# Project name: PROJECT ZIP\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**PROJECT – SPECIFIC**

**CHECKLIST REVISION: ­­­­­­­­­­­­­­­­\_\_\_003B\_(Zip ACE Modified, ME725M1E and ME725M1C see ENG-DCC-006)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

| **Origin of Input**  **(Standards – Internal/External)** | **Design Input** | **Conformance Method** | **Output of Conformance** | **Requirement Status** | **Project Engineer Signature** | **Reviewer Signature** |
| --- | --- | --- | --- | --- | --- | --- |
| **MECHANICAL** | | | | | | |
| Customer Requirements Document MKT-CMR-029, Product Spec ENG-PS-007 PRS 1311, PRS 1312 | Smoke Evacuation Pencil/Extension Nozzles/Zip-Pen Flow rate equal to or greater than Ultra Vac 2110-10 when attached to Mega Vac set on maximum flow using new clean filters | ENG-PRT-228  ENG-PRT-280  ENG-PRT-239 | Flow rate greater than 2110-10, also meets this requirement with extension nozzle attached, see test reports  ENG-RPT-329  ENG-RPT-403  ENG-RPT-344 | Complete | D.G. 5/5/14  M.G. 11/12/14  T.S. 2/21/18  T.S. 6/28/18 | M.E. 5/5/14  M.E 11/12/14  M.E. 2/21/18  M.E. 6/28/18 |
| Customer Requirements Document MKT-CMR-029 | Cord length available in 10’ and 15’ | ENG-PRT-451 | ENG-RPT-558 | Complete | T.S. 2/21/18  T.S. 6/28/18 | M.E. 2/21/18  M.E. 6/28/18 |
| Customer Requirements Document MKT-CMR-029, Product Spec ENG-PS-007PRS 1105 | Cut and Coag buttons approximately same size as Megadyne disposable pencil buttons (e.g. 0035) | ENG-PRT-290 | ENG-RPT-418 | Complete | D.G. 5/5/14  M.G 2/9/15  T.S. 2/21/18  T.S. 6/28/18 | M.E. 5/5/14  M.E. 2/9/15  M.E. 2/21/18  M.E. 6/28/18 |
| Customer Requirements Document MKT-CMR-029, Product Spec ENG-PS-007PRS 1103, PRS 1104 | Gray Pantone 427 pencil handle with inlayed TPR that is Green Pantone 356 and Megadyne logo | ENG-PRT-290 | ENG-RPT-418 | Complete | D.G. 5/5/14  M.G 2/9/15  T.S. 2/21/18  T.S. 6/28/18 | M.E. 5/5/14  M.E. 2/9/15  M.E. 2/21/18  M.E. 6/28/18 |
| Customer Requirements Document MKT-CMR-029 | Gray holster, plug, cord. Plug with Megadyne branding | ENG-PRT-451 | ENG-RPT-558 | Complete | T.S. 2/21/18  T.S. 6/28/18 | M.E. 2/21/18  M.E. 6/28/18 |
| Customer Requirements Document MKT-CMR-029, Product Spec ENG-PS-007PRS 1305 | Tip to nozzle exposure dimension consistent with Ultra Vac 2110-10 | ENG-PRT-290 | ENG-RPT-418 | Complete | D.G. 5/5/14  M.G 2/9/15  T.S. 2/21/18  T.S. 6/28/18 | M.E. 5/5/14  M.E. 2/9/15  M.E. 2/21/18  M.E. 6/28/18 |
| Customer Requirements Document MKT-CMR-029, Product Spec ENG-PS-007PRS 1108, PRS 1113, | Clear, angled handpiece nozzle, extension nozzles | ENG-PRT-290  ENG-PRT-451 | ENG-RPT-418  ENG-RPT-558 | Complete | T.S. 2/21/18  T.S. 6/28/18 | M.E. 2/21/18  M.E. 6/28/18 |
| Customer Requirements Document MKT-CMR-029 | Electrode must be coated with MEGADYNE’s proprietary E-Z Clean® coating. | ENG-PRT-451 | ENG-RPT-558 | Complete | T.S. 2/21/18  T.S. 6/28/18 | M.E. 2/21/18  M.E. 6/28/18 |
| Customer Requirements Document MKT-CMR-029, Product Spec ENG-PS-007PRS 1306, FMEA ENG-RMF-045 | Electrode should fit securely into the pencil collet with wobble comparable to Megadyne disposable pencil (e.g. 0035H). Electrode flexing in collect is less than or equal to a standard electrosurgical pencil collet (e.g. 0035) | ENG-PRT-228 | Wobble is less than or equal to a disposable pencil, see test report  ENG-RPT-329 | Complete | D.G. 5/5/14  T.S. 2/21/18  T.S. 6/28/18 | M.E. 5/5/14  M.E. 2/21/18  M.E. 6/28/18 |
| Product Spec ENG-PS-007 PRS 1313 | Extension Nozzle remains attached to Zip Pen under tensile force applied parallel to pencil body equal to 2 lbs | ENG-PRT-239 | ENG-RPT-344 | Complete | D.G. 5/5/14  T.S. 2/21/18  T.S. 6/28/18 | M.E. 5/5/14  M.E. 2/21/18  M.E. 6/28/18 |
| Customer Requirements Document MKT-CMR-029 | Extension Nozzle available in 2.7” and 5.2” lengths | ENG-PRT-451 | ENG-RPT-558 | Complete | T.S. 2/21/18  T.S. 6/28/18 | M.E. 2/21/18  M.E. 6/28/18 |
| Customer Requirements Document MKT-CMR-029, Product Spec ENG-PS-007PRS 1310, FMEA ENG-RMF-045 | Plug to be compatible with standard ESU and have minimum retention force of 2 lbs | ENG-PRT-228  ENG-PRT-451 | ENG-RPT-329  ENG-RPT-558 | Complete | T.S. 2/21/18  T.S. 6/28/18 | M.E. 2/21/18  M.E. 6/28/18 |
