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Name: Mega Power CB Test Report

Windchill Signature History Report			
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1. ABSTRACT

The Mega Power Electrosurgical Generator and accessories were tested at Underwriters Laboratories (UL) to the requirements of IEC 60601-1 Edition 3.1 and IEC 60601-2-2 Edition 6.0. The Mega Power ESU and its accessories were determined to meet the requirements for the CB Certification.

The UL report , which can be found under the Attachments section of ENG-RPT-058, represents the testing and document review done by UL to go from an IEC 60601-1 Edition 3.0 certification to an Edition 3.1 certification on the Megadyne file # E351663 for the Mega Power ESU and accessories.

After UL completed their GAP analysis of the Megadyne file to go from Edition 3.0 to 3.1 they requested samples for dielectric testing stating that it was the only testing that needed to be redone for the 3.1 certification. The SME for each product family reviewed drawings and provided recommendations for the samples that would represent both the worst-case test condition for dielectric testing and any unique material conditions for dielectric testing. The samples selected for the UL testing are shown in Table 1 – "Samples Selected for UL & EMC Testing for IEC 60601-1 3.0 to 3.1" and where approved by UL.

The test report (E351663-D1001-1/A2/C0-CB) can be found in the Attachments section of ENG-RPT-058 and the CB Certification (US-31415-UL, 2018-03-23) from UL is attached to the Attachments section of this document with the sample selection matrix Table 1.

In August 2018, Megadyne was notified that a transistor on PCB 4010301-01 was at end of life and an alternate needed to be designated. An equivalent alternate Transistor was identified and reviewed by UL. This alternate was added to the list of critical components under report number E351663-D1001-1/A2/C0-CB. New accessories and catalog numbers revised for J and J were also added to the list of critical components, details of these additions are shown on the modification's summary page of the report. The report is attached to the Attachments section of ENG-RPT-058. The CB Certification can be found in the Attachments section of this report.

In December 2019, Megadyne was notified that the toroid in Transformer T6 and T10 on motherboard 4010301-01 needed to be changed due to the toroid going end of life. An alternate toroid was identified and reviewed by UL. The alternate construction of Transformer T6 and T10 was added to the Critical Component list and the report was updated to amendment 3, refer to report number E351663-D1001-CB-2-Amendment-3.pdf. The report is attached to the Attachments section of ENG-RPT-058. The CB Certification can be found in the Attachments section of this report.

In 2019, Megadyne was notified that the transformer used for T1 on motherboard 4010301-01 and 4010301-02 for Mega Power would no longer be supplied by Electronetics, the current sub-tier supplier. Alternate T1 suppliers were identified to be

All Star Electronics, Inc. and Inductors, Inc. UL reviewed the T1 designs provided by All Star Electronics and Inductors. The alternate constructions of T1 were both added to the Critical Component list and the report was updated to 351663-D1001-2/A0/C0-UL. The report is attached to the Attachments section of ENG-RPT-058. The CB Certification can be found in the Attachments section of this report.

In March 2020, the gap assessment (500437614) of 60601-1 ED. 3.0-2005 TO 60601-1 ED. 3.1-2012 identified that the UL report for Mega Power needed to be updated to include 3030HT, 3035HT, 1300SJ and 1300U. On May 6th, 2020. UL completed project number 4789421513 to add these codes and the report was updated to 351663-D1001-2/A1/C0-UL. The report is attached to the Attachments section of ENG-RPT-058. The CB Certification can be found in the Attachments section of this report.

In 2020, Megadyne was notified that the PT9300 Mega Soft film was discontinued and replaced with the PT9520S film. The Mega Soft device is listed as an accessory to the MEGEN1 and the drawings were updated in the report. Refer to report number E351663-D1001-2A2C0-UL.pdf that is attached to the Attachments section of ENG-RPT-058. The CB Certification can be found in the Attachments section of this report.

2. OBJECTIVE

The purpose of the test report is to demonstrate compliance to the standards listed in the Abstract above.

3. RESULTS

See the report from UL under the Attachments Section in Windchill.