Number: ENG-DMR-012
Version: B.23
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Name: Smoke Evacuation Pencil and Accessories, Device Mster Record

Windchill Signature History Report			
Signature	**Role**	**Event Date**	**Vote**
Scheenstra, Jacob [ETHUS] (JScheens)	Regulatory Affairs	07-May-2020 12:58:01 EDT	Approve
Bottaioli, Stephanie [EESUS] (SBottaio)	Manufacturing Engineer	05-May-2020 16:59:16 EDT	Approve
Kumar, Kiran [EESUS NON-J&J] (KKumar16)	Quality Engineering	07-May-2020 14:49:53 EDT	Approve
Borgmeier, Paul [ETHUS] (pborgmei)	Research and Development	06-May-2020 09:40:24 EDT	Approve

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1. INTRODUCTION

This document contains or references the documentation required under US 21 CFR Part 820 and under clause 3, Annex VII of the European Medical Device Directive (MDD) 93/42/EEC.

Required Information:

Name and address of manufacturer:	Megadyne Medical Products, Inc. 11506 South State Street Draper, Utah 84020 USA
Product family classification:*	IIb under rule 9 Annex IX of the MDD
Conformity Assessment Procedure:*	Annex II of the MDD
Documentation on the Quality Management System:	Megadyne's Quality Systems Manual (QA-DOC-001) defines the general Quality System under which all of Megadyne's products are manufactured, and under which non-product-specific quality activities are performed. This Device Master Record (DMR) defines the Quality System used specifically for these products.

* Note: Applies only to CE marked devices

Megadyne's quality system conforms with the requirements of ISO 13485, US 21 CFR part 820, Canadian Medical Device Requirements, and Japan MHLW Ordinance No. 169. In accordance with these requirements, Megadyne's quality management system is continuously maintained, to improve upon its practicability and effectiveness.

The quality management system of Megadyne conforms to ISO 13485 and has been certified by British Standards Institution (BSI) under certificate number FM 639651, to design, manufacture, distribute and service sterile and non-sterile medical devices for electrosurgical use.

Megadyne also performs post market surveillance of products to review experience gained in the post-production phase and institute corrective or preventive action as appropriate. Megadyne will notify the FDA, the Canadian Ministry of Health, Japan Ministry of Health, Labor, and Welfare, the appropriate Competent Authority, and/or other regulatory agencies as required, of incidents and near-incidents, as defined by the EU vigilance system, or other reportable events as defined by the appropriate regulation.

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2. CATALOG/DRAWING NUMBER(S)

Catalog No.	Description
252510*	Zip Pen Smoke Evacuation Pencil with E-Z Clean Electrode, 10 feet of tubing and Holster
2525-10	Zip Pen Smoke Evacuation Pencil with E-Z Clean Electrode, 10 feet of tubing and Holster
252510EC*	Zip Pen Smoke Evacuation Pencil with E-Z Clean Electrode, EC, 10 feet of tubing and Holster
2525-10EC	Zip Pen Smoke Evacuation Pencil with E-Z Clean Electrode, EC, 10 feet of tubing and Holster
252510BN*	Zip Pen Smoke Evacuation Pencil with E-Z Clean Electrode, 10 feet of tubing and Holster Bulk Non-Sterile
2525-10BN	Zip Pen Smoke Evacuation Pencil with E-Z Clean Electrode, 10 feet of tubing and Holster Bulk Non-Sterile
252510ECBN*	Zip Pen Smoke Evacuation Pencil with E-Z Clean Electrode, EC, 10 feet of tubing and Holster Bulk Non-Sterile
2525-10ECBN	Zip Pen Smoke Evacuation Pencil with E-Z Clean Electrode, EC, 10 feet of tubing and Holster Bulk Non-Sterile
252515*	Zip Pen Smoke Evacuation Pencil with E-Z Clean Electrode, 15 feet of tubing and Holster
2525-15	Zip Pen Smoke Evacuation Pencil with E-Z Clean Electrode, 15 feet of tubing and Holster
252515EC*	Zip Pen Smoke Evacuation Pencil with E-Z Clean Electrode, EC, 15 feet of tubing and Holster
2525-15EC	Zip Pen Smoke Evacuation Pencil with E-Z Clean Electrode, EC, 15 feet of tubing and Holster
ME7251C	ACE Blade 700, 2.5", Zip Pen, "C" Connector, 10 ft. tubing
ME7251E	ACE Blade 700, 2.5", Zip Pen, EC Connector, 10 ft. tubing
ME725M1C	ACE Blade 700, 2.5", Modified, Zip Pen, "C" Connector, 10 ft. tubing
ME725M1E	ACE Blade 700, 2.5", Modified, Zip Pen, EC Connector, 10 ft. tubing
2540J*	Zip Pen Nozzle Extension 2.7"
2540	Zip Pen Nozzle Extension 2.7"
2560J*	Zip Pen Nozzle Extension 5.2"
2560	Zip Pen Nozzle Extension 5.2"
2211J*	ULPA Filter
2211	ULPA Filter