| Product Spec ENG-PS-007, IEC 60601-2-2 Clause 201.8.10.4.2, FMEA ENG-RMF-045 PRS 1309 | Cable connection to the plug withstands a strain relief rotational test per IEC 60601-2-2 clause 201.8.10.4.2 | After Gamma Sterilization - ENG-PRT-228  After EO Sterilization – ENG-PRT-302 – Plug and cable are identical to standard pencil (e.g. 0036). Additional testing not required, see ENG-PRT-466 | Test Report ENG-RPT-329  After EO Sterilization – ENG-RPT-452 – Plug and cable are identical to standard pencil (e.g. 0036) | Complete  Complete | D.G. 5/5/14  T.S. 2/21/18  T.S. 6/28/18 | M.E. 5/5/14  M.E. 2/21/18  M.E. 6/28/18 |
| Product Spec ENG-PS-007, PRS 1307, IEC 60601-2-2 Clause 201.8.10.4.2, FMEA ENG-RMF-045 | Cord connection to the pencil strain relief rotational test per IEC 60601-2-2 clause 201.8.10.4.2 | After Gamma Sterilization - ENG-PRT-228  After EO Sterilization – Additional testing not required, see ENG-PRT-466 | After Gamma Sterilization - ENG-RPT-329 | Complete | D.G. 5/5/14  T.S. 2/21/18  T.S. 6/28/18 | M.E. 5/5/14  M.E. 2/21/18  M.E. 6/28/18 |
| Customer Requirements Document MKT-CMR-029, Product Spec ENG-PS-007, PRS 1110 | Cord inside tubing for first 64” minimum and then exists tubing | ENG-PRT-290  ENG-PRT-451 | ENG-RPT-418  ENG-RPT-558 | Complete | T.S. 2/21/18  T.S. 6/28/18 | M.E. 2/21/18  M.E. 6/28/18 |
| Customer Requirements Document MKT-CMR-029 | Cord outside tubing for 4’ minimum | ENG-PRT-451 | EN G-RPT-558 | Complete | T.S. 2/21/18  T.S. 6/28/18 | M.E. 2/21/18  M.E. 6/28/18 |
| Customer Requirements Document MKT-CMR-029, Product Spec ENG-PS-007PRS 1308, FMEA ENG-RMF-045 | Tubing strong and pliable with adequate connection strength, will remain connected to all connection points under tensile force applied parallel to pencil body equal to 4 lbs | After Gamma Sterilization - ENG-PRT-228 and ENG-PRT-451  After EO Sterilization – ENG-PRT-466 | After Gamma Sterilization - ENG-RPT-329 and ENG-RPT-558  After EO Sterilization – ENG-RPT-585 | Complete  Complete | T.S. 2/21/18  T.S. 6/28/18 | M.E. 2/21/18  M.E. 6/28/18 |
| Customer Requirements Document MKT-CMR-029 | Tubing swivel | ENG-PRT-290 | ENG-RPT-418 | Complete | D.G. 5/5/14  M.G 2/9/15  T.S. 2/21/18  T.S. 6/28/18 | M.E. 5/5/14  M.E. 2/9/15  M.E. 2/21/18  M.E. 6/28/18 |
| Usability Spec MKT-US-002; Customer Requirements Document MKT-CMR-029 | Tubing, adjustable location for ergonomics | ENG-PRT-290 | ENG-RPT-418 | Complete | D.G. 5/5/14  M.G 2/9/15  T.S. 2/21/18  T.S. 6/28/18 | M.E. 5/5/14  M.E. 2/9/15  M.E. 2/21/18  M.E. 6/28/18 |
| IEC 60601-2-2 clause 201.7.8.2, Product Spec ENG-PS-007 PRS 1106, FMEA ENG-RMF-045, Customer Requirements Document MKT-CMR-029 | Cut and Coag Buttons per s tandard | ENG-PRT-290 | ENG-RPT-418 | Complete | D.G. 5/5/14  M.G 2/9/15  T.S. 2/21/18  T.S. 6/28/18 | M.E. 5/5/14  M.E. 2/9/15  M.E. 2/21/18  M.E. 6/28/18 |
| Customer Requirements Document MKT-CMR-029, Product Spec ENG-PS-007, PRS 1302, FMEA ENG-RMF-045 | Electrode extraction force to be 1.5 to 4.5 lbs. | ENG-PRT-228 | ENG-RPT-329 | Complete | D.G. 5/5/14  T.S. 2/21/18  T.S. 6/28/18 | M.E. 5/5/14  M.E. 2/21/18  M.E. 6/28/18 |
| IEC 60601-2-2 clause 201.15.4.1.102, Product Spec ENG-PS-007, PRS 1303, FMEA ENG-RMF-045 | Electrode retention per standard | ENG-PRT-228 | ENG-RPT-329 | Complete | D.G. 5/5/14  T.S. 2/21/18  T.S. 6/28/18 | M.E. 5/5/14  M.E. 2/21/18  M.E. 6/28/18 |
| Customer Requirements Document MKT-CMR-029, Product Spec ENG-PS-007, PRS 1301, FMEA ENG-RMF-045 | Button peak activation Force to be between 250 - 700 grams | After Gamma Exposure - ENG-PRT-228  After EO Exposure – Additional testing not required, see ENG-PRT-466  ENG-PRT-594 | After Gamma Exposure - ENG-RPT-329  After EO and Gamma Sterilization 500433702 | Complete  Complete | D.G. 5/5/14  T.S. 2/21/18  T.S. 6/28/18  B.T. 2/27/20 | M.E. 5/5/14  M.E. 2/21/18  M.E. 6/28/18  G.B. 2/27/20 |
| Product Spec ENG-PS-007PRS1304 | Handpiece Nozzle to withstand a minimum20 lbs. vertical force at the distal end of nozzle with handle held horizontal | After Gamma Exposure - ENG-PRT-228  After EO Exposure – Additional testing not required, see ENG-PRT-466 | After Gamma Exposure - ENG-RPT-329 | Complete | D.G. 5/5/14  T.S. 2/21/18  T.S. 6/28/18 | M.E. 5/5/14  M.E. 2/21/18  M.E. 6/28/18 |
