Evaluation of safety for VarioSurg 4

1 Introduction

1.1 The evaluation of safety of ME EQUIPMENT or ME SYSTEM shall be performed by electrically skilled persons (as defined in IEC 61140) who have the appropriate training for testing the equipment under test.

1.2 The procedure in this document is based on IEC 62353.

1.3 Test results must be recorded.

1.4 The order of INSPECTION procedure should be kept.

1.5 This procedure should be done at least every 2 years.

2 INSPECTION

2.1 Visual inspection

This procedure shall be done before any measurement.

2.1.1 Special attention shall be paid to the following;

- safety related marking, labels and labeling are legible and complete;
- the integrity of mechanical parts;
- any damage or contamination e.g. any evidence of spillage;
- assess the relevant ACCESSORIES together with the ME EQUIPMENT or ME SYSTEM (e.g. detachable or fixed POWER SUPPLY CORDS, patient leads, tubing); and
- the required documentation is available and reflects the current revision and/or CONFIGURATION of the ME EQUIPMENT or ME SYSTEM.

2.2 Protective earth resistance

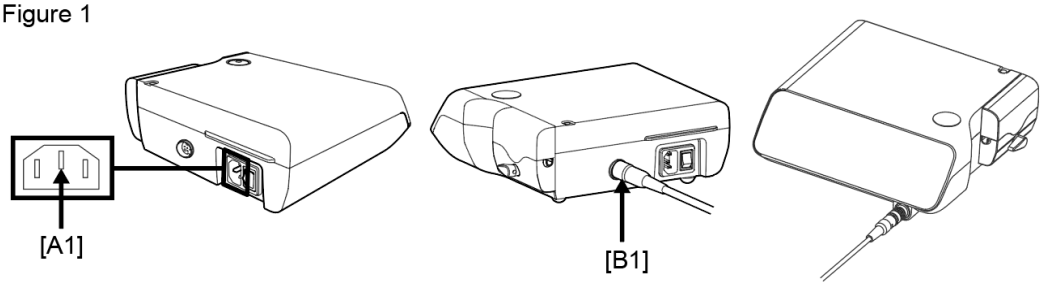
While low current tests (up to 1 A) are recommended, tests using up to 25 A may be used.
Higher value and measured point should be recorded.

2.2.1 Disconnect the power supply cord of the device under the test.

2.2.2 Turn the power switch of the device under the test ON.

2.2.3 Measure resistance between the protective earth connector of the appliance inlet [A1] and protectively earthed ACCESSIBLE CONDUCTIVE PARTS [B1] shown in figure 1.
*When wired foot control connected.

Figure 1

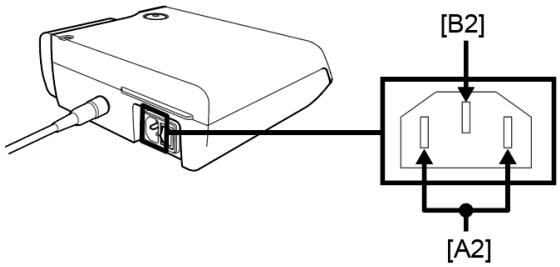


2.3 Insulation resistance

The lowest value and measured point should be recorded.

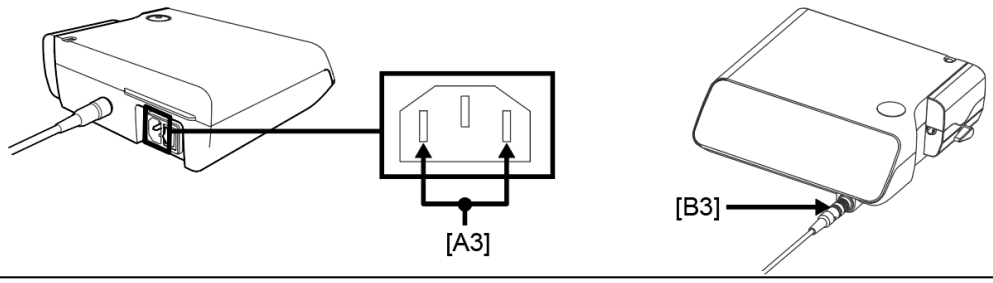
2.3.1 Measure resistance between MAINS PART [A2] and protective earth [B2] shown in figure 2 with a test voltage of 500 V DC.

