AEX™ Generator
Planned Maintenance Manual

Medtronic

Rx Only: Federal Law (USA) restricts these devices to sale by or on the order of a physician.

For a listing of indications, contraindications, precautions, and warnings, please refer to the Instructions For Use (IFU) that accompany the Medtronic disposable devices and/or the AEX™ Generator Operator's Manual.

Table of Contents

Introduction

About this manual

Use of this manual

This manual describes the planned maintenance of the Medtronic AEX™ Generator.

Use this manual when completing planned maintenance on an AEX™ Generator. The procedures in this manual are not intended for any other system.

The information in this manual is current as of the revision date shown on the back cover.

Important: When performing any planned maintenance activity, read the complete step including any admonitions and additional information before attempting to complete the instruction.

Warning: The information contained in this document is intended for the use of qualified personnel only. Biomedical technicians (e.g., ICC Certified Biomedical Equipment Technician [BMET]) or similar personnel performing the steps outlined here shall be fully familiar with all documentation on the functions, operations, warnings and components of the AEX™ Generator. Serious injury can result if the activities described in this document are attempted by unqualified persons.

Conventions used in this manual

Warnings and cautions

Warning: Failure to observe a warning may result in physical injury to the patient or operator. Pay special attention to these items.

Caution: Failure to observe a caution could result in damaged equipment, forfeited time or effort, or the need to stop the use of the system.

Notes

Note: Notes identify important points, helpful hints, special circumstances, or alternative methods.

Related documents

- AEX™ Generator Operator Manual
- Electrical Safety Analyzer Manual (site-specific equipment)
- Electrosurgical Analyzer (ESA) Operator Manual (site-specific equipment)

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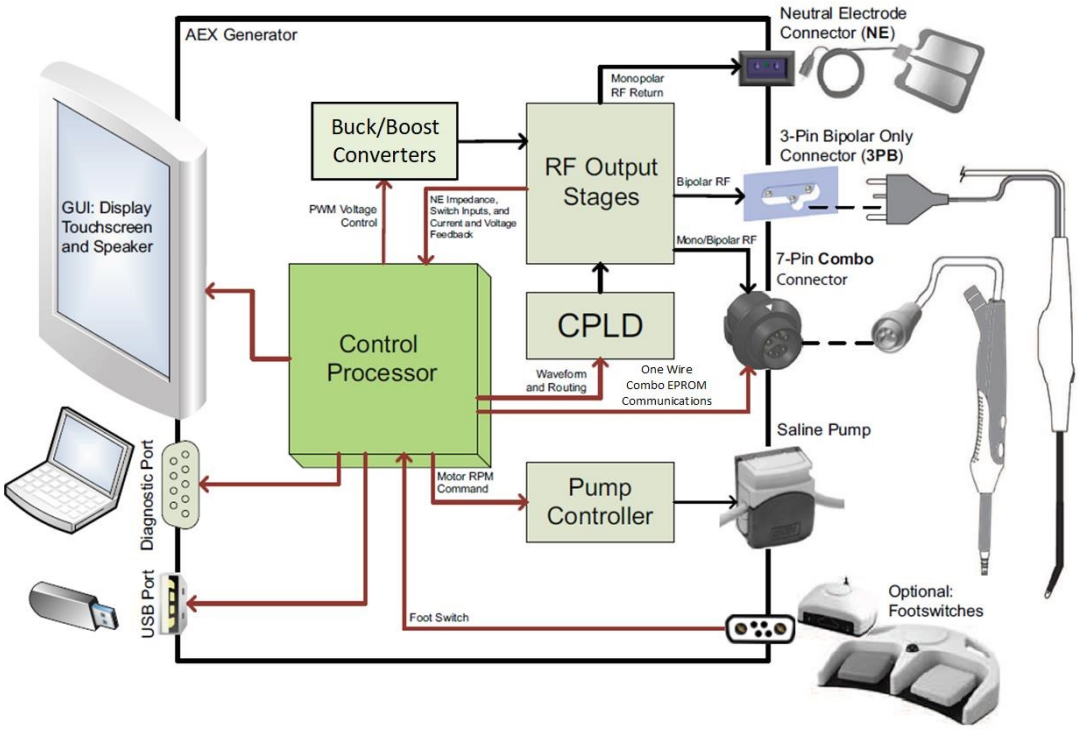
AEX™ Generator Planned Maintenance