| Product Spec ENG-PS-007PRS1314 | ULPA Filter meets 99.999% efficiency rating when tested with 0.1 to 0.2 micron particles | ENG-PRT-290  ENG-PRT-451 | ENG-RPT-418  ENG-RPT-558 | Complete | T.S. 2/21/18  T.S. 6/28/18 | M.E. 2/21/18  M.E. 6/28/18 |
| Customer Requirements Document MKT-CMR-029 | ULPA Filter life should match that of the IC Medical ULPA Filter | ENG-PRT-267 | ENG-RPT-375 | Complete | T.S. 2/21/18  T.S. 6/28/18 | M.E. 2/21/18  M.E. 6/28/18 |
| Product Spec ENG-PS-007PRS1315 | ULPA Filter has a fluid trap | ENG-PRT-290 | ENG-RPT-418 | Complete | D.G. 5/5/14  M.G 2/9/15  T.S. 2/21/18  T.S. 6/28/18 | M.E. 5/5/14  M.E. 2/9/15  M.E. 2/21/18  M.E. 6/28/18 |
| Product Spec ENG-PS-007PRS1316 | ULPA Filter attaches to the Mega Vac and Mega Vac Plus equivalent to existing Megadyne Cat 2210 | ENG-PRT-238 | ENG-RPT-340 | Complete | D.G. 5/5/14  T.S. 2/21/18  T.S. 6/28/18 | M.E. 5/5/14  M.E. 2/21/18  M.E. 6/28/18 |
| Product Spec ENG-PS-007PRS1317 | ULPA Filter accepts and 10 mm threaded connector from 2525-10 Zip Pen, 2110-10 Ultra Vac | ENG-PRT-290  ENG-PRT-451 | ENG-RPT-418  ENG-RPT-558 | Complete | T.S. 2/21/18  T.S. 6/28/18 | M.E. 2/21/18  M.E. 6/28/18 |
| Product Spec ENG-PS-007PRS1318 | Charcoal Filter contains carbon and connects to the Mega Vac and Mega Vac Plus | ENG-PRT-290 | ENG-RPT-418 | Complete | D.G. 5/5/14  M.G 2/9/15  T.S. 2/21/18  T.S. 6/28/18 | M.E. 5/5/14  M.E. 2/9/15  M.E. 2/21/18  M.E. 6/28/18 |
| IEC 60601-1 Clause 11.1.2.2, Product Spec ENG-PS-007 PRS 1319 | Applied Part not intended to supply heat to the patient, Zip Pen handle per IEC 60601-1 clause 11.1.2.2 | ENG-PRT-272 | ENG-RPT-395 | Complete | M.G. 11/12/14  T.S. 2/21/18  T.S. 6/28/18 | M.E. 11/12/14  M.E. 2/21/18  M.E. 6/28/18 |
| IEC 60601-1 Clause 11.1.2.1, Product Spec ENG-PS-007 PRS 1320 | Applied part intended to supply heat to the patient, electrode. IEC 60601-2-2 clause 201.11.1.2.2 provides addition to requirement that indicated disclosure of temperatures and clinical effects is not required. | IEC 60601-2-2 gives and addition to the main standard that states “disclosure of temperature and effects are not required” | Exemption per the particular standard, no output conformance required. | Complete | M.G. 11/12/14  T.S. 2/21/18  T.S. 6/28/18 | M.E. 11/12/14  M.E. 2/21/18  M.E. 6/28/18 |
| Usability Spec MKT-US-002, URS1002 | Holster will insulate device from patient when not in use both thermally and electrically | ENG-PRT-272  ENG-PRT-227 | ENG-RPT-395  ENG-RPT-328 | Complete | T.S. 2/21/18  T.S. 6/28/18 | M.E. 2/21/18  M.E. 6/28/18 |
| Usability Spec MKT-US-002, URS1003 | Collet will have extraction force that insures the electrode will not fall out of the pencil | ENG-PRT-228 | ENG-RPT-329 | Complete | T.S. 2/21/18  T.S. 6/28/18 | M.E. 2/21/18  M.E. 6/28/18 |
| Usability Spec MKT-US-002, URS1004 | Pencil plug will have an extraction force that insures it remains attached during use | ENG-PRT-451 | ENG-RPT-558 | Complete | T.S. 2/21/18  T.S. 6/28/18 | M.E. 2/21/18  M.E. 6/28/18 |
| Usability Spec MKT-US-002 URS1005, URS1008 | Smoke tubing connector will have adequate removal force to insure it stays connected to the filter during typical use | ENG-PRT-438  After EO Exposure – Additional testing not required, see ENG-PRT-466 | ENG-RPT-556 | Complete | T.S. 2/21/18  T.S. 6/28/18 | M.E. 2/21/18  M.E. 6/28/18 |
| Usability Spec MKT-US-002, URS1011 | Extension Nozzles will securely attach to the pencil | ENG-PRT-239  After EO Exposure – Additional testing not required, see ENG-PRT-466 | ENG-RPT-344 | Complete | T.S. 2/21/18  T.S. 6/28/18 | M.E. 2/21/18  M.E. 6/28/18 |
| Usability Spec MKT-US-002, URS2001 | Smoke tubing connector will have removal force in a range that insures that it stays connected to the tubing during use | ENG-PRT-228 (2150, C Connector);  ENG-PRT-451 (2155, 22mm EC Connector)  After EO Exposure – Additional testing not required, see ENG-PRT-466 | ENG-RPT-329 (2150, C Connector);  ENG-RPT-558 (2155, 22mm EC Connector) | Complete | T.S. 2/21/18  T.S. 6/28/18 | M.E. 2/21/18  M.E. 6/28/18 |
| **USABILITY** | | | | | | |