Figure 2



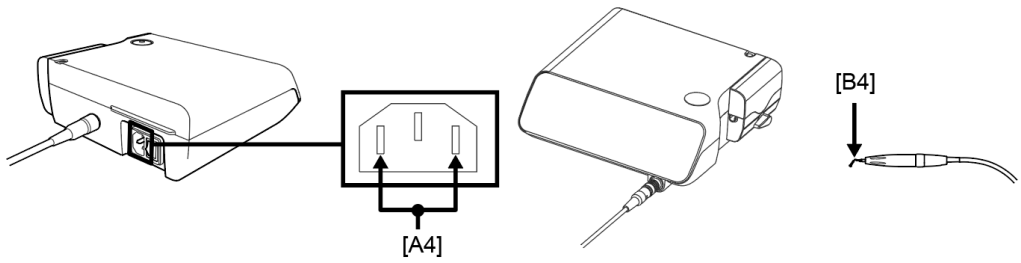
2.3.2 Measure resistance between MAINS PART [A3] and non-earthed ACCESSIBLE CONDUCTIVE PART [B3] shown in figure 3 with a test voltage of 500 V DC.

Figure 3



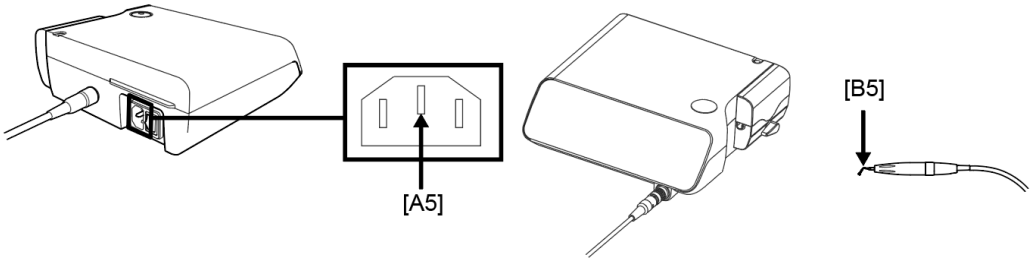
2.3.3 Measure resistance between MAINS PART [A4] and APPLIED PART [B4] shown in figure 4 with a test voltage of 500 V DC.

Figure 4



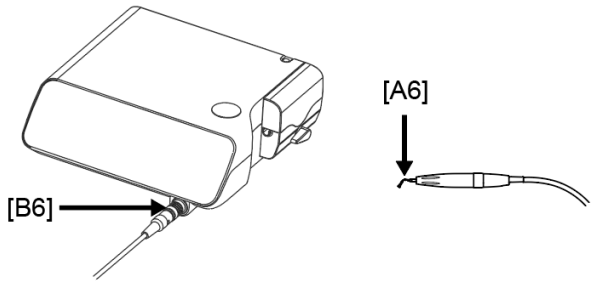
2.3.4 Measure resistance between F-TYPE APPLIED PART [B5] and protective earth [A5] shown in figure 5 with a test voltage of 500 V DC.

Figure 5



2.3.5 Measure resistance between F-TYPE APPLIED PART [A6] and non-earthed earthed ACCESSIBLE CONDUCTIVE PART [B6] shown in figure 6 with a test voltage of 500 V DC.
*When wired foot control connected.