The AEX™ Generator provides radio frequency (RF) energy to a disposable electrosurgical device. This combined system is used to perform electrosurgery. The Generator is capable of delivering multiple CUT, COAG and Transcollation™ modes at various power levels when connected to a disposable device. The 7-pin disposable devices have a memory chip with predetermined set points. See individual device user manuals for specific information. This chip specifies the output power for each set point. The generator reads this 7-pin device memory chip to deliver RF power. The 3-pin devices do not have a memory chip.

Figure 1. *System Component Interface Diagram*



Required qualifications to perform these procedures

Only biomedical technicians with electrical expertise are qualified to complete these procedures.

Required Safety Equipment

- Wear-Indicating Electrical-Protection Gloves, Class 1 ASTM Voltage Rating
- Safety glasses

Required Equipment

The following equipment is required to complete the output power accuracy testing:

- AEX™ Generator
- A neutral electrode (return pad) connector with the pad cut off and the two leads shorted together
- Disposable device
  - 3-pin: Aquamantys™ 6.0 or MBS
  - 7-pin: PlasmaBlade™ X 3.0S or 4.0
- Two test leads with alligator clips on one end and a 4 mm banana plug on the other end
- Electrosurgical analyzer (ESA) capable of measuring RF output at 469 KHz, and ESA user guide
- Safety tester and safety tester user guide for medical units as per IEC #60601

Required Annual Inspections

1. Visually inspect the AEX™ Generator for physical damage. Report damage to Medtronic or your biomedical department. Do not use the AEX™ Generator if it is damaged.
2. Visually inspect the power cord and plug for physical damage. Replace the cord if the insulation has been breached.

   Do not use the Generator if the cord or plug has been damaged and has not yet been replaced.
3. Inspect the fit of the cord to the AEX.

   If the AEX™ Generator receptacle is damaged or loose, return the Generator to Medtronic for repair.
4. Inspect the mating, cleanliness, and absence of damage to the patient connectors. Do not use the AEX™ Generator if the connectors are damaged.
5. Inspect for accumulation of lint or debris within the AEX™ Generator or fan vents. Do not use the AEX™ Generator if lint or debris has accumulated and has not been cleared.

Maintenance Procedures

This section contains information about routine maintenance.

Warning: Do not modify this equipment. Only authorized Medtronic service technicians may make modifications to the AEX™ Generator.

Routine Maintenance

Required qualifications to perform these procedures

Only biomedical technicians with electrical expertise are qualified to complete these procedures.

Recommended Periodic Functional Verification

The AEX™ Generator should be periodically checked for functionality and performance according to the hospital equipment servicing guidelines. Medtronic recommends that the unit's calibration be verified and a safety check be performed by a qualified biomedical technician on an annual basis as outlined in this document. Reference the ESA Manual for specific instructions for safety tests.

Recommended Functional Verification Procedure

The verification and functional check should include:

- Protective earth conductor test
- Earth leakage current measurement (page 8)
- Housing leakage current measurement
- Output power accuracy verification (page 10 and page 11)
- Peristaltic pump test (page 13)
- Power cord inspection (for damage)
- Fuse check (if the system will not start)

Caution: Frequent opening of the fuse compartment can damage the plastic housing. Use care when the fuse compartment must be opened to avoid damage to the housing. Only check the fuses if the system will not power on.

Leakage currents and protective earth conductor test

Required Safety Equipment

- Wear-Indicating Electrical-Protection Gloves, Class 1 ASTM Voltage Rating
- Safety glasses

Make the following connections according to Safety Analyzer instructions and diagram for CF-type equipment:

- Male end of AEX™ Generator's power cord into the safety tester mains socket
- The AEX™ equipotential bonding terminal (see AEX™ Operator's Manual) to safety tester impedance measurement terminal

Perform leakage and PE conductor tests per the user guide of the ESA.

- Table 1 shows leakage current and PE conductor limits that are compliant with IEC #60601 (Class I, Type CF device).
- Refer to the user manuals of testing equipment used for leakage current and protective earth conductor testing.