| Customer Requirements Document MKT-CMR-029, Usability Spec MKT-US-002, PRS 1107, FMEA ENG-RMF-045 | Electrode cannot be inserted incorrectly and is held in place without making electrical contact | ENG-PRT-290 | ENG-RPT-418 | Complete | D.G. 5/5/14  M.G 2/9/15  T.S. 2/21/18  T.S. 6/28/18 | M.E. 5/5/14  M.E. 2/9/15  M.E. 2/21/18  M.E. 6/28/18 |
| Customer Requirements Document MKT-CMR-029, Usability Spec MKT-US-002, Product Spec ENG-PS-007PRS 1109 | Holster, Large enough to hold standard length Pencil with a slot for the tubing to extend out of the holster., color is Pantone 427 | ENG-PRT-239  ENG-PRT-451 | Test Report ENG-RPT-344  ENG-RPT-558 | Complete | D.G. 5/5/14  T.S. 2/21/18  T.S. 6/28/18 | M.E. 5/5/14  M.E. 2/21/18  M.E. 6/28/18 |
| Customer Requirements Document MKT-CMR-029 | Device must be ergonomic | ENG-PRT-453 | ENG-RPT-557 | Complete | T.S. 2/21/18  T.S. 6/28/18 | M.E. 2/21/18  M.E. 6/28/18 |
| Product Spec ENG-PS-007PRS 1001 | Device delivers current to the target tissue to achieve the desired surgical effect | ENG-PRT-453 | ENG-RPT-557 | Complete | T.S. 2/21/18  T.S. 6/28/18 | M.E. 2/21/18  M.E. 6/28/18 |
| Customer Requirements Document MKT-CMR-029 | Device must be minimally obtrusive to the surgical process/procedure | ENG-PRT-453 | ENG-RPT-557 | Complete | T.S. 2/21/18  T.S. 6/28/18 | M.E. 2/21/18  M.E. 6/28/18 |
| Customer Requirements Document MKT-CMR-029 | Tubing, swivel will minimize drag | ENG-PRT-453 | ENG-RPT-557 | Complete | T.S. 2/21/18  T.S. 6/28/18 | M.E. 2/21/18  M.E. 6/28/18 |
| Customer Requirements Document MKT-CMR-029 | Device must have a tactile feel with button push | ENG-PRT-453  ENG-PRT-660 | ENG-RPT-557  ENG-RPT-779 | Complete  Complete | T.S. 2/21/18  T.S. 6/28/18  M.R. 01/15/20 | M.E. 2/21/18  M.E. 6/28/18  G.B 2/27/20 |
| Customer Requirements Document MKT-CMR-029 | Electrode must remain secure during cleaning | ENG-PRT-453 | ENG-RPT-557 | Complete | T.S. 2/21/18  T.S. 6/28/18 | M.E. 2/21/18  M.E. 6/28/18 |
| Customer Requirements Document MKT-CMR-029 | Electrode is easy to insert into the collet | ENG-PRT-452 | ENG-RPT-559 | Complete | T.S. 2/21/18  T.S. 6/28/18 | M.E. 2/21/18  M.E. 6/28/18 |
| Customer Requirements Document MKT-CMR-029 | Electrode is capable of being removed | ENG-PRT-452 | ENG-RPT-559 | Complete | T.S. 2/21/18  T.S. 6/28/18 | M.E. 2/21/18  M.E. 6/28/18 |
| Usability Spec MKT-US-002, URS1001 | IFU will provide graphics showing the options for gripping device | IFU | 3000312-01, 3000317 | Complete | T.S. 2/21/18  T.S. 6/28/18 | M.E. 2/21/18  M.E. 6/28/18 |
| Usability Spec MKT-US-002, URS1006 | IFU will provide warning not to kink the tubing | IFU | 3000312-01, 3000317 | Complete | T.S. 2/21/18  T.S. 6/28/18 | M.E. 2/21/18  M.E. 6/28/18 |
| Customer Requirements Document MKT-CMR-029 | 10 and 15 ft. lengths with 22 mm connector. | ENG-PRT-451 | ENG-RPT-558 | Complete | T.S. 2/21/18  T.S. 6/28/18 | M.E. 2/21/18  M.E. 6/28/18 |
| Customer Requirements Document MKT-CMR-029 | Must evacuate smoke away from the surgical site in an efficient and effective manner. | ENG-PRT-453 | ENG-RPT-557 | Complete | T.S. 2/21/18  T.S. 6/28/18 | M.E. 2/21/18  M.E. 6/28/18 |
| Customer Requirements Document MKT-CMR-029 | Must be able to add extension blades / accommodate a 6.5” tip (0014A, 0014). | ENG-PRT-290 | ENG-RPT-418 | Complete | T.S. 2/21/18  T.S. 6/28/18 | M.E. 2/21/18  M.E. 6/28/18 |
| Customer Requirements Document MKT-CMR-029 | Must be able to visualize the tip during the procedure. | ENG-PRT-453 | ENG-RPT-557 | Complete | T.S. 2/21/18  T.S. 6/28/18 | M.E. 2/21/18  M.E. 6/28/18 |
| Customer Requirements Document MKT-CMR-029 | The MEGADYNE Smoke Evacuation Pencil must be adaptable to the current IC Medical ULPA filter (2210) as well as 22 mm systems such as ERBE via the C connector (2150), EC connector (2155), or other adapter options. Adaptation to other sizes (i.e. ConMed AerDefense, Covidien RapidVac and Buffalo ViroVac) may need to be accommodated via other adapter options, such as the C connector (2150).  Adapters will be developed/provided as necessary to ensure the connection of the MEGADYNE smoke evacuation pencil with a variety of manufacturer’s smoke boxes either via a universal connector size, by adapters or by removing the connector as necessary.  Consideration should be made for IC Medical’s current ULPA filters and customers (aka Canada) who may continue to purchase that filter and need that size connector.  Connection should accommodate the ConMed Aer Defense, Rapid Vac, MiniVac, ERBE and be as universal in fit as possible. | ENG-PRT-438 (testing filter fit compatibility of the Megadyne ZIP-PEN  smoke pencil adapters.) | ENG-RPT-( filter compatibility testing of C and EC smoke evacuation  connectors ) | Complete | T.S. 2/21/18  T.S. 6/28/18 | M.E. 2/21/18  M.E. 6/28/18 |