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Catalog No.	Description
2220J*	Charcoal Filter
2220	Charcoal Filter
2150J*	Universal Adapter
2150	Universal Adapter
2140J*	Connector, Filter/Tubing
2140	Connector, Filter/Tubing
2145J*	Connector, 22mm Male to 10mm Male
2145	Connector, 22mm Male to 10mm Male
2155	Connector, 22mm Female to 10mm Male
2151J*	Tube Adapter
2151	Tube Adapter

*Dash removed and / or J added to select product codes in order to prevent any potential conflict within the J&J system, during product code integration. No changes were made to the design, manufacturing, processing, safety, performance or effectiveness of the product, and the changes have no impact on the device.

3. DEVICE DESCRIPTION

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.

DESCRIPTION

- Main Device - 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 overmolding the circuit board with nonconductive materials.

Clear tubing connects to the nozzle and provides a path for capturing electrosurgical smoke. The electrosurgical cable leaves the tubing through an open port and terminates at a 3-prong electrosurgical plug. The remaining portion of the tubing (without cable inside) terminates at a connector that attaches to the smoke evacuation filter. The connector is attached to the tubing and is included as part of the smoke evacuation pencil for connection to the filter.

The Zip Pen smoke evacuation electrosurgical pencil is available with a 10 ft. cord/tubing (catalog number 2525-10, 252510, ME7251C, ME725M1C) and with 15 ft. cord/tubing (catalog number 2525-15, 252515).

Each Zip Pen is supplied with two additional items:

- A holster which is used to hold the device when it is not in use during the procedure. The holster is a component of the Zip Pen and will not be sold separately.
- A 2.5-inch Megadyne Zip Pen electrode. The electrode is a separate, currently marketed device that received clearance in 2008 via K081791. Other electrosurgical electrodes that meet industry standards and have market clearance may be substituted per customer preference.

The Zip Pen is sold sterile and non-sterile. It is a single use device which is not intended to be cleaned or reused. The non-sterile Zip Pen is sold to kit packers who are responsible for sterilizing the device.

The Zip Pen 2525-10EC 252510EC, 252515EC, 2525-15EC, ME7251E, and ME725M1E are the same as 2525-10, 252510, ME7251C, ME725M1C, 252515 and 2525-15 except that they have a 22mm smoke tubing connector.

- Accessories
  - 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. Nozzle extension catalog number 2540 and 2540J is used with the Zip Pen 4" electrode and nozzle extension catalog number 2560 and 2560J is used with the Zip Pen 6.5" electrode

    The Zip Pen Nozzle Extensions are sold sterile. They are single use devices which are not intended to be cleaned or reused.
  - Two accessory filters are available for use with the MegaVac and MegaVac Plus style smoke evacuators. They provide filtration of the surgical smoke that is removed from 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.

These filters are used simultaneously but do not connect. The collection of air passes through the ULPA filter prior to entering the pump and subsequently passing through the charcoal filter.

These products are provided non-sterile. They are single use components which are not intended to be cleaned or reused. In and of themselves the filters are not devices. They are disposable components of smoke evacuator units (such as Mega Vac and Mega Vac plus).

- Adapters and Connectors:
  - A universal adapter is available. This is the adapter that is sold attached to the Zip Pen and is available separately as a non-sterile accessory. The catalog number is 2150 and 2150J.
  - Four connectors are available. These are sold separately as non-sterile accessories to connect to competitors' smoke evacuators. The catalog numbers are 2140, 2140J, 2145, 2145J and 2155.

4. INTENDED USE

22525-10, 252510, ME7251C, ME725M1C, 2525-15, 252515, 2525-10EC, 252510EC, ME7251E, ME725M1E, 2525-15EC and 252515EC Smoke Evacuation Pencils

Zip Pen smoke evacuation electrosurgical pencil 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. This device conducts an electrosurgical current from an electrosurgical generator and delivers it to the target tissue to achieve the desired surgical effect.