Table 1. *Leakage current and PE conductor limits*

Measured Characteristic	Maximum Value
PE conductor impedance	0.2 Ω
Earth leakage current, normal condition	500 µA
Earth leakage current, single fault condition	1000 µA
Housing or touch leakage current, normal condition	100 µA
Housing or touch leakage current, single fault condition	500 µA

RF Output Power Accuracy Verification

Warning: External load resistors used to test the output of the AEX™ Generator will become extremely hot. Use extreme caution to avoid any contact. All load resistors must be properly mounted and isolated from any flammable materials.

Caution: The ESA must have a current rating of at least 2.5 Arms. Do not test the AEX™ Generator with a load of less than 50 ohms on the output, or RF currents in excess of 2.5 amps RMS will occur.

Required qualifications to perform these procedures

Only biomedical technicians with electrical expertise are qualified to complete these procedures.

Bipolar power output test with Aquamantys™ (3-pin)

Required Safety Equipment

- Wear-Indicating Electrical-Protection Gloves, Class 1 ASTM Voltage Rating
- Safety glasses

Use Aquamantys™ (3-pin) 6.0 mm disposable electrodes.

1. Attach the alligator clip of each lead to the bipolar electrodes.

   Caution: Do not let the clips touch. If the clips touch, they will create a short, and there will not be enough output for an accurate test.

2. Attach the banana plug to the ESA.
3. Test the RF output at the 20 watt, 110 watt, and 220 watt settings with the output loaded at 100 ohms, Table 2.

   The measured RF output power should be equal to the set power ±20%.

Note: Prime must be performed before 3-pin device can activate. Prime can be performed without the tubing inserted into pump.

Note: Priming the pump is loud.

Table 2. *AEX™ Power output specs for 3-pin device*

Setting	Power (Watts)	Impedance (Ohms)	Tolerance
20 W	20 W	100	± 20% (16–24)
110 W	110 W	100	± 20% (88–132)
220 W	220 W	100	± 20% (176–264)

Contact Medtronic technical support at +1 800 595 9709 for further assistance.

Testing failure

If bipolar testing fails, confirm that the alligator clips are placed one clip per lead and not touching. Test again.

If the test still fails, contact Medtronic technical support at +1 800 595 9709.

Monopolar power output test with PlasmaBlade™ X (7-pin)

Required Safety Equipment

- Wear-Indicating Electrical-Protection Gloves, Class 1 ASTM Voltage Rating
- Safety glasses

The monopolar power output test verifies the accuracy of the RF energy output.

Table 3 shows the minimum number of settings to test for accuracy. Table 4 shows an expanded list of settings for hospitals that require it.

1. Connect the 7-pin device to the AEX generator.
2. Connect the tip of the PlasmaBlade™ X 7-pin device to the ESA leads using an alligator clip.

   Caution: Attach the alligator clip to the metal edge of the blade. Other parts are isolated and will not work.
3. Connect the shorted leads of the neutral electrode to the ESA leads using an alligator clip.
4. Set the load on the ESA to the value indicated in Table 3 or Table 4.

   Refer to the ESA Instruction manual for set up instructions.
5. Power on the generator and adjust to the appropriate set point in Table 3 or Table 4.
6. Press the button (yellow for CUT and blue for COAG) on the PlasmaBlade™ X device to activate RF.

   Measure the output power on the ESA.

   Refer to Table 3 or Table 4 for accuracy of measured power depending on the type of device connected.
7. Repeat step 1 through step 6 for the settings in Table 3 or Table 4.