| **ELECTRICAL** | | | | | | |
| IEC 60601-2-2 Clause 201.8.8.3.101 and 201.8.8.3.102, Product Spec ENG-PS-007PRS 1404 | Cable meets High Frequency Leakage | After Gamma Sterilization - ENG-PRT-227(To specify dielectric withstand testing required on zip pencil )  ENG-PRT-283 (The purpose of this test protocol is to specify HF and Mains dielectric withstand testing of the Zip Pen handle ).  )  After EO Sterilization – ENG-PRT-302 – Cable is identical to standard pencil (e.g. 0036). Additional testing not required, see ENG-PRT-466 | Test Report ENG-RPT-328 ( To document compliance of Zip pencil dielectric withstand after shipping extremes and accelerated ageing to simulate 3 years expiration life)  ENG-RPT-412 (Test report after accelerated aging to simulate three years expiration life, shipping extremes and ship testing.)  After EO Sterilization – ENG-RPT-452 (The purpose of this study is to provide objective evidence that the ZIP-PENTM Smoke Evacuation Pencil (15 foot cord length) satisfies defined customer requirements when used within actual or simulated-use environments in a manner consistent with the Package Insert. ) | Complete  Complete | T.S. 2/21/18  T.S. 6/28/18 | M.E. 2/21/18  M.E. 6/28/18 |
| IEC 60601-2-2 Clause 201.8.8.3.101 and 201.8.8.3.103, Product Spec ENG-PS-007, PRS 1405 | Cable meets High Frequency dielectric withstand | After Gamma Sterilization - ENG-PRT-227  ENG-PRT-283  After EO Sterilization – ENG-PRT-302 – Cable is identical to standard pencil (e.g. 0036). Additional testing not required, see ENG-PRT-466 | Test Report ENG-RPT-328  ENG-RPT-412  After EO Sterilization – ENG-RPT-452 | Complete  Complete | T.S. 2/21/18  T.S. 6/28/18 | M.E. 2/21/18  M.E. 6/28/18 |
| IEC 60601-2-2 Clause 201.8.8.3.101 and 201.8.8.3.104, Product Spec ENG-PS-007, PRS 1406 | Cable meets Mains Frequency dielectric withstand | After Gamma Sterilization - ENG-PRT-227  ENG-PRT-283  After EO Sterilization – ENG-PRT-302 – Cable is identical to standard pencil (e.g. 0036). Additional testing not required, see ENG-PRT-466 | Test Report ENG-RPT-328  ENG-RPT-412  After EO Sterilization – ENG-RPT-452 | Complete  Complete | T.S. 2/21/18  T.S. 6/28/18 | M.E. 2/21/18  M.E. 6/28/18 |
| IEC 60601-2-2 Clause 201.8.8.3.103, Product Spec ENG-PS-007, PRS 1407 | Smoke Evacuation Pencil, Zip Pen meets High Frequency dielectric withstand | After Gamma Sterilization - ENG-PRT-283  After EtO Sterilization – ENG-PRT-330(This is a protocol for demonstration of EO compatibility and not an EO validation.  )  ENG-PRT-594 | After Gamma Sterilization - ENG-RPT-412  After EtO Sterilization – ENG-RPT-476 (The purpose of this test report is to document that the Zip Pen meets the requirements for dielectric withstand after exposure to EO sterilization.)  After Gamma and EtO Sterilization 500433702 | Complete  Complete  Complete | T.S. 2/21/18  T.S. 6/28/18  B.T. 2/27/20 | M.E. 2/21/18  M.E. 6/28/18  G.B. 2/27/20 |
| IEC 60601-2-2 Clause 201.8.8.3.104, Product Spec ENG-PS-007, PRS 1408 | Smoke Evacuation Pencil, Zip Pen meets Mains Frequency dielectric withstand | After Gamma Sterilization - ENG-PRT-283  After EtO Sterilization – ENG-PRT-330  ENG-PRT-594 | After Gamma Sterilization - ENG-RPT-412  After EtO Sterilization – ENG-RPT-476  After Gamma and EtO Sterilization 500433702 | Complete  Complete  Complete | T.S. 2/21/18  T.S. 6/28/18  B.T. 2/27/20 | M.E. 2/21/18  M.E. 6/28/18  G.B. 2/27/20 |
| IEC 60601-2-2 Clause 201.8.8.3.104, Product Spec ENG-PS-007, PRS 1401 | Plug meets Mains Frequency dielectric withstand | After Gamma Sterilization - ENG-PRT-227  After EO Sterilization – ENG-PRT-302 – Plug is identical to standard pencil (e.g. 0036). Additional testing not required, see ENG-PRT-466 | After Gamma Sterilization - ENG-RPT-328 ENG-RPT-412  After EO Sterilization – ENG-RPT-452 | Complete  Complete | T.S. 2/21/18  T.S. 6/28/18 | M.E. 2/21/18  M.E. 6/28/18 |