- 2540, 2540J 2560, 2560J, 2211, 2211J, 2220, 2220J, 2140, 2140J, 2145, 2145J, 2150, 2150J, 2151, 2151J, and 2155 are accessories to other medical devices. Their intended use falls under the device they are used with.

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5. REGULATORY AUTHORIZATIONS

5.1. FDA

5.1.1. Establishment Registration
1721194

5.1.2. Device Listing
See table below

5.1.3. 510(k) Number
See table below

5.2. CE-Marking –
Certificate Number: See table below
Declaration of Conformity: See table below

5.3. Canada License
See table below

Product Code	Device Listing	510(k)	EC Certificate	EU Declaration of Conformity	Canada License
252510	D236969	K141587	CE 640176	RA-DOC-014	95041
2525-10	D236969	K141587	CE 640176	RA-DOC-014	95041
252510EC	D236969	K141587	CE 640176	RA-DOC-014	N/A
2525-10EC	D236969	K141587	CE 640176	RA-DOC-014	N/A
252510BN	D236969	K141587	N/A	N/A	N/A
2525-10BN	D236969	K141587	N/A	N/A	N/A
252510ECBN	D236969	K141587	N/A	N/A	N/A
2525-10ECBN	D236969	K141587	N/A	N/A	N/A
252515	D236969	K141587	N/A	N/A	N/A
2525-15	D236969	K141587	N/A	N/A	95041
252515EC	D236969	K141587	N/A	N/A	N/A
2525-15EC	D236969	K141587	N/A	N/A	N/A
ME7251C	D236969	K141587	CE 640176	RA-DOC-017	95041
ME7251E	D236969	K141587	CE 640176	RA-DOC-017	95041
ME725M1C	D236969	K141587	CE 640176	RA-DOC-017	95041
ME725M1E	D236969	K141587	CE 640176	RA-DOC-017	95041
2540J	D236969	K141587	CE 640176	RA-DOC-014	95041
2540	D236969	K141587	CE 640176	RA-DOC-014	95041
2560J	D236969	K141587	CE 640176	RA-DOC-014	95041
2560	D236969	K141587	CE 640176	RA-DOC-014	95041

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Product Code	Device Listing	510(k)	EC Certificate	EU Declaration of Conformity	Canada License
2211J	D236969	K141587	N/A	RA-DOC-013	95041
2211	D236969	K141587	N/A	RA-DOC-013	95041
2220J	D236969	K141587	N/A	RA-DOC-013	95041
2220	D236969	K141587	N/A	RA-DOC-013	95041
2150J	D236969	K141587	N/A	RA-DOC-013	95041
2150	D236969	K141587	N/A	RA-DOC-013	95041
2140J	D236969	K141587	N/A	RA-DOC-013	95041
2140	D236969	K141587	N/A	RA-DOC-013	95041
2145J	D236969	K141587	N/A	RA-DOC-013	95041
2145	D236969	K141587	N/A	RA-DOC-013	95041
2155	D236969	K141587	N/A	RA-DOC-013	95041
2151J	D236969	K141587	N/A	RA-DOC-013	95041
2151	D236969	K141587	N/A	RA-DOC-013	95041

6. PERFORMANCE SPECIFICATION

6.1. Zip Pen Smoke Evacuation Pencils 2525-10, 252510, ME7251C, ME725M1C, 2525-15, 252515, 2525-10EC, 252510EC, ME7251E, ME725M1E, 2525-15EC and 2525-15EC and Extension Nozzles 2540, 2540J, 2560 and 2560J

6.1.1. These devices meet the relevant requirements of ANSI/AAMI 60601-1 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance

6.1.2. These devices meet the relevant requirements EN 60601-2-2 Medical electrical equipment, Part 2: Particular requirements for the safety of high frequency surgical equipment.

6.1.3. Refer to the following documents for specific requirements and compliance information:

Document Number	Title
ENG-PS-007	Product Specification, Smoke Evacuation Pencils and Accessories
ENG-IOM-012	Input/Output Conformance Test Matrix, ZIP
ENG-IOM-004	Input/Output Conformance Test Matrix, ACE Blade

6.1. ULPA Filter, Charcoal Filter and Universal Adapter

6.1.1. These devices meet the relevant requirements of their product specification ENG-PS-007

7. STERILIZATION

The Zip Pen smoke evacuation pencil (2525-10, 252510, ME7251C, 2525-10EC, 252510EC, ME7251E, 2525-15, 252515, 2525-15EC and 252515EC) and Nozzle Extensions (2540, 2540J, 2560 and 2560J) are sterilized by exposure to Co-60 radiation, in accordance with ISO 11137 *Sterilization of health care products – Requirements for validation and routine control - Radiation sterilization*, and AAMI/TIR 33, *Radiation Sterilization-Substantiation of 25 kGy as a Sterilization Dose-Method VD Max*. These devices are not validated for other sterilization processes. They are not intended to be re-sterilized.