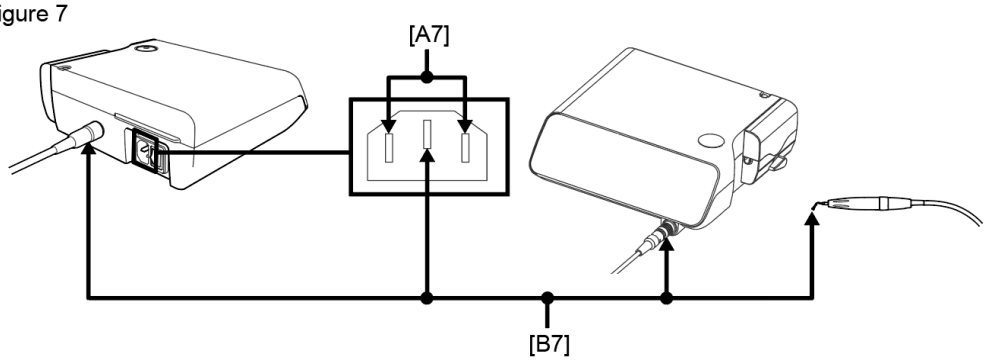
Figure 6



2.4 Equipment leakage current

2.4.1 Measure leakage current between MAINS PART [A7] and ACCESSIBLE CONDUCTIVE PART and APPLIED PART all connected part [B7] shown in figure 7.
*When wired foot control connected.

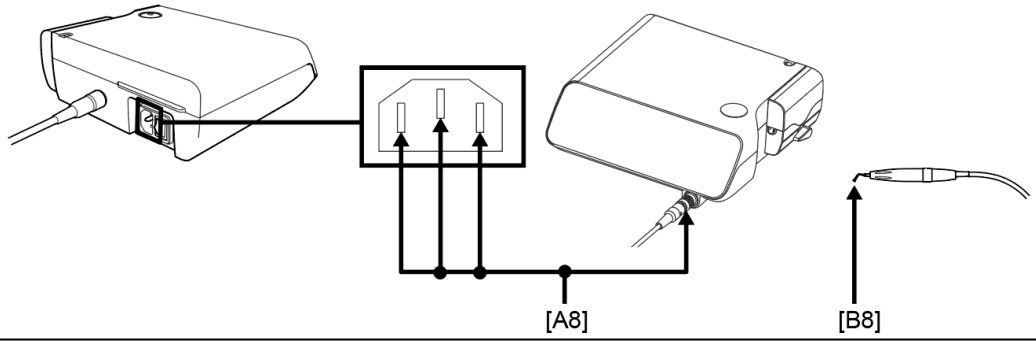
Figure 7



2.5 Applied part leakage current

2.5.1 Measure leakage current between MAINS PART, protective earth, and non-earthed ACCESSIBLE CONDUCTIVE PARTS, all connected part [A8] and F-TYPE APPLIED PART [B8] shown in figure 8.

Figure 8



2.6 Functional test

Perform the operation check based on the OM-DE1131MA VarioSurg4 operation manual "Check before treatment" included with the product.

2.6.1 The handpiece works at requested mode.

2.6.2 No abnormal noise in running.

2.7 Interval

2.7.1 This procedure should be done at least every 2 years.

TEST RECORD

Responsible organization	Test before putting into service ☐ Recurrent test ☐ Test after repair ☐

Equipment		
Model		VarioSurg 4
Manufacturer		NAKANISHI INC.
Applied part type		BF
Class of protection		I
Mains connection		Detachable power supply cord
Serial number	Control unit	
	Handpiece	

Test						
Procedure No	Item	Acceptance criteria	Measured point	Measured value	PASS	FAIL
2.1	Visual inspection				☐	☐
2.2	Protective earth resistance	< 200mΩ		Ω	☐	☐
2.3.1	Insulation resistance	> 2MΩ		MΩ	☐	☐
2.3.2	Insulation resistance	> 7MΩ		MΩ	☐	☐
2.3.3	Insulation resistance	> 70MΩ		MΩ	☐	☐
2.3.4	Insulation resistance	> 70MΩ		MΩ	☐	☐
2.3.5	Insulation resistance	> 70MΩ		MΩ	☐	☐
2.4.1	Equipment leakage current	< 1000μA		μA	☐	☐
2.5.1	Applied part leakage current	< 5000μA		μA	☐	☐
2.6	Functional test				☐	☐

Measurement equipment

Note
Next recurrent test necessary in ☐6/ ☐12/ ☐18/ ☐24 months.

Overall Assessment

☐ No safety or functional deficiencies were detected.

☐ Deficiencies detected but no direct risk to continue clinical use. Correction required.

☐ Equipment shall be taken out of operation until deficiencies are corrected.

☐ Equipment does not comply - Modification / Exchange of components / Taking out of service is recommended!

Operator	Date	Signature