| Product Spec ENG-PS-007, PRS 1402 | Zip Pen fingerswitch, Cut and Coag, activation resistance of 50 ohms maximum | ENG-PRT-227  ENG-PRT-594 | Test Report ENG-RPT-331(Zip pen **SMOKE EVACUATION ELECTROSURGICAL PENCIL guide)**  Test Report 500433702 | Complete  Complete | T.S. 2/21/18  T.S. 6/28/18  B.T. 2/27/20 | M.E. 2/21/18  M.E. 6/28/18  G.B. 2/27/20 |
| Product Spec ENG-PS-007, PRS 1403 | Zip Pen Pencil fingerswitch non-activation resistance of 100,000 ohms minimum | ENG-PRT-227  ENG-PRT-594 | Test Report ENG-RPT-331  Test Report 500433702 | Complete  Complete | T.S. 2/21/18  T.S. 6/28/18  B.T. 2/27/20 | M.E. 2/21/18  M.E. 6/28/18  G.B. 2/27/20 |
| IEC 60601-2-2 Clause 201.11.6.5 b), Product Spec ENG-PS-007, PRS 1409, FMEA ENG-RMF-045 | Handheld portion meets Fluid Ingress Test requirements | After Gamma and EO Sterilization - ENG-PRT-439 (The purpose of this test protocol is to specify testing required on the Zip Pen with improved seal on the PCB to show compliance The protocol will be run on both gamma sterile and EO exposed product.  )  ENG-PRT-594 | After Gamma and EO Sterilization - Test Report ENG-RPT-555 (The objective of this test report is to document that the Zip Pen complies with requirements for fluid ingress after modifications were made to improve the design.)  After Gamma and EtO Sterilization 500433702 | Complete  Complete | T.S. 2/21/18  T.S. 6/28/18  B.T. 2/27/20 | M.E. 2/21/18  M.E. 6/28/18  G.B. 2/27/20 |
| **BIOLOGICAL** | | | | | | |
| ISO 10993-1, Product Spec ENG-PS-007, PRS 1501, PRS 1504, FMEA ENG-RMF-045 | Patient contact portion of device (cable and plug) are non cytotoxic per ISO 10993-1:2009 clause 6.2.2.2 | ENG-PRT-235 (Biocompatibility test), ND Biocompatibility (See ENG-PRT-451) | ENG-RPT-337 **(SMOKE EVACUATION ELECTROSURGICAL PENCIL guide)** (ref. Nelson Labs Reports 723539 and 724187), New Deantronics Report R130811-E, see ENG-RPT-558 | Complete | T.S. 2/21/18  T.S. 6/28/18 | M.E. 2/21/18  M.E. 6/28/18 |
| ISO 10993-1, Product Spec ENG-PS-007, PRS 1502, FMEA ENG-RMF-045 | Materials of construction are non sensitizing per ISO 10993-1:2009 clause 6.2.2.3 | ENG-PRT-235 | ENG-RPT-337 (ref. Nelson Labs Report 723540) | Complete | D.G. 5/5/14  T.S. 2/21/18  T.S. 6/28/18 | M.E. 5/5/14M.E. 2/21/18  M.E. 6/28/18 |
| ISO 10993-1, Product Spec ENG-PS-007, PRS 1503, FMEA ENG-RMF-045 | Materials of construction are non irritating per ISO 10993-1:2009 clause 6.2.2.4 | ENG-PRT-235 | ENG-RPT-337 (ref. Nelson Labs Report 723541) | Complete | D.G. 5/5/14  T.S. 2/21/18  T.S. 6/28/18 | M.E. 5/5/14  M.E. 2/21/18  M.E. 6/28/18 |
| **STERILIZING** | | | | | | |
| ISO 11137, Product Spec ENG-PS-007, PRS 1101, FMEA ENG-RMF-045 | Zip Pen is compatible with Gamma sterilization to 50 kGy | ND Sterilization Protocol P131209-E | New Deantronics Report R140310-E, see Zip DHR | Complete | D.G. 5/5/14  T.S. 2/21/18  T.S. 6/28/18 | M.E. 5/5/14  M.E. 2/21/18  M.E. 6/28/18 |
|  |  | ME7251C and ME7251E  ND Sterilization Protocol P170829-E  See ZIP DHR | ME7251C and ME7251E  New Deantronics Report R171106-E, see Zip DHR | Complete | T.S. 2/21/18  T.S. 6/28/18 | M.E. 2/21/18  M.E. 6/28/18 |
| Product Spec ENG-PS-007, PRS 1101.5 | The device meets all essential design inputs after sterilization by EO exposure, applying only to ME725M1C and ME725M1E | ENG-PRT-441(This protocol defines the product ship testing requirements of EO sterilized product and  verifies package performance after shipping.), ENG-PRT-446(Mega Power Motherboard Transistor Change Verification) | ENG-RPT-535(6-Pack shipping configuration to  distribute Zip Pens has no effect on the packaging integrity of the EO sterile product.), ENG-RPT-585 | Complete | T.S. 6/28/18 | M.E. 6/28/18 |
| ISO 11137, Product Spec ENG-PS-007, PRS 1111, FMEA ENG-RMF-045 | Nozzle Extensions meet all essential design inputs with Gamma sterilization to 50 kGy maximum | ND Sterilization Protocol P131209-E | New Deantronics Report R140310-E, see Zip DHR | Complete | D.G. 5/5/14  T.S. 2/21/18  T.S. 6/28/18 | M.E. 5/5/14  M.E. 2/21/18  M.E. 6/28/18 |