The Zip Pen smoke evacuation pencils ME725M1C and ME725M1E are EO sterilized as outlined in ENG-WI-001 - Sterilization Chart. EO sterilization meets all requirements as outlined by ISO 1093-7:2009, ISO 11135:2014, and ISO 11138-2:2009.

The Zip Pen smoke evacuation pencils 2525-10BN, 252510BN, 252510ECBN and 252510ECBN are sold non-sterile. These catalog items are sold to kit packers who are responsible for sterilization of the device.

8. BIOCOMPATIBILITY

Materials for the Zip Pen smoke evacuation pencil and Extension Nozzle family have been tested in accordance with the requirements of ANSI/AAMI/ISO 10993-1 *Biological evaluation of medical devices – Part 1: Guidance on selection of tests* for external communicating devices that are tissue communicating with limited contact duration. The biocompatibility results are reported in test report ENG-RPT-337. The specific tests performed and the Nelson labs report numbers are identified below:

Test Description	Test Report (Nelson Lab #)	Test Results
Cytotoxicity (MEM elution)	723539 and 724187	Slight Reactivity
Irritation	723541	Non Irritant
Sensitization	723540	No Sensitization Reaction

The ULPA Filter (2211), and Charcoal Filter (2220) are non-patient contact devices made out of common industry materials. Biocompatibility is not required for these devices.

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9. RISK MANAGEMENT

Risk Management is conducted in accordance with QA-SOP-015, *Hazard Assessment and Risk Analysis,* and is documented in ENG-RMF-044, *Hazard Assessment;* ENG-RMF-045, *Risk Analysis;* ENG-RMF-043, *Risk Management Plan and* MKT-US-002, *Usability Specification*

In addition to the documents listed above, the ACE Blade 700 products utilize the references in the E-Z Clean DMR, ENG-DMR-001.

10. ESSENTIAL REQUIREMENTS

The way the Zip Pen smoke evacuation pencils, Extension Nozzles and Filters product family meets the Essential Requirements, as defined by the Medical Devices Directive (MDD 93/42/EEC), is documented in RA-ER-009, *Essential Requirements Matrix*

11. DEVICE QUALITY PLAN

11.1. Quality System Procedure are referenced in the Site Quality Plan (QA-DOC-007).

11.2. Design control

Design reviews were completed at the concept, design, and validation phases of the product development using the applicable procedures (see QA-DOC-007). The Design History File is stored in Document Control under project name ZIP.

The ACE Blade 700 product utilizes the ZIP and ACE (project name ALPHA) DHFs as it followed the Abbreviated Design Control process as part of ENG-SOP-005 rev 009 section 7.3.1.1. In addition to referencing these two DHFs, a ZIP ACE DHF has been created which contain all newly generated ACE Blade 700 related documentation.

11.3. Identification and traceability

Finished product and raw materials are lot coded, in accordance with the applicable procedures (refer to QA-DOC-007).

11.4. Process control

11.4.1. Process Summary

The Zip Pen is assembled, packaged and sterilized at an outside contractor. Upon receipt, the sterilization certificate and certificate of conformance are reviewed for compliance to specification prior to acceptance into finished goods. Final product acceptance is documented on form QA-FRM-017 *Final Lot Release*.

The Nozzle Extensions are assembled, packaged and sterilized at an outside contractor. Upon receipt, the sterilization certificate and certificate of conformance are reviewed for compliance to specification prior to

acceptance into finished goods. Final product acceptance is documented on form QA-FRM-017 *Final Lot Release*.

The ULPA Filter and Charcoal Filter are assembled at an outside contractor. Upon receipt, the certificate of conformance is reviewed for compliance to specification prior to acceptance into finished goods. Final product acceptance is documented on form QA-FRM-017 *Final Lot Release*.

11.4.2. Process Validation

Validated processes (validated in accordance with ENG-SOP-009, Process Verification and Validation and QA-SOP-009, Sterilization Validations) used in the manufacture of Zip Pen and Nozzle Extensions are the assembly process, package sealing, and sterilization. These operations are performed at an outside contractor. The same validation processes will apply and the records for those validations will be stored at the outside contractor.