Table 3. *Minimum AEX™ Power Output Specs for PlasmaBlade™ X (7-pin)*

Setting	Mode	Power (Watts)	Impedance (Ohms)	Tolerance
Cut 8	Medium Cut	50	500	40.0–60.0
Cut 10	High Cut (Blend 2)	50	500	40.0–60.0
Coag 5	Low Coag	35	500	28.0–42.0
Coag 8	High Coag	40	1000	32.0–48.0

Table 4. *Expanded AEX™ Power Output Specs for PlasmaBlade™ X (7-pin)*

Setting	Mode	Power (Watts)	Impedance (Ohms)	Tolerance
Cut 1	Low Cut	0.5	100	0.0–1.7
Cut 2	Low Cut	2.0	100	1.0–3.0
Cut 3	Low Cut	6	100	3.8–6.1
Cut 4	Low Cut	10	100	8.0–12.0
Cut 5	Low Cut	20	100	16.0–24.0
Cut 6	Medium Cut	20	500	16.0–24.0
Cut 7	Medium Cut	35	500	28.0–42.0
Cut 8	Medium Cut	50	500	40.0–60.0
Cut 9	High Cut (Blend 1)	25	500	20.0–30.0
Cut 10	High Cut (Blend 2)	50	500	40.0–60.0
Coag 1	Low Coag	15	500	12.0–18.0
Coag 2	Low Coag	20	500	16.0–24.0
Coag 3	Low Coag	25	500	20.0–30.0
Coag 4	Low Coag	30	500	24.0–36.0
Coag 5	Low Coag	35	500	28.0–42.0
Coag 6	High Coag	30	1000	24.0–36.0
Coag 7	High Coag	35	1000	28.0–42.0
Coag 8	High Coag	40	1000	32.0–48.0
Coag 9	High Coag	45	1000	36.0–54.0
Coag 10	High Coag	50	1000	40.0–60.0

Contact Medtronic technical support at +1 800 595 9709 for further assistance.

Testing failure

If monopolar testing fails, confirm that the alligator clips on the monopolar device is clipped to the edges of the blade, not the flat part of the blade. Test again.

If the test still fails, contact Medtronic technical support at +1 800 595 9709.

Peristaltic pump test

Required Safety Equipment

- Wear-Indicating Electrical-Protection Gloves, Class 1 ASTM Voltage Rating
- Safety glasses

Prime test

1. Power on the AEX™ Generator.
2. Plug the Aquamantys™ 3-pin device into the front panel connector of the AEX™ Generator.
3. Adjust the seal power to 100 Watts.
4. Open the pump head so that the rollers are visible.
5. Activate the prime function and observe the speed of the pump
   The rollers should move fast for a maximum of 19 seconds, then stop.

High speed test

6. Adjust the flow setting on the generator to high (3 drops).
7. Activate RF using the Aquamantys ™ 3-pin device.
   The pump speed must be slower than the prime speed.
8. Deactivate RF.

Medium speed test

9. Adjust the flow setting on the generator to medium (2 drops).
10. Activate RF using the 3-pin device.
    Pump speed must be slower than high speed.
11. Deactivate RF.

Low speed test

12. Adjust the flow setting on the generator to slow (1 drop).
13. Activate RF using the Aquamantys™ 3-pin device.
    The pump speed must be slower than medium speed.
14. Deactivate RF.

Contact Medtronic technical support at +1 800 595 9709 for further assistance.

Cleaning

Warning: *Electric shock hazard.* Always unplug the Generator from the wall outlet prior to cleaning.

The Generator is not sterilizable.

1. Clean the front display, cover, and cord with a mild detergent or mild disinfecting solution and a damp cloth.

Whenever possible, use non-flammable agents for cleaning and disinfection. If flammable agents must be used for cleaning, disinfecting, or as solvents, they should be allowed to evaporate before surgery.

Caution: Do not allow fluids to enter the chassis. Do not use alcohol, caustic, corrosive, or abrasive materials on the front display, cover, and cord, as they may cause damage to the equipment. Medtronic recommends following hospital procedures for cleaning the outside of the Generator after each patient.

For accessory cleaning and maintenance, refer to the user documentation provided with the accessory.

Contact Medtronic technical support at +1 800 595 9709 for further assistance.

Responsibility of the Manufacturer

Medtronic is responsible for the safety, reliability, and performance of the AEX™ Generator only under the following circumstances:

- Installation and setup procedures in this planned maintenance guide and the operator manual are followed.
- Assembly operation, readjustments, modifications, or repairs are carried out by persons authorized by Medtronic.
- The AEX™ Generator is connected to electrical wiring which complies with local codes and regulatory requirements.
- The equipment is used in accordance with the AEX™ Generator instructions for use.

For warranty information, refer to the AEX™ Generator Operator Manual.

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