| **PACKAGING** | | | | | | |
| Product Spec ENG-PS-007, PRS 1801, 1802 | Shipping case will be RSC design corrugated box; one IFU will be packed per box. | ENG-PRT-290 | ENG-RPT-418 | Complete | D.G. 5/5/14  M.G 2/9/15  T.S. 2/21/18  T.S. 6/28/18 | M.E. 5/5/14  M.E. 2/9/15  M.E. 2/21/18  M.E. 6/28/18 |
| Product Spec ENG-PS-007, PRS 1801, 1804 | ME series products:  Shipping case will be RSC design corrugated box; ACE Blade 700 products will include an ACE IFU in addition to a ZIP IFU in each case. | Verify by inspection of drawing  ACE 700 Shipper Box Artwork | ME7251C  ME7251E,  ME725M1C  ME725M1E  3900316 (shipper box artwork) | Complete | T.S. 2/21/18  T.S. 6/28/18 | M.E. 2/21/18  M.E. 6/28/18 |
| Product Spec ENG-PS-007, PRS 1101, 1601 | Zip Pen Pencil is packaged individually in a sterile barrier package and cartons of 20 each | ENG-PRT-290 | ENG-RPT-418 | Complete | D.G. 5/5/14  M.G 2/9/15  T.S. 2/21/18  T.S. 6/28/18 | M.E. 5/5/14  M.E. 2/9/15  M.E. 2/21/18  M.E. 6/28/18 |
| Product Spec ENG-PS-007, 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. | Verify by inspection of drawing  ACE 700 Shipper Box Artwork | ME7251C  ME7251E,  ME725M1C  ME725M1E  3900316 | Complete | T.S. 2/21/18  T.S. 6/28/18 | M.E. 2/21/18  M.E. 6/28/18 |
| Product Spec ENG-PS-007, PRS 1101, 1602 | Extension Nozzles are packaged individually in a sterile barrier package and cartons of 10 each | ENG-PRT-290 | ENG-RPT-418 | Complete | D.G. 5/5/14  M.G 2/9/15  T.S. 2/21/18  T.S. 6/28/18 | M.E. 5/5/14  M.E. 2/9/15  M.E. 2/21/18  M.E. 6/28/18 |
| ISO 11607-1, Product Spec ENG-PS-007, PRS 1102, 1603, 1604, 1803, FMEA ENG-RMF-045 | Packaging will protect the device from damage and maintain sterile barrier during transit test per ASTM D4169, cycle DC13 at assurance level II | ENG-RPT-229  ENG-PRT-239 (Protocol results after 5 years ageing simulation)  ME7251C and ME7251E  ENG-PRT-425 (The purpose of this protocol is to define the product ship testing requirements and  verify package performance post ship testing.)  ME725M1C and ME725M1E  ENG-PRT-441 | ENG-RPT-330(This is a protocol for demonstration of EO compatibility and not an EO validation.)  ENG-RPT-344  ENG-RPT-401(ENG-RPT-401  )  ENG-RPT-413(The objective of this test report is to document the ship testing that was done to give  accelerated aging to simulate three years  expiration life, exposure to transport and storage conditions and package  performance)  ENG-RPT-503(The objective of this test report is to document ship testing that was done on the Zip Pen after accelerated aging to simulate three years expiration life,  exposure to transport and storage conditions and package performance testing per  protocol)  ME7251C and ME7251EENG-RPT-546  ME725M1C and ME725M1E  ENG-RPT-535 | Complete  Complete  Complete | T.S. 2/21/18  T.S. 6/28/18 | M.E. 2/21/18  M.E. 6/28/18 |
| ISO 11607-1, Product Spec ENG-PS-007, PRS1720, 1733, 1920, 1935 | Labeling must remain clear and legible under shipping, handling and storage conditions | ENG-PRT-229  ENG-PRT-239  ENG-PRT-465 (Orange Label after EO) | ENG-PRT-330  ENG-PRT-344  ENG-RPT-401  ENG-RPT-413  ENG-RPT-503  ENG-RPT-581 (Orange Label after EO) | Complete | T.S. 2/21/18  T.S. 6/28/18 | M.E. 2/21/18  M.E. 6/28/18 |
| ISO 11607-1, Product Spec ENG-PS-007, PRS 1605, FMEA ENG-RMF-045 | ULPA Filter and Charcoal Filter devices will be packaged individually in poly bags and in shipping carton of 10 units per carton for ULPA Filters and 25 units per carton for Charcoal Filter | ENG-PRT-238 | ENG-RPT-340 | Complete | T.S. 2/21/18  T.S. 6/28/18 | M.E. 2/21/18  M.E. 6/28/18 |
| IEC 60601-1:2005 Clause 7.2, ISO 15223, Product Spec ENG-PS-007 PRS 1701 - 1722 | Zip Pen and Extension Nozzles unit labeling | ENG-PRT-290  Verify by inspection of drawing for ME7251C & ME7251E, ME725M1C & ME725M1E | ENG-RPT-418  3900311-01  3900312-01  3900313-01  3900314-01(Pouch) | Complete | D.G. 5/5/14  M.G 2/9/15  T.S. 2/21/18  T.S. 6/28/18 | M.E. 5/5/14  M.E. 2/9/15  M.E. 2/21/18  M.E. 6/28/18 |
| ISO 15223, Product Spec ENG-PS-007 PRS 1734 - 1740, PRS 1742 | 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. | By Design. | 3151135-01 3151137-01(label) | Complete | T.S. 2/21/18  T.S. 6/28/18 | M.E. 2/21/18  M.E. 6/28/18 |