For the ACE Blade 700 product family, blade insertion validations were performed and are documented in ENG-PRT-444 and ENG-RPT-573 and ENG-PRT-445 and ENG-RPT-576.

For product codes ME725M1E and ME725M1C Megadyne Medical Products is responsible for EO Sterilization. As such, a process validation was performed to ensure that upon reception non-sterile product labeled sterile is properly sterilized. See ENG-PRT-474 and ENG-RPT-586.

11.4.3. Bill of Materials

The Bill of Materials identifies all of the specific components and materials (including labeling) for a given assembly or subassembly. The structure of Bills of Material is defined by ENG-SOP-004, Bill of Material.

11.4.4. Travelers

The Zip Pen, Nozzle Extensions and Filters are assembled, packaged, labeled, and sterilized (where applicable) at an outside contractor. The traveler shall be controlled per the quality system of the contractor.

For product codes ME725M1E and ME725M1C, the traveler that controls the reception and sterilization of non-sterile product labeled as sterile is in traveler OPER-FRM-134.

11.4.5. Work Instructions

The Zip Pen, Nozzle Extensions and Filters are assembled, packaged, labeled and sterilized (where applicable) at an outside contractor. The

Work Instructions shall be controlled per the quality system of the contractor.

There is one internal work instruction OPER-WI-048 for pallet loading of product to be EO sterilized which applies to ME725M1E and ME725M1C.

11.4.6. Assembly Drawings

When appropriate, assembly drawings are established to facilitate the completion of a task. All pertinent assembly drawings are identified by document number within the appropriate Bill of Materials.

11.4.7. Manufacturing Environment

The Zip Pen and Nozzle Extensions are manufactured and assembled in a controlled environment. These products are manufactured at an outside contractor. The environment is controlled by the quality system of the contractor.

11.5. Inspection and testing

11.5.1. Receiving

Receiving inspection processes are in accordance with established procedures (refer to QA-DOC-007). The inspection of Zip Pen Pencils, Nozzle Extensions and Filters are documented on form QA-FRM-017 *Final Lot Release*.

These catalog numbers are assembled, packaged, and labeled at an outside contractor. The receiving inspection process will consist of a review of the supplier certificate of compliance and sterilization certification where applicable.

11.5.2. In-Process Inspection

These catalog numbers are assembled, packaged, and labeled at an outside contractor. In-process inspections for the Zip Pen, Nozzle Extensions and Filters are controlled by the quality system of the contractor.

11.5.3. Final Product Inspection

The general process for final product inspection and release is defined by established procedures for Final Product Release (refer to QA-DOC-007).

11.6. Control of inspection, measuring and test equipment

These catalog numbers are assembled, packaged, and labeled at an outside contractor. The control of measuring and test equipment shall be accomplished per the quality system of the contractor.

11.7. Inspection and test status

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Inspection and test status for this device is indicated in accordance with established procedures.

11.8. Control of nonconforming product

Non-Conforming product is controlled in accordance with established procedures.

11.9. Handling, storage, packaging, preservation, and delivery

11.9.1. Product Label

The pouch, and shipping box labels are identified by specific numbers on the appropriate Bill of Materials.

Product Ref	Drawing Document # / BOM Document #
252510	252510
2525-10	2525-10
252510	252510
2525-10	2525-10
252515	252515
2525-15	2525-15
252515	252515
2525-15	2525-15
252510EC	252510EC
2525-10EC	2525-10EC
252510EC	252510EC
2525-10EC	2525-10EC
252515EC	252515EC
2525-15EC	2525-15EC
252515EC	252515EC
2525-15EC	2525-15EC
ME7251C	ME7251C
ME7251C	ME7251C
ME725M1C	ME725M1C
ME725M1C	ME725M1C

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Product Ref	Drawing Document # / BOM Document #
ME7251E	ME7251E
ME7251E	ME7251E
ME725M1E	ME725M1E
ME725M1E	ME725M1E
ME7251C-01 ME7251E-01 ME725M1C-01 ME725M1E-01	ME7251C-01 ME7251E-01 ME725M1C-01 ME725M1E-01
2540J	2540J
2540	2540
2540J	2540J
2540	2540
2560J	2560J
2560	2560
2560J	2560J
2560	2560
2211J	2211J
2211	2211
2211J	2211J
2211	2211
2220J	2220J
2220	2220
2220J	2220J
2220	2220
2150J	2150J
2150	2150
2140J	2140J

Product Ref	Drawing Document # / BOM Document #
2140	2140
2145J	2145J
2145	2145
2151J	2151J
2151	2151
2155	2155

11.9.2. Instructions for Use

The Instructions for Use for this product is identified by a specific number on the appropriate Bill of Materials. Refer table in section 11.9.1 for Product Codes and respective BOM as listed on the product drawing.

