appropriate symbol

5.4.3.5. PRS 1940: The symbol for “manufacturer” followed by Megadyne (Registered Trade mark), Company name, address, city, state, zip code, phone number and fax number.

5.4.3.6. PRS 1941: The product trade name

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|---|--|--|
| Megadyne Medical Products Inc. | PRODUCT SPECIFICATION | Document Number: ENG-PS-007 |
| | Smoke Evacuation Pencil and Accessories | Revision: 007 |
| | | Page 19 of 20 |

5.4.3.7. PRS 1942: A graphic representation of the product

5.4.3.8. PRS 1943: The product lot number preceded by the appropriate symbol

5.4.3.9. PRS 1944: The graphical symbol showing the appropriate transport and storage conditions.

5.4.3.10. PRS 1945: The symbol indicating the number of units in the case.

5.4.3.11. PRS 1946: The labeling must remain clear and legible under normal shipping, handling and storage conditions.

5.5. Expiration Date

5.5.1. Sterile Smoke Evacuation Pencil, Zip-Pen; Extension Nozzles

5.5.1.1. PRS 2001: The sterile devices shall meet packaging, mechanical and electrical design input requirements after 3 years accelerated aging from date of manufacture. Accelerated aging temperature shall not exceed 55° C.

5.5.1.2. PRS 2002: The sterile device shall meet packaging, mechanical and electrical design input requirements at 3 years real time aging from date of manufacture. The product may be released to market based on accelerated aging. Product will be put into the real time age system per Work Instruction ENG-WI-009.

5.5.2. Bulk Non-Sterile Smoke Evacuation, Zip Pen does not have an expiration date.

5.5.3. ULPA Filter and Charcoal Filters do not have an expiration date

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|---|--|--|
| Megadyne Medical Products Inc. | PRODUCT SPECIFICATION | Document Number: ENG-PS-007 |
| | Smoke Evacuation Pencil and Accessories | Revision: 007 |
| | | Page 20 of 20 |

6. REVISION

| Revision | Document Change Order Number | Description of Change | Effective Date |
|--|---------------------------------|---------------------------------------|----------------|
| A | 14-049-01 | Initial Release | 2014-05-01 |
| B | 14-071-01 | Update for ULPA Filter Media | 2014-06-12 |
| C | 14-086-01 | Change name from E-Z Clear to Zip-Pen | 2014-08-19 |
| See MasterControl for subsequent revisions | | | |