| IEC 60601-1:2005 Clause 7.2, SOP MKT-SOP-001, Product Spec ENG-PS-007 PRS 1901 - 1920 | Zip Pen and Extension Nozzles Case labeling | ENG-PRT-290  Verify by inspection of drawing for ME7251C & ME7251E, ME725M1C & ME725M1E | ENG-RPT-418  3151073-01  3151074-01  3151075-01  3151076-01(Shipping label) | Complete | D.G. 5/5/14  M.G 2/9/15  T.S. 2/21/18  T.S. 6/28/18 | M.E. 5/5/14  M.E. 2/9/15  M.E. 2/21/18  M.E. 6/28/18 |
| IEC 60601-1:2005 Clause 7.2, ISO15223, Product Spec ENG-PS-007 PRS 1721 - 1733 | Filter unit labeling | ENG-PRT-290 | ENG-RPT-418 | Complete | T.S. 2/21/18  T.S. 6/28/18 | M.E. 2/21/18  M.E. 6/28/18 |
| IEC 60601-1:2005 Clause 7.2, SOP MKT-SOP-001, Product Spec ENG-PS-007 PRS 1921 - 1935 | Filter Case Labeling | ENG-PRT-290 | ENG-RPT-418 | Complete | T.S. 2/21/18  T.S. 6/28/18 | M.E. 2/21/18  M.E. 6/28/18 |
| Product Spec ENG-PS-007 PRS 1606 | Zip Pen Bulk Non-Sterile packaged in case of 30 and double bagged | Refer to drawings 2525-10BN and 2525-10ECBN | Verified on drawings 2525-10BN and 2525-10ECBN | Complete | T.S. 2/21/18  T.S. 6/28/18 | M.E. 2/21/18  M.E. 6/28/18 |
| Product Spec ENG-PS-007 PRS 1607, PRS 1741 | Zip Pen Bulk Non-Sterile will maintain package integrity after transit test per ASTM D4169 cycle DC13 assurance level II | ENG-PRT-325(The purpose of this protocol is to define the product ship testing requirements and  evaluate the carton performance after ship testing.) | ENG-RPT-475(Test report) | Complete | T.S. 2/21/18  T.S. 6/28/18 | M.E. 2/21/18  M.E. 6/28/18 |
| Customer Requirements Document MKT-CMR-02 | Pencil cord to be wrapped (in a material that will keep the cord contained) during shipping and in packaging | ENG-PRT-451 | ENG-RPT-558 | Complete | T.S. 2/21/18  T.S. 6/28/18 | M.E. 2/21/18  M.E. 6/28/18 |
| Product Spec ENG-PS-007 PRS 1112, 1114 | Extension nozzles, ULPA and charcoal filter, device in conjunction with its packaging is free from damage during normal shipping, storage, and handling | ENG-PRT-238 | ENG-RPT-340 | Complete | T.S. 2/21/18  T.S. 6/28/18 | M.E. 2/21/18  M.E. 6/28/18 |
| **ENVIRONMENTAL** | | | | | | |
| Product Spec ENG-PS-007 PRSS 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. | UL Testing | ENG-RPT-059(**MEGA POWER CB TEST REPORT)** | Complete | T.S. 2/21/18  T.S. 6/28/18 | M.E. 2/21/18  M.E. 6/28/18 |
| DMR ENG-DMR-012, Product Specification ENG-PS-007PRS 2001 | Zip Pen and Extension Nozzles to meet packaging, mechanical, and electrical requirements after accelerated aging at 55°C to simulate 3 years of shelf life. | ENG-PRT-227  ENG- PRT -228  ENG- PRT -229  ENG-PRT-230(Fluid ingress test)  ENG-PRT-239  ME7251C & ME7251E  ENG-PRT-425  ENG-PRT-421(Gray Sumitomo A4 Heat Shrink Design Qualification)  ME725M1C & ME725M1E  ENG-PRT-466 | ENG-RPT-328  ENG-RPT-329  ENG-RPT-330  ENG-RPT-331  ENG-RPT-344  ENG-RPT-546  ENG-RPT-536(Gray Sumitomo A4 Heat Shrink Design Verification)  ME725M1C & ME725M1E  ENG-RPT-585 | Complete  Complete | D.G. 5/5/14  T.S. 2/21/18  T.S. 6/28/18 | M.E. 5/5/14M.E. 2/21/18  M.E. 6/28/18 |
| DMR ENG-DMR-012, Product Specification ENG-PS-007PRS 2002 | Zip Pen and Extension Nozzles to meet packaging, mechanical, and electrical requirements at 3 years real time aging after 3 years from date of manufacture | ENG-WI-009  ME725M1C & ME725M1E – ENG-PRT-467 | To be completed in three years after real time aging | Pending | D.G. 5/5/14  T.S. 2/21/18  T.S. 6/28/18 | M.E. 5/5/14  M.E. 2/21/18  M.E. 6/28/18 |
| Product Spec ENG-PS-007 PRS 1202 | Device shall be capable of being transported and stored at temperature range of -40°C to +50°C and humidity range of 15% to 95%. | ENG-PRT-229  ENG-PRT-327  ME7251C & ME7251E  ENG-PRT-425  ME725M1C & ME725M1E  ENG-PRT-441 | ENG-RPT-330  ENG-RPT-413  ENG-RPT-503  ME7251C & ME7251E  ENG-RPT-546  ME725M1C & ME725M1E  ENG-RPT-535 | Complete | T.S. 2/21/18  T.S. 6/28/18 | M.E. 2/21/18  M.E. 6/28/18 |

# REVISION HISTORY

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| --- | --- | --- | --- |
| **Revision** | **Document Change Order Number** | **Description of Change** | **Effective Date** |
| A | 14-071-01 | Initial Release | 2014-06-12 |
| See MasterControl and Windchill for subsequent revisions | | | |

DOCUMENT FORM # 1050020-10 REV B