11.9.3. Special Shipping or Storage Requirements

Zip Pen and Nozzle Extensions shall maintain package integrity after exposure to package ship test requirements defined in ASTM D4169 distribution cycle DC13 assurance level II (note that low pressure test will not be performed).

Zip Pencils are validated for shipping and storage as follows:

Short Duration Transport and Storage:

Temperature -40°C to 55°C

Humidity 15% to 95%

Transport and Storage:

Temperature 5°C to 50°C

Humidity 15% to 95%

Barometric Pressure does not have a significant effect on the Zip Pen, Nozzle Extensions and their packaging. These products are packaged with Tyvek®[1] 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. Testing for this attribute is not required.

[1] Tyvek® is a registered trademark of E.I. DuPont de Nemours, Inc

11.9.4. Packaging Specifications

11.9.4.1. Sterile Zip Pen

Sterile product is packaged individually in a Multivac style pouch with Tyvek® top and Nylon bottom.

11.9.4.2. Sterile Nozzle Extensions

Sterile product is packaged individually in a Tyvek® peel pouch.

11.9.4.3. ULPA Filters, Charcoal Filters, and Universal Adapters are packaged in poly bags.

11.9.4.4. Bulk non-sterile Zip Pen is bulk packaged in double poly bags.

11.9.5. Known Expiration Life Data, Zip Pen and Nozzle Extensions

Sterile product is marked with an expiration date of 3 years after the date (month) of sterilization. Rationale for this Expected Service Life is shown in Appendix I. The Bulk Non-Sterile Zip Pen, ULPA Filters, Charcoal Filters, and Universal Adapters are non-sterile and are not marked with an expiration date.

11.10. Training

Personnel assembling the Zip Pen, Nozzle Extensions, Filters and Universal Adapter are trained in the specific methods and procedures used in the device manufacture. Some of these catalog numbers are assembled, packaged, and labeled at an outside contractor. The training records shall be controlled per the quality system of the contractor.

11.11. Servicing

Not Applicable.

11.12. Statistical methods

Statistical methods used in the inspection and manufacture of the Zip Pen, Nozzle Extensions, Filters and Universal Adapter are performed in accordance with established procedures (QA-DOC-007). Some of these catalog numbers are assembled, packaged, and labeled at an outside contractor. The statistical techniques shall be controlled per the quality system of the contractor.

12. APPENDICES

APPENDIX NO.	TITLE
I	Expected Service Life Rationale

13. REVISION HISTORY

The revision history of the DMR is maintained in Megadyne's Document Repository System (MasterControl or Windchill), as part of the applicable document (Infocard) number.

Megadyne Medical Products, Inc.	DEVICE MASTER RECORD	Document Number ENG-DMR-012
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APPENDIX I

Rationale for Zip Pen Expected Service Life:

Engineering Considerations:

The Zip Pen family of products are sterile single use devices. The use of the device is limited to one surgical case on one patient. The rationale for this limitation is that after use on one patient it is not practical to clean and sterilize the device for reuse. The device has complex surfaces and tubing that will hold biohazard contamination from the patient and will not be cleanable. The device cannot be sterilized by steam autoclave as is typically done with reusable devices. This is because the materials of construction are not high temperature materials.

Product shelf life:

The product is packaged in a large nylon Form Fill Seal (FFS) tray with a Tyvek lid. The product shelf life is limited by the ability of this package to maintain a sterile barrier. The materials themselves are rated by the respective manufacturers to maintain a sterile barrier as long as specific transport and storage conditions are maintained.

The product itself is made from various plastics with a fiberglass circuit board and metal switches and collet. The plastics are suitable for long term life as long as specific transport and storage conditions are maintained. However, product shipping and handling during transit cannot be controlled by Megadyne. Therefore testing is performed to simulate possible conditions that may degrade the product and packaging. This testing requires selection of a target shelf life. The design team selected a shelf life of three years for this testing. Three years is an adequate time for product delivery, warehousing and order processing to provide the customer with acceptable lead time to plan for material usage in their procurement cycle.