

ENGLISH

1. General

The device shall be maintained and serviced on a regular basis, at least once a year, based on the requirements of IEC60603 - *Medical electrical equipment - Recurrent test and test after repair of medical electrical equipment*.

For details about performance of the inspection as well as the assessment of the results of the tests strictly follow the requirements of IEC60603.

The following sections refer to referenced chapters in the above mentioned standard and serve to support the inspection accordingly.

Use only certified testing equipment intended and designed to perform tests according IEC60603.

2. Visual inspection (5.2 - IEC60603)

- The device fuse inserted at the rear end of Robotex complies with the data given in the Hardware User Guide, Patient Support System (check imprinting on the fuse).
- All Warning Labels as defined in the Hardware User Guide, Patient Support System are complete, legible and show no damage.
- The Robotex housing, including the bellows is not damaged or loose. All parts are securely fastened.
- The covers and mechanical parts of the ON/OFF-switches are not damaged, loose or otherwise impaired by wear.
- The covers and mechanical parts of the Lock All push buttons are not damaged, loose or otherwise impaired by wear.
- The cover of the Battery Charger does not show any cracks or other damage.
- No twists or cracks in cable jacket and no damage to connectors.

Open the left cover shell of Robotex. Inspect the functional earth conductor (FE) connecting the upper and lower metal housing plate and verify the connection is not impaired by wear or fatigue (see figures 5.2/3 for details).

- There are no obvious cracks in the isolation or sharp bending of the conductor.
- The mechanical connection of the conductor to upper AND lower housing plate is not loose.

3. Measuring of protective earth (PE) resistance (5.3.2 - IEC60603)

Disconnect the Battery Charger and switch Robotex "OFF".

Verify that the resistance of the protective earth connection between upper and lower metal housing plate of Robotex complies with the requirements of IEC60603 (see figure 4 for details).

- The measured internal PE resistance shall not exceed 0.2 Ω.

4. Leakage currents (5.3.3 - IEC60603)

Perform an Equipment Leakage Current test with Robotex and verify the Equipment Leakage Current from accessible conductor parts complies with the requirements of IEC60603 (see figure 5 for details).

- The Equipment Leakage Current shall not exceed the limits as specified in IEC60603.
- Allowed limits differ depending on the type of medical event setup. For details please refer to IEC60603.

5. Measurement of insulation resistance (5.3.4 - IEC60603)

The insulation resistance shall only be measured at the Battery Charger. Therefore disconnect the Battery Charger from Robotex.

Verify the insulation resistance between the primary and secondary circuits of the Battery Charger in accordance with the requirements of IEC60603 (see figure 6 for details).

- The insulation resistance shall meet as a minimum the limits as specified in IEC60603.

6. Functional test (5.4 - IEC60603)

The safety-related functions of the equipment shall be tested as follows:

- Test the Service Lock mechanism: Both arresting bolts can be operated easily to both the "Locked" and the "Unlocked" position. The indicator lights on the "Lock All" push buttons are lit on both sides of Robotex if an arresting bolt is not in its normal "Unlocked" position.
- Test the Service Brake Release: Follow the instructions in the Hardware User Guide, Patient Support System to perform a Service Brake Release. The function works as described. After the test Robotex indicates the occurrence of a Service Brake Release and a "Warning" procedure is required.
- Inspect and test the correct function of the ON/OFF-switches: The device can be turned "ON" and "OFF" by operating the switches on either side. Both switches are lit to indicate the "ON" state of Robotex.
- Inspect and test the correct function of the Lock All push buttons: The device can be "Locked" and "Unlocked" by operating the push buttons on either side. Both buttons are lit to indicate the "Locked" state of Robotex.
- Test the Emergency OFF (EMO):



- Danger of damage to the Linear system if the Emergency Off switch is activated while the Linear is in operation. Contact local service specialist to attend and supervise the testing!

Perform a Robotex maneuver. During movement press the Emergency OFF push button of the Linear. Robotex stops immediately.

7. Reporting of results (6.1 - IEC60603)

All tests performed as stated above shall be documented comprehensively.

For further information please see the Hardware User Guide, Patient Support System or consult Brainlab customer support.



Figure 1:
Opening left cover shell



Figure 2:
No obvious cracks in the isolation or sharp bending of the conductor



Figure 3:
The mechanical connection of the conductor to upper and lower housing plate is not loose



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